CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW & POLICY

517 College Street, Suite 400, Toronto, Ontario M6G 4A2 (416) 923-3529 FAX (416) 960-9392

Biotechnology Policy Development:

Volume II

By Courage and Skof

1987

BIOTECHNOLOGY POLICY DEVELOPMENT: VOLUME II

This report has been funded in total by the Ontario Ministry of the Environment. This does not necessarily signify that the contents reflect the views and/or policies of the Ontario Ministry of the Environment nor does mention of trade names or commercial products constitute endorsement or recommendation for use .

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ENVIRONMENTAL IMPLICATIONS OF BIOTECHNOLOGY

By

Dr. Bernard Glick and Yvonne Skof

With assistance from Tiina Kurvits

Canadian Environmental Law Research Foundation

August 1986

ENVIRONMENTAL IMPLICATIONS OF BIOTECHNOLOGY

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I INTRODUCTION

THE DEFINITION OF BIOTECHNOLOGY

Biotechnology, in its broadest sense, can be defined as the use of biological systems to provide goods and services. In this sense, biotechnology has been used for centuries through the use of microorganisms, to produce wine and cheese and through cross-breeding to grow hardier plants and animals.

However, this definition ignores the fact that modern biotechnology, along with both the promise and concern it has engendered, is generally associated in the minds of both the scientific community and the lay public with certain new technologies. The most prominent among the so-called enabling technologies are recombinant DNA and cell fusion. It is these technologies which allow scientists to develop new life forms, i.e., microorganisms, plants, and higher animals with a modified gene complement, or unique hybrids, and which form the scientific basis for modern biotechnology.

The purpose of this paper is to describe and discuss the potential environmental impacts of biotechnology and it is the latter definition that is used in this discussion. Applications and impacts of traditional biotechnology will also be discussed where these provide either significant parallels with newer applications or useful insights into the potential effects of modern genetic manipulations. The final section

describes environmental implications generally as well as for specific applications.

The following sections set the stage for the discussion of potential effects by describing the enabling technologies and the nature of current applications of these technologies.

II THE ENABLING TECHNOLOGIES

A. INTRODUCTION

In 1973, Herbert Boyer and Stanley Cohen carried out the first recombinant DNA experiment. This experiment had such a profound impact on the field of biotechnology that the field can now be divided into two significant eras: before Boyer and Cohen (BBC) and after Boyer and Cohen (ABC). [1] Recombinant DNA techniques allow researchers to combine DNA from distantly related biological species. Genetic alterations brought about by recombinant DNA techniques can also be developed much more rapidly and specifically than those induced by traditional methods.

DNA, the "molecule of life" present in all living cells contains information necessary to do three things: initiate its own duplication (replication), read selective portions of the genetic material it contains (transcription), and use the information that it reads to code for proteins which will maintain the processes of life (translation).

Replication involves the creation of new DNA from the information encoded in pre-existing, or "template", DNA, resulting in two double-stranded DNA molecules, each containing one new and one old strand of DNA. [2]

Transcription is the process whereby information in the chromosomal DNA is made available to the cell by transferring

that information to a piece of messenger ribonucleic acid (mRNA). All information is encoded in mRNA by groups of three nucleotides, called codons. Each codon specifies either a particular amino acid or a stop signal. Groups of codons are then organized into genes, which encode amino acid sequences that form proteins.[3]

Translation of the information in the mRNA is the process by which proteins are synthesized. The first, or "start", codon on the mRNA is translated when transfer RNA (tRNA) containing the appropriate anticodon attaches to it. The other end of the tRNA is linked to the first amino acid of the protein. The second codon is then recognized by a specific tRNA anticodon, which brings in the second amino acid. Amino acids continue to be joined in the same manner as the mRNA moves through the ribosome, until a stop codon is reached. At that point both the mRNA and the protein are released from the ribosome.[4]

A living cell regulates the expression of its DNA by a variety of methods, for example, the cellular and subcellular location, level of expression, post-translational modification and temporal expression of protein products.[5]

B. CONVENTIONAL MUTAGENESIS AND SELECTION

A mutation is a change in the DNA of a cell, which, if translation occurs, could result in the incorporation of an

erroneous amino acid into a protein, in turn affecting the chemical reactions which are carried out by the cell. A mutation which alters one nucleotide is called a "point mutation" and may either cause an improper amino acid to be inserted into a protein or signal the synthesis of the protein to stop prematurely. A "deletion mutation" results from the deletion of one or more nucleotides. Such a change to the DNA may cause a shift in reading frame.[6] A frameshift mutation may also result from the addition of one or more nucleotides.[7]

Mutations occur spontaneously or, at a higher frequency, are induced by irradiation or the presence of mutagenic chemicals.[8] The traditional method for genetically improving organisms is by induced mutagenesis followed by selection of the altered (superior) phenotype. For example, the organism which synthesizes penicillin originally secreted only 60 milligrams of antibiotic per litre of culture but, after repeated rounds of mutagenesis and selection, the modified organism was able to secrete 7 grams per litre of culture.[9]

C. RECOMBINANT DNA

Genetic engineering by recombinant DNA technology is based upon the use of a number of naturally occurring enzymes from living cells, including restriction endonucleases. These enzymes normally protect microorganisms from the invasion of

foreign organisms by digesting or cutting up the DNA of the invading organism. Each restriction endonuclease cuts DNA at a specific nucleotide sequence.[10] The cell is immune to the action of its own endonuclease[11] since it methylates its DNA within the sequence which the restriction endonuclease recognizes.

Various methods can be used to transfer foreign DNA into a host organism: 1) Transformation involves the taking up of free DNA, usually in the form of a plasmid, by a cell and the incorporation of that DNA into that cell;[12] 2) Conjugation involves the plasmid-mediated transfer of genetic material from one bacterium to another by means of cell to cell contact;[13] 3) Transduction occurs when a virus (e.g., a bacteriophage or retrovirus) is used to transfer genetic material from a donor to a host;[14] and 4) Micromanipulation is a method of transforming host DNA in higher organisms, by injecting free DNA into animal[15] or plant cells[16] in culture.

In genetic engineering a "vector" is used to carry foreign DNA into a host organism. A restriction endonuclease cuts the vector (which is usually circular) at a particular point so that exogenous DNA can be inserted. The foreign DNA segment is then cut with the same endonuclease to enhance its ability to attach to the vector. When the ends of the foreign DNA have joined to the ends of the vector, creating a circle, some small gaps will remain at the joints.[17] T4 TNA ligase is used to seal these gaps.[18]

Vectors used to carry DNA from a donor organism into a host organism include plasmids, bacteriophages, cosmids, retroviruses and transposons.

1. Plasmids

Plasmids are small circular, double-stranded molecules of DNA which contain an origin of replication that ensures the plasmid DNA will be replicated in the host cell.[19]

A plasmid may be conjugative or non-conjugative.[20] A conjugative plasmid is capable of transferring a copy of the plasmid into a non-plasmid-containing bacterium.[21] Some bacterial DNA may also be transferred by this process.[22] While a non-conjugative plasmid is generally non-transmissible, it may also be 'mobilized' into another bacterium by a third bacterium carrying a conjugative plasmid.[23]

Plasmids may have either a broad host range, in which case they may exist in a number of different, often quite unrelated, microorganisms, or a narrow host range, in which case they are usually stable only in one particular microorganism.[24] The latter may be preferable as vectors in instances where transmission of the vector between different organisms is of concern.[25]

Many plasmids carry genes which confer a selective advantage, such as antibiotic resistance, onto the bacteria that they transform.[26] However some plasmids (often referred to as

"cryptic plasmids") have not yet been characterized with respect to phenotypic traits.[27] Because cryptic plasmids may express currently unknown traits when subjected to environmental stresses, there may be greater risk in using these vectors for recombinant organisms that will be released outside of a contained facility.

Another important characteristic of a plasmid is its "copy number" within a particular cell. High copy number plasmids will produce high levels of a cloned gene product. However, this may not always be desirable. When plasmids are present in large numbers they increase the metabolic strain on the host cell.[28] The excess gene products they produce may also be lethal to the cell.[29] Plasmids with high or regulatable copy number are most useful in a closed system (e.g., fermentor) but, because the transformed microorganism may readily lose the plasmid[30] they may be somewhat unstable in a natural environment.

2. Bacteriophages (Viruses which infect Bacteria)

Many common viral vectors are derivatives of the bacteriophage lambda which is able to integrate into the E. coli chromosome. In this integration the isolated, or cloned, gene behaves similarly to one cloned into a plasmid, replicating along with the host chromosome.[31]

Alternatively, foreign DNA may be spliced into phages which, when injected into them, will kill infected cells.[32]

Certain vectors derived from the wild-type lambda virus are able to cause such lytic infections only if foreign DNA is inserted into the vector.[33]

Transduction may be used to transfer DNA from one bacterium to another. In this process a lysogenic phage integrates into the chromosome of the host bacterial cell and replicates along with it until the induction of the lytic state, whereupon many new phage particles are formed, eventually causing cell lysis. Some phage particles may be defective in that they contain portions of plasmid or bacterial chromosomal DNA.[34] If these defective, 'transducing' phages are used to infect new bacterial cells, the bacteria-derived DNA they carry may be incorporated into the genome of the new bacterium by the process of homologous recombination.[35]

3. Cosmids

A cosmid is a plasmid containing a portion of the DNA of bacteriophage lambda, including the cos site, which is recognized by the machinery which packages phage DNA into a phage head and tail. The cosmids are "packaged" in vitro, and, the resultant 'virus' particles are then used to infect a host. Once inside the host bacterial cell the cosmid replicates as a plasmid. Transformed host cells are identified by a drug resistance marker on the cosmid vector.[36] Cosmids can carry relatively large amounts of foreign DNA (up to approximately 40 kb).

4. Retroviruses

Retroviruses have potential as vectors for genetic engineering in humans. Retroviruses contain RNA rather than DNA as their genetic material and therefore code for the enzyme, reverse transcriptase, which enables them to form DNA from an RNA template.[37] The cDNA form, i.e., the DNA complementary to the viral RNA, of retroviruses can integrate into various sites of the host genome and affect the expression of nearby genes.[38] In addition, retroviruses have nucleotide sequences which are very similar to those contained in unstable DNA elements, known as transposons.[39] Nonetheless they are considered ideal vectors for human gene therapy because they are small, contain very few genes, and can be easily modified. These viral vectors are 'disarmed' by removing the genes which code for their coat protein, and which permit them to transform the host cell into a cancerous cell. Since they are unable to replicate, they will simply serve to carry the genes into the host.[40]

5. Transposons

A transposon is a discrete segment of DNA which can duplicate itself and 'jump' to another position on an organism's genome or to another DNA molecule.[41] A transposon does not contain an origin of replication, thus it cannot exist independently and must be integrated into either plasmid, bacteriophage, or chromosomal DNA.[42] Transposons have a

repeating sequence (usually an inverted repeat) at each end of the molecule. It is believed that these sequences serve as recognition sites for enzymes involved in transposon movement.[43] In any event, they may contribute to the structural instability of DNA molecules containing transposons, by providing potential sites for homologous recombination.[44] Transposons can insert DNA, invert DNA, or cause the deletion of adjacent DNA.[45]

In using transposons as vectors the gene coding for transposase (the enzyme which catalyzes the transposition of the transposon) may be deleted from the transposon, to limit its movement.[46]

D. ANIMAL CELL FUSION

Antibodies are important components of the immune system which recognize and bind to foreign antigens, beginning a process to destroy or expel the antigen.[47] Each antigen has a number of specific sites, known as antigenic determinants or epitopes, to which an antibody may bind.[48] Generally many different antibodies, each with an affinity for a single epitope, are produced in response to a particular antigen.[49] Using cell fusion techniques, it is possible to develop a clone of cells that secretes an antibody which recognizes only one epitope of an antigen. Kohler and Milstein developed

this technique by injecting a mouse with an antigen and then removing antibody-producing spleen cells from the mouse, which they fused to mouse myeloma cells. These fused cells continued the antibody-production function of the spleen cells, while exhibiting the ability to divide indefinitely (conferred by the myeloma cells). These hybrid spleen-myeloma cells are referred to as "hybridomas". A culture of one of these hybridoma cells will secrete antibodies which recognize only one epitope and are called monoclonal antibodies.[50] Hybridomas require specialized media and growth conditions and cannot proliferate outside of the laboratory.[51]

Researchers hope to use this technique for therapeutic purposes. To do so, antibodies derived from human lymphocytes would have to be produced. However, technical problems have been encountered,[52] therefore, the major application of monoclonal antibodies to date has been in the area of diagnostics.[53]

E. PLANT CELL FUSION

PROTOPLAST FUSION (OR SOMATAIC HYDRIDIZATION)

Two cells can be fused to force a single cell by removing their cell walls by enzyme treatment,[54] fusing the protoplasts and regenerating the cell wall.

A new plant, which contains a combination of genes from both parent cells, may be grown from the fused cell. In this manner, the genetic material from plants that are sexually incompatible can be combined[55] but a major drawback to this technique is the fact that these hybrids are often genetically unstable.[56]

A variation on this process pairs one protoplast to cell components, such as chloroplasts or mitochondria of a second protoplast.[57]

PROTOPLAST REGENERATION

Cultured cells of some plant species may be regenerated into a whole plant. The process of regeneration begins with a callus, which is a culture of undifferentiated cells. Culture conditions are then adjusted, allowing the cells to proliferate and differentiate into the common organs and tissues of a normal plant.[58] This process works for only a limited number of species and, while there is interest in regenerating large numbers of tree and crop species, the present inability to do so limits the use of this process.[59]

SOMOCLONAL VARIATION

Plant cells grown in tissue culture tend to undergo spontaneous mutations so that selective pressures, such as the presence of salt, applied to plant cells in culture have the potential of producing new plants with agronomic value.[60] The ability to regenerate a particular plant from the cell culture is crucial to the success of this technique.[61]

III APPLICATIONS OF BIOTECHNOLOGY

In this section, various applications of biotechnology are discussed to provide a backdrop for the evaluation of the potential environmental impacts of biotechnology. The following discussion is therefore intended to be illustrative rather than comprehensive.

Some of the applications include discussion of products derived using traditional biological techniques for specific purposes, including nitrogen fixation, microbial pesticides, waste treatment and pollution control, and microbial ore leaching and recovery. In these instances the final product lies along a continuum, beginning with an organism marginally performing its function, and ending with one that is highly specialized and very efficient in what it does. One may move along this continuum toward the perfect microorganism (or group of microorganisms) by using traditional methodologies of mutagenesis and selection, the new enabling technologies, or a combination of the two.

SYNTHETIC VACCINES

Traditional vaccines generally consist of either attenuated or killed viruses. These vaccines are formed from viruses that retain the ability to induce a complete immune response but lose their disease-causing capabilities.

Both types of traditional vaccines cause problems in their application. For example, care must be taken to ensure that the viruses are either weakened to a proper level or are properly inactivated (individuals have sustained a viral infection as a direct result of an insufficiently attenuated virus[62]), and that they contain no other contaminating viruses. They both have a limited shelf life as well. For these reasons, better forms of vaccine have been sought.

Since a limited number of epitopes are responsible for initiating the immune response, only those portions of the viral protein need be present to elicit antibody formation. A vaccine which contains only that portion of the invading viral protein is called a synthetic vaccine. These peptides may be produced either directly by chemical synthesis or indirectly by recombinant DNA techniques. The resulting vaccine is free from harmful contaminants.[63]

These peptides may elicit the production of adequate levels of neutralizing antibodies, or they may be used for immunologically priming an animal. An example of priming involves the injection of the peptides, corresponding to the antibody-recognition site of the poliovirus, into rabbits. Although only insignificant amounts of antibody are formed initially, rabbits primed in this manner will produce much higher levels of antibody than will unprimed animals upon injection with poliovirus particles.[64]

SUBUNIT VACCINES

Subunit vaccines are those which contain either the entire set of viral proteins or a subset of the viral proteins responsible for eliciting an immune reaction, but do not contain an entire virus, as do the traditional vaccines. These antigenic proteins may be either purified from a complete virus, or created using recombinant DNA methods.

Single antigenic proteins are more stable, better characterized, and free from other viral contaminants. However, their ability to invoke antibody formation is often considerably lower than that of a complete virus (possibly because the structure of the protein is altered in some way when it forms part of the intact viral particle).[65]

Recombinant DNA techniques are being considered to fight parasitic, as well as viral diseases, such as malaria, which is caused by the invasion of the parasite Plasmodium.[65A]

VACCINIA VACCINES

Recombinant DNA techniques have been used to create a live vaccine, which elicits a better immune response than an antigenic protein, because it continually creates new antigens, thereby prolonging the effectiveness of the vaccine. Moss and Paoletti have (separately) developed such a vaccine using the vaccinia virus -- the same virus used to protect people from smallpox, which turned out to be an ideal host for the insertion of novel genes coding for immunogenic proteins.[66]

Like the natural virus, the recombinant vaccinia virus infects humans slowly (since man is not its natural host). The immune system responds, but it takes a few days before the virus is inactivated by antibody action. In the interim, it continues to replicate both itself and the foreign antigenic protein it contains. Thus, every infected cell will contain significant amounts of the foreign gene product, and therefore be protected from the infecting viral strain which naturally produces that protein.[67]

This method of vaccination has several advantages: it is relatively simple and inexpensive to manufacture large quantities of the vaccine, the virus is stable even in the absence of refrigeration, and it is possible to immunize an animal against many diseases using one recombinant vaccinia virus.[68] Vaccinia-based recombinant vaccines have been developed against rabies, influenza and hepatitis B viruses.[69]

DNA DIAGNOSTICS

Recently it has become possible to routinely chemically synthesize short stretches of DNA of a defined sequence using automated 'gene-machines'. One use for this newly-formed DNA is as a diagnostic probe. Natural double-stranded DNA can be separated into two separate strands so that when the probe is added to a mixture of such single-stranded DNA, it will seek out and bind to the sequences with which it forms complementary

base pairs. As a result, the genes containing the DNA segment of interest may be identified.[70] This technology may be used for the prenatal diagnosis of genetic diseases as well as to test for latent viral (or bacterial) infections.[71]

IMMUNOLOGICAL DIAGNOSTICS

Hybridomas produce a single gene product, monoclonal antibodies, which are highly specific and recognize only one type of antigenic determinant. They can therefore be used for specific diagnostic tests. Such tests, using monoclonal antibodies, can be used to test for pregnancy,[72] to diagnose various diseases,[73] to detect tumour-associated antigens in cancer patients,[74] to signal the presence of illicit drugs in the bloodstream,[75] and to determine hormone levels in patients.[76]

SPECIFIC DRUG DELIVERY

Therapeutic drug molecules could be attached to monoclonal antibodies, which recognize antigenic determinants associated with specific tissues or tumour cells. Thus the drug is effectively concentrated in the cells requiring treatment.[77]

PHARMACEUTICALS AND ENZYMES

Pharmaceuticals, enzymes and antigenic proteins are all produced in a similar fashion. A cloning vector containing the gene of interest is introduced into an E. coli cell, which

multiplies to form a colony of cells. This operation is scaled-up for industrial purposes to enable large populations of these transformed E. coli to grow in a large fermentation tank. To enhance the stability of the recombinant organisms, the expression of the cloned gene is generally minimized until the final stage of the fermentation process. The desired product is then extracted from the cells, and purified.[78]

A large number of useful products may be created in this manner. Human growth hormone, produced in this manner, is used to treat hypopituitarism, or dwarfism, in children.[79] An important agricultural product is bovine growth hormone, which stimulates milk production in cows.[80] Human insulin is also now manufactured using rDNA methodologies.[81]

Other proteins may also be created in this manner. Unfortunately, however, it is still somewhat unclear as to whether the production of these proteins in bacteria will result in the contamination of the final product with bacterial antigens which cause unwanted side effects in some individuals.[82]

ANTIBIOTICS

Secondary metabolites are compounds that are not absolutely necessary for an organism's growth, but which are produced under a defined set of circumstances.[83] Antibiotics are important secondary metabolites that are generally the result of complicated metabolic pathways involving several enzymes.[84]

Antibiotics are complex, usually nonprotein molecules which are lethal to certain microorganisms, and are therefore the primary means of combatting a bacterial infection.[85]

Conventional mutation and selection has led to an increased antibiotic yield. However, modern biotechnology techniques are now being applied to increase antibiotic yield and even to create new antibiotics.[86]

FINE CHEMICAL PRODUCTION

In theory, virtually all organic chemicals could be produced biosynthetically. However, for the great majority, chemical synthesis is more cost-effective. Therefore, biological methods have been employed only for the manufacture of certain specialty chemicals.[87]

Genetic engineering can be employed to facilitate existing biological synthesis routes. For example, a microorganism can be used to simplify the production of vitamin C (l-ascorbic acid), from D-glucose.[88]

BIOMASS UTILIZATION

Green plants utilize some of the energy they produce through photosynthesis to create carbohydrates, including starch, lignin, cellulose, and other materials. This plant material is referred to collectively as biomass, a renewable resource, which can be processed biologically to form a variety

of products, including alcohol and single cell proteins. Considerable effort has been directed towards developing strains of recombinant microorganisms, which are able to convert starch and cellulose into commercial products.[89] While considerable progress has been made, the major impediments to the widescale development of this technology are economic rather than scientific.

SINGLE-CELL PROTEIN

Single-cell protein consists of dried and granulated bacterial, yeast, algal, or fungal cells which have a high protein content (50-70% protein).[90] These proteins are generally used in this form as an additive to animal feed, but can also be used as a milk substitute processed for human consumption.[91] While this protein substitute is more expensive to produce than the competitive soybean meal in developed countries, there is relatively widespread use of microorganisms as a protein source in other parts of the world.[92] Efforts to apply genetic engineering procedures to improve protein yields or quality have been rather limited.[93]

BACTERIAL FERTILIZER

Nitrogen is an essential plant nutrient, often a limiting factor in plant growth. Some plants, in particular legumes, can form a symbiotic relationship with bacteria (e.g., Rhizobia[94]) which have the ability to fix atmospheric nitrogen and supply

the host plant with nitrogen-containing compounds. Nitrogen-fixing, or diazotrophic, bacteria stimulate plant growth and development by a variety of mechanisms in addition to providing the plant with fixed nitrogen and have been used to increase yields from legumes for nearly a hundred years. In 1985 a patent was taken out describing a process for Rhizobium inoculant production, whereby rhizobia grown in bulk were added to sterile ground peat, which was then applied to seeds. Since that time Rhizobium strains have been applied in large numbers to legumes, in lieu of nitrogen fertilizer.[95]

Biotechnology is currently being used in an effort to enhance symbiotic nitrogen fixation, and to extend this ability to non-legume plants.[96] Extension of the host range of Rhizobium to non-legume plants is complicated, because the host and bacterial metabolic processes are closely integrated. For example, the host plant cell regulates expression of the bacterial nitrogen fixation genes, the bacteria derepress certain host genes as well and Rhizobium depends on the host plant to supply its nutritional requirements.

A better understanding of these complex processes will be required in order to achieve this goal of extending nitrogen fixation to non-legumes.[97] Nevertheless, researchers are currently examining the feasibility of inducing cereal plants to form nodules similar to those in legume plants, which nitrogen-fixing bacteria could then inhabit. Another possibility

is to genetically modify nitrogen-fixing bacteria, so that they will be able to associate with the roots of cereal plants even in the absence of root nodules.[98]

A much more difficult project is the transfer of nitrogen-fixation genes, "nif genes", from a bacterium into a cereal plant. It is unlikely that this feat will be accomplished in the near future, if ever.[99]

Finally, there has recently been considerable interest in the development by recombinant DNA technology of free-living, as well as symbiotic, diazotrophs as bacterial fertilizers. While this work is still in its infancy, organisms which might be used include Azospirillum, Azotobacter, Klebsiella, and cyanobacteria.[100]

MICROBIAL PESTICIDES

Microbial pesticides are attractive because, unlike chemical pesticides, they tend to be target species specific and do not appear to induce resistance development in their target organisms.[101] Bacillus thuringiensis (B.t.) has been used on various crops and trees against Lepidoptera (in the larval stage). It was first registered for use as a pesticide in the United States in 1961.[102] B.t. is also registered as a microbial pest control agent in agriculture and forestry in Canada.[103] Experience with this microorganism provides useful information that should be considered when this bacterium is

modified using rDNA techniques. For example, B.t. exhibits low direct toxicity to non-target organisms, although there is some evidence of toxicity to bees. However, predators (e.g., birds) of the target Lepidoptera may be poisoned indirectly upon consumption of the treated insects.[104] Finally, B.t. proved to be genetically stable during product development, i.e., it did not easily mutate to produce a modified toxin or to increase its host range. There is, however, evidence that genetic material is transferred between species of Bacillus.[105]

Genetic engineering techniques may be used to expand the host range, virulence, or stress tolerance of a naturally-occurring microorganism.[106] Applications have already been made in the United States for permission to field test two different types of genetically engineered microbial pesticides: altered strains of Pseudomonas fluorescens and P. syringae.

The Monsanto Corporation has recently reported engineering a strain of Pseudomonas fluorescens to carry a toxin-producing gene derived from Bacillus thuringiensis. The modified P. fluorescens expresses the B.t. toxin which is lethal to certain soil insects. In commercial application, the altered bacteria would be used to coat corn seeds at the time of planting with the expectation that, as the corn plant develops, its roots would be free from invasion by soil insects.[107]

Natural, or wild-type, strains of Pseudomonas syringae synthesize a protein which is responsible for ice crystal

formation. In a mutant 'ice-minus' strain created using rDNA technology the ice-crystallizing gene has been deleted. It is hoped that potato, strawberry and other crop plants sprayed with large numbers of the modified bacteria would therefore be more resistant to frost damage. It has been argued that 'ice-minus' mutants created using rDNA have greater genetic stability than ice-minus bacteria created as a result of conventional mutagenesis and selection. This is because the rDNA mutant strain is free from silent mutations caused by uncharacterized DNA which differs from the wild-type genome that might tend to lessen the bacteria's ability to compete effectively against and then replace the wild-type strains which currently inhabit these crop plants. 'Ice-minus' bacteria are classified as pesticides since they are intended to displace naturally occurring bacteria of the same species.[108]

HYBRID PLANTS

A number of hybrid plants have already been created using the technique of protoplast fusion. For example, in one experiment an albino mutant of Nicotiana tabacum was fused with a dark green, sexually-incompatible Nicotiana species. The hybrid plant, produced from regenerated fused cells, was light green in colour and exhibited hornworm resistance.[109]

GENETICALLY ENGINEERED PLANTS - rDNA

There is currently considerable effort directed towards

the introduction of foreign DNA (derived either from plants or microorganisms) into plants in order to confer advantageous traits upon them.[110] However, serious problems remain to be solved before commercial application will be possible. Very little is understood about the regulation of gene expression in plants. The vectors presently used for DNA transfer in plants are derived from the Ti and Ri plasmids of Agrobacterium tumefaciens and A. rhizogenes, respectively.[111] The region of the Ti or Ri plasmid which is actually transferred and incorporated into the host chromosome is referred to as T-DNA or transferred DNA. The foreign gene is inserted within this region of the plasmid.[112] These vectors are limited in that they can only be used to infect dicotyledonous plants, hence at the present time this technique cannot be applied to many crop plants, including grasses and cereals.[113] Furthermore these vectors transfer DNA to the cell nucleus, but not to important DNA-containing cell organelles, such as mitochondria and chloroplasts.[114] An additional disadvantage is that the insertion of the foreign DNA occurs essentially at random, into one of many potential insertion sites.[115]

In an effort to overcome some of the limitations imposed by the use of the Ti and Ri plasmid systems, several direct gene transfer protocols have been developed. These protocols have been used to transfer foreign DNA into protoplasts of both monocots and dicots, and through pollen.[116]

Researchers at Calgene, Inc. in Davis, California have reported creating tobacco plants with increased resistance to the herbicide glyphosate. Tobacco cells were transformed by a mutant aro A gene derived from the bacterium Salmonella typhimurium. The product of this gene is a modified enzyme, which increases the organism's resistance to glyphosate. The vector used to effect this transfer was the Ri plasmid of A. rhizogenes. Cells transformed in this manner were regenerated into plants which exhibited a greater glyphosate tolerance than did control plants.[117]

WASTE TREATMENT AND POLLUTION CONTROL

A strain of Pseudomonas capable of degrading four classes of chemicals found in oil spills has been developed by combining genes from four different Pseudomonas strains, each capable of degrading one of the four chemicals. The 'degradation genes', located on bacterial plasmids, were readily transferred to create a microorganism capable of degrading all four compounds. Oil spills could be cleaned up by coating straw with this engineered bacterium and dropping this coated straw into them. The oil will be absorbed by the straw and degraded by the bacteria. There are instances, however, when it may be more appropriate to use a combination of the four wild-type bacteria to degrade chemical spills. This would allow preferential selection for the bacterial populations able to degrade the main chemical in the spill.[118]

In a similar manner, microorganisms have been produced with the ability to degrade a variety of industrial chemicals and could be used to clean up spills of dangerous or toxic chemicals.[119]

MICROBIAL ORE LEACHING AND RECOVERY

The process of microbial ore leaching uses bacteria to transform mineral ores into a soluble state, to improve mineral extraction. The bacteria may extract the metal directly, or they may produce chemical substances which act to remove the metal.[120] Bacteria have been selected and used in mining for approximately twenty-five years, so that today approximately 10% of the copper produced in the United States is obtained through microbial mining.[121] In Canada, microbes have been used for the 'underground solution mining' of uranium. In this process water is pumped into underground mines containing metal-dissolving bacteria. When the water is returned to the surface, dissolved uranium can be extracted.[122]

Microorganisms are also useful for metal recovery since they can concentrate metals from dilute solutions, either for industrial waste treatment or as a form of mineral extraction. In this application, microorganisms bind metals, and then concentrate them internally.[123]

Recombinant DNA techniques could be used to improve the mineral-leaching abilities of organisms naturally occurring in

mines. One candidate for such modification is the bacterium Thiobacillus ferrooxidans which leaches copper, iron, sulphur, and uranium.[124] However further knowledge of bacterial structure, bacterial-rock interface, and interactions between various populations of ore leaching microorganisms is desirable.[125]

MICROBIAL OIL RECOVERY

Oil recovery might be enhanced by using microorganisms that form certain chemicals that enhance the flow and hence the yield of petroleum from an oil well. Carbon dioxide is one product considered useful for this purpose. Another is Xantham gum, produced by Xanthomonas campestris.[126] It is envisioned that either the microbially produced chemical or the microorganism itself could be injected into the well. In order to be able to survive a well environment, however, microorganisms would have to be able to withstand high temperatures, extremes in pH, the presence of sulphur and salt, and the limited availability of oxygen and water.[127].

Genetic engineering could be utilized to modify the genome of a microorganism so that different chemicals could be produced to enhance oil recovery. In addition, the bacteria could be altered to tolerate the extreme conditions found within an oil well.[128]

IV ENVIRONMENTAL IMPLICATIONS OF BIOTECHNOLOGY

INTRODUCTION

As with any technology, there are risks associated with the development of biotechnology and with the application of its products, both from an occupational health, and a wider environmental perspective. The products of biotechnology are of three types: inanimate purified chemicals, killed microorganisms, or live genetically-altered organisms. These products and the processes used in developing them have the potential to impact only those directly involved in the production process or to cause wide-scale perturbations in the natural environment. However, one cannot yet readily predict the impact of the introduction of a particular organism into a new environment and problems exist in developing a methodology to adequately assess these risks. In the case of genetically engineered organisms, "no historical and scientific data base exists concerning the behavioural characteristics of genetically engineered organisms in the environment, and no standard ecological methodology for predicting the outcome of an exotic introduction currently exists."[129]

Anticipating the impact of a large-scale environmental release of genetically-engineered microorganisms is particularly difficult because, unlike higher plants and animals, they reproduce rapidly and may travel great distances. Furthermore,

their potential interactions with other organisms in the environment are not well understood.[130] A meaningful environmental impact assessment requires the following information about the microorganism: classification, strain history, survival and growth patterns, potential to transfer genetic material, dispersal, and possible methods of monitoring the organism or containing it within a specified area.[131] In most cases substantial research is still required to answer these questions.

A further problem in predicting impact is that most available information comes from contained experiments in a laboratory or greenhouse and the results cannot easily be used to make predictions about an organism's behaviour upon release. In the field, selection pressures are exerted upon the organism, which may cause it to undergo both physiological and genetic changes. New properties or traits could appear in response to these environmental stresses.[132]

In addition, while ecologists may need a great deal of time to adequately address these issues, demands for this information by regulatory agencies could place researchers under unrealistic time constraints.[133] Another problem is that information necessary for a full assessment of risks may be withheld in a company's efforts to protect commercial secrets.[134]

Despite these constraints, considerable effort has been put into assessing the potential impacts of biotechnology. The

nature of these impacts is discussed below, primarily in terms of environmental impact.

CONTAINED APPLICATIONS

In these applications, a genetically transformed organism produces a gene product in a large fermentation vessel. The product is then extracted, purified, and tested prior to its sale. Therefore the potential hazards are related to occupational health and safety, improper waste treatment of dead cells from the purification process, and the unintended release of the microorganism. In the case of unintended release, the risk considerations would be similar to those arising when a live altered organism is purposefully released into the environment to perform a given task. However, the risk is not expected to be as great because a microorganism developed to produce large amounts of a single gene product requires special media and growth conditions to survive and is thus unlikely to proliferate outside of such a controlled environment.[135] One of the most important determinants of risk is whether the product is pathogenic.

Within the factory, worker safety is optimized when appropriate biological and physical containment facilities are used in the production process. Biological containment consists of choosing a debilitated host-vector system that has a low

probability of surviving or of transferring genetic material to other organisms, should it escape from the fermentation vessel.

It is generally accepted that recombinant DNA organisms accidentally released from the laboratory will not be able to survive in the environment because they are debilitated in some way.[136] Debilitation in this sense refers to a physiological rather than an ecological weakness. However, organisms which are weak in this sense may still have an adaptive advantage in the environment. Enfeebled organisms should be tested in the environment to ensure that they will not survive in nature.[137]

One type of debilitated host used for genetic engineering is E. coli K-12. Since E. coli is a natural colonizer of the human colon, an escaped organism carrying a foreign gene could have unexpected effects on human populations. Therefore a weakened form (which is sensitive to bile salts, requires special nutrients to survive, and takes two times longer to reporduce than the wild-type strain) was produced for genetic research.[138] Risk assessment studies show that E. coli K-12 is safe for healthy researchers, but that it can colonize the intestines of those on antibiotic therapy, presumably because competition from indigenous strains is reduced and selection occurs for antibiotic resistant phenotypes.[139] Several studies have shown that E. coli K-12 does not colonize the human colon, suggesting the greater competitive ability of the indigenous microbes as a likely explanation.

Physical containment is achieved by: (1) the use of proper fermentation facilities and ventilation systems, (2) the hiring of skilled personnel who are trained in proper and safe operating practices and techniques, and (3) ensuring that these facilities are located in a well-designed facility, which protects the environment outside the production area.[141]

The level of containment should be matched to the perceived level of risk arising from the industrial activity. Ideally, both the host to be modified and the final host-vector system should be non-pathogenic. Where pathogenic organisms are in use, the containment levels must be correspondingly higher. The vector used for the transfer of foreign DNA should be well-characterized, free from harmful DNA sequences, and poorly mobilizable.[142]

The determination of whether or not an organism is pathogenic is a difficult task. First of all, pathogenicity depends upon the interaction of the microorganism and the person exposed. The person's susceptibility as a host for a particular pathogen depends upon his age and health, as well as the presence of medications in his body.[143] Secondly, pathogenicity tests performed in animals are only of limited usefulness in predicting pathogenicity in humans. This is because some animals are immune to organisms that cause disease in humans, and vice versa and the tests usually do not cover a wide range of dosage levels or possible routes of infection.[144]

Numerous hazards exist when modified microorganisms are used in industrial production. Although the fermentation process is a relatively safe one, possibilities exist for exposure through releases to the air or accidental spills.[145] A good guide for containment during the fermentation process is found in the NIH guidelines, which are generally perceived as being reasonable and adequate.[146] As a result of many years of the safe application of biotechnology to industrial processes, these guidelines have become progressively less stringent. Relaxation of the guidelines has been based on a good safety record,[147] together with experience that has been gained by thousands of laboratories worldwide regarding the intrinsic nature of the risks involved. However, some questions still remain with respect to whether a complete scientific investigation of the risks has been carried out.[148]

Exposure to the end product or the waste remaining after purification are other potential hazards. A biologically active product, such as an antibiotic or toxin, may cause allergic reactions in some workers.[149] Similarly, an improperly purified product can be dangerous to its ultimate consumer. Thus, steps must be taken to ensure all contaminants are removed from the final product.[150] An industrial purification process may result in a waste product comprised of numerous microorganisms, which will have to be treated. If the microorganisms are

pathogenic, they will first be killed by physical or chemical means. Improper disposal of these wastes could create an environmental problem.[151]

Finally, when the product of a biotechnological process is a purified substance, such as human insulin, the purity and efficacy of that substance is readily ascertainable. In fact, such substances may be treated and assessed using criteria established for the same or similar substances isolated from traditional sources.[152]

KILLED MICROORGANISMS FORMING THE PRODUCT

The potential impacts in this case are generally the same as those mentioned above. However, there is a problem of toxins remaining in such cells, particularly when the products are not purified. For example, single cell proteins are feed or food supplements derived from dried cells with a high protein content. In 1973, two Japanese companies abandoned production of their yeast-produced SCP's, because of claims that the product might contain carcinogenic hydrocarbons.[153] In addition there is a very small, but finite, possibility that the DNA from these organisms could be transferred to other organisms.

GENETICALLY MODIFIED ORGANISMS RELEASED TO THE ENVIRONMENT

GENERAL

It is generally agreed among scientists that a certain

amount of caution should be used before approving any deliberate release of genetically altered species into the environment.

Undoubtedly, the greatest environmental concerns arise when the final product of biotechnology is a new live organism released into the environment to perform a particular function.

Ecological "disasters" have been caused by the introduction of foreign, naturally occurring species into a new ecosystem. For example, gypsy moths, which were introduced into the United States from Europe, periodically defoliate millions of acres of American forests.[154] Some ecologists feel that the ecological concerns presented by organisms developed by recombinant DNA techniques or cell fusion are no different from those encountered when any species is introduced into a new environment. For example, Frances Sharples, a terrestrial ecologist at Oak Ridges National Laboratory, expresses the following opinion:

> I believe that the likelihood of an organism becoming established in a given environment is an ecological question regardless of the origin or nature of the differences that makes such an organism new or novel. The proportion of the genome which is 'new' is not necessarily correlated with the degree of impact an organism can have on an ecological system. I believe that the analogy between recombinant organisms and introduced species is a valid one.[155]

In contrast, others argue that such engineered organisms may indeed present new ecological risks. There are several reasons for this. First of all, genetic manipulation allows unique

combinations of genetic material which would never occur in nature. Donald Clay of the U.S.Environmental Protection Agency has stated: "Genetic technologies for the first time allow the recombination of genes or organisms that could not or would not recombine in nature; this leads to novel organisms.[156] Secondly, biotechnology allows new species to be created at a much faster rate than occurs in nature.[157] Thirdly, with these techniques, thousands of individuals with the same genetic alteration can be introduced into an ecosystem at the same time.[158] Finally, the technique by which a new organism is produced can influence the genetic stability of an organism, the extent of alteration to existing DNA, and the amounts of possibly un-characterized DNA added to the organism.[159]

PREDICTING THE ORGANISM'S ENVIRONMENTAL IMPACT

Given the differing views of scientists and the general lack of experience with large-scale introductions of live altered organisms into the environment, it becomes difficult to predict the effects of a particular environmental release.

The ability to predict the behaviour of a modified organism in the environment depends in part upon how it was produced. Some scientists feel that genetically-engineered organisms aid the prediction, because the entire nucleotide sequence of the added gene can be determined; others feel that predictability is reduced because the recombinant organism becomes a source for the dispersal of the new gene within the ecosystem.[160]

Martin Alexander has suggested a conceptual framework for the assessment process.[161] Thus, the probability of a deleterious effect from the release of a modified microorganism (P) is a function of six factors, P_1, P_2, P_3, P_4, P_5, and P_6, where:

P_1 is the probability the organism will be released

P_2 is the probability the organism will survive

P_3 is the probability that the surviving organism will be able to multiply

P_4 is the probability that the organism will be transported to a site where it may have an effect

P_5 is the probability that genetic information coding for a deleterious trait will be transferred to another species

P_6 is the probability that the engineered organism, or an organism to which it transfers its DNA, will harm the ecosystem

For deliberate releases, it is assumed that the organism will be released, i.e., that $P_1=1$. The other elements of this equation are discussed below.

Although Alexander's framework was developed with genetically engineered organisms in mind, the same principles apply to the selective application of large numbers of naturally occurring organisms (for example, in microbial mining, bacterial fertilization and pest control). However, in these cases a history should exist for the particular organism(s) in question with

respect to survival, behaviour, and possibly environmental interactions, considerably simplifying the calculation of the relevant probabilities.

SURVIVAL

Ecologists have differing views with respect to the ability of organisms (from any origin) to successfully establish themselves within a new ecosystem. On the one hand, Brock argues that microbiological communities are generally at equilibrium and the species are optimally adjusted to their surroundings. Novel genotypes therefore have difficulty establishing themselves within a community unless selection pressures change.[162] On the other hand, Regal argues that communities of higher animals are generally adequately (but not perfectly) adapted to their environment and the systems often deviate from an equilibrium position. Furthermore, he feels that ecosystems will be particularly prone to invasion by modified organisms which can overcome limiting factors in the environment, such as organisms that can withstand temperature extremes.[163] Under either view there is some possibility that a novel organism introduced into an ecosystem will survive.

Numerous factors affecting the survival of a released organism have been identified, including: the season of the release, the pH of the environment, the extent of adsorption of the microorganism to the soil, the water content of the soil,

the soil type and the presence of nutrients.[164] Death of microorganisms could be caused by toxins in the soil, solar radiation, acidity, bacteriophages, predators or lack of essential nutrients.[165]

Another factor affecting survival is the amount of DNA contained within the cell. Generally, bacteria which carry extra plasmids as a result of genetic engineering are less able to survive than their parental strains, unless the plasmid carries a trait conferring some selective advantage on the host, because the cell expends extra energy replicating this additional DNA. Further energy drains occur if the cell actually expresses any of the gene products encoded by the foreign DNA.[166] However, exceptions to the general rule occur, even in commonly used host-vector systems. For example, E. coli K-12 strain x^{1776} survived longer when it contained the plasmid pBR322.[167]

GROWTH AND MULTIPLICATION

Alexander has advanced the view that significant ecosystem impact is not caused by a small number of individuals, but rather by large populations. Therefore one must be concerned with a surviving organism's potential for growth and multiplication.[168] Organisms which are capable of tolerating the environment stresses as well as successfully competing will proliferate in the environment. However, research is required

to determine the factors that enable certain surviving species, but not others, to grow and multiply.[169] An understanding of the factors that make a microorganism competitive in a specific field situation is not readily ascertained by monitoring the behaviour of that organism in a laboratory setting.

DISSEMINATION

In order for the engineered organism to have an adverse effect it must be brought into contact with organisms or environments which could be harmed by it.[170] Dispersal from the target environment enables the organism to find a growing site with more favourable conditions, thus enhancing its growth potential and therefore its ability to modify its environment.[171]

All organisms have the potential for dispersal. Animals can travel using their own locomotive capabilities and plant seeds and pollen can travel considerable distances. Microorganisms, however, have the greatest capacity for dispersal, often being able to travel hundreds or thousands of miles.[172]

A single microorganism may be dispersed by one or more of the following methods: 1) air 2) water 3) animal vectors, and 4) direct human contact. A variety of factors influence the efficiency of bacterial dispersal. As a general rule, the larger the initial population of microorganisms released to

the environment, the more extensive will be their dispersal. It also appears that microorganisms introduced into certain environments will spread more efficiently, although the effect of habitat on dispersal is not clearly understood.[173]

Successful aerial dispersal depends upon the amount of time the bacteria can survive in the air, and the size and shape of the particles to which the bacteria are adsorbed.[174]

Properties of the water, including current and wave action, are major factors in water dispersal.[175] Popular animal vectors are earthworms and burrowing mammals (for soil bacteria), bees and other insects.[176] Direct contact is a common dispersal mechanism in infectious diseases.[177]

An interesting hypothesis is that bacteria may affect their own dispersal by controlling their adhesion to or release from particles, or by alteration of particle size (e.g., ice formation around ice-nucleating bacteria).[178]

TRANSFER OF GENETIC MATERIAL

It is possible that deleterious effects to the environment could result when the released organism transfers DNA to another organism which then modifies the environment.[179] For example, herbicide resistance could be transferred from a modified crop plant to a weed. In order to determine the probability of transfer, two factors must be considered. One is the stability of the engineered host-vector system. Conversely,

the genetically engineered organism could obtain a new undesirable trait from other organisms in the environment.

Most of the literature on this question concentrates on the possibility that the released organism will pass its DNA to other organisms. DNA can be transferred sexually or horizontally by plasmids, viruses, or transposons. Once again, the greatest potential for genetic exchange occurs in micro-organisms, which are naturally able to exchange genetic material between species and even genera.[180] This genetic information can be transferred by the mechanisms of conjugation, transduction, and transformation.

Researchers have attempted to use safe vectors or to 'disarm' potentially harmful vectors that are used to insert foreign DNA into a host in order to minimize the risk of gene transfer. However, this strategy has not been entirely successful. For example, while non-conjugative plasmids are generally used as cloning vectors, it has been shown that these generally non-transmissible plasmids can be mobilized if a conjugative plasmid co-exists in the donor cell, or a triparental mating occurs (whereby a third bacterium is used to introduce a conjugative plasmid into the donor cell).[181] The plasmid pBR322 is such a non-conjugative plasmid, which is considered to be poorly mobilizable by triparental mating.[182] However, laboratory strains of E. coli containing pBR322 were able to transfer this

plasmid to recipient bacteria that had been isolated from raw wastewater, when they were incubated with a mobilizer strain of E. coli (containing a conjugative plasmid).[183] It has also been shown that pBR322 can be mobilized from cells which contain both a conjugative plasmid and the plasmid Col K. As a result a new vector derived from pBR322 was constructed, in which part of the DNA necessary for transfer by conjugation was deleted. This derived vector is called pAT153, and is considered non-mobilizable.[184]

The concept of 'disarming' a vector can best be understood in relation to transposon vectors. As previously described, transposons are small, very mobile DNA segments which insert into DNA at numerous positions, Their mobility makes them somewhat unstable vectors. However, transposons carry DNA encoding for transposase, an enzyme necessary for their movement. This vector may therefore be disarmed by removing its ability to produce transposase,[185] but the potential for acquiring the transposase from another source, and thus re-mobilizing the vector, should be considered.

Finally, the transferred and vector DNA sequences should be designed to be as stable as possible. There are certain DNA configurations which are considered unstable, since they are prone to homologous recombination and deletion formation: short direct repeats, inverted repeats, multiple tandem promoters, and long terminal repeats.[186] When these DNA characteristics

are present in recombinant DNA organisms, concerns about the stability of the genetic material arise.

DELETERIOUS EFFECTS

The probability of a negative impact on the environment by the released engineered organism (or another organism to which it has transferred genetic material) depends on such a multiplicity of factors, that they can only be considered on a case-by-case basis. Therefore the potential impacts of selected examples will be discussed below.

Deleterious environmental impacts will generally fall into one of the following categories:

1. Competition with or replacement of an established species
2. Unrestrained species growth due to lack of natural enemies
3. Unexpected infectivity, pathogenicity or toxicity
4. Infectivity, pathogenicity or toxicity to non-target organisms
5. Transfer of genetic traits to unintended recipients (e.g., from crop plants to weeds)
6. Deleterious effect caused by escape into an unintended environment (for example, ice-minus bacteria may migrate north, harming plants which require a freezing season in order to grow)
7. Modification of biogeochemical or biological cycle processes, such as the nitrogen cycle
8. Unanticipated modification of the abiotic environment (e.g., interference with rainfall)

9. Secondary effects, such as the increased use of herbicides because of the presence of herbicide-resistant plants

In each environmental application, the possibility of any one of the above effects should be considered.

POTENTIAL CONCERNS RELATED TO SELECTED APPLICATIONS OF BIOTECHNOLOGY

VACCINIA VACCINES

Even though the vaccinia virus has been used safely in the eradication of smallpox, there are some concerns about using it as a live recombinant vaccine. The virus functions as a weakened virus, however, since little is known about its attenuation mechanism, a recombinant DNA vaccine may prove more virulent than anticipated. Although the virus has a broad host range, its effect differs from species to species. Therefore, the potential danger of a live recombinant DNA vaccine being transferred between species should be considered.[187] Past experience has shown that the vaccinia virus itself may result in undesirable side effects, including skin eruptions and central nervous disorders.[188] Vaccinia vaccines have recently been shown to be an effective means of immunizing foxes against rabies so that it is likely that this type of vaccine will be utilized in an attempt to eradicate rabies in wild animals.[189]

BACTERIAL AND FUNGAL FERTILIZERS

A 1975 experiment, carried out to develop the nitrogen-fixing ability of Rhizosphere microorganisms indigenous to a particular pine tree species, by K.L. Giles and H.C.M. Whitehead of New Zealand, demonstrated that the combination of two non-pathogenic organisms could result in a fused organism exhibiting unexpected pathogenicity. Protoplasts of Azotobacter vinelandii were fused with protoplasts of the mychorrizal fungus Rhizopogon, both populations of cells being non-pathogenic. One strain of the fused cells killed tree seedlings to which it was applied. The hyphae of this strain were found not only in the intercellular spaces of the plants (as expected), but also within the root cortex cells. In this instance, this modification turned a normally non-pathogenic, symbiotic fungus into one which was lethal to tree seedlings. However, this type of deleterious effect could easily be detected by laboratory testing.[190]

MICROBIAL PESTICIDES

In the development of the "ice-minus" bacteria, certain precautions were taken to minimize environmental risks. Modification was carried out by means of a deletion, effectively preventing reversion to the wild-type and avoiding the danger of inserting any uncharacterized DNA.[191] Notwithstanding the fact that most strains of P. syringae are natural pathogens for several major crops,[192] the strains used in this experiment

were isolated from asymptomatic plants and failed to exhibit pathogenicity in their isolated or engineered state.[193]

Environmental concerns raised by opponents of this experiment include: the possibility that these bacteria will migrate north proving harmful to northern plants which require a frost season in order to grow,[194] the possibility that the ice-minus gene will be transferred to insects thereby increasing the host range[195] and the concern that rainfall may be inhibited by displacement of the wild-type bacteria by the ice-minus strain (because the ice-crystallization protein is considered to play an important role in the formation of snow and rainfall).[196]

The development of a Pseudomonas strain which carries and expresses the B.t. toxin is somewhat more problematic. Initial concerns are the same as those related to chemical pesticides: human and non-human health effects, and environmental contamination by the toxin they produce.[197] It is also possible that this living, multiplying pesticide may prove harmful to earthworms and other beneficial soil organisms.[198] Genetic engineering designed to enhance the commercial success of a microbial pesticide may unexpectedly increase its host range or virulence.[199] The proponents of this experiment have considered fumigation as a possible means of controlling this pesticide, in the event that it displays harmful characteristics.[200]

GENETICALLY ENGINEERED PLANTS

Since portions of the DNA of a weed species may be quite similar to portions of the DNA of a related crop species, there is a risk that a trait conferring a selective advantage on a plant (e.g., herbicide resistance in a field treated with herbicide) may be transferred to a closely related weed.[201] In this light, the potentially unstable "direct repeat" sequences bordering the T-DNA (on the Ti plasmid) are a concern, since these sequences enhance recombination and therefore the possibility of transfer of this genetic trait.

A secondary effect would be an increased use of the herbicide, increasing environmental contamination and posing possible risks to human health.[202]

There is also some concern that plants which have been genetically engineered by inserting DNA sequences which were not fully characterized, could produce a toxic protein or secondary metabolite. Such plants should therefore be tested for toxicity.[203]

WASTE TREATMENT AND POLLUTION CONTROL

The degradation of lignin is one of the slowest reactions in biomass degradation. If an organism was engineered to rapidly break down this material, the rate of conversion of biomass to gases and other by-products of microbial fermentation (such as ethanol) would occur much more rapidly,[204] which in turn

would alter the nutrient cycling process. These organisms would also have the potential to attack live trees (largely composed of lignocellulose).[205] However, given the fact that untreated lignocellulose is highly resistant to hydrolysis, it is likely that any process which involved the digestion of lignocellulosics would have to be performed in some sort of closed fermentation vessel under controlled conditions.[206]

Microorganisms used to degrade oil and industrial chemicals could also have unintended consequences. For example, they could leave their intended environment, begin degrading other related compounds or break down the substrate into a new, toxic, compound.[207] Small-scale experiments would be useful in more accurately assessing the nature of the potential risk.

MICROBIAL ORE LEACHING AND RECOVERY

Bacteria modified to leach minerals and released in a mine could cause harm if they subsequently invaded a different environment. For example, because plants require iron in an unoxidized state as a nutrient, invasion of the environment by large numbers of bacteria which oxidize iron could detrimentally affect plant populations.[208] Similarly, bacteria engineered to concentrate metal from an aqueous solution could deplete essential minerals (used to form enzyme co-factors), if they escaped to and proliferated in a freshwater ecosystem.[209]

V CONCLUSION

The environmental impact of a particular genetic manipulation is very difficult to predict a priori. At present, the only way to attempt assessment of the risks is on a case-by-case basis, with both the end product and the method by which it was developed as relevant considerations in such an assessment.

There is a great need for data on the behaviour of genetically engineered organisms in the environment. As additional knowledge is obtained about the nature, survival, and stability of various vectors, hosts and host-vector systems, and as scientific expertise in predictive models develops, the task should become more manageable.

FOOTNOTES

1. J.J. Pasternak, "Activities in Genetic Engineering and the Biosciences," in Proceedings, Biotechnology Day 1: Identifying Opportunities in Biotechnology, October 6, 1983), 53-59, at 53-54.

2. Karl Drlica, Understanding DNA and Gene Cloning (New York: Wiley & Sons, 1984) 52-57.

3. Ibid., at 27-36, and 186.

4. Ibid., at 36-42.

5. Bernard R. Glick and Gordon K. Whitney, "Optimization of the Production of Foreign Proteins in Recombinant Escherichia coli" (processed, Department of Biology, University of Waterloo, 1986).

6. Drlica, supra footnote 2, at 57-61.

7. Ibid., at 189.

8. David A. Hopwood, "The Genetic Programming of Industrial Microorganisms" (Sept. 1981), 245 Scientific American, 91-102, at 92-93.

9. Yair Aharonowitz and Gerald Cohen, "The Microbiological Production of Pharmaceuticals" (Sept. 1981), 245 Scientific American, 141-152, at 144.

10. Drlica, supra, footnote 2, at 195-96.

11. R.W. Old and S.B. Primrose, Principles of Gene Manipulation, 3rd ed. (Cambridge: Blackwell Scientific Publications, 1985), 21.

12. (i) Drlica, supra footnote 2, at 198.

    (ii) Monroe W. Strickberger, Genetics, 2nd ed. (New York: Macmillan Publishing, 1976), at 860.

    (iii) Harvey S. Price, Exec. Dir., Biotechnology at Work: Glossary of Terms, (Rockville, Maryland: Industrial Biotechnology Association, 1985), 7.

13. (i) G. Stotzky and H. Bābich, "Fate of Genetically-Engineered Microbes in Natural Environments" (Dec. 1984), 7 Rec. DNA Tech. Bull. 163-88, at 165.

(ii) J.W. Gillett, "Genetic Stability of Engineered Microorganisms" (July 1986), 10 Environmental Management 488-493, at 489-91.

(iii) Drlica, supra footnote 2, at 173 and 187.

14. (i) Stotzy and Babich, supra footnote 1 (i), at 166.

(ii) Strickberger, supra footnote 12 (ii), at 861.

(iii) Price, supra footnote 12 (iii), at 7.

15. Old and Primrose, supra footnote 11, at 262-4.

16. Peter D. Shargool, "Biotechnological Applications of Plant Cells in Culture" (1985), 3 Biotech. Advs. 29-38, at 31-32.

17. Drlica, supra footnote 2, at 80.

18. Old and Primrose, supra footnote 11, 30-34.
Drlica, supra footnote 2, at 80.

19. Drlica, supra footnote 2, at 94.

20. Old and Primrose, supra footnote 11, at 47-48.

21. (i) Stotzky and Babich, supra footnote 1 (i), at 165.

(ii) Drlica, supra footnote 2, at 173.

22. Stotzky and Babich, supra footnote 13 (i), at 165.

23. Ibid., at 166.

24. Ibid., at 165.

25. Gillet, supra footnote 13 (ii), at 489.

26. (i) Drlica, supra footnote 2, at 95.

(ii) Stotzky and Babich, supra footnote 13 (i), at 164.

27. (i) Stotzky and Babich, supra footnote 13 (i), at 164.

(ii) Old and Primrose, supra footnote 11, at 47.

28. (i) Old and Primrose, supra footnote 11, at 149.
    (ii) Stotzky and Babich, supra footnote 13 (i), at 164.
    (iii) Glick and Whitney, supra footnote 5.

29. Glick and Whitney, supra footnote 5.

30. Stotzky and Babich, supra footnote 13 (i), at 164.

31. Drlica, supra footnote 2, at 105-7 and 191.

32. Ibid., at 103-4 and 191.

33. Old and Primrose, supra footnote 11, at 77-78.

34. Stotzky and Babich, supra, footnote 13 (i), at 166.

35. (i) Gillett, supra footnote 13 (ii), at 490-91.
    (ii) Stotzky and Babich, supra footnote 13 (i), at 166.

36. Old and Primrose, supra footnote 11, at 85-87.

37. Drlica, supra footnote 2, at 69 and 196.

38. Susan Gottesman, "Genetic Variation and Gene Transfer," in Harlyn O. Halvorson, David Pramer, and Marvin Rogul, eds., Engineered Organisms in the Environment: Scientific Issues, proceedings of a cross-disciplinary symposium held in Philadelphia, Pennsylvania, 10-13 June 1985 (Washington, D.C.: American Society for Microbiology, 1985) 226-27, at 226.

39. Drlica, supra footnote 2, at 162.

40. Harold M. Schmeck, "Operation a gene ouvert," June 1986, L'Actualite 93-95.

41. (i) Drlica, supra footnote 2, at 157-58 and 198.
    (ii) F.E. Sharples, "Spread of Organisms with Novel Genotypes: Thoughts from an Ecological Perspective" (June 1983), 6 Rec. DNA Tech. Bull. 43-56, at 52.
    (iii) Stotzky and Babich, supra footnote 13 (i), at 164-65.

42. Stotzky and Babich, supra footnote 13 (i), at 166.

43. Drlica, supra footnote 2, at 158.

44. Mary-Dell Chilton, "A Vector for Introducing New Genes into Plants" (June 1983), 248 Scientific American 51-59, at 56.

45. Old and Primrose, supra footnote 13 (i), at 151.

46. Drlica, supra footnote 2, at 158-60.

47. Ibid., at 152.

48. Ronald C. Kennedy, Joseph L. Melnick and Gordon R. Dreesman, "Anti-diotypes and Immunity" (July 1986), 255 Scientific American 48-56, at 48.

49. Cesar Milstein, "Monoclonal Antibodies" (Oct. 1980), 243 Scientific American 66-74, at 66.

50. (i) Milstein, supra footnote 49, at 158-66.

    (ii) Robert R. Weaver, "Beyond Supermouse: Changing Life Genetic Blueprint (Dec. 1984), 166 National Geographic 818-47, at 830 and 833.

51. For example see, Milstein, supra footnote 49, where he successfully isolated fused immunoglobin-secreting cells on a selective medium (e.g. HAT) and discovered that clones of these cells could be maintained "in culture".

52. Milstein, supra footnote 49, at 166.

53. United States, Congress, Office of Technology Assessment, Impacts of Applied Genetics: Micro-Organisms, Plants, and Animals (Washington, D.C.: U.S. Government Printing Office, 1981), 71.

54. Sheldon Krimsky, "Regulatory Policies on Biotechnology in Canada" (Manuscript, Science Council of Canada, October 1984), at 12.

55. U.S., Congress, O.T.A., supra footnote 53, at 145.

56. (i) Canada, Canadian Agricultural Research Council, "Research and Development for Canada's Agricultural and Food System" (report, CARC, April 28, 1983) at 20-21.

    (ii) U.S., Congress, O.T.A., supra footnote 53, at 145.

57. U.S., Congress, O.T.A., supra footnote 53, at 145.

58. (i) U.S., Congress, O.T.A., supra footnote 53, at 141-42.

(ii) Weaver, supra footnote 50 (ii), at 834.

59. U.S., Congress, O.T.A., supra footnote 53, at 149-50.

60. (i) Ralph W.F. Hardy, "Biotechnology in Agriculture: Status, Potential, Concerns," in Albert H. Teich, Morris A. Levin, and Jill H. Pace, eds., Biotechnology and the Environment: Risk & Regulation, proceedings of a seminar series conducted by the American Association for the Advancement of Science for the U.S. Environmental Protection Agency (Washington, D.C.: AAAS, 1985), 99-108, at 100.

(ii) Shargool, supra footnote 18, at 32.

(iii) Canada, CARC, supra footnote 56 (i), at 20.

61. Krimsky, supra footnote 54, at 12.

62. F. Brown, "Synthetic Viral Vaccines" (1984), 3 Ann. Rev. Microbiol. 221-35, at 221-23.

63. Ibid., at 223 and 228-33.

64. Ibid., at 231-33.

65. Ibid., at 226-8.

65A. G. Nigel Gordon, "Molecular Approaches to Malaria Vaccines" (May, 1985), 252 Sci. Amer. 52-59.

66. J.A.R. Keus, "An accidental human trial of recombinant vaccinia virus: a step towards the acceptance of live recombinant vaccines?" (May 1986), 4 Trends in Biotechnology 105 - 106, at 105.

67. Ibid.

68. Ibid., at 106.

69. Ibid.

70. Bernard Conrad Cole, "Making Genes with Machines" (Sept./ Oct. 1981) 1 High Technology 60-68, at 60-65.

71. (i) H.H. Kazazian, Jr., "Gene Probes: Applications to Prenatal and Postnatal Diagnosis of Genetic Disease" (Sept. 1985), 31 Clinical Chemistry 1509-13.

71. (ii) Cole, supra footnote 70, at 60-68.

(iii) DuPont, Biotechnology Systems, NEN Research Products, "Synthetic Nucleic Acid Probes," #E-80010.

72. Weaver, supra footnote 50 (ii), at 836.

73. U.S., Congress, O.T.A., supra footnote 53, at 72.

74. (i) U.S., Congress, O.T.A., supra footnote 53, at 72.

(ii) Denise E. Bu'Lock, "Diagnostic and Medical Applications: Monoclonal Antibodies" (1983), 1 Biotech. Advs. 81-93, at 84-85.

75. U.S., Congress, O.T.A., supra footnote 53, at 72.

76. Ibid.

77. (i) Milstein, supra footnote 49, at 166.

(ii) Weaver, supra footnote 50 (ii), at 830.

78. U.S., Congress, O.T.A., supra footnote 53, at 63.

79. Ibid., 67.

80. Weaver, supra footnote 50 (ii), at 827.

81. U.S., Congress, O.T.A., supra footnote 53, at 65-67.

82. Ibid., at 72.

83. Scott R. King, "Economic Impacts of Biotechnology" in Albert H. Teich, Morris A. Levin, and Jill H. Pace, eds., in Biotechnology and the Environment: Risk & Regulation, proceedings of a seminar series conducted by the American Association for the Advancement of Science for the U.S. Environmental Protection Agency (Washington, D.C.: AAAS, 1985), 29-49, at 33-34.

84. Aharanowitz and Cohen, supra footnote 9, at 144.

85. U.S., Congress, O.T.A., supra footnote 53, at 75.

86. Ibid., at 75-76.

87. Krimsky, supra footnote 54, at 11.

88. Stephen Anderson, Cara Berman Marks, Robert Lazarus, Jeffrey Miller, Kevin Stafford, Jana Seymour, David Light, William Rastetter, and David Estell, "Production of 2-Keto-L-Gulonate, an Intermediate in L-Ascerbate Synthesis, by a Genetically Modified Erwinia herbicola" (Oct. 1985), 230 Science 144-149.

89. (i) U.S., Congress, O.T.A., supra footnote 53, at 90.

(ii) Canada, CARC, supra footnote 56 (i), at 120-21.

90. (i) J.M. Litchfield, "Single-Cell Proteins" (Feb. 1983), 219 Science 740-46.

(ii) (re: bacterial and yeast cells) Martin Sherwood, "The Case of the Money-Hungry Microbe" (July 1984), 2 Bio/Technology 606-9, at 606.

(iii) (re: bacterial and fungal cells) Canada, CARC, supra footnote 56 (i), at 120-21.

91. Sherwood, supra footnote 90 (ii), at 606-9.

92. Litchfield, supra footnote 90 (i).

93. J.D. Windass, M.J. Worsey, E.M. Pioli, D. Pioli, P.T. Baeth, D. Byron, K. Powell, and P.J. Senior, "Improved Conversion of Methanol to Single-Cell Protein by Methylophilus methylotrophus, (Oct. 1980) 287 Nature 396-401.

94. Janet I. Sprent, "Benefits of Rhizobium to Agriculture" (May 1986) 4 Trends in Biotechnology 124-29.

95. Ibid., at 124-25.

96. (i) Sprent, supra footnote 94, at 124-29.

(ii) Canada, CARC, supra footnote 56 (i), at 69-82.

97. Sprent, supra footnote 94, at 128.

98. Weaver, supra footnote 50 (ii), at 840.

99. Approximately nineteen different bacterial genes are required for the nitrogen fixation system. These would have to be isolated, modified so that they could function in regulatable manner in a plant, and introduced into a plant cell. A whole plant, capable of passing the nif genes onto its progeny would then have to be regenerated from the transferred cell. Within the plant, nitrogen fixation would have to occur in

99. an anaerobic environment, because oxygen inactivates nitrogenase, a key enzyme in the nitrogen-fixation process. Since nitrogen-fixation is an energy-intensive process the source of energy for this reaction must also be considered. These and numerous technical difficulties remain to be resolved, suggesting that this is a formidable task.

See:

(i) Weaver, supra footnote 50 (ii), at 840.

(ii) James H. Krieger, "Plant Biotechnology Experts Assess Hopes for Long and Short Term" (October 29, 1984), 62 Chemical & Engineering News 16-19, at 19.

(iii) R. Robson, C. Kennedy and J. Postgate, "Progress in Comparative Genetics of Nitrogen Fixation," (Aug. 1983) 29 Can. J. Microbiol. 954-67.

(iv) J.R. Postgate, "Biological Nitrogen Fixation: Fundamentals" (1982), B296 Phil. Trans. R. Soc. Lond. 375-85.

100. (i) C. Elmerich "Molecular Biology and Ecology of Diazotrophs Associated with Non-Leguminous Plants" (Nov. 1984), 2 Bio/Technology 967-78.

(ii) B.R. Glick, J.J. Pasternak, and H.E. Brooks, "The Development of Azotobacter as a Bacterial Fertilizer by the Introduction of Exogenous Cellulase Genes," in S. Hasnain, J. Lamptey and M. Moo-Yong, eds., First Bioenergy Specialists Meeting on Biotechnology, (Ottawa: National Research Council of Canada, 1985), 180-93.

(iii) N.W. Lem and B.R. Glock, "Biotechnological Uses of Cyanobacteria" (1985), 3 Biotech. Adv. 195-208.

101. F. Betz, M. Levin, and M. Rogul, "Safety Aspects of Genetically-Engineered Microbial Pesticides" (Dec. 1983), 6 Rec. DNA Tech. Bull. 135-45, at 135.

102. Ibid., at 138.

103. Canada, National Research Council of Canada, Bacillus Thuringiensis: Its Effects on Environmental Quality (Ottawa: NRCC, 1976), 7.

104. Ibid., 7-9.

105. Ibid., 7-9.

106. Betz, Levin, and Rogul, supra footnote 101, at 135-6.

107. Monsanto, "Facts: Proposed Small-Scale Field Test of a Genetically-Engineered Soil Bacterium," (pamphlet, St. Louis, Missouri, 4/86).

108. "Release of Strains of Pseudomonas Syringae and Erwinia Herbicola" (June '83), 6 Rec. DNA Tech. Bull. 68-69.

109. U.S., Congress, O.T.A., supra footnote 53, at 145.

110. Anne K. Vidaver, "Plant-Associated Agricultural Applications of Genetically-Engineered Microorganisms: Projections and Constraints" (Sept. 85) 8 Rec. DNA Tech. Bull. 97-101, at 99.

111. Ibid.

112. Mary-Dell Chilton, supra footnote 44, at 53 and 56.

113. (i) U.S., Congress, O.T.A., supra footnote 53, at 146.
(ii) Vidaver, supra footnote 110, at 99.

114. Vidaver, supra footnote 110, at 99.

115. Ibid.

116. (i) I. Petrykus, R.D. Shillito, M.W. Saul, and J. Paszkowski, "Direct Gene Transfer: State of the Art and Future Potential" (1985), 3 Plant Mol. Biol. Reporter 117-128.
(ii) Y. Ohta, "High Efficiency Genetic Transformation of Maize by a Mixture of Pollen and Exogenous DNA" (Feb. 1986), 83 Proc. Natl. Acad. Sci. 715-9.

117. (i) Robert Shields, "Engineering Herbicide Resistance" (Oct. 1985), 317 Nature 668.
(ii) "The First Expression of a Commercially Valuable Foreign Gene in a Major Crop Plant" (March 1985), 35 Bioscience 391.

118. U.S., Congress, O.T.A., supra footnote 53, at 126-27.

119. Krimsky, supra footnote 54, at 10-11.

120. U.S. Congress, O.T.A., supra footnote 53, at 117.

121. Corale L. Brierley, "Microbial Mining" (Aug. 1982) 247 Scientific American 44-53, at 44.

122. U.S. Congress, O.T.A., supra footnote 53, at 117.

123. Ibid., at 118-19.

124. D.G. Lundgren and M. Silver, "Ore Leaching by Bacteria" (1980), 34 Ann. Rev. Microbiol. 263-83, at 267 and 276-77.

125. U.S. Congress, O.T.A., supra footnote 53, at 118.

126. (i) U.S., Congress, O.T.A. supra footnote 53, at 120.

(ii) Zsolt Harsanyi, "Biotechnology and the Environment: An Overview," in Albert H. Teich, Morris A. Levin and Jill H. Pace, eds., Biotechnology and the Environment: Risk and Regulation, proceedings of a seminar series conducted by the American Association for the Advancement of Science for the U.S. Environmental Protection Agency (Washington, D.C.: AAAS, 1985), 15-21, at 20.

127 (i) U.S., Congress, O.T.A., supra footnote 53, at 121.

(ii) Harsanyi, supra footnote 126 (iii), at 20.

128. U.S., Congress, O.T.A., supra footnote 53, at 122.

129. U.S., Congress, Subcommittee on Investigations and Oversight, Committee of Science and Technology, The Environmental Implications of Genetic Engineering, (Washington: U.S. Government Printing Office, Feb. 1984), 21

130. Laura Tangley, "Engineered Organisms in the Environment? Not Yet" (Dec. 1983), 33 Bioscience 681-82, at 682.

131. Harlee Strauss, Dale Hattis, Guy Page, Kathryn Harrison, Shawna Vogel and Charles Coldart, "Genetically-Engineered Microorganisms: I. Identification, Classification, and Strain History" (Mar. 1986), 9 Rec. DNA Tech. Bull. 1-15, at 1.

132. Judith Miller, "Harmful Environmental Effects of Biotechnology: Consequences of a Deliberate Release," in The Regulation of Biotechnology, a one day conference presented by the Canadian Environmental Law Research Foundation (Toronto: CELRF, October 9, 1984) 1-21, at 5.

133. Laura Tangley, "Releasing Engineered Organisms into the Environment" (Sept. 1985), 35 Bioscience 470-73, at 473.

134. "Organisms that Got Away" (May 30, 1985) 106 New Scientist 4.

135. United States, National Institutes of Health, Department of Health and Human Services, Guidelines for Research Involving Recombinant DNA Molecules, 51 Federal Register 16957-16985.

136. Stuart A. Newman, "The 'Scientific' Selling of rDNA" (July/Aug. 1982), 24 Environment 21-3 & 53-7, at 23.

137. Albert H. Teich, Morris A. Levin, and Jill H. Pace, eds., Biotechnology and the Environment: Risk & Regulation (Washington, D.C.: American Association for the Advancement of Science, 1985), 129.

138. Stotzky and Babich, supra footnote 13 (i), at 163-4.

139. Paul S. Cohen and David C. Laux, "E. coli Colonization of the Mammalian Colon: Understanding the Process" (June 85), 8 Rec. DNA Tech. Bull. 51-54.

140. Stotzky and Babich, supra footnote 13 (i), at 167.

141. OECD, "Safety in Biotechnology", (press release, Paris, December 9, 1985), 1-56, at 27-28.

142. Ibid., at 29.

143. C.H. Collins, "Safety in Microbiology: A Review", (Feb. 1984), 1 Biotechnology and Genetic Engineering Reviews 141-165, at 147

144. Ibid., at 155

145. John E. Donalds, "Applications of Biotechnology in the Chemical Industry," in Albert H. Teich, Morris A. Levin, and Jill H. Pace, eds., Biotechnology and the Environment: Risk & Regulation, proceedings of a seminar conducted by the American Association for the Advancement of Science for the U.S. Environmental Protection Agency (Washington, D.C.: AAAS, 1985) 79-86, at 83.

146. Theodore Cooper, "The Impact of Biotechnology on the Pharmaceutical Industry," in Albert H. Teich, Morris A. Levin, and Jill H. Pace, eds., Biotechnology and the Environment: Risk and Regulation, proceedings of a seminar

146. series conducted by the American Association for the Advancement of Science for the U.S. Environmental Protection Agency (Washington, D.C.: AAAS, 1985) 61-71, at 67.

147. Eden Fisher, "The Management and Assessment of Risks from Recombinant Organisms" (1985), 10 Journal of Hazardous Materials 241-61, at 257-58.

148. Newman, supra footnote 136, at 21-23 and 53-57.

149. M. Kuenzi, F. Assi, A. Chmiel, C.H. Collins, M. Donikian, J.B. Dominguez, L. Financsek, L.M. Fogarty, W. Frommer, F. Hasko, J. Hovland, E.H. Houwink, J.L. Mahler, A. Sandkvist, K. Sargeant, C. Sloover, and G. Tuijnenburg Muijs, "Safe Biotechnology, General Considerations" (1985), 21 Appl. Microbiol. Biotechnol. 1-6, at 3.

150. Teich, Levin, and Pace, supra footnote 137, at 73.

151. Kuenzi et.al., supra footnote 149, at 4.

152. Cooper, supra footnote 146, at 62 and 66.

153. Sherwood, supra footnote 90 (ii), at 607.

154. U.S., Congress, I.&O., S.& T., supra footnote 129, at 18.

155. Ibid., at 22.

156. Ibid., at 22 (footnote).

157. Michael Trotter, "From Alchemy to Algeny: An Interview with Jeremy Rifkin" (1983), 13 The Ecologist 153-53, at 151.

158. Tangley, supra footnote 133, at 472.

159. U.S., Congress, I.& O., S.& T., supra footnote 129, at 22-23.

160. Edward A. Adelberg, "Summary of Proceedings," in Harlyn O. Halvorson, David Pramer and Marvin Rogul, eds., Engineered Organisms in the Environment: Scientific Issues, proceedings of a cross-disciplinary symposium held in Philadelphia, Pennsylvania, 10-13 June 1985 (Washington, D.C.: American Society for Microbiology, 1985) 233-35, at 234.

161. Martin Alexander, "Ecological Consequences: Reducing the Uncertainties" (Spring 1985), 1 Issues in Science and Technology 57-68, at 63-64.

162. Robert K. Colwell, "Biological Responses to Perturbation: Genome to Ecosystem," in Harlyn O. Halvorson, David Pramer, and Marvin Rogul, eds., Engineered Organisms in the Environment: Scientific Issues, proceedings of a cross-disciplinary symposium held in Philadelphia, 10-13 June 1985 (Washington, D.C.: American Society for Microbiology, 1985) 230-32, at 230.

163. (i) Colwell, supra footnote 162,at 230.

(ii) Tangley, supra footnote 133, at 472.

164. Martin Alexander, "Survival and Growth of Bacteria" (July 1986), 10 Environmental Management 464-469, at 465-66.

165. Ibid., at 466.

166. Stotzky and Babich, supra footnote 13 (i), at 168.

167. Ibid.

168. Alexander, supra footnote 161, at 62.

169. Alexander, supra footnote 164, at 467.

170. Alexander, supra footnote 161, at 62-3.

171. David A. Andorv, "Dispersal of Microorganisms with Emphasis on Bacteria" (July, 1986) 10 Environmental Management 470-487, at 470.

172. U.S., Senate, Subcommittee on Toxic Substances and Environmental Oversight, Committee on Environment and Public Works, The Potential Environmental Consequences of Genetic Engineering (Washington: U.S. Government Printing Office, 1984) 70.

173. Andorv, supra footnote 171, at 482-83.

174. Ibid., at 473-76 and 482.

175. Ibid., at 476 and 483.

176. Ibid., at 477.

177. Ibid.

178. Ibid., at 476 & 482.

179. U.S., Senate, T.S. & E.O., E.& P.W., supra footnote 172, at 69.

180. U.S., Congress, I.& O., S.& T., supra footnote 129, at 15 (footnote).

181. Stotzky and Babich, supra footnote 13 (i), at 166.

182. Ibid.

183. Michael A. Gealt, Mark D. Chai, Kevin B. Alpert, and Jayne C. Boyer, "Transfer of Plasmids of pBR322 and pBR325 in Wastewater from Laboratory Strains of Escherichia coli to Bacteria Indigenous to the Waste Disposal System" (Apr. 1985), 49 Applied and Environmental Microbiology 836-41.

184. Old and Primrose, supra footnote 11, at 69-70.

185. Drlica, supra footnote 2, 158-59.

186. (i) Old and Primrose, supra footnote 11, at 151.
(ii) Chilton, supra footnote 44, at 56.

187. Keus, supra footnote 66, at 106.

188. F. Brown, G.C. Schild and G.L. Ada, "Recombinant Vaccinia Viruses as Vaccines" (Feb. 1986), 319 Nature 549-50, at 550.

189. J. Blancou, M.P. Kieny, R. Lathe, J.P. Lecocq, P.P. Pastoret, J.P. Soulebot, and P. Desmette, "Oral Vaccination of the Fox Against Rabies Using a Live Recombinant Vaccinia Virus" (July 1986), 322 Nature 373-75.

190. U.S., Congress, I.& O., S.& T., supra footnote 129, at 19 and 63.

191. Ibid., at 22-23.

192. David Pimental, "Using Genetic Engineering for Biological Control: Reducing Ecological Uncertainties," in H.O. Halvorson, D. Pramer, and M. Rogul, eds., Engineered Organisms in the Environment: Scientific Issues (Washington, D.C.: American Society for Microbiology, 1985) 129-40, at 135.

193. S.E. Lindow, "Ecology of Pseudomonas syringae Relevant to the Field Use of Ice-Deletion Mutants Constructed in Vitro for Plant Frost Control," in H.O. Halvorson, D. Pramer, and M. Rogul, eds., Engineered Organisms in the Environment: Scientific Issues (Washington, D.C.: Americal Society for Microbiology, 1985) 23-35, at 31.

194. Miller, supra footnote 132, at 5.

195. "Organisms That Got Away," supra footnote 134.

196. Reginal Rhein, Jr., "'Ice-Minus' May End Killer Frosts - And Stop the Rain," November 25, 1985, Business Week 42.

197. Betz, Levin and Rogul, supra footnote 101, at 137.

198. Tangley, supra footnote 133, at 471.

199. Betz, Levin and Rogul, supra footnote 101, at 137.

200. Ronald M. Atlas, "State of the Art: Case Histories of Engineered Organisms for Environmental Release," in H.O. Halvorson, D. Pramer and M. Rogul, Engineered Organisms in the Environment: Scientific Issues, proceedings of a cross-disciplinary symposium held in Philadelphia, 10-13 June 1985 (Washington, D.C.: American Society for Microbiology, 1985) 223-25, at 223.

201. Kathleen H. Keeler, "Implications of Weed Genetics and Ecology for the Deliberate Release of Genetically-Engineered Crop Plants" (Dec. 1985), 8 Rec. DNA Tech. Bull. 165-72, at 165.

202. U.S., Senate, T.S.& E.O., E.& P.W., supra footnote 172, at 155-58.

203. Winston J. Bull, "Safety Concerns and Genetic Engineering in Agriculture" (Jan. 1985), 227 Science 381-84, at 382.

204. Teich, Levin and Pace, supra footnote 137, at 130.

205. (i) L.T. Fan, Y.H. Lee, and M.M. Gharpuray, "The Nature of Lignocellulosics and their Pretreatments for Enzymatic Hydrolysis" (1982), 23 Adv. Biochem. Eng. 157-87.

(ii) L.G. Ljungdahl and K.E. Erikssen, "Ecology of Microbial Cellulose Degradation" (1984), 8 Adv. Micro. Ecol. 237-99.

206. (i) Fan, Lee and Gharpuray, supra footnote 205 (i).

(ii) Ljungdahl and Erikssen, supra footnote 205 (ii).

207. Simon A. Levin and Mark A. Harwell, "Potential Ecological Consequences of Genetically Engineered Organisms" (July 1986), 10 Environmental Management 495-514, at 509.

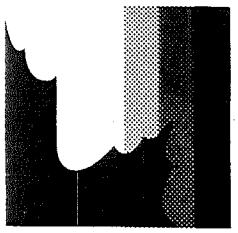
208. Ibid.

209. Ibid.

2. AGENDA AND PARTICIPANTS: SEPTEMBER 15, 1986, SEMINAR

Canadian Environmental Law Research Foundation

La Fondation canadienne de recherche du droit de l'environnement



ENVIRONMENTAL EFFECTS OF BIOTECHNOLOGY

Canadian Bar Association-Ontario
Education and Meeting Centre
Suite 1000
120 Adelaide Street West
(between Bay and York Streets)
Toronto, Ontario

September 15, 1986
9:00 a.m. to 5:00 p.m.

AGENDA

1. Introduction

   a. CELRF Biotechnology Program
   b. Goals of the Seminar

2. Applications of Biotechnology

3. Environmental Effects of Biotechnology

   a. Concerns with Contained Applications
   b. General Environmental Concerns
   c. Predicting Environmental Effects - Alexander's Conceptual Approach
   d. Examples of Effects Relating to Selected Applications of Biotechnology
   e. Recommendations

4. Concluding Remarks

243 Queen Street West, 4th Floor, Toronto, Ontario, M5V 1Z4 (416) 977-2410

LIST OF PARTICIPANTS - SEPTEMBER 15, 1986

Dr. Claude Bishop
Director
Division of Biological Sciences
National Research Council
100 Sussex Drive
Ottawa, Ontario
K1A 0R6

Ms. Penny Chan
Research Officer
Advisory Council on Occupational
Health and Safety
400 Univeristy Avenue
Toronto, Ontario

Ms. Irene Courage
Barrister and Solicitor
16 Shields Avenue
Toronto, Ontario

Dr. David Collins-Thompson
Department of Environmental Biology
University of Guelph
Guelph, Ontario
N1G 2W1

Mr. Jack Donnan
Senior Economist
Policy and Planning Branch
Ministry of the Environment
135 St. Clair Avenue West
Toronto, Ontario
M4V 1P5

Dr. Cecil Forsberg
Department of Microbiology
University of Guelph
Guelph, Ontario

Dr. Clare A. Franklin
Chief, Environmental and Occupationa
Toxicology Division
Environmental Health Directorate
Health and Welfare Canada
Tunney's Pasture
Ottawa, Ontario
K1A 0L2

Dr. Bernard Glick
Department of Biology
University of Waterloo
Waterloo, Ontario

Ms. Sheri Glover
Research Mangement Office
Corporate Policy and Planning
Ministry of the Environment
135 St. Clair Ave. West
Toronto, Ontario
M4V 1P5

Dr. Neil Gray
Corporate Biotechnology Advisor
C-I-L, Inc.
2101 Hadwen Road
Sheridan Park
Mississauga, Ontario
L5K 2L3

Dr. Don Hart
Beak Analytical Services Ltd.
6870 Goreway Drive
Mississauga, Ontario
L4V 1P1

Dr. Colin Mayfield
Department of Biology
University of Waterloo
Waterloo, Ontario
N2L 3G1

Dr. V.N. Iyer
Department of Biology
Carleton University
Ottawa, Ontario

Mr. Terry McIntyre
Biotechnology Centre
Commercial Chemicals Branch
Environment Canada
15th Floor, Place Vincent Massey
351 St. Joseph Blvd.
Hull, Quebec
K1A 0E7

Mr. Goff Jenkins
Agricultural and Industrial
Chemicals Section
Intergovernmental Relations and
Hazardous Contaminants
Coordination Branch
40 St. Clair Avenue West, 7th Floor
Toronto, Ontario
M4V 1M2

Dr. Earl Nestmann
Cyanamid Canada
2255 Sheppard Avenue East
Willowdale, Ontario
M2J 4Y5

Mr. Don Lush
Beak Analytical Services Ltd.
6870 Goreway Drive
Mississauga, Ontario
L4V 1P1

Dr. Jack Pasternak
Department of Biology
University of Waterloo,
Waterloo, Ontario
N2L 3G1

Mr. Doug Macdonald
Executive Director
Canadian Environmental Law Research
Foundation
Toronto, Ontario

Mr. Ed Piche
Program Coordinator
Research Management Office
Corporate Policy and Planning
Ministry of the Environment
135 St. Clair Avenue West
12th Floor
Toronto, Ontario
M4V 1P5

Dr. Andrew A. Potter
University of Saskatchewan
Veterinary Infectious Disease
Organization
124 Veterinary Road
Saskatoon, Saskatchewan
S7N 0W0

Ms. Yvonne Skoff
Canadian Environmental Law Research
Foundation
Toronto, Ontario

Dr. D. Rokosh
Supervisor, Biohazards
Aquatic Contaminants Section
Water Resources Branch
Ministry of the Enviroment
125 Resources Road
Rexdale, Ontario
M9W 5L1

Dr. N.A. Straus
Botany Department
University of Toronto
6 Queen's Park Crescent West
Toronto, Ontario
M5S 1A1

Dr. Francis Rolleston
Medical Research Council of Canada
Jeanne Mance Building
Tunney's Pasture
Ottawa, Ontario
K1A 0W9

Dr. Jack Trevors
Department of Environmental Biology
University of Guelph
Guelph, Ontario

Dr. M. Salamone
Aquatic Contaminants Section
Waster Resources Branch
Ministry of the Environment
125 Resources Road
Rexdale, Ontario
M9W 5L1

Dr. Bob Watson
Chemistry and Biology Research
Institute
Research Branch
Agriculture Canada
Ottawa, Ontario
K1A 0C5

Dr. Vern Seligy
Molecular Genetics Group
Division of Biological Sciences
National Research Council
100 Sussex Drive
Ottawa, Ontario
K1A 0R6

Dr. Jack Wearing
Monsanto Canada Inc.
2330 Argentia Road
P.O. Box 787,
Streetsville Post Office
Mississauga, Ontario
L5M 2G4

Dr. R.C. Wyndham
Botany Department
University of Toronto
6 Queen's Park Crescent West
Toronto, Ontario
M5S 1A1

3. PAPER TITLED "POLICY ISSUES RAISED BY THE APPLICATION OF BIOTECHNOLOGY"

POLICY ISSUES RAISED BY

THE APPLICATION OF BIOTECHNOLOGY

By

Ms. Irene Courage and Yvonne Skof

Canadian Environmental Law Research Foundation

October 1986

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4. Information Issues

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5. Liability and Compensation

"Release" means the intended release of BTP's into the environment, the disposal of BT wastes and accidental release of BTP's, production materials used in the process of modern biotechnology and BT wastes.

1.3 Legislation Discussed in the Paper

The paper is limited to Ontario and Canadian legislation.

Modern biotechnology has not been dealt with specifically in Canadian or Ontario legislation. However, certain legislation may apply either to the production processes or products or wastes generated by modern biotechnology. To facilitate analysis, such legislation has been divided into the following four groups:

(1) Environmental Legislation:
- Environmental Contaminants Act[1]
- Clean Air Act[2]
- Canada Water Act[3]
- Transportation of Dangerous Goods Act[4]
- Environmental Assessment & Review Process Guidelines Order[5]
- Environmental Assessment Act[6]
- Environmental Protection Act[7]
- Ontario Water Resources Act[8]
- Dangerous Goods Transportation Act, 1981[9]

(2) Agricultural Protection Legislation:
- Fisheries Act[10]
- Migratory Birds Convention Act[11]
- Animal Disease & Protection Act[12]
- Plant Quarantine Act[13]
- Livestock Pedigree Act[14]
- Artificial Insemination of Livestock Act[15]
- Plant Diseases Act[16]
- Animals for Research Act[17]
- Weed Control Act[18]

POLICY ISSUES RAISED BY THE APPLICATION OF BIOTECHNOLOGY

CHAPTER 1. - INTRODUCTION

1.1 Purpose and Scope of This Paper

The use of the products of modern biotechnology outside of laboratories and production facilities has raised concerns about potential negative impacts on the natural environment. The purpose of this paper is to identify the issues raised by the release of both products and wastes from modern biotechnology and to assess whether the provisions of Ontario and Canadian legislation apply to such releases.

1.2 Definitions

Biotechnology has been used for many years in agricultural industries. A common example is the cross-breeding of plants. Yet, the public's perception seems to be that only the more modern forms of biotechnology, such as genetic engineering, are potentially dangerous and require regulation. This paper concerns modern biotechnology which is defined as : "The provision of goods and services using recombinant DNA and cell fusion techniques." The resulting products are referred to in this paper as "the products of modern biotechnology" or "BTP's". BTP's can be:

(1) Living BTP's;
(2) Killed BTP's; or
(3) Inanimate BTP's.

The wastes generated by modern biotechnology, including no longer useful BTP's, are referred to as "BT wastes".

The focus of this paper is upon releases to the open environment and not upon contained applications.

(3)	Product Oriented Legislation:	The Hazardous Products Act[19] Food & Drugs Act[20] Pest Control Products Act[21] The Pesticides Act[22] The Feeds Act[23] The Fertilizers Act[24] The Seeds Act[25]
(4)	Worker Protection Legislation (and Guidelines):	Medical Research Council Guidelines for handling of recombinant DNA molecules and animal viruses & cells[26] Canada Occupational Health and Safety Regulations[27] Occupational Health and Safety Act[28]

For the purposes of this paper the focus will be on environmental legislation, agricultural protection legislation and product oriented legislation. In an all encompassing regulatory system dealing with modern biotechnology, worker protection legislation would definitely be relevant. However, the focus of this paper is on environmental concerns, which are only incidentally addressed by worker protection legislation in that safety measures within the work place might help prevent environmental contamination. A number of federal and provincial statutes which could be marginally relevant have been omitted including:

> The Canada Shipping Act,[29] the Ocean Dumping Control Act,[30] the Canada Wildlife Act,[31] the Northern Inland Waters Act,[32] the Arctic Waters Pollution Prevention Act,[33] the Department of Agriculture Act,[34] the Agricultural Products Marketing Act,[35] the Livestock and Livestock Products Act,[36] the Meat Inspection Act,[37] the Criminal Code,[38] the Atomic Energy Control Act,[39] the Health Protection and Promotion Act, 1983,[40] the Milk Act,[41] the Mining Act,[42] the Live Stock Medicines Act,[43] the Insurance Act,[44] the Forest Tree Pest Control Act,[45] and the Public Lands Act.[46]

Marginal consideration has been given to:

> The Access to Information Act,[47] the Nuclear Liability Act,[48] the Patent Act,[49] the Pesticide Residue Compensation Act,[50]

the Forestry Development and Research Act,[51] the Fisheries and Ocean Research Advisory Council Act,[52] the Industrial and Regional Development Act,[53] the Agricultural Research Institute of Ontario Act,[54] and the Experimental Farm Stations Act.[55]

1.4 Reasons for Regulation

Modern biotechnology may be regulated for any of the following purposes:

(a) protection of the environment from the adverse effects of intentional releases of the products of modern biotechnology, the disposal of wastes or accidental releases of the products of modern biotechnology, the wastes from modern biotechnology or materials used in the production process. Wastes may include products generated during production and wastes left after the products of modern biotechnology have served their purpose.

(b) protection of human health, either as an element of environmental protection legislation or, in the form of health protection legislation directed at people dealing with the relevant materials or processes. Worker protection legislation, especially, is aimed at the protection of human health.

(c) quality control of the products of modern biotechnology. A strong case for quality control exists where the products are used directly in human beings, such as pharmaceutical products and food. Also, where the products are used in agriculture, quality control may be essential as they may influence the quality of the meat, eggs, or dairy products produced. A current example would be the use of growth hormone in cows.

(d) protection of agricultural resources. This objective may be attained by environmental legislation, but protection of agricultural resources may have specific additional requirements and it may also be more limited in scope than general environmental protection.

(e) consumer protection, especially where the product could be dangerous if flawed or used improperly.

(f) the promotion of research and development through information sharing. Regulation might require dissemination of information.

1.5 Content of the Paper

In addressing the issues raised by the potential release of BTP's or BT wastes, the following questions have been raised:

Chapter II	What should be the subject of the regulation?
Chapter III	How should the subject be regulated? In other words, what activities could and should be regulated in establishing a regulatory scheme?
Chapter IV	How can the government obtain the necessary information and how does this relate to the public's desire for access to information and the legitimate concerns of the industry to protect valuable information?
Chapter V	What are the civil liability consequences of illegal releases, accidental releases, and their unanticipated adverse effects, and what provisions have been made for compensation?

Chapter VI — How can one ensure compliance with a regulatory scheme?

Chapter VII — Which jurisdiction could and should regulate in the field?

Chapter VIII — What policy issues should be addressed in establishing a regulatory scheme?

1.6 Subject Matter Excluded From the Paper

The focus of this paper is on environmental protection. Therefore, the discussion of potentially relevant worker protection legislation has been excluded. Also, consideration of legislation aimed at the protection of human health is limited. For example, any use of BTP's within the human body itself is beyond the scope of this paper. As the field of modern biotechnology is broad, the authors have been unable to exhaustively discuss all potentially relevant legislation and, to the extent legal analysis is provided, have partially relied upon authoritative text books as opposed to original research of case law.

CHAPTER 2. - THE SUBJECT OF REGULATION

2.1 Policy Issues to be Addressed

1. What should be the subject of regulation?

   (a) The use of modern biotechnology processes, the release of certain products and/or wastes, or both the products and the processes.
   (b) If the release of certain products and/or wastes is regulated, what products or wastes should be covered?
   (i) all BTP's and BT wastes:
   (ii) living BTP's and BT wastes only; or
   (iii) all exotic living organisms.

2. Is such subject covered under existing legislation?

3. If not, would an amendment of definitions contained in existing legislation be sufficient to cover the subject or is a special regime needed with regard to biotechnology products?

4. If special modern biotechnology product legislation is enacted, how should it relate to existing legislation?

   (a) should the special legislation prevail if there is a conflict?
   (b) should the regulated BTP or BT waste be exempted from other legislation?
   (c) should certain BTP's and BT wastes be exempted from special legislation if they are regulated under other legislation?

5. Where there is duplication in legislation or a double aspect to the regulation, is there a need to harmonize legislation or centralize the administration and enforcement of such legislation?

2.2 Current Legislation

BTP's, or BT wastes could be covered by provisions of the following statutes.

1. The Environmental Contaminants Act, applies to a "substance", defined as:

> ... any distinguishable kind of inanimate matter
> (a) capable of becoming dispersed in the environment, or
> (b) capable of becoming transformed in the environment into matter described in (a).[1]

Currently, living BTP's would not fall under this definition. However, there is some indication that this definition will be expanded by deleting the reference to inanimate.

2. The Clean Air Act, sets maximum quantities and concentrations for the release of contaminants."Air contaminant" is defined as:

> ...a solid, liquid, gas or odour or a combination of any of them that, if emitted into the ambient air, would create or contribute to the creation of air pollution[2]

"Air pollution" is defined as:

> ...a condition of the ambient air arising wholly or partly from the presence therein of one or more air contaminants, that endangers the health, safety or welfare of persons, that interferes with normal enjoyment of life or property that endangers the health of animal life or that causes damage to plant life or to property.[3]

The definition of air contaminant does not explicitly refer to organisms and no standards with regard to living organisms have been set. Therefore, the application of the Clean Air Act is likely to be limited to inanimate BTP's.

3. The Canada Water Act provides for the management of Canada's water resources. It prohibits the unauthorized deposit of waste in water quality management areas. "Waste" is defined as:

> ...any substance that, if added to any waters, would degrade or alter or form part of a process of degradation or alteration of the quality of those waters to an extent that is detrimental to their use by man or by any animal, fish or plant that is useful to man, and includes any water that contains a substance in such a quantity or concentration, or that has been so treated, processed or changed, by heat or other means, from a natural state that it would, if added to any waters, degrade or alter or form part of a process of degradation or alteration of the quality of those waters to an extent that is detrimental to their use by man or by any animal, fish or plant that is useful to man.[4]

BTP's or wastes from biotechnology processes could fall under this definition. The Act also concerns cleaning agents containing phosphates, nutrients and water conditioners. A "nutrient" is defined as:

> ... any substance or combination of substances that, if added to any waters in sufficient quantities, provides nourishment that promotes the growth of aquatic vegetation in those waters to such densities as to
> (a) interfere with their use by man or by any animal, fish or plant that is useful to man, or
> (b) degrade or alter or form part of a process of degradation or alteration of the quality of those waters to an extent that is detrimental to their use by man or by any animal, fish or plant that is useful to man...[5]

Although this definition was not written with BTP's in mind, it could cover BTP's and wastes with such qualities.

4. The Environmental Protection Act prohibits the release of contaminants in excess of amounts and levels prescribed by the regulations,[6] and prohibits the discharge of contaminants which impair or are likely to impair the natural environment, or which are likely to injure property, plants, animals or persons.[7] "Contaminant" is defined as:

> ...any solid, liquid, gas, odour, heat, sound, vibration, radiation or combination of any of them resulting directly or indirectly from the activities of man that may,

(i) impair the quality of the natural environment for any use that can be made of it,
(ii) cause injury or damage to property or to plant or animal life,
(iii) cause harm or material discomfort to any person,
(iv) adversely affect the health or impair the safety of any person,
(v) render any property or plant or animal life unfit for use by man,
(vi) cause loss of enjoyment of normal use of property, or
(vii) interfere with the normal conduct of business.[8]

In Part IX, regarding spills, "pollutant" is defined as:

> ...a contaminant other than heat, sound, vibration, or radiation, and includes any substance from which a pollutant is derived.[9]

Although the definition of contaminant is intended to be broad, it does not specifically refer to organisms. An argument could be raised that living BTP's may be covered under "any solid or liquid" but it is not convincing.

5. The Ontario Water Resources Act prohibits the deposition or discharge of material in waters where such material or any derivative of such material causes or may cause injury to any person, animal, bird or any living thing as a result of the use or consumption of any plant, fish or other living matter or thing in the water or in the soil in contact with the water.[10]

The Act defines "sewage" as including:

> ...drainage, storm water, commercial wastes and industrial wastes and such other matter or substance as is specified by regulations made under clause 44(1)(i)[11]

This Act would prohibit the discharge of BTP's or wastes which may cause injury.

6. The Transportation of Dangerous Goods Act defines "dangerous goods" as:

> ... any product, substance or organism included by its nature or by the regulations in any of the classes listed in the schedule.[12]

The Schedule to the Act contains nine classes of dangerous goods including Class 6 Division 2: "organisms that are infectious or that are reasonably believed to be infectious to humans or to animals and the toxins of such organisms."[13], and Class 9: "Miscellaneous products, substances or organisms considered by the Governor in Council to be dangerous to life, health, property or the environment when handled, offered for transport or transported and prescribed to be included in this class."[14] Certain BTP's would be covered under these definitions.

7. The Dangerous Goods Transportation Act, 1981 defines "dangerous goods" as:

> ... any product, substance or organism included by its nature or by the regulations in any of the classes listed in the Schedule.[15]

The Schedule to the Act contains nine classes of dangerous goods including Class 6, "Poisonous (toxic) and infectious substances"[16] and Class 9:

> Miscellaneous products, substances and organisms considered by the Lieutenant Governor in Council to be dangerous to life, health, property or the environment when transported in a vehicle on a highway and prescribed to be included in this class.[17]

Certain BTP's would fall within these definitions.

8. The Fisheries Act prohibits the discharge of a deleterious substance. A "deleterious substance" is defined as:

> ...(a) any substance that, if added to any water, would degrade or alter or form part of a process of degradation or alteration of the quality of that water so that it is rendered or is likely to be rendered deleterious to fish or fish habitat or to the use by man of fish that frequent that water, or
>
> (b) any water that contains a substance in such quantity or concentration, or that has been so treated, processed or changed, by heat or other means, from a natural state that it would, if added to any other water, degrade or alter or form part of a process of degradation or alteration of the

> quality of that water so that it is rendered or is likely to be rendered deleterious to fish or fish habitat or to the use by man of fish that frequent that water,
> and without limiting the generality of the foregoing includes
> (c) any substance or class of substances prescribed pursuant to paragraph (12)(a)[the Regulations],
> (d) any water that contains any substance or class of substances in a quantity or concentration that is equal to or in excess of a quantity or concentration prescribed in respect of that substance or class of substances pursuant to paragraph (12)(b) [the Regulations],
> (e) any water that has been subjected to a treatment, process or change prescribed pursuant to paragraph (12)(c) [the Regulations][18]

BTP's and wastes which are deleterious and discharged such as to enter water frequented by fish are covered under this statute.

9. The Migratory Birds Convention Act, prohibits the depositing of substances harmful to migratory birds in any waters or any area frequented by migratory birds.[19] This could cover BTP's.

10. The Animal Disease and Protection Act concerns veterinary biologics. A "veternary biologic" is defined as:

> ...(a) any helminth, protozoa or micro-organism,
> (b) any substance or mixture of substances derived from animals, helminths, protozoa or micro-organisms, or
> (c) any substance of synthetic origin,
> manufactured, sold or represented for use in
> (d) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in animals, or
> (e) restoring, correcting or modifying organic functions in animals.[20]

The Act also concerns animal pathogens such as bacteria and viruses. The Act clearly applies to BTP's.

11. The Plant Quarantine Act, prohibits the introduction into Canada, or the spreading within Canada, of "any pest or any plant or other matter that is infested or likely to be infested with a pest or

that constitutes a biological obstacle to the control of any pest".[21]

"Pest" is defined as:

> ... any insect, plant or animal organism, virus, bacterium, disease, or disease inciting agent causing or capable of causing injury or damage to any begetable, any part, product or byproduct of vegetable or any plant material.[22]

"Plant or other matter" is defined as:

> ... any plant, plant material, material equipment, carrier, container, article[23] or other thing that may contain or carry any pest.

BTPs or BT wastes, which would be pests of infest plant or other matter would be prohibited under this statute.

12. The Livestock Pedigree Act, as amended, concerns pure-bred animals. Where the Act applies to the transfer of embryos, embryo splitting, micro-manipulation of embryos and genetic engineering it regulates modern biotechnology.

13. The Artificial Insemination of Livestock Act concerns the non-natural deposit of semen into the genital tract of a domestic femal live-stock animal.[25] Artificial insemination can be part of a modern biotechnological process.

14. The Plant Diseases Act defines "plant disease" as:

> ... any disease or injury of plant that is caused by an insect, virus, fungus, bacterium or other organism[26] and that is designated a plant disease in the regulations.

Plant is defined as:

> ... any tree, shrub, vine, tuber, bulb, corn, rhizome[27] or root, or the fruit or any other part of them.

Living BTP's or BT wastes causing diseases in plants would be covered by this Act.

15. The Weed Control Act imposes a duty on every person in possession of land to destroy all noxious weeds thereon.[28] "Noxious weed" is defined as: "a plant that is designated under this Act as a noxious weed."[29]

The provincial cabinet may designate noxious weeds by regulation. Once a BTP or BT waste is designated as a noxious weed, it is covered under the Weed Control Act. To date, none have been so designated. The duty to destroy noxious weeds does not apply to noxious weeds or weed seeds which are so far distant from any place used for agricultural or horticultural purposes that they cannot affect such a place.[30]

16. The Hazardous Products Act defines "hazardous product" as: "any product or substance in Part I or Part II of the Schedule."[31] Apparently, the schedules do not contain any BTP's, but they could be included in the future.

17. The Food and Drugs Act concerns cosmetics, drugs, foods and medical devices. A "drug" is defined as including:

> ...any substance or mixture of substances manufactured, sold or represented for use in
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
> (b) restoring, correcting or modifying organic functions in man or animal or
> (c) disinfection in premises in which food is manufactured, prepared or kept.[32]

"Food" is defined as including:

> ...any article manufactured, sold or represented for use as food or drink for man, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.[33]

"Food additive" is defined in the regulations as:

> ...any substance, including any source of radiation, the use

19. The Pesticides Act concerns the use of pesticides, including products designed to alter the growth, development or characteristics of any plant life that is not a pest. It defines "pesticide" as:

> ...any organism, substance or thing that is manufactured, represented, sold or used as a means of directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest or of altering the growth, development or characteristics of any plant life that is not a pest and includes any organism, substance or thing registered under the Pest Control Products Act (Canada)[38]

"Pest" is defined as:

> ...any injurious, noxious or troublesome plant or animal life other than man or plant life or animal life on or in man and includes any injurious, noxious or troublesome or organic function of a plant or animal.[39]

BTP's used as pesticides come under this definition.

20. The Feeds Act concerns animal feed. "Feed" is defined as:

> ...any substance or mixture of substances containing amino acids, antioxidants, carbohydrates, condiments, enzymes, fats, minerals, non-protein nitrogen products, proteins or vitamins, or pelletizing,, colouring, foaming or flavouring agents and any other substance manufactured, sold or represented for use
>
> (a) for consumption by livestock,
>
> (b) for providing the nutritional requirements of livestock or
>
> (c) for the purpose of preventing or correcting nutritional disorders of livestock, or any substance for use in any such substance or mixture of substances.[40]

A policy decision has been made to the effect that live microbial cultures will be evaluated as drugs prior to incorporation into feeds for direct feeding to livestock.

BTP's used as or in animal feeds would fall under this definition.

> of which results in, or may reasonably be expected to result in it or its by-products becoming a part of or affecting the characteristics of a food.[34]

The definition expressly excludes nutritive material used, recognized or commonly sold as an article or ingredient of food, vitamins, mineral nutrients and amino acids not listed as additives in the regulations, spices, seasonings, flavouring preparation, essential oils, oleoresins, natural extractives, agricultural chemicals not listed as additives in the regulations, food packaging materials and components thereof and drugs recommended for administration to animals that may be consumed as food.

BTP's sold as drugs or food would be covered by the above definitions.

18. The Pest Control Products Act regulates the manufacture and use of pesticides, referred to as "control products". A "control product" is defined as:

> ... any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly controlling, preventing, destroying, mitigating, attracting or repelling any pest, and includes,
>
> (a) any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a control product to which it is added, and
>
> (b) any active ingredient used for the manufacture of a control product.[35]

"Pest" is defined as:

> ... any injurious, noxious or troublesome insect, fungus, bacterial organism, virus, weed, rodent or other plant or animal pest, and includes any injurious, noxious or troublesome organic function of a plant or animal.[36]

Clearly, BTP's to be used as pesticides would fall under the definition of control product. Also, this Act has been interpreted broadly to apply to ice-minus bacteria and microbial pesticides.[37]

21. The Fertilizers Act concerns fertilizers and supplements. "Fertilizer" is defined as:

> ...any substance or mixture of substances containing nitrogen, phosphorous, potassium or other plant food, manufactured, sold or represented for use as a plant nutrient.[42]

A "supplement" is:

> ...any substance or mixture of substances, other than a fertilizer, manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields.[43]

22. The Seeds Act defines "seed" as: "plant part of any species belonging to the plant kingdom represented, sold or used to grow a plant."[44]

23. The Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells[45] of the Medical Research Council of Canada deal with protection against hazards of research involving recombined DNA molecules and animal viruses and cells.

24. The Canada Occupational Health and Safety Regulations[46] pertain to dangerous substances. A "dangerous substance" is defined as:

> ...a hazardous substance or a chemical, physical or biological agent that, because of a property it possesses, is dangerous to the safety or health of a person exposed to it.

Once it has been determined that a BTP, or its waste is dangerous to a person's health or safety it would be covered.

25. The Occupational Health and Safety Act was drafted to protect workers against health and safety hazards in the work place.[47] The Act applies to all work places except private homes and farming

operations. Under the Act, "designated substance" is defined as:

> ...a biological, chemical or physical agent or a combination thereof prescribed as a designated substance to which the exposure of a worker is prohibited, regulated, restricted, limited or controlled.[48]

Once it is established that a BTP is potentially hazardous it could qualify as a designated substance under the Occupational Health and Safety Act.

2.3 Evaluation

Modern biotechnology as such has not been regulated. Yet, certain BTP's and BT wastes are subject to existing legislation. The release of inanimate, and possibly killed BTP's and BT wastes, may be subject to environmental protection legislation if such release could result in harm to the environment. Living BTP's and BT wastes tend to be outside the scope of environmental protection legislation except to the extent they degrade or alter water. In the latter case, the Canada Water Act might apply. If BTP's or BT wastes are released into Ontario waters and render, or contribute to rendering, the water unfit for consumption by any form of life, the Ontario Water Resources Act would apply.

Releases which may result in harm to agricultural resources such as water frequented by fish, animals, plants, or migratory birds, are covered by agricultural protection legislation.

Product oriented legislation covers the specific BTP's mentioned in the legislation. It appears to be concerned mainly with the quality of the BTP. However, under the Pest Control Products Act and the Pesticides Act the issue of environmental safety needs to be addressed. Concerns relating to agricultural resources are relevant under the Seeds Act, the Feeds Act, and the Fertilizers Act.

BTP's and BT wastes can be, and are, regulated under worker pro-

tection legislation. The main focus of this kind of legislation is on the production process by seeking to ensure the safety of the workers involved in the process. Environmental protection would only be incidental.

One of the issues raised is whether one should regulate the process of modern biotechnology or the products of modern biotechnology: current environmental protection legislation focuses on the release of certain substances. If a similar approach is taken to the regulation of living BTP's and BT wastes, regulation of the "product", including wastes, would follow. Regulation of the production process appears more relevant to address worker protection and quality control rather than to ensure environmental control.

CHAPTER 3.

ACTIVITIES TO BE REGULATED

3.1 Policy Issues to be addressed

Once the subject matter of regulation has been determined, a decision needs to be made as to what activity or activities should be regulated. During this decision-making process the following issues need to be addressed:

1. What concerns need to be addressed and how much weight does each concern carry where different concerns lead to conflicting decisions. These concerns may include:

   (a) protection of the environment;
   (b) protection of agricultural resources;
   (c) safety in transportation;
   (d) promotion of research and development;
   (e) worker and/or handler protection;
   (f) consumer and/or user protection;
   (g) need for BTP's in sufficient amounts at a reasonable price;
   (h) marketing of BTP's;
   (i) international obligations;
   (j) study of BTP's.

2. When do such concerns arise:

   (a) on normal use;
   (b) on improper or unexpected use including use in anticipated geography;
   (c) upon waste disposal at production stage;
   (d) upon waste disposal of BTP after use;
   (e) upon spill of wastes generated during production or during transportation, storage or use of BTP;

(f) upon use during or followed by unusual environmental circumstances such as flood, storm, unusual temperatures;
(g) upon unexpected migration or transport.

3. Which activities should be regulated:

(a) production
(b) storage
(c) use
(d) sale
(e) import and/or export
(f) waste disposal
(g) spills
(h) transportation

4. Do we need to regulate all activities or would regulation of a limited number of activities be sufficient?

5. If it is decided that certain activities should be regulated, is there a need to differentiate between activities involving different products or wastes and if so what criteria should be used to establish categories? Possible criteria include:

(a) Use of product, for instance, pharmaceuticals, animal products, seeds, pesticides, foods, feeds.
(b) The type of product, such as viruses, microbes, plants, animals or humans.
(c) The risk level due to the nature of the product, such as pathogens versus benign organisms.
(d) The risk level due to the nature of the use such as enclosed versus open environment; small scale, versus large scale use.
(e) The nature of the relationship between the product and the environment; for instance, more stringent regulation for BTP's which are exotic to the ecosystem.

6. Where BTP's are used within a confined space such as a factory or laboratory, would the regulation of their use in such confined

space be sufficient to address environmental concerns raised by accidentally released products or wastes.

7. How should one define production? Theoretically, even the smallest experiment resulting in the production of one altered cell could be considered production. On the other hand the regulation of production could be restricted to production for commercial use. Between those extremes only production of a certain quantity could be regulated or production requirements could be adjusted to the level of perceived risk in production of specific products.

8. Should all releases to the environment be regulated or should there be exemptions for :

   (a) Scientific research
   (b) Research by licensed individuals or institutions
   (c) Small scale releases on private land by owners or their agents.

9. Which of the following forms of regulation should be used?

   (a) General prohibition unless permit or licence is granted;
   (b) General prohibition unless BTP or BT waste is exempted in legislation
   (c) Obligation to notify and if government agency does not react within certain amount of time the activity is permitted. Yet, the government agency may require a permit or licence within a set period of notification (c.f. U.S. Toxic Control Substances Act).
   (d) No restriction unless danger is established by the government, but an obligation to notify the government of the intended production (for instance, regulations of only such products as are proven to be hazardous).
   (e) Voluntary guidelines for production and/or use which could evolve into mandatory regulation.

3.2 Current Legislation

3.2.1. Production

Environmental protection statutes hardly address production requirements at all. Under the Environmental Contaminants Act manufacturers who produce a chemical compound for the first time in quantities exceeding 500 kilograms in 1 calendar year must notify Environment Canada within three months of the manufacturing of the chemical and must provide information respecting any danger to human health or the environment posed by the compound [1] (subsection 4(6)). Even if a BTP were considered a chemical compound, production is likely not to exceed 500 kilograms and notification would only occur after three months. Under the Environmental Protection Act stop and control orders [2] may be issued prohibiting or regulating production. The prohibition under the Pest Control Products Act against manufacturing under unsafe conditions could be considered as an environmental protection provision as well.[3]

Under current legislation the production of certain BTP's is regulated for the purpose of protection of agricultural resources. Many statutes require licences. The licencing authorities could include requirements aimed at environmental concerns or refuse licences in case of unacceptable environmental risks. Under the Fisheries Act the Minister of Fisheries and Oceans may require modifications to "Works and Undertakings" which result or are likely to result in the deposit of deleterious substances in waters frequented by fish, which would constitute an offence under section 33 of the Fisheries Act.[4]

Permits issued under the Plant Quarantine Act often contain conditions for the use of pests or infested plant or other matter in research or industrial use.[5]

Under the Artificial Insemination of Livestock Act all semen producing business, inseminators and semen processing supervisors must be licenced. Under the Animals for Research Act supply facilities must be registered.

be licenced.[7] Animals that are bred and reared in a supply facility must at all times be kept separate from other animals owned by the operator of the facility.[8]

Under the Animal Disease and Protection Regulations persons preparing, manufacturing, preserving or testing a veterinary biologic must do so under and in accordance with an establishment licence.[9] In addition, persons manufacturing a veterinary biologic must obtain a product licence.[10] Applications for product licences must include test results to enable the Minister of Agriculture to analyze products, and, where requested, samples of the product must be submitted.[11] Licenced manufacturers are subject to annual inspection. The regulations also contain requirements for operating a licenced establishment[12] and establish standards for animal semen production and distribution centers.[13]

Workers protection legislation addresses the safety of the workplace. Environmental concerns are addressed incidentally where the statutes address containment. Disclosure requirements may assist in the administration of environmental legislation if such information is shared.

Quality control of food and drugs is currently regulated under the Food and Drugs Act. Under this Act the production of a drug under unsanitary conditions is prohibited.[14] The sale of Schedule D drugs requires a licence from the Minister which indicates that the manufacturing premises, process and conditions are adequate to ensure that the drug will be safe for use.[15] Drugs obtained by rDNA procedures, insulin, interferon and antibiotics prepared from micro-organisms are listed in Schedule D to the Act and manufacturers of such drugs must comply with specific requirements applicable to the particular drug for which they are licenced.[16] Manufacturers of new drugs must obtain a notice of compliance which requires the submission of information.[17] Licences for manufacturers of Schedule D drugs expire annually.[18] In addition, the Minister of Health may suspend or cancel licences if he believes any condition exists which will not ensure the safety of the drug for use.[19]

New drugs are drugs containing new ingredients or a new combination of drugs for which a new claim is made and that have not been sold in Canada for sufficient time and in sufficient quantity to establish their safety and effectiveness.[20] Where an existing drug is being produced using a new production method, such drug is not considered to be a new drug. For instance, if insulin were to be produced by means of an enhanced bio technology process, such insulin would not be considered a new drug. However, manufacturers must inform the Minister of changes in information submitted. Therefore, the Minister could become aware of the change in production process.[21]

The Food and Drug Act prohibits the manufacture of food under unsanitary conditions,[22] but does not further regulate the manufacture of human food. The federal government has been unable to set quality standards under the Food and Drug Act for constitutional reasons.

The Pest Control Products Act prohibits the manufacture of any control products under unsafe conditions.[23]

The production of animal feed is subject to the Feeds Act.[24] A schedule to this Act contains lists of single ingredient feeds permissable for use as well as a number of prohibited ingredients.[25] Mixed feeds, unless exempt, must be evaluated for safety and efficiency and registered by Agriculture Canada prior to the manufacture or sale of the feed in Canada.[26] The Act and Regulations contain a number of exemptions, including, feed for export outside Canada, which is so labelled,[27] and feed manufactured for experimental purposes at a university where certain conditions have been met.[28] Feeds must conform to prescribed standards and be packaged and labeled as prescribed.[29] Feeds and feed ingredients are subject to field inspection, sampling and laboratory analysis to ensure compliance with the legislation and to verify accuracy of labels.[30]

None of the current legislation establishes a central registry system for BTP's produced in either Canada or Ontario. Yet, the Food and Drugs Act establishes a registration system for drugs.[31] The Pest Control Products Act enables the Governor-in-Council to make regulations respecting the registration of pesticides and of establishments which manufacture them.[32] At present the regulations contain registration requirements for pesticides "imported into, sold or used in Canada,"[33] but not pesticides simply "manufactured" or "produced" within Canada.

3.2.2 Storage

The Environmental Protection Statutes do not contain requirements for the storage of BTP's. However, certain storage requirements could be contained in an approval of the Director of the Environment under the Environmental Protection Act.[34] Regulations under the Transportation of Dangerous Goods Act also contain different "packing groups" which relate to the necessary containment level.[35]

A number of agricultural protection statutes contain provisions for storage. The Animal Disease and Protection Act authorizes the enacting of regulations respecting the storing of animal semen and veterinary biologics.[36] Regulation making powers under the Artificial Insemination of Livestock Act include the power to prescribe the place at which and the conditions under which semen may be frozen and stored.[37] Under the Livestock Pedigree Act breed associations are empowered to establish rules and regulations concerning the storage of embryos.

The Pest Control Products Act prohibits the storage of control products under unsafe conditions.[39] Regulations outline requirements for the packaging and storage of control products. Every registrant must keep records of all quantities of control products stored by him.[40] It seems that these provisions are aimed more at the protection of environment then at the quality of the relevant control products.

A Director appointed under the Pesticides Act may issue a stop order if the storage of a pesticide or substance or thing containing a pesticide causes an emergency endangering human health or the environment.[41] Control orders may be issued where the storage of a pesticide or a substance or thing containing a pesticide would affect the quality of the environment or human health or otherwise cause injury or harm or impair the safety of any person.[42] The Ministry of the Environment must maintain an alphabetical index record of the names of all persons to whom orders are directed.[43]

The Food and Drugs Act prohibits the sale of a drug that was stored under unsanitary conditions.[44] The preservation of any food under unsanitary conditions is prohibited,[45] and the sale of any food that was packaged or stored under unsanitary conditions is prohibited.[46] These provisions seem irrevelant for environmental protection.

The MRC Guidelines address the physical containment of experimental animals and insects, but do not contain other storage requirements for BTP's. Under the Canada Occupation Health and Safety Regulations dangerous substances must be stored in a manner which protects the safety and health of employees and minimizes the hazard related to that substance.[47]

3.2.3. Use

Current environmental protection legislation, with the following exceptions, does not address the issue of use of substances or organisms which could be BTP's. Under the Environmental Contaminants Act it is prohibited to knowingly use for a prescribed commercial, manufacturing or processing purpose a substance or member of a class of substances specified in the Schedule to the Act in either Canada or a prescribed geographical areas.[48] It is conceivable that the use of a BTP would be the subject of a control order, stop order or program approval under the Environmental Protection Act.[49]

Agricultural protection legislation does not regulate the use of organisms or substances which could be BTPs other than the Livestock Pedigree Act which authorizes breed associations to establish rules and regulations concerning the implantation of embryos.

Of the product oriented legislation only the Pest Control Products Act and the Pesticides Act deal with the issue of use. As they deal with outdoor use they apply directly to environmental releases of BTP's which are pesticides. The Pest Control Products Act prohibits the use of a control product under unsafe conditions.[51] Regulations outline requirements for the registration and use of control products and exemptions from these provisions.[52] Registration of a control product may be refused where the applicant fails to establish merit or value of the product for purposes claimed or where the use of the product would lead to unacceptable risk of harm to the public health, plants, animals, the environment, or things on or in relation to which the product is intended to be used.[53]

The Pesticides Act regulates all pesticide use in Ontario through a system of licences, schedules and permits. Only pesticides that have been registered under the Federal Pest Control Products Act and are subsequently scheduled for use in Ontario by the Pesticide Advisory Committee are legal for use in Ontario.[54] The Director may issue stop orders in cases of emergency[55] and control orders to regulate or mitigate the use of a pesticide that causes or is likely to cause impairment of the quality of the environment, or which is likely to harm human, animal or plant life.[56]

3.2.4. Sale

Four agricultural protection statutes regulate sale, apparently mainly from a consumer protection point of view. The Animal Disease and Protection Act regulates the sale of animals, animal products and by-products, animal pathogens and veterinary biologics. Regulations under the Act contain labelling requirements for veterinary biologics.[57] This enables the Minister to prohibit

by order, the introduction of anything used with respect to animals, or any animal or animal product which could cause a contagious or infectious disease among animals.[58] Yet introduction need not occur through the sale of products. It is a wider concept, and is aimed more at the protection of agricultural resources. Under the Livestock Pedigree Act a seller of an altered or genetically manipulated embryo must disclose full particulars to the purchaser. Breed associations require information necessary to determine the genetic makeup of an animal as a requirement for registration. Under the Artificial Insemination of Livestock Act semen produced in Ontario can only be sold or offered for sale if it has been collected, identified and processed by a licenced person.[60] Only licenced inseminating businesses may sell livestock semen produced outside Ontario.[61] Under the Plant Diseases Act only a licenced person may deal in nursery stock.[62]

Worker protection statutes do not address the issue of sale other than the Occupational Health and Safety Act which obliges manufacturers, distributors and suppliers to notify a Director in writing of their intent to distribute or supply for commercial or industrial use in a work place any new biological or chemical agent or combination of such agents.[63]

All product oriented legislation contains provisions with regard to the sale of the regulated products. These provisions might be relevant to control environmental releases if use or spillage of the products pose environmental risks.

The Hazardous Products Act prohibits the unauthorized sale of hazardous products.[64] Products listed in Part I are prohibited outright while products listed in Part II may not be sold except as authorized by regulation. Regulations contain packaging and labelling requirements for some products listed in Part II of the Schedule to the Act.

The Food and Drugs Act prohibits the sale of a drug that is adulterated or that was manufactured or stored under unsanitary conditions.[65] In addition, the sale of sub-standard drugs is prohibited.[66] Drugs listed in Schedule D may not be sold without a Ministerial indication that the manufacturing premises, process and conditions are adequate to ensure that a drug will not be unsafe for use.[67] Manufacturers of schedule D drugs must be licenced to sell a particular drug.[68] New drugs may not be sold unless a notice of compliance is obtained.[69] Yet a manufacturer may sell a new drug to qualified clinical investigators, provided the required informatio is provided to the Minister and the approval of the Minister is obtained.[70]

The Food and Drugs Act prohibits the sale of any food that has in or upon it any poisonous or harmful substance, is unfit for human consumption, is adulterated, consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance or was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.[71] These provisions are not likely to become relevant as the possibility of environmental contamination through use or spillage of food is remote.

The Pest Control Products Act prohibits the sale of pest control products unless they have been registered and conform to prescribed standards and packaging and labelling requirements.[72] Every registrant must keep records of all quantities of control products stored, manufactured or sold by him.[73] Regulations provide for certain exemptions from registration.[74] Draft guidelines are being prepared relating to the registration of micro-biological agents as pesticides.

Under the Pesticides Act all persons selling pesticides must do so in accordance with a licence, and are limited to pesticides classified by the regulations, unless the sale is exempt.

Under the Feeds Act all mixed feeds must be evaluated for safety and efficiency and be registered by Agriculture Canada prior to the sale of the feed in Canada, unless exempt.[77] Feeds must also conform to prescribed standards and be packaged and labelled as prescribed.[78] Regulations detail standards[79] and

packaging[80] and labelling requirements.[81] Every single ingredient feed sold under a name set out in italics in an item of Schedule IV must conform to the description of that feed set out in the Schedule and to the standards prescribed in the regulations.[82]

The Fertilizers Act prohibits the sale of a fertilizer or supplement that has not been registered as prescribed, does not conform to prescribed standards or is not packaged and labelled as prescribed.[83] In addition, the sale of fertilizers or supplements containing destructive ingredients or properties harmful to plant growth when used according to the directions on the label is prohibited.[84] The regulations provide for a number of exemptions.[85]

Under the Seeds Act only seeds prescribed for sale in Canada may be sold in Canada. The regulations outline general standards for seeds,[86] as well as labelling requirements.[87] In addition, there are standards for specified varieties of seeds.[88]

3.2.5. Imports and Exports

Federal environmental protection legislation does address the issue of import, but it is unlikely that these provisions will apply to the bulk of the BTP's anticipated to be imported. Ontario environmental protection legislation does not contain provisions with regard to importation or exportation.

Under the Environmental Contaminants Act importers must notify Environment Canada if they import a chemical compound into Canada for the first time in quantities exceeding 500 kilograms in a calendar year. They must provide information concerning the name of the compound and the quantity imported during that year and information respecting any danger to human health or the environment posed by the compound.[89] The importation for certain prescribed uses of a substance or member of a class of substances specified

in the Schedule to the Act, into Canada or a more limited prescribed geographical area is prohibited.[90] Regulations may also be made prescribing the maximum quantity or concentration of any substance or member of a class of substances specified in the Schedule that may be contained in products imported into Canada.[91] No export controls are provided for in the Act.

The Clean Air Act prohibits the importation into Canada of any fuel that contains any element or additive in a concentration that exceeds the concentration prescribed with respect to that element or additive in relation to such fuel.[92] This provision is unlikely to apply to a BTP.

Under the Canada Water Act it is prohibited to import into Canada any cleaning agent or water conditioner that contains a prescribed nutrient in a concentration that is greater than the prescribed maximum permissable concentration.[93] Currently the list of prescribed nutrients does not include BTPs.

Four agricultural protection statutes contain import and export provisions. The Animal Disease and Protection Act enables the Minister to prohibit the importation of animals, animal products or by-products or other things used in respect of animals for preventing the introduction of contagious or infectious diseases among animals.[94] Inspectors at the border may quarantine, order the removal from Canada or order the destruction of animals, animal products, animal by-products, feed stuffs or other things imported into Canada if infection is suspected.[95] The Regulations contain extensive species,[96] products,[97] and by-products[98] specific importation provisions. Among other things, permits are required for the importation of animal embryos,[99] animals containing a transplanted embryo,[100] animal pathogens,[101] animal blood,[102] or semen,[103] and veterinary biologics.[104] A certificate by a veterinarian may also be required. A veterinarian certificate is required for the export of an animal embryo or an animal in which an animal embryo has been transplanted.[105]

Under the Plant Quarantine Act and Regulations a permit and a health certificate are required for the importation of any plant or other matter that is likely to be infested with a pest.[106] All plant or other matter admitted into Canada must be examined at the port of entry or at a place within Canada specified by the inspector.[107] The regulations grant exemptions,[108] and prescribe treatment for specified plant or other matter under certain circumstances.[109] Plants or other matter must be labelled according to the regulations.[110] Inspectors may issue health certificates in respect of any plant or other matter to be exported from Canada.[111] The Plant Health Division maintains a record of the quarantine import requirements of other countries and certifies Canadian product compliance with those requirements.

Breed Associations empowered under the Livestock Pedigree Act have established guidelines for eligibility for registration of animals produced from imported embryos. They are similar to those for animals produced from domestic embryos.[113] The Act does not contain any export controls. Under the Artificial Insemination of Livestock Act a licence is required to sell or to offer for sale any semen produced outside Ontario.[114]

The Plant Diseases Act does not contain any import restrictions. A certificate as to the "freedom from plant disease" of plants under section 17 may serve as a notification to exporters. The Animals for Research Act does not explicitly address importation or exportation issues. However it implicitly allows for the importation of animals for research.[115]

Worker protection legislation does not address the import/export issue.

A number of the federal product oriented statutes contain provisions with regard to import and export. Their main purpose is to support requirements for production or sale in Canada.

Under the Hazardous Products Act the importation of hazardous products listed in Part I of the Schedule is prohibited. The importation of products listed in Part II is permitted only under the conditons specified in the regulations.[116] There are no export controls.

Under the Food and Drugs Act the importation of drugs, the sale of which would be in violation of the Act or Regulations, is prohibited.[117] Packaged drugs neither manufactured for sale in Canada nor sold in Canada are exempt from the Act provided the package is marked "Export" and the manufacturer has certified that the product does not contravene any known requirements of the law of the country to which it is to be consigned.[118]

The importation of foods, the sale of which would be a violation of the Act or Regulations is prohibited.[119] Imported foods are subject to many of the requirements relating to sale of domestically produced foods. Packaged foods, neither manufactured for sale in Canada, nor sold in Canada, are exempt from the Act provided the package is indicated as being for export and the manufacturer has certified that the product does not contravene any known requirements of the law of the country to which it is to be consigned.[120]

Under the Pest Control Products Act it is prohibited to import a control product, unless it has been registered, conforms to prescribed standards and is packaged and labelled as prescribed.[121] Imports of control products must be accompanied by a declaration setting out the information required by the Regulations.[122] Exports and interprovincial movements of control products are prohibited unless the products were manufactured under prescribed conditons in a registered establishment.[123] The Pesticides Act does not contain any import/export provisions.

3.2.6. Waste Disposal

The Environmental Contaminants Act does not address waste disposal as such. However, it does provide for regulations setting standards in terms of quantity and concentration for the release of specific substances into the environment.[124] Conditions of release and geographical areas in which restrictions on release apply may be prescribed as well.[125] No standards or conditons have been set with regard to modern biotechnology or BTPs.

The Clean Air Act allows the federal cabinet to establish air quality objectives, guidelines, and standards. Sanctions are provided only for the contravention of "standards."[126] The Minister of the Environment may formulate air quality objectives representing "tolerable", "acceptable", and "desirable" ranges of concentration for a contaminant released into the atmosphere, which may then be prescribed by cabinet.[127] National emission guidelines, stating the quantities and concentrations of an air contaminant which should not be emitted from any source, may also be published by the federal cabinet.[128] The cabinet may prescribe enforceable national standards relating to the quantity and concentration of an air contaminant whenever emissions from a specified stationary source constitute a significant danger to persons or are likely to violate international obligations.[129] Upon the Minister's recommendation, national emission standards may also be set with respect to federal works undertakings and business.[130] Federal-provincial agreements relating to air quality objectives could result in standards being set for certain enterprises or geographical areas within a province.[131] Specific standards may also be prescribed, upon the Minister's advice, where it it believed that an air contaminant originating from a Canadian source creates or contributes to air pollution that may reasonably be expected to constitute a significant danger to the health, safety or welfare of persons abroad, provided that their government provides reciprocal protection for Canadian citizens.[132]

The Environmental Protection Act prohibits the discharge into the environment of contaminants in excess of amounts and levels prescribed by the regulations.[133] The regulations list contaminants and allowable levels of concentration. Section 13(1) contains a general prohibition against the release of contaminants into the natural environment, if they are likely to cause harm, notwithstanding any other provision of the Act or the Regulations. Certificates of approval are required for waste management systems and waste disposal sites.[134] BTP's have not been listed as contaminants and it is unclear as to whether they would be considered as contaminants under the current definition.

Under the Ontario Water Resources Act the Minister may make regulations prescribing standards of quality for potable and other water supplies, sewage and industrial waste, effluents, receiving streams and water courses.[135] Water quality objectives have been set for many substances, but not for living BTP's. Discharges of substances which may impair water quality, but which do not have established tolerances or criteria, will be judged on a case-by-case basis, but BTP's have never been addressed.[136]

Under the Fisheries Act regulations may be made authorizing the deposit of waste, pollutants or deleterious substances within prescribed quantities or concentrations.[137] The general prohibition against the deposit of deleterious substances contained in section 33(2) operates as a waste disposal requirement. Regulations have been developed permitting effluent discharges in six industrial sectors.[137A]

Under the Migratory Birds Convention Act it is prohibited to deposit or permit the deposit of any substance harmful to migratory birds in any waters or any area frequented by migratory birds.[138]

Under the Animal Disease and Protection Act contaminated animals, semen or animal semen exposed to a communicable disease may be destroyed.[139] Licenced veterinary biologic establishments must ensure that animal wastes, contaminated matter and dead animals are

decontaminated before being removed or discharged from the establishment.[140] Establishments must have adequate draining, plumbing and sewage to handle all wastes. Suitable traps and vents must also be provided.[141] Where required, veterinary biologic establishments must be capable of being mainatined free of air-borne contaminants to any degree and preventing the escape of micro-organisms there from.[142]

Permits issued under the Plant Quarantine Act may specify waste disposal requirements.[143] Other agencies may be consulted about advice for essential requirements, including the Canadian Wildlife service, Health and Welfare Canada, the Health of Animals Division of Agriculture Canada, Fisheries and Oceans and provincial departments and agencies.

Under the Plant Diseases Act an inspector is empowered to order the destruction of diseased plants.[145] No general waste disposal requirements are contained in the Act.

The Pest Control Products Act does not deal directly with the issue of waste disposal. However, under the Regulations the environmental release of a non-registered product is restricted to studies conducted on the premises of the researcher or on premises for which the Director has issued a research licence.[146] Waste disposal requirements may be included on the label of a registered control product.[147] For pest control products containing a new ingredient, information regarding the disposal of the product and suitable methods for its neutralization in the environment is required.[148] Under the Pesticides Act the discharge, emission or deposit of a pesticide or any substance or thing containing a pesticide into the environment is prohibited, if it is likely to cause damage or harm or impairment to the environment to a greater extent than would necessarily result from the proper use of the pesticide.[149] Where the disposal of a pesticide causes an emergency, a stop order may be issued[150] and where the disposal of a pesticide causes or is likely to cause impairment of the quality of the environment or otherwise causes injury or harm to plants, animals or man, a control order may be issued.[151] The Minister may order repair of certain damage caused by

the emission or discharge of a pesticide or substance or thing containing a pesticide.

3.2.7. Spills

The Canada Water Act does not address the issue of spills. The Clean Air Act does not directly deal with spills, but does provide for more expedient procedures for the prescription of emission standards if such is essential to meet an emergency situation.[152] Under the Environmental Contaminants Act, it is prohibited to spill, during commercial or manufacturing activities, any specified substance into a prescribed environment in quantities or concentrations exceeding the prescribed maximum.[153]

According to the Transportation of Dangerous Goods Act spills must be reported to an inspector or another prescribed person by those who at the time had the charge, management or control of the dangerous goods in question. They also must, as soon as possible, take all reasonable emergency measures consistent with public safety to repair or remedy any dangerous condition. Inspectors may take reasonable emergency measures or request that such measures be taken by others that they consider qualified.[154] The expenses of such emergency measures can be recovered from the person(s) responsible for the spill or those who contributed to it. A person engaged in any activity to which this Act applies is deemed to have been at fault unless he establishes, on a balance of probabilities, that he and any others for whom he is by law responsible took all reasonable measures to comply with the Act and Regulations. There is a two year limitation.[155] Regulations require the filing of a summary emergency response plan prior to offering certain dangerous goods for transport and the number of such plans must be contained in documents carried on the vehicle or other means of transportation.[156]

Part IX of the Environmental Protection Act deals extensively with spills but may not apply to BTP's. Spill is defined when used with reference to a pollutant as a discharge,

(a) into the natural environment,

(b) from or out of a structure, vehicle or other container, and

(c) that is abnormal in quality or quantity in light of all the circumstances of the discharge,

and when used as a verb has a corresponding meaning.[157]

Part IX does not apply to the disposal of animal wastes in accordance with normal farming practices.[158] Where a spill could have a deleterious effect on the environment every person having control of the spilled pollutant and every person who spills or causes or permits a spill of the pollutant must notify the Ministry of the Environment, the Municipality or Regional Municipality in which the spill occured, and if possible, the owner of the pollutant as well as the person having control of the pollutant.[159] The owner of a pollutant and the person having control of the pollutant that is spilled must do everything practicable to prevent and eliminate the adverse effects and to restore the natural environment.[160] The Minister of the Environment may give directions to employees and agents of the Ministry if it is in the best interest of the public to do so and the Minister is of the opinion that neither the person having control of the pollutant nor the owner of the pollutant will counter the adverse effects of the spill, because they cannot be located, or otherwise, or the person having control or ownership of the pollutant requests the assistance of the Minister.[161] The spilled pollutant must be disposed of in accordance with an order of or direction by the Minister of the Environment, in accordance with an approval of the Director or pursuant to an order, requirement or direction by the Director.[162] The Act also provides for compensation for damages incurred.[163]

The Minister of the Environment must be informed of any release of a contaminant into the natural environment that is likely to cause harm[164] and he may order the repair of any resulting damage to land, water, property or plant life.[165]

Under the Ontario Water Resources Act a person or municipality discharging or causing permitting the discharge or deposit of polluting material into water or into a water course or from whose control any such material escapes into water or into a water course must notify the Minister of the Environment.[166] The Director may order a municipality or industrial or commercial enterprise to have on hand specified equipment to alleviate the effects of impairment of quality of water that may be caused by the municipality or by the industrial or commercial enterprise.[167]

The regulations under the Animal Disease and Protection Act contain procedures to identify, contain and eradicate infectious diseases in animals. These provisions could be considered as aimed at preventing the "spill" of contagious material.

Applications for permits issued under the Plant Quarantine Act must outline precautions to be taken to prevent the spreading of pests during transporting of pests, plants other matter.[168] No permit will be issued unless an inspector is satisfied that satisfactory measures will be taken to prevent the spreading witin Canada of the pest.[169] Provisions also permit the seizure, detention, forfeiture, confiscation and destruction of infested plant or other matter.[170]

Under the Fisheries Act spills must be reported immediately if any damage or danger to fish, fish habitat or the use of fish by man can reasonably be expected to result and reasonable measures must be taken to mitigate or remedy any adverse effects.[171]

Under the Plant Diseases Act where an inspector finds a plant disease or any cause or organisms of a plant disease, he may order the person in charge to disinfect any plants, land, building, vehicle or container or to treat or destroy any plants. He may also order that plants that may become infected not be grown for a specific period of time where causes organisms of a plant disease have been found in the soil or premises.[172] Regulations may provide for programs and measures for the control and eradication of

plant diseases.[173]

The MCR Guidelines require emergency plans for foreseeable laboratory accidents, such as spills.[174] Under the Canada Occupational Health and Safety Regulations every dangerous substance shall be stored, handled and used in the work place in a manner consistent with the minimization of risk.[175]

Under the Pest Control Products Act packages for control products must be sufficiently durable and be designed so as to safely contain the product.[176] Requirements relating to spills are assessed in relation to individual products and may be incorporated into requirements relating to labelling,[177] instructions for use[178] and containers for control products.[179] Under the Pesticides Act discharges out of the normal course of events which are likely to harm the environment must be brought to the attention of a Director appointed pursuant to the Act.[180] The Minister of the Environment may require the person responsible to clean up any spill or other discharge within specified time periods.[181] The Ministry could also use stop orders and control orders to handle spills.[182] Under the Regulations fires, accidents and thefts involving pesticides must be reported.[183]

3.2.8. Transportation

The Transportation of Dangerous Goods Act requires the filing of an emergency response plan for the transportation of infectious substances which are included in Schedule XII, Part II.[184] The Regulations contain safety requirements for the transport of dangerous goods, including the training of persons engaged in these activities.[185] Documentation requirements in the Act are developed by Environment Canada pursuant to the terms of a memorandum of understanding. Health and Welfare Canada is involved in responding to emergency response plans filed by shippers of infectious substances. The Act provides for agreements with the provinces for implementation where federal jurisdiction does not apply.[187] In the future, amendments to the Regulations will address

packaging, handling, storage and segregation requirements. Labelling and marking requirements already exist for products falling within ivision two of Class 6.[189] Transport Canada is concerned only with accidental releases during transport. It believes that in such circumstances any biotechnological products are likely to be rendered inactive by fire or exposure to other substances.

The Environmental Protection (General Waste Management) Regulation[191] establishes a "manifest" system or system of numbered documents to regulate the transportation and handling of waste. Waste may include waste from BTP's. It does not address the transportation of BTP's as such.

Under the Animal Disease and Protection Act a permit is required to transport animal pathogens imported into Canada to or from any laboratory, research institute or hospital.[192] Part XII of the Regulations contains provisions for the transportation of animals entering or leaving Canada or within Canada.

Under the Plant Quarantine Act it is prohibited to knowingly convey within or from Canada any pest or any plant or other matter that is infested or likely to be infested with a pest or that constitutes a biological obstacle to the control of any pest except as provided by the Act or Regulations.[193] Plants or other matter that is likely to be infested with a pest or that constitutes a biological obstacle to the control of any pest must be conveyed within or from Canada under a movement certificate.[194] Specified plants or other matter, transported within Canada, must undergo prescribed treatments or comply with certain conditions such as processing or inspection, prior to their conveyance.[195] Certain shipments of specified plants or other matter admitted into Canada must be treated in the prescribed manner.[196]

The Plant Diseases Act prohibits the transport or shipment from a nursery or the premises of a dealer in nursery stock of any plant having a plant disease.[197]

Under the Pest Control Products Act inter-provincial movements of control products are prohibited unless the products were manufactured under prescribed conditions in a registered establishment.[198] The Pesticides Act regulates transportation of pesticides in Ontario. The Regulations contain provisions concerning the transportation of pesticides.[199]

3.3. Evaluation of Current Legislation

3.3.1. Environmental Protection Legislation

Current environmental protection legislation focuses on the release of substances which are known to contaminate the environment. It does not require an evaluation of the safety of actual or potential releases into the environment. It does not regulate the storage or sale of any product or substance and only addresses the use of certain substances to a limited extent. However, once it is established that certain substances or organisms may be harmful to the environment, stop orders, control orders and program approvals could contain requirements with regard to use and storage.

Environmental protection legislation contains extensive provisions to deal with waste disposal and spills of contaminants. However, it should be kept in mind that current environmental protection legislation probably does not regulate living organisms, with the exception of the Ontario Water Resources Act and potentially the Canada Water Act. Environmental legislation, both on the federal and provincial level addresses the transportation of dangerous goods, including infectious substances. It appears that the major shortcomings of the environmental protection legislation are its "after the fact" approach, including the lack of pre-production evaluation, and the fact that the legislation is tailored to deal with chemical substances and radioactive substances.

3.3.2. Agricultural Protection Legislation

At the moment, evaluation and assessment of BTP's at the production stage is more likely to occur under agricultural protection legislation. Agricultural protection legislation provides for pre-production assessment. Storage requirements appear to address quality control more than environmental concerns. Use is not regulated except under the Livestock and Pedigree Act. Four agricultural protection statutes contain sale provisions which are aimed primarily at consumer protection. Import provisions contained in Federal Statutes are included to prevent the spreading of diseases, pests and to control the quality of embryos and products used for artificial insemination. Waste disposal requirements in the relevant legislation are related to the protection of agricultural resources, not the environment at large. Provisions concerning spills are aimed at the prevention or spreading of disease and pests and protection of agricultural resources. Transportion requirements are aimed at preventing the spread of diseases and pests. The major problem with agricultural protection legislation is that its focus is limited to the protection o f agricultural resources. In addition, the pre-production assessment is limited to specific products covered under the relevant agricultural legislation.

3.3.3. Product Oriented Legislation

Product oriented legislation applicable to BTP's contains production requirements, but pre-production assessment is aimed mainly at quality control of the products. Only the Food and Drugs Act contains storage provisions and they relate to the quality of the products. The Pest Control Products Act and the Pesticides Act regulate use, for the purpose of protecting the environment. The relevant provisions could serve as a model for future legislation covering a wider range of BTP's and BT wastes. All product oriented legislation contains sale provisions. Some of these are aimed at consumer protection, such as in the Hazardous Products Act, the Food and Drug Act and the Seeds Act. Others regulate the sale where there is a risk to the environment, such as the Pest Control Products Act and the Pesticides Act. Others are aimed at the

protection of agricultural resources such as the Seeds Act, the Fertilizers Act and to some extent the Feeds Act. Federal legislation contains importation requirements aimed at supplementing sale regulation. Waste disposal, spills and transportation have been dealt with only under the Pest Control Products Act and the Pesticides Act. Environmental protection appears to be the main reason for these provisions.

Most product oriented legislation controls production. Yet it only covers a limited number of BTP's and even fewer BT wastes. Not all product oriented legislation prohibits the production of non-approved products. It is only where it is established that a product may be dangerous or harmful that it is subjected to extensive regulation. Regulation of use is limited at best and waste disposal is dealt with only incidentally. Therefore, regulation under product oriented legislation may prevent or restrict the production and sale of potentially harmful BTP's, but it does not address the specific concerns of environmental releases.

CHAPTER 4 - INFORMATION ISSUES

4.1 Policy Issues to be Addressed

The following information issues should be addressed when decisions are made concerning regulation of enabling biotechnology

1. What information is needed by a particular government agency to perform its functions?

2. How does the government obtain information necessary to
   (a) draft legislation and/or regulations.
   (b) assess risks of release on a case-by-case basis including:
      i) information about the relevant products, processes and/or wastes.
      ii) background information necessary to predict effects.

   (c) react to emergencies (for instance, the submission of emergency response plans?)

3. How does the government monitor production and release for the purpose of

   (a) deepening its understanding of modern biotechnology and the effects of releasing BTP's and BT wastes?

   (b) enforcement of relevant legislation?

4. Who should provide information to the government?
   (a) inventors
   (b) producers
   (c) users
   (d) government officials, researchers, laboratories or data base operators within the government agency concerned
   (e) officials, researchers, laboratories or data base operators in other government agencies
   (f) universities

(g) other researchers, laboratories, or data base operators
(h) importers
(i) others

5. Who should be allowed access to information provided to a government agency?
   (a) specified officials and/or employees within the government agency.
   (b) specified officials in other government agencies, (e.g. should the Ministry of the Environment be informed when a permit is granted to use pesticides under the Pesticides Act, or should the Patent Office communicate all information related to modern biotechnology to other federal and/or provincial government agencies involved such as the Health Protection Branch of the Ministry of the Environment).

   (c) outside contractors hired to assist in assessment, monitoring or other functions,
   (d) workers and other individuals handling the relevant product,

   (e) individuals likely to be affected by the production or use of the BTP's

   (f) the public at large, including the media.

6. How should confidential information be protected?

7. Should there be rules establishing what kind of information should be public and what should be confidential?

8. If outside consultants are used by government agencies, how should confidentiality be protected?

(a) by an undertaking not to disclose the information,

(b) by an undertaking not to use the information,

(c) by an undertaking not to engage in any research in the relevant area,

(d) by an undertaking not to publish any articles in the relevant area.

8(A) How would such undertakings be enforced?

9. Could there be a conflict of interest if any of the following were engaged as consultants for the purpose of assessment, monitoring or otherwise?

(a) government officials who after participation in the assessment accept employment or contract work with an industry,
(b) government officials who after participation in the assessment accept employment at a university or other research institute,
(c) university staff,
(d) experts engaged in non-competing industries,
(e) experts engaged in competing industries.

10. Both government and industry could benefit in sharing information. Do we need one government agency to collect and catalogue data with regard to modern bio technology? And, if so, who should perform this function?

10(A) With regard to traditional industries, the disclosure of information by industry has been promoted under the patent law in that the inventor is given an exclusive right to use a certain invention and the public has access to information about the invention. Should BTP's and the processes be patentable?

10(B) a) can one sufficiently describe a BTP to qualify for a patent under the current Patent Act.

b) Can life forms be patented under the current Patent Act? (considering viruses, organisms, plants, animals and genetically engineered humans).

c) is the patenting of life forms morally reprehensible?

11. Is the current patent law satisfactory if applied to current biotechnology or BTP's?

12. Under Section 41 of the Patent Act a special regime is established for chemicals intended for use as food or medicine to ensure that chemicals can be available to the public at a low price. Should a similar regime be established for all or certain BTP's?

13. If a modern biotechnology data bank is established, what should it be used for?

a) sharing of information within government only,
b) providing information for emergency response plans,
c) providing information to universities and other research institutuions,
d) providing information to Ontario or Canadian industry.

14. If a data bank is established, should certain information be classified and only be provided to government agencies, or should two data banks be established, one with confidential information available to the public.

4.2. Existing Legislation

4.2.1 Issuance of Permits and Licences

A large number of statutes require the submission of information as part of a permit or approval system. Most of these are contained in agricultural protection or product oriented legislation, but the submission of information is required under some environmental legislation as well. Under the Clean Air Act inspectors may require the submission of plans and specifications from persons proposing to construct, alter or extend a work that will form part of the federal work, undertaking, or business, the operation of which is likely to result in the emission into the ambient air of an air contaminant. [1] Under the Environmental Assessment Act an environmental assessment must be submitted before certain undertakings are commenced, (either by a public body or a major private enterprise designated by the Regulations). [2] Under the Environmental Protection Act the submission of information may be required prior to the issuance of a program approval [3] and information must be furnished before a certificate of approval for a waste disposal site can be issued. [4] The Ontario Water Resources Act requires the submission of plans for water works and sewage works, including alterations of existing works. [5]

Under the Fisheries Act an "authorization to deposit a deleterious substance" can be obtained, which requires the submission of certain requested information, including the results of tests and monitoring. [6]

Under the Animal Disease and Protection Act information must be submitted when an application is made for a product licence, an establishment licence or an import permit relating to a veterinary biologic. [7] Licence holders must give notice of changes or addition to information already provided. [8]

Applications for permits under the Plant Quarantine Act must contain information regarding the purpose for which the pest, plant or other matter is to be used, its origin, destination, and details of the proposed means of tranportation and related safety precautions. [9]

The information required may lead to the inclusion of permit conditions relating to the use of the pest.[10]

Applications for registration under the Pest Control Products Act must be accompanied by sufficient information to allow the Minister to determine safety, merit and value of the control product. The results of scientific investigations must be submitted as well for new products or products which will be used on living plants and animals which will eventually be consumed by man. Copies of forms accompanying imports of control products must be forwarded to a District Director.[11]

Under the Feeds Act proof of efficacy and safety for livestock and humans is required in the evaluation for registration of mixed feeds and prior to the listing of a single ingredient feed in Schedule IV.

The Fertilizers Act requires the submission of information when applying for registration of a fertilizer or supplement.[13] Information must be submitted which is necessary to determine the safety, merit and value of the fertilizer or supplement for which the application is made.[14] A person packing carrier materials used to carry Rhyzobium species must provide the Minister of Agriculture with results of scientific investigations respecting the effectiveness of the product for its intended purposes and must include the minimum number of viable cells of Rhyzobium species.[15]

Environmental assessment may also occur on the federal level under the Environmental Assessment and Review Process Guidelines Order.[16] Government departments which have decision making authority over proposals, including initiatives, undertakings or activities referred to as "initiating departments", must determine whether the proposal would or could produce significant adverse environmental effects, whether there are unknown potential adverse environmental effects or whether public concern about the proposal is such that a public review is desirable.[17] Under any of these circumstances the proposal must be referred to the Minister of the Environment for public review by an environmental assessment panel. This process applies to proposals undertaken by a federal department

with decision making authority and by certain crown corporations,[18] to proposals which may environmentally affect areas of federal responsibility, or occur on federally administered lands, and to proposals funded by the national government.[19] This is not necessarily a permit or licencing statute. However, if the initiating department determines that there are significant or potential environmental effects, application of the process could prevent the proposed initiative, undertaking or activity.

4.2.2. Monitoring

There are some provisions in current legislation which provide for monitoring by the government or monitoring by producers. In addition, some statutes provide for an obligation to submit information, which could form the basis of monitoring by the government. Finally a large number of statutes provide for inspection which again could be used for a monitoring program.

Under the Clean Air Act the Minister of the Environment may establish and operate a system of air pollution monitoring stations throughout Canada. This would include research information and data collection activitites. Federal - provincial cooperation in research and monitoring activities is provided for as well.[20] In carrying out his duties under this Act, the Minister may consult with and organize conferences with, representatives of industry and labour, provincial and municipal authorities and other interested persons, regarding ambient air quality and air pollution control.[21] The Minister may require that information about business operation be provided by the operator of any work, undertaking or business believed on reasonable grounds to be resulting in the emission into the ambient air of an air contaminant.[22]

Under the Environmental Contaminants Act persons who manufacture or import chemical compounds into Canada for the first time in quantities exceeding 500 kilograms in a calendar year must within three months notify Environment Canada of the name of the compound, the quantity manufactured or imported during that year and information with respect to danger to human health or the environment posed by the compound.[23] Under certain circumstances the Minister may require the submission of information concerning chemicals already in Canada. The Minister

may require information about specified substances which are to be imported, processed or manufactured for the purpose of ascertaining whether such substances are entering or are likely to enter the environment in quantities that may constitute a danger to human health or the environment.[24] If the Minister of the Environment or the Minister of National Health and Welfare suspect that a substance is entering or is likely to enter the environment in a quantity or concentration or under conditions that may constitute a danger to human health or the environment, either Minister may collect data and conduct investigations, provide information and consultative services and make recommendations respecting measures to control the presence in the environment of the substance or any class of substances of which it is a member.[25] The Ministers may jointly appoint advisory committees to review data collected, to receive representations from interested parties or concerned members of the public and to advise the Ministers respecting control measures.[26] Reports by such joint committees must be made public.[27] In carrying out their data collection and investigation functions the Ministers must, wherever reasonably possible, act jointly and make use of the facilities of other departments of the Canadian government. They may also enter into cooperative agreements with the provinces upon receiving cabinet approval or cooperate with other government departments, in order to facilitate data collection and investigation.[28]

Under the Transportation of Dangerous Goods Act the Minister of Transport may request the disclosure of information relating to the formula, composition or chemical ingredients of any product, substance or organism as well as such other information as the Minister deems necessary.[29]

Regulations under the Environmental Protection Act may set monitoring requirements[30] and control orders may order monitoring as well.[31]

Under the Ontario Water Resources Act the Director may require that returns be submitted by owners of water works and sewage works

on such matters as may be required.[32]

Under the Fisheries Act, a person authorized to deposit a deleterious substance may be required to conduct sampling, analysis, tests, measurements or monitoring and to report information required to determine whether the deposit is being carried out in the manner authorized. Furthermore, persons who carry on or plan to conduct an undertaking that results in or is likely to result in either the offence of the deposit of a deleterious substance into water frequented by fish or that of a harmful alteration of fish habitat may be required to provide the Minister of Fisheries and Oceans with sufficient plans, specifications, analyses, samples, studies and other information to enable him to determine if one of these offences is being committed or is likely to be committed and what, if any, mitigating or preventative measures should be undertaken.[34]

Under the Plant Quarantine Act once a permit is issued for research, continuous monitoring of the research is required.[35] The Plant Health Division of the Food Production and Inspection Branch of Agriculture Canada has frequent liaison with other regulatory agencies and research institutions.

Under the Animals for Research Act the operator of a registered research facility is required to submit reports respecting animals used in the research facility for research as required under the Regulations.[3]

Under the Hazardous Products Act where the Minister of Consumer and Corporate Affairs has reason to believe that a product or substance is hazardous, he may require submission of information with regards to the formula, composition or chemical ingredients of the product or substance and such other information as the Minister deems necessary for the purpose of determining whether the product or substance is or is likely to be a danger to the health or safety of the public.[37]

Inspection provisions are contained in a large number of statutes and can be found in: The Environmental Contaminants Act,[38] the Canada Water Act,[39] the Environmental Assessment Act,[40] the Environmental Protection Act,[41] the Ontario Water Resources Act,[42] the Fisheries Act,[43]

the Animal Disease and Protection Act,[44] the Plant Quarantine Act,[45] the Plant Diseases Act,[46] the Animals for Research Act,[47] the Food and Drug Act,[48] both with respect to food and drugs, the Pest Control Products Act,[49] the Pesticides Act,[50] the Feeds Act,[51] the Fertilizers Act,[52] the Seeds Act,[53] and the Transportation of Dangerous Goods Act.[54]

4.2.3. Contingency Plans

Under the Environmental Protection Act every person having control of a pollutant that is spilled and every person who spills or causes or permits a spill of a pollutant must notify the Ministry of the Environment, the relevant municipality, the owner of the pollutant and the person having control of the pollutant, of the spill, the circumstances thereof and the action that the person has taken or intends to take with respect to the spill. A Director of the Environment may require additional information. A police officer or municipal employee who is informed of the spill or who investigates the spill must notify the Ministry of the Environment as well.[55] In addition, every person responsible for a source of contaminant must furnish such information such as a provincial officer requires for the purposes of the Environmental Protection Act.[56]

Under the Ontario Water Resources Act every municipality or persons responsible must notify the Minister when they discharge, deposit, permit the escape of polluting material.[57]

Under the Transportation of Dangerous Goods Act any discharge, emission or escape of dangerous goods must be reported.[58] The Minister may direct a public inquiry to be conducted where a release of dangerous goods in the course of their handling or transport has resulted in death or injury to any person, danger to health or safety of the public or damage or danger to property.[59]

Under the Transportation of Dangerous Goods Regulations (SOR/85-77) any person who offers dangerous goods listed in Schedule XII for transport must file a summary of an emergency response plan with the Director of the Transport of Dangerous Goods Directorate, Department of Transport.[60] Consignees and carriers must do the same in certain circumstances.[61]

Under the Fisheries Act the deposit or a serious and imminent danger of a deposit of deleterious substances out of the normal course of events must be reported, if damages to fish or their habitat would

reasonably be expected to result therefrom.[62]

Under the Animal Disease and Protection Act licence holders must give notice of any evidence of a significant deficiency in safety, potency or efficacy of a veterinary biologic.[63] Owners, breeders and dealers of animals and veterinarians must give notice of any reportable disease.[64] The Regulations also contain extensive provisions relating to testing of flocks and herds for the purpose of identifying and eradicating diseases.

4.2.4. Data Sharing

No modern biotechnology data bank currently exists. However, an existing agency may be able to commence one. For instance, National Research Council of Canada[65] is empowered to:

a. undertake, assist or promote scientific research,
b. have charge of and direction or supervision over, research by persons desiring to avail themselves of the facilities offered,
c. carry on work and manufacturing of an experimental and developmental nature,
d. publish, sell or distribute scientific and technical information
e. operate a national science laboratory

The NRC maintains an in-house biohazards committee and a sub-committee (DNA experimentation). The latter interprets the medical research guidelines for laboratory handling of DNA and acts as an advisory panel for the administrator. The operation of a data bank would be within the jurisdiction of the NRC.

The Agriculture Research Institute of Ontario must inquire into programs of research and select and recommend areas of research in respect of agriculture, veterinary medicine and household science, and must stimulate interest in research as a means to developing in Ontario a high degree of efficiency in the production and marketing of agricultural products.[67] A director of research must coordinate research programs, maintain a balance among various areas of research, monitor efficiency of research programs and establish various operation budgets.[68] This institute could maintain a data bank relating to agricultural research in Ontario, but its jurisdiction seems to be too limited for an extensive data bank involving both environmental and health aspects.

4.2.5 Access to Information

4.2.5.1. Obligation to Disclose

Currently a number of statutes impose an obligation to disclose information. Under the Environmental Assessment Act the Minister of the Environment must give notice to the public of the place or places where environmental assessments and the subsequent review thereof may be inspected whereupon any person may inspect such environmental assessment and review.[69] In addition, hearings by the Environmental Assessment Board are open to the public unless the circumstances, in the opinion of the Board or sitting Board members favour a hearing in camera.[70] The Minister must maintain records of every undertaking in respect of which environmental assessment has been submitted under the Environmental Assessment Act consisting of the assessment, a ministerial review, written submissions received and any decision of the Environmental Assessment Board or the Minister together with written reasons. Upon request these records are available for inspection.[71]

Under the Canada Water Act where a Federal-Provincial water quality management agency recommends a water quality management plan to the Minister of the Environment it must cause the plan to be published in the Canada Gazette and a summary of the plan must be published in a newspaper of general circulation in the area affected by the plan.[72]

Panel reviews under the Environmental Assessment and Review Process Guidelines Order are public. The "initiating department" must ensure that the public has access to the information concerning the proposal and has the opportunity to respond to it, in accordance with the spirit and principles of the Access to Information Act.[73] The Federal Environmental Assessment Review Office must assist the initiating department in these matters and must publish summaries of public information provided by the initiating department. It must inform the Minister of the Environment in a public report on the implementation of the assessment process by the initiating department.[74] Every panel must conduct a public information program to advise the public of its review and to ensure that the

public has access to all relevant information that any member of the public may request.[75] All information submitted to a panel must become public information and the panel must allow the public access to and sufficient time to examine and comment on the information submitted to it prior to a hearing.[76] At the end of its review the panel must prepare a report containing its conclusions and recommendations for decisions and transmit the report to the Minister of the Environment and the Minister responsible for the initiating department. The Ministers must make the report available to the public.[77]

There are a number of limitations to this review process. Firstly, in special circumstances the Chairman of the Environmental Assessment Panel may vary the requirements and procedures with regard to public review.[78] Secondly the order provides for a self-assessment procedure and no public hearing will be held if the initiating department is of the opinion that a review is unnecessary. Thirdly, where the initiating department has a regulatory function, some of its responsibilities in the review process may be amended so as not to interfere with its decision making responsibilities.[79] For example, the initiating department must reach decisions about the extent to which the Panel's recommendations should become binding requirements upon the government, ensure that Ministerial decisions based on the recommendations are incorporated into the design, construction, and operation of the proposal; establish suitable implementation, inspection and monitoring programs, and ensure that the above decisions are made public in some manner. However, where the initiating department has a regulatory function, in respect of the proposal under review, such obligations may not interfere with the decision making responsibilities of that initiating department.[80]

Under the Transportation of Dangerous Goods Act reports on public inquiries held after the release of handled or transported dangerous goods has resulted in death or injury to any person, danger to the health and safety of the public or damage to property must be published.[81]

Under the Environmental Protection Act the Environmental Compensation

Corporation must make an annual report to the Minister of the Environment who must submit such a report to the federal cabinet and then lay it before the Assembly of the province. As a consequence it would become public information.[82] A number of statutes provide for the submission of annual reports to Parliament (or the Provincial Assembly) including the Patent Act,[83] the Transportation of Dangerous Goods Act,[84] the Dangerous Goods Transportation Act, 1981, the Clean Air Act,[85] and the Canada Water Act.[86]

4.2.5.2. Obligation to Disclose on Request

The Access to Information Act[87] obliges certain federal government institutions to provide access to information contained in records under their control subject to specific limitations. Canadian citizens and landed immigrants may request copies of government records from the government institution responsible for the information. Government institutions must publish reference information which is contained in the access register. A fee is charged to cover expenses. The Act contains a number of exemptions, the most important of which are:

1. Records containing trade secrets or financial, commercial, scientific or technical information belonging to the federal government which has substantial value or is reasonably likely to have substantial value, information the disclosure of which could prejudice the competitive position of a government institution, scientific, or technical information obtained through research by an officer or employee of a government institution, the disclosure of which could reasonably be expected to deprive the officer or employee of priority of publication or information which could materially injure financial interests of the government of Canada or the ability of the government to manage the Canadian economy or could result in undue benefit to any person,[88] and;

2. Third party information including trade secrets of a third party; financial, commercial, scientific or technical information that is confidential information supplied to a government

institution and is treated consistently in a confidential manner by the third party, information the disclosure of which could reasonably be expected to result in material financial loss or gain or could prejudice the competitive position of a third party or information which could interfere with contractual or other negotiations of a third party.[89] However, records containing the results of product or environmental testing carried out by or on behalf of a government institution must be disclosed unless the testing was done as a service to a person, group or organization other than a government institution and for a fee. Records may be disclosed with the consent of a third party. Records may be disclosed if they do not contain trade secrets of a third party, if such disclosure would be in the public interest as it relates to public health, public safety or protection of the environment and, if such public interest in disclosure outweighs the financial loss or gain to, prejudice to the competitive position of or interference with contractual or other negotiations of a third party.[90]

The Ontario Legislative Assembly has given first reading to an Act to Provide for Freedom of Information and Protection of Individual Privacy.[91] It contains access to information provisions similar to the Access to Information Act. The bill contains a right of access to records under the control of institutions of the Ontario government provided such record does not fall within one of the exemptions listed in the Act. The heads of government institutions must as soon as practicable disclose any record to the public or persons affected if such is in the public interest and the record reveals a grave environmental, health or safety hazard to the public.[92] The exemptions include third party information being

"...a record that reveals a trade secret or scientific, technical, commercial or financial information, supplied in confidence implicitly or explicity, where the disclosure could reasonably be expected to,

a) prejudice significantly the competitive position or interfere significantly with contractual or other negotiations of a person, group of persons, or organizations;

b) result in information of the same kind no longer being supplied to the institution, where,

i) the information was supplied to the institution on a confidential basis

ii) it is in the public interest that similar information continue to be supplied to the institution; or

c) result in undue loss or gain to any person, group, committee or financial institution or agency."

However, records will be disclosed where the public interest in disclosure outweighs the interest of any person, group of persons, or organization in keeping it confidential.[93]

The Patent Act[94] contains a number of access to information provisions. All information submitted to the Patent Office, except caveats and information submitted in connection with applications for patents that are still pending or have been abandoned, must be open to the inspection of the public.[95] The Commissioner of Patents must at least once a year publish a list of all patents granted. With the approval of the Federal Cabinet he may cause such specifications and drawings as are deemed of interest or essential parts thereof to be printed for distribution or sale.[96] Because of the specification requirements in section 36 of the Patent Act, a competitor would be able to produce the product on the basis of the information disclosed by the government.

4.2.5.3. Authorization to Disclose

A number of statutes contain provisions permitting government departments to publish information. These include the Department of National Health and Welfare Act,[97] the Environmental Protection Act,[98] the Canada Water Act,[99] the Transportation of Dangerous Goods Act,[100] the National Research Council of Canada Act,[101] the Ontario Water Resources Act,[102] the Pesticides Act,[103] the Environment Assessment Act.[104]

4.2.6. Protection of Confidentiality

A number of statutes contain provisions aimed at protecting trade secrets and other confidential commercial and economic information. Under the Environmental Assessment Act a provincial officer must

preserve secrecy in respect of all matters that come to his or her knowledge in administering the Act except:

a) "as may be required in connection with the administration of the Act and the Regulations or any proceedings under this Act or the regulations;

b) to his counsel; or

c) with the consent of the person to whom the information relates"[105]

Except in proceedings under the Environmental Assessment Act or regulations provincial officers may not be required to give testimony in any civil suit or proceedings with regard to information obtained by them in the course of the administration of the Act.[106] If the disclosure of certain matters is undesirable because the interest of any person affected or the public interest against disclosure outweighs the desirability of disclosure, the Minister of the Environment may make an order preventing the disclosure for the protection of such person or the public interest.[107] Also, hearings by the Environmental Assessment board may be held in camera.[108]

Under the Environmental Protection Act provincial officers must preserve secrecy in respect of all matters that come to their knowledge in the course of the administration of the Act.[109] The same exceptions as are cited under the Environmental Assessment Act apply, as well as the provision with regard to testimony in civil suits. However, information in respect of the deposit, addition, emission or discharge of a contaminant into the natural environment is excluded from the confidentiality provision[110] applied to directors, employees and agents of the Environmental Compensation Corporation with the exceptions quoted under the Environmental Assessment Act as well as an exception for information in respect of a spill of a pollutant.[111]

Under the Pesticides Act provincial officers must preserve secrecy in respect of all matters that come to their knowledge in the course of administrating the Act except as to information in respect of:

a) impairment or potential impairment of the quality of the environment for any use that can be made of it; or

b) harm or potential harm to or an adverse effect on any property arising from or likely to arise from the handling, storage, use, disposal, transportation or display of a pesticide or a substance or a thing containing a pesticide."

In addition the exemptions apply that were quoted under the Environmental Assessment Act.[112]

Under the Transportation of Dangerous Goods Act information disclosed to the Minister of Transport: (a) pursuant to a request for information with regard to the formula, composition or chemical ingredients of any product, substance or organism; (b) pursuant to an inspection of the books, records or documents; or (c) as part of an inquiry, is privileged and no person may be required to disclose such information except in legal proceedings relating to the administration or enforcement of Transportation of Dangerous Goods Act. Yet, this privilege does not apply to the extent that it relates only to the dangerous properties of any product, substance or organism without revealing the formula, composition or chemical ingredients thereof, or to the extent that it is required to be disclosed or communicated for the purposes of emergency involving the health or safety of any person or the public. No person to whom any privileged information has been provided may disclose such information nor allow any other person to inspect or have access to such information except for the purpose of the administration or enforcement of the Transportation of Dangerous Goods Act. Any information relating to the composition of any product or substance, provided pursuant to another federal statute may be disclosed to the Minister of Transport or a person designated by him for the purposes of the administration or enforcement of the Transportation of Dangerous Goods Act with the consent in writing of the person by whom the information was provided.[113]

Under the Hazardous Goods Act information received by the Minister of Consumer and Corporate Affairs or the Minister of Health and Welfare from a manufacturer concerning the formula, composition, or chemical ingredients of a product or substance is privileged and may not be disclosed to any other person except as may be necessary for the administration or enforcement of sections dealing with the inclusion or deletion of products from the Schedules to the Act.[114]

4.2.7. Industrial Trade Secrets and Patents

The processes used to create BTP's and the nature of BTP's themselves are valuable information for the scientists and corporations who have developed them. The nature of the production processes and the BTP's produced are likely to qualify as trade secrets,[115] the owners of which will want to prevent others from using them.

Those who have the knowledge about production processes and BTP's could either refrain from disclosing information - and hope that no others will discover the relevant production process or BTP's - or apply for a patent. If a patent is obtained, the production process will become public knowledge, but such knowledge cannot be commercially used for seventeen years. Also, obtaining a patent enables the inventor to reap the benefits from his invention through licencing. Governments may want to regulate the patenting and licencing process if disclosure and availability of information to the academic and commercial community is desirable.

Under the Patent Act an inventor or his legal representative may apply for a patent for an invention that was:

a) not known or used by any other person before he invented it,
b) not described in any patent or in any publication printed in Canada or in any other country more than two years before presentation of the petition hereunder mentioned, and

c) not in public use or on sale in Canada for more than two years prior to his application in Canada."

by presenting a petition to the Commissioner of Patents.[116] Patents are no longer available for chemically prepared foods and drugs.[117] "Invention"[118] is defined as:

"any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter".

An applicant for a patent must provide the title or name of the invention and send in a specification of the invention.[119] In the specification he must correctly and fully describe the invention and its operation or use as contemplated by the inventor and set forth clearly the various steps in a process of the method of construction, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make, construct, compound or use it.[120] In the case of a process he must explain the necessary sequence of the various steps, so as to distinguish the invention from other inventions and he must particularly indicate and distinctly claim the part, improvement or combination which he claims as his invention.[121] The specification must end with a claim or claims stating distinctly and in explicit terms the things or combinations that the applicant regards as new and in which he claims an exclusive property or privilege.[122] Every patent that is granted is presumed to be valid unless a party attacking it can prove it is invalid.[123] Patents expire after 17 years.

Even if patents are available, the protection provided to the invention, may not be sufficient. The patent will only be valid within the country in which it is obtained. The description of the process or BTP's within the patent application may not be sufficient to cover all anticipated uses and small changes in the product may not be covered.

A patentee may be forced to licence his or her patent under certain circumstances. Firstly, after the expiration of three years the Attorney General of Canada or any interested person may ask for relief under the Patent Act, if there has been an abuse of rights under the patent. An abuse is deemed to exist, inter alia in the following circumstances:

1. If the patent is capable of being worked in Canada and is not being worked on a satisfactory scale (however, the Commissioner of Patents may adjourn the application and give the patentee more time to work the invention in Canada),

2. If the working in Canada is being hindered by importation by the patentee or persons claiming under him or purchasing from him, or by others against whom the patentee is not taking or has not taken any proceedings for infringement,

3. If the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms.

4. If the patentee by refusing licences, or licences on reasonable terms, is hindering new industries or if the public interest requires licences,

5. If any trade or industry or person engaged therein is unfairly prejudiced, and

6. If the patent is for a process to use for making materials and the manufacture, use or sale of materials are prejudiced.[124]

For the purpose of determining whether there has been any abuse it must be taken into account that patents for new inventions are granted not only to encourage invention, but also to secure that new inventions shall, so far as possible, be worked on a commercial scale in Canada without undue delay.[125]

The Commissioner of Patents could grant relief by ordering the grant of a licence to the applicant, ordering an exclusive licence to the applicant if necessary, in light of the need to raise capital, and, if licencing will not bring the desired results he may order the patent to be revoked unless the patentee fulfills certain conditions in a specified time period.[126] In situations where the patent is for a process to use or make materials and the manufacture, use or sale of materials is prejudiced, the Commissioner may grant a licence to the applicant and to such of his customers and containing such terms as the Commissioner may think expedient.[127] If such a remedy were ineffective, the Commissioner may order the patent to be revoked unless the patentee fulfills certain conditions within a specified period of time.[128]

In addition, the federal government may at any time use any patented invention by paying to the patentee a reasonable compensation as determined by the Commissioner of Patents.[129]

The application of Canadian Patent law to the processes and products of modern biotechnology may cause problems. Firstly, the issue arises whether life forms can be patented. It may be impossible to accurately describe the product to be patented. For instance, how does one accurately describe a turkey with a larger breast. In addition, reproduction of the process may not be sufficiently easy to obtain a patent. Finally, there is an ethical issue to be addressed in the patenting of life forms. Few people may object to the patenting of certain plant forms or microbes. The patenting of animals becomes more questionable; the patenting of human life forms was considered by one of the authors to be slavery.[130]

Some of these concerns were addressed by the Patent Appeal Board and Commissioner of Patents.[131] Abitibi sought a patent in respect of two claims directed to a microbial system. The Patent Appeal Board held that all new life forms are patentable which are produced en masse as chemical compounds and are prepared, and formed in such large numbers that any measureable quantity will possess uniform properties and characteristics.[132] This decision extends to all micro-

organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses, and protozoa. To fulfill the requirements of section 36 of the Patent Act the inventor must describe his original method of production with such clarity that if it can be repeated others can do so, but, if the organism can only be reproduced from itself, it would be sufficient if the inventor places samples of the organism in a culture collection to which others have access. To be patentable, the organism must not have existed previously in nature and it must be useful in the sense that it carries out some useful known objective, such as separating oil from sand, producing anti-biotics or the like. It cannot be a mere laboratory curiosity whose only possible claim to utility is as a starting material for further research. It must be sufficiently different from known species that it can be said that its creation involved the necessary element of inventive ingenuity.

The Board also discussed whether higher life forms could be patented as an obiter dicta. It stated that whether higher life forms are patentable, such as plants and animals, is debatable. However, if an inventor creates a new and unobvious insect which did not exist before it is every bit as much a new tool of man as a micro-organism. With still higher life forms, it is of course, less likely that the inventor will be able to reproduce it at will and consistently, as more complex life forms tend to vary more from individual to individual. But if eventually it becomes possible to achieve such a result, and the other requirements of patentability are met, there is no reason why it should be treated differently.[133] It remains to be seen whether this case will be followed by higher courts.

In Re-Application for Patent of Connaught Laboratories, the Patent Appeal Board and Commissioner of Patents allowed a claim for a patent for a new bovine cell line useful to produce insulin. The case followed the Re-Application of Abitibi Co.

The Patent Act contains special provisions with regard to chemicals intended for use as food or medicines. No patents are issued

for new substances prepared or produced by chemical processes and intended for food or medicine.[135] However, the production method or process is patentable. The question as to whether a process is a chemical process is to be taken in the popular sense, not the technical sense, with the approach of an informed layman with a reasonable understanding of the character of the operation.[136] For instance, the isolation of an antibiotic secreted from micro-organisms was held to be a chemical process.[137] Food may also include feed stuffs for animals produced for human consumption.[138]

In addition, the Commissioner of Patents must grant a licence to use inventions intended or capable of being used for the preparation or production of a food or medicine, unless he sees good reason to the contrary. The Commissioner must fix the amount of a royalty or other consideration to the inventor, having regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.[139] The applicant must file a bond with the Commissioner to secure the payment of royalties.[140] The Commissioner of Patents is not required to inquire as to public safety in the production of the food or medicine, as that is the responsibility of the Food and Drug Directorate.[141] The granting of a compulsory licence does not authorize the licencee to prepare, produce, import or sell any medicine contrary to, or otherwise than, in accordance with the requirements of the Foods and Drugs Act and the regulations thereunder and any other law applicable thereto.[142]

4.3 Evaluation

Currently environmental protection legislation does not require a permit or approval prior to the release of BTP's. Yet, the Ontario Ministry of the Environment has considerable experience in assessing environmental impacts under various statutes, such as the Environmental Protection Act and the Environmantal Assessment Act. Pre-release approvals are required under certain agricultural protection statutes and product oriented statutes. . . . Provisions under the Pest Control Products Act, the Pesticides Act and Food and Drug Act, could be used as models if a pre-release approval system were to be incorporated into environmental protection legislation.

A general data base on modern biotechnology and its environmental effects is lacking. Such a data base would be necessary to assess risks. It would also enhance the ability to monitor for effects, since potential danger signals would become known. Serious consideration should also be given to establishing a data base for each assessing authority.

Both the Ministry of the Environment and Environment Canada have the power to monitor effects of releases of chemical substances into the environment. As a result of the definitions in the relevant legislation discussed in Chapter 2, this monitoring power does not apply to releases of living BTP's or their wastes. However, with the appropriate amendments to definitions and sufficient funding, a monitoring system could be established. Monitoring provisions are included in a number of agricultural protection statutes. Monitoring provisions in product oriented legislation are limited.

Current environmental protection legislation requires spills to be reported, so that the government may take the necessary emergency measures. Only the Transportation of Dangerous Goods Act requires the submission of emergency response plans in advance. The submission of emergency response plans as a condition for the production, release or transport of BTP's could be incorporated into

legislation, where the nature of the BTP's, their wastes, or the processes used in their production create a potential hazard.

Data sharing between industry and government with a view to promoting research and development already occurs on an informal basis. Formalization of this process may be unnecessarily cumbersome. Where a producer or user needs a licence or permit he may be required to submit information in order to obtain it. Mandatory submission of information solely for the purpose of data sharing may not be politically feasible.

Under current legislation the public has access to information where an environmental assessment is carried out. However, circumstances in which environmental assessments are required are extremely limited. Once information is submitted to the federal access to it under the Access to Information Act may be obtained. In the future, information made available to the Ontario government may be obtained under the Act to Provide for the Freedom of Information and Protection of Individual Privacy. Yet, access to so-called "third party" information is limited unless disclosure is in the public interest as it relates to public health, public safety or protection of the environment. Some legislation requires the submission of annual reports to either Parliament or the Provincial Assembly. In theory, such information is available to the public.

Current confidentiality provisions would protect commercial information such as formulae, ingredients and processes, but not information concerning adverse environmental effects. For instance, under the Transportation of Dangerous Goods Act, information about the formula, composition or chemical ingredients of products, substances or organisms is protected but information relating to the dangerous properties of products, substances or organisms must be disclosed.

If an invention relating to a modern bio-technology process or BTP is patented, information will become available to government and the public. However, such disclosure of information depends solely on the commercial decision of the inventor to apply for a patent.

Such information will be too haphazard to form the basis of environmental legislation or assessment. Nevertheless, if no other means are available to obtain the information, it could be useful as a secondary source especially for building up general background knowledge within the relevant Ministry or Department. Patent law may be useful to promote research, development and production of useful BTP's such as those used to clean up environmental contamination.

CHAPTER 5 LIABILITY AND COMPENSATION

5.1 Policy Issues to be Addressed

1. What kind of damages and injuries are to be expected in case of illegal releases, accidental releases, or intended releases which have unanticipated effects upon:
   a) health,
   b) agricultural resources, or
   c) the environment in general?

2. If damage or injuries occur, who should bear the burden of such damage or injuries?

3. Under the current legal regime, how would one establish causation between the release of a BTP and adverse effects, if a living BTP had been released many years before the adverse effects were discovered, where it is alleged that the adverse effects were caused.

   a) by the living BTP and its posterity,
   b) by a mutation of the BTP,
   c) by another organism to which properties of the BTP were transmitted,
   d) by a new organism formed by a combination of the released BTP and another organism?

4. Under the current legal regime how would one establish causation between a release and adverse effects, if a killed BTP or an inorganic BTP had been released several years before the adverse effects were discovered, where it is alleged that the adverse effects were caused.

   a) by the BTP,
   b) by another organism to which properties of the BTP were transmitted?

5. Under the current legal regime, how can one establish causation if a BTP is released in one area and adverse effects then occur in another geographic area with a different climate, vegetation, fauna, or ecosystem?

6. Should legislation be enacted facilitating the establishment of causation, for instance by establishing strict liability or creating statutory presumptions?

7. If legislation were enacted setting a standard of care for handling or releasing BTP's or BT wastes, what should such standard care be for

   a) experimental small scale releases into the environment,
   b) small scale commercial releases into the environment,
   c) releases due to an accident from a confined experiment,
   d) releases due to an accidental release from a confined commercial use, and
   e) waste disposal?

8. Should the standard of care be different for:

   a) living BTP's,
   b) killed BTP's,
   c) inanimate BTP's
   d) exotic organisms other than BTP's, and
   e) chemicals?

9. Should compliance with legislation or a permit be a sufficient defence in an action for negligence?

10. If modern bio-technology legislation were to provide sanctions, should civil liability be imposed as well?

11. Should the release of the following be considered a dangerous activity giving rise to strict liability:

   a) living BTP's
   b) killed BTP's
   c) inanimate BTP's
   d) other exotic living organisms?

12. Are civil liability, compensation and injunctions proper tools for:

a) ensuring the safe use of BTPs and safe BT waste disposal,
b) compensating those who suffered from adverse effects of releases,
c) compensating victims for damage to property,
d) protecting the environment, especially rare non-commercial species,
e) preserving genetic variety, and
f) allocating the burden of preventative and clean-up costs?

13. Would civil liability compensation and injunctions be fair plaintiffs and defendants:

a) under the current legal regime,
b) if the definitions of contaminant and pollutant in the Environmental Protection Act were to include BTP's and BT wastes,
c) if a strict liability regime were established,
d) if there were mandatory insurance, or
e) if a compensation fund were established?

14) If one were to conclude that common law causes of action are inadequate to address the liability and compensation issues arising from the release of BTP's, should statutory provisions attempt to supplement the common law (for instance by facilitating the proof of causation) or should an entirely new statutory scheme be established for liability and compensation?

15. If a statutory scheme for liability and compensation were established, should the common law provisions be preserved as a fall-back?

16. If a new statutory scheme were established should liability vary depending on:

a) whether the release was accidental or wilfull,
b) whether the defendant complied with the law, including permits,
c) whether the release was caused by the defendant or by a person under his or her control,
d) whether the defendant is an individual, a corporation, or a government agency, including a municipality,
e) whether the release was the result of research by a university or other non-commercial institution.

17. What remedies are appropriate (see also Chapter on compliance)

a) monetary compensation, sufficient to repair any damage or injury caused,
b) monetary compensation sufficient to restore the property of the plaintiff to its state prior to the accident,
c) injunctions,
d) order to clean up and otherwise mitigate or repair damages,
e) an order to install control equipment,
f) an order to comply with statutory provisions or licencing requirements,
g) revocation of permits or licences.

18. Who should bear the burden of unexpected adverse effects?

a) the person who first created the BTP,
b) the producer or manufacturer of the BTP,
c) the user of the BTP,
d) the provincial government of the province where the damage is sustained,
e) federal government,
f) the government which received taxes on either the income earned in relation to the development, production or use of the BTP, or which received taxes on the sale of the BTP,
g) a government operated fund created for this purpose,or
h) insurance?

19. If mandatory insurance is decided upon should there be private insurance or a government insurance scheme or fund?

20. Should insurance requirements be placed upon persons or institutions involved in:

a) research and development,
b) commercial production,
c) sale of BTP's,
d) use of BTP's in an open environment,
e) use of BTP's in a confined environment,or
f) disposal of BT wastes ?

21. Should some evidence of financial responsibility be required, such as the posting of security or a bond, as a condition for a licence or permit for:

a) research and development,
b) open-field testing,
c) commercial production,
d) sale,
e) use of BTP's in an open environment,
f) use of BTP's in a confined environment, or
g) BT waste disposal ?

22. If a fund were established under provincial legislation what should it cover:

a) compensation for damage sustained in Ontario from releases in Ontario,
b) compensation for damages sustained in Ontario from releases elsewhere,
c) compensation for damages sustained elsewhere due to releases in Ontario,
d) compensation for damage elsewhere due to the use of BTP's produced in Ontario,
e) compensation for the costs of clean-up in Ontario,

f) funding for research and development, and/or
g) compensation for operators of biotechnology industries who have had their permits or approvals revoked?

23. If a fund were established under provincial legislation who would be entitled to claim against this fund?

a) Ontario residents,
b) all persons sustaining damage, compensation for which is covered under the fund, or
c) only those who have not contributed themselves to the damage sustained?

24. If a fund were established under provincial legislation how should it be funded?

a) through a tax on the use of BTP's,
b) through a tax on the sale of BTP's,
c) through a tax on BT wastes generated,
d) through a royalty on all BTP's tested in Ontario,
e) through a royalty on all BTP's produced in Ontario,
f) through a tax on the income related to the development, production or use of BTP's.

25. If a fund were established, should it cover potential damage related to all kinds of BTP's or should it be limited to:

a) living BTP's
b) BTP's which are known to carry more than average risk, or
c) all living organisms?

26. If claims on the fund should exceed the money contributed to the fund should the province's general revenue fund be used:

a) for compensation to victims suffering personal injury,
b) for compensation of property damage sustained by individuals

corporations and/or government agencies, including municipalities,

c) to finance clean-ups, and/or

d) to fund research and development

27. Should a person suffering adverse effects from the release of BTP's be entitled to compensation from the federal or provincial Crown if:

a) he or she suffered personal injury,

b) he or she suffered damage to property, and/or

c) he or she incurred clean-up costs?

28. What obligations should prospective plaintiffs have to mitigate damages?

29. If it is decided to enact legislation with regard to civil liability and/or insurance, should there be one general statute dealing with these matters, or should current legislation be amended, such as :

a) the Environmental Protection Act,

b) the Pesticides Act,

c) the Transportation of Dangerous Goods Act,

d) the Animal Disease and Protection Act,

e) the Plant Quarantine Act, and

f) the Food and Drugs Act ?

30. Should there be limits on the liability of researchers, producers and/or users;

a) regardless,

b) if they complied with the law, including permits and were not negligent,

c) if they paid into a fund, or

d) if they were insured?

31. If liability is limited what should be the limit?

5.2 Common Law

5.2.1 Negligence

In an action for negligence a plaintiff must establish that;[1]

1) The defendant owed him a duty of care.

2) The defendant breached that duty.

3) Material damage resulted from the defendant's breach of duty.

Where there is government regulation, the violation of a statute may indicate a breach of duty of care. The statutory requirement may "afford a specific, and useful, standard of reasonable conduct", against which the defendant's actions may be judged.[2] Conversely, where a defendant acted in accordance with a government licence or permit it will be difficult to establish that he breached a duty of care to the plaintiff. The plaintiff has the burden to prove causation on the balance of probabilities, which in the case of damage caused by released BTP's may be extremly difficult. There is some indication that material contribution may be sufficient as a measure of causation.[3] Probably the greatest difficulties in establishing negligence will be determining the source of the organisms causing the damage, proving a causal connection between exposure to one or more BTP's or their derivatives and the damage which allegedly resulted therefrom, and accurately assessing the damages at the time of trial.

5.2.2. Strict Liability

Where there is a non-natural use of land and an escape of a BTP, a waste product or possibly a derivative of a BTP, the court may impose strict liability under the so-called rule of Rylands v. Fletcher[4] in which it was said that:

"If a person brings, or accumulates, on his land anything which, if it should escape may cause damage to his neighbour, he does so at his peril. If it does escape and causes damage, he is responsible, however careful he may have been, and whatever precautions he may have taken to prevent the damage." [5]

Rylands v. Fletcher has been employed in cases involving poisonous fumes from a fumigation operation, gas vapour from a factory, the death of a cow caused by arsenic from a smelter and to the herbicide 2-4D, which was sprayed by airplane, damaging neighbors crops, since this was an unusual operation involving increased danger.[6] In addition, wild animals and domestic animals with known vicious propensities have also attracted strict liability.[7] The use of organic matter as land fill in a residential area also attracted civil liability where escaped methane gas led to an explosion when a car was started.[8]

There are five defences to strict liability including consent of the plaintiff, the fault of the plaintiff, an act of God, deliberate act of a third person and legislative authority. An act of God is an extraordinary phenomenon of a nature which cannot be foreseen. The courts have limited the scope of this defence, but it could be applied where there are unexpected mutations in a BTP. The most likely defence would be legislative authority Where an activity is authorized by legislation, no strict liability is imposed unless the defendant is found to have been negligent.[9]

5.2.3 Nuisance

A nuisance is an unreasonable interference with the use and enjoyment of land by its occupier or with the use and enjoyment of a public right to use and enjoy public rights of way. A distinction must be made between private and public nuisance. A private nuisance is an unreasonable interference with the use and enjoyment of land which may result in physical damage to the land (or an interest in land) or in injury to the health, comfort or convenience of its occupier.[10] Private nuisance is actionable only where the plaintiff has suffered material or substantial

damage, such as a serious risk to health.[11]

Public nuisance, on the other hand, is essentially criminal or quasi-criminal in nature. Most of the litigation about public nuisance is conducted in criminal courts. Yet, it is possible to bring a private suit for a public nuisance if the claimant has suffered special damage as a result of it.[12] An individual may not sue for his own particular damages, unless he has suffered special damages beyond those suffered by the community as a whole, such as personal injury or damage to property. The court will then treat the action essentially as an action in private nuisance.[13]

Private nuisance actions alleging physical damage to property are treated differently by the courts than those claiming personal discomfort. In the former case, the nature of the neighbourhood in which the nuisance occurred is irrevelant, whereas in the latter situation the court will consider the nature of the locality (i.e. residential, commercial or industrial) in determining whether the interference is unreasonable. Furthermore, the inconveniences will be examined to ensure that they are viewed as discomforts by ordinary, sober and simple standards (as opposed to dainty and fastidious ones).[14]

The defences of prescription and statutory authority are available in an action framed in private nuisance.[15] A prescriptive right cannot authorize the creation of a public nuisance.[16]

5.2.4. Riparian Rights

A riparian proprietor (i.e. an owner or occupier of land bordering a watercourse), is entitled to certain rights arising from his ownership of the bank. Of particular interest is his right to receive the water which flows past his land "in its natural flow, without sensible alteration in its character or quality."[17] However, this right is subject to an unlimited right of upstream riparian owners to use the water flowing past their land for ordinary uses - such as drinking and washing - and their

right to use the water for "reasonable" extraordinary uses necessarily incidental to the use and enjoyment of their land.[18] However, any extraordinary use which results in a sensible alteration to the quality of the water would be "unreasonable."[19] A riparian proprietor need not show proof of damages; he need only establish that someone has interfered with his right to the flow of water past his land without sensible alteration in its quality.[20] A polluter may successfully defend a riparian rights action where he has acquired a prescriptive right to pollute, or where he does so under the authority of a statute.[21]

5.2.5 Trespass

A trespass is a direct, unauthorized interference with anothers' land.[22] The most common form of trespass is entry on another's land, but a trespass can be committed by a physical object or noxious substance coming into contact with another's land.[23] A positive action is required on the part of the defendant; a simple omission to act will not constitute a trespass.[24] Trespass is actionable per se, without proof of damages.[25] Once the plaintiff has established that a trespass occurred, the onus shifts to the defendant to justify its conduct.[26]

5.2.6. Remedies

A plaintiff who successfully establishes one of the above common law causes of action is entitled to damages or an injunction.[27] An injunction to refrain from violating the plaintiff's rights will be much more readily granted in a riparian rights action than in other actions, because a failure to grant the injunction would be equivalent to expropriating a riparian proprietary right.[28]

An injunction is a discretionary remedy of the court. The court may award damages in lieu of a requested injunction if the injury to the plaintiff's legal rights:

1. is small
2. is capable of being estimated in money, and
3. can adequately be compensated by a small money payment.

and if the case is one in which it would be oppressive to the defendant to grant an injunction.[29]

A quia timet may be obtained to prevent a proposed activity which is likely to cause harm.[30] In this case, the plaintiff must show "a strong case of probability" that the harm will result.[31]

5.3 Current Legislation

Statute law has complemented the common law in a number of ways. Provisions in different acts may:

1) Facilitiate compensation to victims of a violation or accident;
2) Allocate the costs of remedial action by
   a) ordering remedial action and providing for compensation by the government;
   b) ordering remedial action at the expense of the person taking such action, or
   c) ordering the payment of the costs of remedial action taken by the government.
3) Limit liability;
4) Require insurance or bonding.

5.3.1. Compensation to Victims

Part IX of the Environmental Protection Act provides for strict liability:

"a) For a loss or damage incurred as a direct result of,
   i) the spill of a pollutant that causes or is likely to cause adverse effects,

ii) the exercise of any authority under subsection 88(1) or the carrying out of or attempting to carry out a duty imposed or an order or direction made under this Part, or
iii) neglect or default in carrying out a duty imposed or an order or direction made under this Part;

b) For all reasonable costs and expense incurred in respect of carrying out or attempting to carry out an order or direction under this Part" (subsection 87(2))

Both the owner of the pollutant and the person having control of the pollutant would be held liable under this section.[32] If the defendant can establish that he took all reasonable steps to prevent the spill or that the spill was wholly caused by an event or action outside of his control he will not be held liable for some damages.[33] The Act also provides for joint and several liability where two or more persons are liable to pay compensation under section 87.[34]

Some statutes provide for a "deep pocket" for the victims of either an accident or a violation of the relevant legislation. The relevant statutes either provide a right to compensation from the Crown combined with some form of subrogation of the plaintiff's action to the Crown or the establishment of a fund or a corporation which provides compensation to victims and can recover the amount paid out from the responsible person.

Under Part IX of the Environmental Protection Act a person entitled to compensation for reasonable costs and expenses incurred in respect of carrying out or attempting to carry out an order or direction under Part IX and entitled to payment of such compensation by the Crown in Right of Ontario.[35] Where compensation has been paid the Crown has the right to recover in the place of the person to whom the compensation was paid to the extent of the amount paid plus costs in a court of competent jurisdiction.[36] The Environmental Protection Act provides for the establishment of an environmental compensation corporation as an agency of the Crown in right of Ontario.[37] Where a person is entitled to compensation from the Crown under Part IX, such person may apply to the

Environmental Compensation Corporation for payment.[38] Where payment is made, the Corporation has the right on the behalf of the Crown in right of Ontario to recover in the place of the person to whom the payment was made to the extent of the payment and any costs of the Corporation.[39] It should be kept in mind that not all BTP's and their wastes will fall under the definition of pollutant in Part IX of the Environmental Protection Act. Also, it would not provide for compensation where injury or damage is sustained due to an authorized release which has unanticipated consequences.

Under the Pesticide Residue Compensation Act the Minister of Agriculture may pay compensation to farmers who are unable to sell their product as a result of the presence in or upon that product of a pesticide residue of a pesticide that is registered under the Pest Control Products Act and was used in accordance with governmental recommendations, directions or concurrences.[40] No compensation will be paid if the residue is present because of a fault of the farmer, his employee or agent, or of a previous owner of the land on which the product was grown, or that previous owner's employee or agent.[41] Payment of compensation will be refused until the farmer has taken necessary steps to reduce the loss or to pursue any action in law against the manufacturer of the pesticide or any other person whose act or omission resulted in, or contributed to, the presence of the pesticide residue in or upon the product. The Minister as a condition for payment of any compensation, require the consent of the farmer to pursue on his behalf any legal action against such manufacturer or other person.[42]

Under Part V of the Environment Protection Act dealing with waste management, a "waste well disposal security fund" has been established out of which persons whose drinking water is affected by reason of the operation of any well that is a waste disposal site may make a claim for compensation.[43] Owners of waste disposal site must pay into the fund a fee which is calculated upon the amount and type of waste disposed of in the well. Payment of compensation is limited to the amount available in the fund.[44]

If a federal-provincial water resource management program under the Canada Water Act is agreed upon between the two levels of government, such agreements must specify the proportions in which any compensation awarded or agreed to be paid to anybody suffering a loss as a result of the program is to be paid by the Minister of the Environment and the provincial government or governments.[45] To date, no such provision has been included in any agreement made pursuant to the Act.

5.3.2.1. Remedial Action and Compensation

Under Part V of the Environmental Protection Act owners of waste disposal sites or waste management systems who have suffered pecunary loss as a result of a decision not to renew or to suspend or to revoke a certificate of approval to operate such a site or system may apply for compensation, provided such owner has previously received a certificate of approval and has strictly complied with the Act and the Regulations. Payment will be made out of the consolidated revenue fund.[47]

Under the Animal Disease and Protection Act the Minister of Agriculture or his appointee may cause an animal to be destroyed, if it is affected with or suffering from or suspected of being affected with or suffering from an infectious or contagious disease or has been in contact with or in close proximity to such an animal. He may also cause the destruction of animal products or by-products, feed stuffs, hay and other things affected with or suspected of being affected with an infectious disease.[48] In addition, where infected animals of those suspected of being affected with a disease, are sold or offered for sale, they may be seized by an authorized person. Where a veterinary examination confirms that they are infected, these seized animals and any affected articles may be destroyed.[49] The owner of the relevant animals, by-products or other things that have been destroyed may be compensated, provided he has complied with the Act.[50]

The Plant Quarantine Act provides for the confiscation of plants or other matter which constitute a hazard because of infestation.[51] Regulations may provide for the destruction of infested plants or other matter and prohibit or restrict the sale or disposition of any plant or other matter that is infested or constitutes a biological obstacle to the control of any pest. They may provide for the restriction from general or specific agricultural use of any property or premises infested or suspected of being infested with any pest. They may also provide for the removal from any place of any plant or other matter or any animal material that presents an obstacle to treatment ordered pursuant to the Act or that may be adversely affected by such treatment (section4). The Minister of Agriculture may order compensation to be paid in respect of any plant or other matter destroyed or prohibited or restricted from sale or for restrictions placed on the use of any property or premises pursuant to the Act.[52]

5.3.2.2. Orders to Take Remedial Action

Orders to take remedial action can be seen as administrative orders aimed at compliance with the relevant statute. They may also provide for the allocation of costs of clean up for any accidents and other spills.

Under the Environmental Protection Act the Minister of the Environment may order polluters to take necessary steps to repair the injury or damage caused if it is in the public interest to do so (section 16). The Director of the Environment may order preventative measures as well (section 17). Part IX of the Environmental Protection Act imposes a duty on owners and those in control of a pollutant to prevent, eliminate and ameliorate adverse effects of a spill and to restore natural environment.[53]

Under the Transportation of Dangerous Goods Act the persons who at the time of an accident have the charge, management or control of the relevant dangerous goods must take all reasonable

emergency measures consistent with public safety to repair or remedy any dangerous condition or reduce or mitigate any danger to life, health, property or the environment that could result from the accident.[54]

Under the Fisheries Act the owner of a deleterious substance or the person who has the charge, management or control thereof, or the person who causes or contributes to a spill which may endanger fish or their habitat, must as soon as possible in the circumstances take all reasonable measures to prevent the spill or to counteract, mitigate or remedy any adverse effects that may result.[55]

Under the Environmental Assessment and Review Process Guidelines Order the initiating department must ensure that mitigation or compensation measures are implemented if such could prevent the potentially significant adverse environmental effects of a proposal.[56]

Under the Ontario Water Resources Act a Director may direct changes be made in the location of the discharge of effluent and in sewage works which are being operated without approval and such changes must be carried out by the person who established, extended or changed such sewage works.[57]

Under the Pesticides Act the Minister of the Environment may order the repair of damage caused by the release of a pesticide or a substance or thing containing a pesticide. Persons responsible for a pesticide or a substance or thing containing a pesticide must clean up and decontaminate everything that has come into contact with that pesticide by any means which was not in accordance with the Pesticides Act.[58] The Minister of the Environment could also use his powers to issue stop orders and control orders to accomplish clean-up.[59]

5.3.2.3. Order to Pay Costs of Clean-Up

Orders to pay for clean-up performed by the government can be classified as an administrative sanction aimed at compliance.

Yet, they also allocate the costs of clean-ups.

Under the Environmental Protection Act Part V, the Director under the Act, may order the removal of waste from any disposal site which was not approved[60], or may order an owner to take any necessary action to bring a waste management system into conformity with Part V of the Act or the Regulations.[61] If the owner of the site or the person responsible for it does not comply with an order to do so, the Director may charge the person to whom the order was directed with the costs of the necessary works.[62]

Under the Fisheries Act where there is an unauthorized deposit of a deleterious substance in water frequented by fish, the owner of the deleterious substance or the person who has the charge, management or control thereof or persons who cause or contributed to the deposit are liable for all costs and expenses incurred by the government to prevent any deposit or to counteract, mitigate or remedy any resulting adverse effects.[63] Similarly, they are liable for all losee of income incurred by any licenced commercial fisherman to the extent that such a loss can be established to have been incurred as a result of the deposit or a subsequent prohibition to fish resulting therefrom.[64] This liability does not depend on proof of fault or negligence. However, no liability will ensue if the defendant establishes that the occurence giving rise to the liability was wholly caused by certain events outside of his control.[65]

Under the Environmental Protection Act the Crown in Right of Ontario has a right to compensation for all reasonable costs and expenses incurred in respect of carrying out or attempting to carry out an order or direction under Part IX of the Environmental Protection Act from the owner of the pollutant and the person having control of the pollutant, unless the defendant can establish that he took all reasonable steps to prevent the spill, or that the spill was caused by certain causes out of his control.[66] The Minister is authorized to give directions to employees and agents of the Ministry to clean up spills, if necessary.[67]

Under the Transportation of Dangerous Goods Act the the federal government may recover the costs and expenses of complying with safety measures, disposing of abandoned or deteriorated dangerous goods and taking emergency measures from any persons who, through their fault or negligence or that of others for whom by law they are responsible, caused or contributed to the unsafe situation necessitating the measures.[68] Any defendant engaged in any activity to which the Act applies has a strict liability, unless he can establish he took all reasonable measures to comply with the Act and the Regulations.[69]

5.3.3. Limits on Liability

The Nuclear Liability Act is an interesting example of a statutory limitation of liability within a particular industry aimed at enhancing the development of that industry. The Act requires operators of nuclear intallations to "maintain with an approved insurer insurance against the liability imposed upon him by this Act".[70] The operator's liability in the event of a nuclear accident is limited to an amount much lower than that of potential claims arising from such an incident.[71] The Act limits payments to victims of a major accident to $75,000,000 unless Parliament authorizes more money to be spent.[72]

A number of statutes limit the liability of those who are in charge of its administration. For instance, the Pesticides Act provides that no action or other proceedings for damages or otherwise shall be instituted against an employee of the Ministry of the Environment, a member of the Environmental Appeal Board or of the Pesticides Advisory Committee or a Crown employee who is a provincial officer or is acting under the direction of an employee of the Ministry of the Environment, or such member or provincial officer for any act done in good faith in the execution or intended execution of any duty or authority. However, this does not relieve the Crown of liability in respect of a tort committed by an agent or servant of the Crown to which it would

otherwise be subject.[73] Many other statutes have similar provisions, (for instance, the Environmental Protection Act).[74]

Under the Transportation of Dangerous Goods Act any person requested to take reasonable emergency measures in the event of a spill of dangerous goods is not personally liable, either civilly or criminally in respect of any act or omission in the course of complying with a request, unless it is shown that he did not act reasonably in the circumstances.[75]

5.3.4 Insurance and Bonding

Under Part V of the Environmental Protection Act concerning waste management an applicant for a certificate of approval for a waste management system or waste disposal site must provide security sufficient to assure satisfactory maintenance of the site or the removal of waste from it if the Director considers such removal necessary.[76]

Under the Pesticides Act a person in control of an extermination business must insure against liability or furnish a bond.[77]

Under the Transportation of Dangerous Goods Act the Minster of Transport may require evidence of financial responsibility in the form of an insurance or indemnity bond from anyone who handles, offers for transport or transports dangerous goods.[78] Non-residents may be required to file the name of a person in Canada willing to act as their agent.[79]

Under the Seeds Act a bond must be posted upon importation and is forfeited where a violation of the Act or Regulations is discovered.[80]

5.4 Evaluation

Issues of civil liability and compensation may arise upon illegal use, in case of accidents and due to unanticipated adverse consequences of legal intentional releases. Because of our lack of knowledge the kinds of damages and injuries to be expected cannot be predicted with certainty. It is conceivable that some forms of damage and injury can be compensated for with money or can be corrected at a certain cost. However, other types of damages or injuries may be irreversible and/or of a non-monetary nature, such as the extinction of a non-commercial species or the loss of some natural beauty. The common law will provide for monetary compensation in a limited number of circumstances. A regulatory scheme may be able to increase the instances in which monetary compensation is available, but non-monetary losses are difficult, if not impossible, to compensate using legislative means.

In many instances, the outcome of a common law action will be uncertain. The courts have not yet decided whether the release of a BTP is a non-natural use of land, or whether the spreading of BTP's should be considered an escape, giving rise to strict liability of its owner. Also, if an action for negligence is brought, the courts have not yet formulated a standard of care for the use and release of BTP's and for BT waste disposal. Similarly, the courts have not given any opinion as to whether the release of BTP's which enter onto another's land is an unusual interference with the use of such land.

The problems that arise in applying common law to chemical contamination of the environment also arise in its application to the release of BTP's. However, additional issues arise due to the fact that some BTP's are alive and may multiply, spread, change and combine with other living organisms and maybe even substances. In many cases, it may be impossible to prove a causal connection on a balance of probabilities between a release and an adverse phenomenon that may be discovered many years later or at a great distance.

Even if the effects occur in the same location and the BTP has not changed, we may be unable to establish a link between releases and effects due to our lack of knowledge of modern biotechnology and ecological impacts.

Especially in the case of damage or injury caused by unanticipated adverse effects of intended releases, liability issues are complex. If the release occurred under a government permit, and was considered safe under the scientific knowledge of the time, it would be difficult to establish that a defendant breached his or her duty of care and it may be unfair to hold such a person liable.

If a policy decision is made that victims of unanticipated adverse effects of releases, accidental releases and/or illegal releases are to be compensated, the common law needs to be supplemented by a statutory cause of action or a compensation scheme. A statutory cause of action may not be effective where the cause of the adverse effects cannot be established with certainty and/or the person responsible for the release cannot be found. Under current legislation, some causes of action are created. Under Part IX of the Environmental Protection Act, a strict liability offence is created against owners of pollutants and persons having control of pollutants that are spilled. The Fisheries Act obliges the person responsible for an unauthorized deposit of a deleterious substance to compensate licenced commercial fishermen who need not prove fault or negligence.

Another way this issue has been addressed in existing legislation is by entitling the plaintiff to compensation from the Crown and allowing the Crown to recover from the defendant. An example of this is again Part IX of the Environmental Protection Act where a person is entitled to compensation from the Crown for cleaning up a spill and if compensation has been paid, the Crown may recover such costs from the relevant defendant.

The third solution under current legislation is contained in Part V of the Environmental Protection Act. It provides for a fund for the compensation of those whose drinking water is affected by the operation of a waste disposal well. A similar fund is feasible for those who are affected by reason of the release of BTP's. In their current form, none of these compensation schemes would apply to BTP's especially due to the definition of "pollutant" in the Environmental Protection Act. However, similar schemes could be established by regulation.

From a defendant's point of view, the current common law system is extremely risky. First, no standards of care have been established. Secondly, it appears that the probability of large scale adverse effects of BTP's is low, but that if BTP's behave differently than expected, or BTP's intended for a confined use escape, consequences could be severe. It may be unfair to expose those who use or release BTP's to extreme liabilities especially where the use or release of BTP's occurred under government supervision. Therefore, limits on liability may be desirable to shield those involved in research, development and commercial use of BTP's against unexpected high liability. Current legislation does not address these concerns. The regulation of the nuclear industry may be taken as a model of regulation, combining limitation of liability with an obligation to maintain insurance.

It may well be that a proper balance between compensation to potential plaintiffs and protection against erratic liability of potential defendants could be struck by establishing a mandatory insurance scheme or a fund. Examples of mandatory insurance are contained in the Pesticides Act and the Nuclear Liability Act. Current legislation provides for this only where BTP's are pesticides. Private insurance could be relied upon, provided that it is available at a reasonable price, as otherwise, the modern biotechnology research and development and/or industry could be unduly hindered in Ontario. As an alternative, a statutory limit on liability could be combined with an obligation to

post a bond as is required for instance of operators of waste management systems or waste disposal sites under the Environmental Protection Act. In the case of those involved in modern bio technology security could be required prior to the issuance of a permit to conduct research or commercial production. Yet, it may be problematic to determine what amount of security is required to cover adverse effects, the nature of which is currently unknown. Finally, a modern biotechnology fund could be considered to compensate those who suffer damage or injury as a result of the use or release of BTP's. In addition, it may be used to fund further research and to finance clean-ups.

One issue to be addressed is whether the funds should be financed by industry and maybe those testing BTP's in Ontario or whether the government should subsidize the fund either in total or only if the claims on the fund exceed the contributions to the fund. Contributions to the fund could take the form of licences or permit fees, royalties or taxes.

Current legislation does not allocate the responsibility to clean up any BTP's other than pesticides, which have been released accidentally or which have unanticipated adverse effects. Allocation of responsibility for clean-up legislation may be necessary to speed up the clean-up process. Under the Environmental Protection Act the owner of a pollutant and the person having control of the pollutant must clean up the potentially harmful spills. Those who cause or permit contamination may be ordered to repair injury or damage. Even if the definitions of contaminant and pollutant are extended, they would not cover the situation where adverse effects occur and the person responsible for the relevant release cannot be tracked down. It may be necessary to empower government officials to take remedial action and charge those responsible for the release, as can be currently done under Parts V and IX of the Environmental Protection Act, under the Fisheries Act, and under the Transportation of Dangerous Goods Act. Alternatively, clean-ups could be funded out of the general revenue or a special fund or insurance scheme.

* ECC may fund clean-up.

Another option would be to order remedial action by the person on whose property the adverse effects are occurring, and, if such person is not responsible for the release, compensation could be offered. Examples of such a scheme are contained in the Animal Disease and Protection Act and the Plant Quarantine Act.

6. COMPLIANCE AND ENFORCEMENT

6.1. Policy Issues to Be Addressed

1. How can compliance with any regulatory scheme be obtained?
2. How can voluntary compliance be fostered?
   (a) perceived fairness of the system;
   (b) perceived usefulness of the system;
   (c) limit on civil liability if statute of licence is complied with;
   (d) compliance as condition for a grant or government contract;
   (e) inform those who may release so as to convince them of the need to comply (this may foster points a) and b).)
3. Are enforcement provisions necessary, desirable and/or effective?
4. How does one detect the release of BTP's into the environment, given the fact that very small amounts may be involved?
5. Would restriction on the sale of BTP's, such as sale only to licenced users, assist in the prevention of unauthorized releases?
6. What information should be made available to the enforcing agency?
   (a) information submitted as part of an application for a permit or licence,
   (b) information provided for on-going monitoring
   (c) information submitted as part of an information sharing program, and
   (d) information submitted to other government agencies?
7. Are the inspection powers of provincial officers under the Environmental Protection Act sufficient to detect unauthorized releases.
8. Is it possible and desirable to perform regular on-site inspections of:
   (a) modern biotechnology research facilities,
   (b) modern biotechnology industrial facilities, and/or
   (c) sites where BTP's are released?

9. How easy is it to produce BTP's and how does one regulate releases on private property?
10. What compliance inducing powers should be given to the administering authority?
    (a) inspection
    (b) search and seizure
    (c) seizure and detention
    (d) confiscation of BTP's and/or production materials
    (e) stop-order
    (f) control order
    (g) order to perform certain acts, eg. to clean up or to have pollution control equipment on the premises,
    (h) performance of duties which producers or users have neglected such as clean-up of spills, and the recovery of the costs thereof from the offenders either through collection via tax rolls or as a debt due to the Crown.
11. What court imposed sanctions should be included?
    (a) fine
    (b) imprisonment
    (c) forfeiture
    (d) injunction
    (e) action by A-G to restrain activities
    (f) order to take certain action
12. Should penalties for corporate violators be different from those for individual violators?
13. Should corporate officers and directors be personally liable for violations by Corporations?

6.2 CURRENT LEGISLATION

6.2.1. Voluntary Compliance

An example of voluntary compliance is the compliance by industry with the MRC Guidelines[1] or the voluntary compliance with Guidelines for research involving recombinant DNA molecules issued by the U.S. National Institute of Health.[2] Guidelines compliance is voluntary partly because of anticipated benefits,

such as a safe working environment and also because compliance may reduce the chance of civil liability. Presumably, compliance with the guidelines would be considered a reasonable standard of care for the industry. An anticipated benefit of compliance may be that private insurance, administered separately from the relevant regulations, could provide that benefits will only accrue if one complies with relevant legislation.

"Voluntary" compliance may also result from co-operation with government officials who in the absence of such compliance could enforce the law. Co-operation with officials of the Ministry of the Environment during the 1970's comes to mind here.

Officials of the Ministry of the Environment have conducted information seminars for potential waste generators. Apparently this has greatly contributed to compliance with environmental legislation concerning waste disposal.[3]

6.2.2. Detection

Detection of a violation is a pre-requisite for enforcement procedures. Detection could be fostered by including any of the following in the relevant legislation:

(1) obligation to maintain records which may be examined
(2) an obligation to answer requests for information
(3) an obligation to submit information on request
(4) an obligation to monitor by the producer
(5) inspection by government officials
(6) a monitoring program by government officials and
(7) seizure of samples, products or tools.

Most statutes aimed at environmental protection provide for the appointment of either inspectors or provincial officers with powers similar to those of inspectors. An inspector often has the power to enter at any reasonable time, any place, other than a private dwelling in which he believes on reasonable grounds there is any prohibited or regulated substance in violation of the relevant legislation, examine any such substance, open and examine any receptacle, package, product or object which he has reason to believe contains any such substance and possibly even take samples of the substance. He may often examine and take copies of documents that he believes on reasonable grounds to contain information relevant to the enforcement of the relevant legislation. Some statutes provide that, with a warrant, an inspector may enter and search any place in which he believes on reasonable grounds there is a substance or product by means of or in relation to which any provision of the relevant legislation has been contravened. In exigent circumstances when it is not practical to obtain a warrant an inspector may enter and search the place without a warrant. This would be permitted when obtaining a warrant would result in danger to human life or safety or the loss or destruction of evidence. Owners or persons in charge of a place must assist the inspectors and no person may obstruct or hinder an inspector.[4]

Under the Environmental Contaminants Act the Minister of the Environment may request specified information by notice in the Canada Gazette.[5] The Minister of the Environment and the Minister of Health and Welfare may require notification by any person engaged in any commercial, manufacturing or processing activity involving a substance which may cause a significant danger to human health or the environment by notice in the Canada Gazette.[4(1)(a)] Further information may be obtained by requesting it in a written individual notice.[6] They may also require, in a written notice, that specified tests be carried out by manufacturers or importers of such substances.[7]

Under the Transportation of Dangerous Goods Act, the Minister of Transport, may by written notice, request information relating to the composition of any product from manufacturers or distributors which he deems necessary for the proper enforcement of the Act.[8] In addition, dangerous occurences must be reported by the person in charge at the time of the mishap.[9]

Under the Environmental Protection Act provincial officers may survey from time to time anything that they have reason to believe is or may be a source of contaminant and report to the Ministry of the Environment.[10] Persons responsible for sources of contaminants must furnish such information as a provincial officer requires for the purposes of the Act or the Regulations.[11] Under the Environmental Assessment Act, no person shall refuse to provide a provincial officer with information required for the purposes of the Act or Regulations thereunder.[12]

Most federal environmental legislation provides for seizure.[13]

Most agricultural protection statutes have inspection provisions. Inspections are permitted during the day or during reasonable hours upon reasonable grounds and for the purpose of carrying into effect the provisions of the relevant legislation. Many allow for inspection, the opening of receptacles etc., the taking of samples and the copying of documents.[14]

In addition information can be obtained as part of the licencing process or other approval processes. Some statutes also contain reporting requirements.

Under the Fisheries Act the Minister of Fisheries may request information from actual or potential polluters.[15] Spills which may result in danger or damage to fish or fish habitat must be reported.[16]

Under the Animal Disease and Protection Act information must be submitted upon application for a product licence, an establishment licence or an import permit for a veterinary biologic.[17] Licence holders must give notice of changes and additions to information already provided,[18] and notice of any evidence of a significant deficiency in safety, potency or efficacy of a veterinary biologic.[19] Animal semen production centers must keep records and conduct specified tests on every animal admitted.[20] Section 91.3 of the Regulations sets out general record-keeping requirements. Owners, breeders and dealers of animals as well as veterinarians must give notice of the appearance of any reportable disease.[21]

Applications for permits under the Plant Quarantine Act must be accompanied by information.[22] Discovery of non-indigenous pests in Canada must be reported to the Minister as well.[23]

Under the Animals for Research Act operators of registered research facilities must submit reports respecting animals used in the research facility for research.[24] Information would also be submitted upon the application for a licence or upon a request for registration.[25]

The following federal statutes contain seizure provisions: the Fisheries Act,[26] the Migratory Birds Convention Act,[27] the Animal Disease and Protection Act,[28] the Plant Quarantine Act.[29] Ontario agricultural protection legislation does not provide for seizure.

All product oriented legislation contains inspection provisions similar to those in the environmental protection and agricultural resources protection legislation.[30]

Under the Hazardous Products Act the Minister of Health and Welfare may request information from manufacturers.[31]

Under the Pest Control Products Act information and in certain circumstances samples are submitted upon application for the registration of a control product. Results of scientific investigations may be required.[32] Every registrant is required to maintain records of all quantities of control products stored, manufactured or sold by him.[33] Copies of importer's declarations accompanying imported control products must be forwarded to a District Director.[34]

Under the Pesticides Act information must be submitted upon application for a licence to operate an extermination business or to sell pesticides.[35] A person responsible for a pesticide must provide any requested information to a provincial officer conducting an investigation into that pesticide.[36]

Under the Feeds Act information must be submitted prior to registration of a mixed feed or listing of a single ingredient feed.[37]

Under the Fertilizers Act information must be submitted upon application of a fertilizer or a supplement.[38]

Under the Seeds Act the Director may require information from importers of seeds in considering whether to allow importation.[39]

All product oriented legislation other than the Pesticides Act provides for seizure.[40]

6.2.3 Sanctions

Punishment in a broad sense could be inflicted in any of the following ways.

Denial of Benefits

- Withdrawal of financial support.
- Termination of government contracts.
- Refusal to issue further licences or permits.
- Revocation or withdrawal of existing permits or licences.
- Refusal of entry into the country.

Sanctions imposed by administrative authorities	Seizure and detention.
	Order by administrative authority to refrain from further violations.
	Order by administrative authority to take remedial action.
Court imposed sanctions	Fine.
	Forfeiture.
	Imprisonment.
	Court order to refrain from further violations.

6.2.3.1 Denial of Benefits

Environmental protection legislation, agricultural protection legislation and product oriented legislation do not provide for financial support for research or the production of BTP's. In the area of workers' protection, the MRC requires compliance with the MRC Guidelines in order to obtain research funding. Compliance with any legislation could be made a condition for providing government funding, even compliance with legislation from another jurisdiction. Also where the government would place an order for BTP's it could make compliance with existing legislation a condition of the contract.

Under the Animal Disease and Protection Act the Minister of Agriculture may order compensation to be paid to owners of animals slaughtered because of the application of the Act. However, such compensation may be withheld if the owner or the person having charge of the animal has been guilty in relation to the animal of an offence against the Animal Disease and Protection Act.[41]

Some environmental protection legislation provides for the issuance of permits or licences or approvals. The program approval provisions in the Environmental Protection Act come closest to a permit provision. With respect to waste management, certificates of approval are required to operate a waste management site or waste disposal system.[43] Approvals of a Director under the Ontario

Water Resources Act are necessary in order to build or alter sewage works.[44]

Under a number of the agricultural protection statutes licences, permits or registrations could be refused, suspended, revoked or not renewed. Under the Animal Disease and Protection Act the Minister of Agriculture may cancel or suspend licences.[45]

Under the Plant Quarantine Act, the importation into Canada for educational, scientific, or industrial purposes of any pest or plant or other matter that is infested with a pest or considered a biological hazard to the control of any pest is allowed in accordance with a permit.[46] However, as this is a permit for individual importations, the potential of refusal of future permits may not be sufficiently threatening and it may be impossible to administer. A movement A movement certificate is required for conveyance of infested plant material in Canada.[47] Future permits could be refused to known violators.

Under the Plant Diseases Act the Director may refuse to issue a licence or may suspend, revoke or refuse to renew a licence where the Act would not be or has not been complied with.[48]

Under the Animals for Research Act a licence for an operator of a supply facility may be suspended or revoked, or the Director may refuse to issue such licence where the operator has not properly maintained the facilities, equipment or materials or has failed to observe or carry out the provisions of the Animals for Research Act.[49] The Director for the same reasons may refuse to renew the licence or may suspend or revoke it.[50] The Director may refuse to register a research facility or suspend, revoke or refuse to renew registration where the facility does not have, inter alia the proper compounds, tools, implements, buildings and dietary materials necessary, or the operator or his employees or associates have failed to comply with the Act or the Regulations.[51]

A number of product oriented statutes provide for licencing or registration and the potential suspension or revocation of such licences or registrations. Where conditions exist that fail to ensure that a product would be safe for use, licences and notices of compliance may be cancelled or suspended.

Under the Pest Control Products Act the Minister can cancel and suspend the registration of control products.[52]

Under the Pesticides Act licences to operate an extermination business or to sell, offer for sale or transfer a pesticide may be revoked or suspended or not renewed where the Act or a term or condition of the licence is violated, or in the case of incompetence, improper past conduct, impossibility to comply, gross negligence or fraud.[53] The Director may refuse to issue or may cancel the permit for a land or structural extermination, may impose terms and conditions and, may alter the terms and conditions of the permit that has been issued in prescribed circumstances.[54] The term of a licence expires automatically on the 15th day of February in the year following the year in which it was issued.[55]

Compliance with the Feeds Act is achieved primarily by the refusal to register a feed, the refusal to list a single feed ingredient in Schedule IV to the Act or the cancellation of a prior registration of a feed or cancellation of a prior listing of a feed.[56]

Under the Fertilizers Act the registration of fertilizers may be cancelled or suspended if the products do not meet the regulatory requirements.[57]

Under the Seeds Act imported seeds require an authorization of the Director before they can be released out of bond.[58] The bond is forfeited where violation of the Act or Regulations is discovered.[59]

6.2.3.2 Sanctions Imposed by Administrative Authorities

Most federal statutes provide for detention after seizure by inspectors or similar officials. Detention ends when the inspector is of the opinion that the Act and the Regulations have been complied with, the owner agrees to the destruction of the detained article, the anticipated danger has been prevented or adequately reduced, or the specified time period expires, unless proceedings have been instituted in which case the article may be detained until the proceedings are concluded.[60]

A number of environmental protection statutes provide for administrative orders to take certain action or to cease certain activities. Under the Clean Air Act an inspector may order the operator of a federal work, undertaking or business to take action necessary to reduce emissions of an air contaminant to a level that will not contravene the emission standard.[61] If the operator fails to comply with such an order, or the operation of the federal work, undertaking or business results in emissions which would constitute a serious danger to health, the inspector may order the operator to cease operation.[62] Under the Transportation of Dangerous Goods Act, the Minister of Transport or a person designated by him may order any person engaged in the handling, offering for transport or transporting dangerous goods to cease any such activity or to carry it on in the manner directed, if necessary, for the protection of public safety, property or the environment unless the Act provides for other remedies.[63]

Where, in the opinion of the Director, a release causes an immediate danger to human life, the health of any persons or to property, the Director may issue a stop order directed to the person responsible for the source of contaminant.[64] The Environmental Protection Act has several provisions for administrative orders. When a report of a provincial officer contains a finding that a contaminant is released into the environment in excess of the maximum permissable amount, concentration or level, the Director may issue a control order to the person responsible therefore.[65] The Minister of the Environment may also order

the repair of damage to land, water, property or plant life, by the person responsible for contamination if it is in the public interest to do so.[66] The Director may order a person to take certain preventative measures if contamination from an undertaking is likely.[67] In addition, the Director may order action required to bring waste management systems and waste disposal sites into conformity with Part V.[68] The Minister may issue orders to prevent, eliminate or ameliorate adverse effects of spills and to restore the environment.[69] He may also order any intermediate action or procedural steps that are necessary for the implementation of any action specified in the main order.[70]

Under the Fisheries Act the Minister of Fisheries and Oceans may direct a person authorized to deposit a deleterious substance to conduct sampling, analyses, tests, measurements, or monitoring to install or to operate special equipment, to comply with specified procedures, and to report to the Minister.[71] The Minister may also require modifications or additions to works or undertakings that result or are likely to result in the deposit of a deleterious substance in water frequented by fish or the harmful alteration, disruption or destruction of fish habitat. He may also order a restriction of business operations, subject to the regulations or, where none exist, with the approval of the federal cabinet. The Minister may also direct the closing of the work or undertaking for a specified period if he has obtained cabinet approval.[72]

Under the Animal Disease and Protection Act an inspector or constable may require that any animal or thing moved out of an infected place in violation of the Act be taken back within the limits of that place.[73] Inspectors may also order the cleansing and disinfection of yards, stables, sheds or other premises if deemed necessary.[74]

Regulations under the Plant Quarantine Act provide for emergency orders to destroy plants and other matter.[75]

Under the Plant Diseases Act an inspector may order the person in charge of the premises to disinfect any plants, buildings, vehicles or containers or to treat or destroy any plants where he finds a plant disease or any causal organism of a plant disease in or on any premises or vehicle.[76] Where an inspector finds any causal organisms of a plant disease in the soil of any premises he may prohibit the growth of certain plants as may become infected by such causal organisms.[77]

Animal care committees in research facilities may halt research resulting in contravention of the Animals for Research Act.[78] Where an inspector appointed under the Weed Control Act finds noxious weeds or weed seeds on land in an area within his jurisdiction he may order the person in possession of the land to destroy the noxious weeds or weed seeds.[79]

Under the Pesticides Act the Minister of the Environment may order, if he feels it to be in the public interest, the person responsible for a pesticide or substance or thing containing a pesticide to take action to prevent or repair injury or damage or to restore environmental quality, where the pesticide causes or is likely to cause damage or injury to or impairment of a) the quality of the environment b) any property or water c) plant or animal life or d) a person.[80] A Director appointed under the Pesticides Act may make a control order where the handling, storage, use, disposal, transportation or display of a pesticide or a substance or thing containing a pesticide causes or is likely to cause impairment of the quality of the environment, injury or damage to property or plant or animal life, or harm or discomfort to any person or adversely affects or is likely to affect adversely the health of any person, impair or is likely to impair the safety of any person or would render or is likely to render any property or plant or animal life unfit for use by man.[81] The Director or a provincial officer may issue a stop order if he believes that an emergency exists.[82]

A number of statutes empower an administrative official to take action where the person responsible is in default. Most of them also allow the costs and expenses of such action to be recovered either by means of a court action or through the addition of the expenses to the tax rolls. In the case of spills governed by the Environmental Protection Act, the Minister of the Environment may direct the employees and the agents of the Ministry to clean up the spill, where the Minister considers it to be in the public interest and he is of the opinion that neither the person having control of a pollutant nor the owner of the pollutant that was spilled will act to clean up or such person cannot be identified or located or such person requires assistance.[83] The Crown in Right of Ontario would then have a right to compensation from the owner of the pollutant and the person having control of the pollutant.[84] This right can be enforced by action in a court of competent jurisdiction.[85] In addition, where a pollutant is spilled and causes or is likely to cause adverse effects, a municipality, a regional municipality, and a designated person may do everything practicable to clean up the spill and are entitled to be compensated by the owner of the pollutant and the person having control of the pollutant for all reasonable costs and expenses incurred in so acting. This right to compensation may be enforced by action in a court of competent jurisdiction.[86]

Under the Fisheries Act in the event of a spill of a deleterious substance causing a serious and imminent danger to fish or their habitat the inspector may take remedial measures if he deems such measures necessary (or direct that such measures be taken by the owner of the deleterious substance or the person causing the spill).[87]

Under the Animal Disease and Protection Act an inspector or constable may move any animal or thing which was moved out of an infected place in violation of the Act back into that place at the expense of the owner of such animal or thing.[88]

Under the Weed Control Act an inspector may cause noxious weeds or weed seeds to be destroyed if an order to destroy such is not complied with. The expenses incurred by the inspectors will be charged to the person in possession of the relevant land. If such person fails to pay, the municipality shall pay the expenses and add the amount to the collector's roll against the land concerned and it shall be collected in the same manner as taxes under the Municipal Act.[91] In addition, Municipal councils may order inspectors to destroy noxious weeds or weed seeds on subdivided portions of the municipality and on lots not exceeding 10 acres. Expenses will be added to the collector's roll and charged against the respective land concerned.[92]

Under the Pesticides Act where the Minister or the Director has authority to order or require that any matter or thing be done, the Minister may order that, in default of its being done by the person ordered or required to do it, such matter or thing shall be done at the expense of such person and the Minister may recover the cost of doing it by action in a court of competent jurisdiction as a debt due to the Crown.[93]

6.2.3.3 Sanctions Enforced by the Courts

All statutes provide for fines or for summary conviction offences which through application of the Criminal Code would lead to fines. The highest fines are found in environmental protection legislation. Under the Clean Air Act penalties of up to $200,000.00 per offence can be imposed for contravention of certain air emission standards. Each day that these contraventions continue is considered a separate offence.[94] The Environmental Contaminants Act provides for a maximum penalty of $100,000.00.[95] The Transportation of Dangerous Goods Act provides for fines of up to $50,000.00 for a first conviction. The Environmental Assessment Act provides for the fines of $5,000.00 per day for a first conviction and $10,000.00 per day for a second conviction.[97] The general offence provision of the Environmental Protection Act provides for penalties of $5,000.00 per day for a first conviction and $10,000.00 per day for the second conviction.[98] Fines for offences relating to hauled liquid hazardous wastes are higher: between $2,000.00 and $25,000.00 per day inclusive for a first offence, and between $4,000.00 per day and $50,000.00 per day inclusive for a second offence.[99] Under Bill 112, it is proposed to increase the fines under the general offence provisions of the Environmental Protection Act for corporations to $10,000.00 per day for the first conviction and $20,000.00 per day for the second conviction.[100]

Agricultural protection statutes contain much lower fine provisions, with the exception of the Fisheries Act, which contains penalties of up to $50,000.00 for a first offence and up to $100,000.00 for a second offence for the deposit of deleterious substances into water frequented by fish.[101] Other agricultural protection statutes have relatively low fines, such as a minimum of $500.00 and a maximum of $5,000.00 under the Animal Disease and Protection Act[102] and a maximum of $500.00 for the first offence and a maximum of $1,000.00 for the second offence under the Animals for Research Act.[103] Some product oriented statutes provide for substantial fines, such as the Seeds Act which provides for a maximum fine of $25,000 upon summary conviction.[104] The

Pesticides Act provides for a maximum of $5,000.00 per day for a first offence and a maximum of $10,000.00 per day for a second offence, scheduled to be increased to $10,000 for the first offence and $20,000.00 per day for the second offence for corporations under Bill 112.[10] Other product oriented statutes have rather low fines such as the Fertilizers Act which provides for a maximum of $2,000. for an individual,[107] the Feeds Act which provides for a maximum of $2,000.00 for a violation of an individual, but which leaves a maximum for a corporation in the discretion of the Court if prosecuted upon indictment[108] and the Pest Control Products Act which provides for summary conviction or indictable offences.[109]

A large number of statutes provide for a more severe penalty in case of a second offence or second conviction, including the Environmental Protection Act[110] the Environmental Assessment Act,[111] the Ontario Water Resources Act,[112] the Transportation of Dangerous Goods Act,[113] the Dangerous Goods Transportation Act, 1981,[114] the Weed Control Act,[115] the Plant Diseases Act,[116] the Animals for Research Act,[117] the Fisheries Act,[118] and the Pesticides Act.[119] A number of statutes provide that each day an offence continues it is considered as a new offence, including the Environmental Protection Act,[120] the Environmental Assessment Act,[121] the Ontario Water Resources Act,[122] the Environmental Contaminants Act,[123] the Clean Air Act,[124] and the Pesticides Act.[125]

Most of the environmental protection legislation, the agricultural protection legislation and the product oriented legislation provides for imprisonment with the exception of the Clean Air Act, the Canada Water Act, the Weed Control Act, the Artifical Insemination of Livestock Act and the Pesticides Act. The Environmental Protection Act does not provide for imprisonment other than where it refers to the Ontario Water Resources Act.[126] The Plant Diseases Act only provides for not more than 30 days imprisonment.[127] The Animal Disease and Protection Act provides for a maximum of 5 years imprisonment;[128] other relevant legislation contains prison sentences of at most two years while some provide for a maximum of one year, six months, three months or two months.

The Feeds Act contains higher penalties if the accused is a corporation as opposed to an individual.[129] Similar provisions have been proposed in Bill 112 for the Environmental Protection Act.[130] Under the Ontario Water Resources Act[131] municipalities and corporations may be punished with higher sanctions than individuals.[132] Under the Transportation of Dangerous Goods Act[133], the Environmental Contaminants Act[134] and the Feeds Act[135] an officer, agent or director of a corporation who directed, authorized, assented to, acquiesced in or participated in the commission of an offence can be held personally liable.

Under Bill 112 it is proposed that a Court may increase a fine imposed under the Environmental Protection Act, the Ontario Water Resources Act or the Pesticides Act by an amount equal to the amount of monetary benefit acquired or accrued to a person as a result of the commission of an offence.[136]

A number os statutes provide for Court injunctions including the Ontario Water Resources Act[137], Environmental Assessment Act[138], the Environmental Protection Act[139], the Clean Air Act[140], the Canada Water Act[141], the Fisheries Act[142], the Pesticides Act[143]. Under the Fisheries Act[144] and the Clean Air Act[145] the Attorney General may commence a prosecution to enjoin any conduct that constitutes an offence under the relevant legislation. These injunction provisions are all related to the protection of the environment.

A large number of statutes contain forfeiture provisions including the Transportation of Dangerous Goods[146], the Environmental Contaminants Act[147], the Plant Quarantine Act[148], the Seeds Act[149], the Pest Control Products Act[150], the Fertilizers Act[151], the Feeds Act[152], the Animal Disease and Protection Act[153], The Migratory Birds Convention Act[154] and the Hazardous Products Act.[155]

6.3 Evaluation

Because of the small scale of biotechnology operations and the potential problems in detection of any unauthorized small scale field testing or other releases, the regulation of modern biotechnology may need to use incentives to comply which do not depend on detection but on voluntary compliance. One way of promoting compliance would be to make limitation of liability and insurance coverage dependent on compliance with the legislation. Environmental legislation appears to use enforcement to foster compliance, though the Ministry of the Environment has promoted voluntary compliance through consultation and dissemination of information.

The establishment of a permit or licencing system for the release of BTP's would assist in fostering compliance as information would be provided to the licence or permit issuing authority and the possibility of revocation, suspension or refusal to renew could be used as an incentive to comply. Currently, most environmental protection legislation does not require licences or permits, but they are required under agricultural protection legislation and certain product oriented legislation. The system used in the pesticides area under the Pest Control Products Act and Pesticides Act could serve as a model. All relevant legislation contains inspection provisions. Serious consideration should be given as to how such provisions can be amended to enable detection of illegally released BTP's or BT wastes.

Some agricultural protection and product oriented statutes require reporting and record keeping. Reporting and record keeping on production of BTP's and generation of BT wastes would assist in detection. Under environmental protection legislation reporting is required after potentially harmful substances are released, not upon the use of BTP's reporting requirements. The Environmental Contaminants Act with regard to newly manufactured or imported substances does not apply to BTP's and only becomes effective after large quantities have been imported or produced.

Seizure provisions may be useful as an instrument for detection as well. They are contained in most federal statutes, but are lacking in provincial legislation.

Forfeiture of either BTP's or production equipment may be useful as an additional sanction, especially when expensive equipment needs to be used to produce BTP's. Forfeiture of equipment might be useful to prevent future unauthorized releases. Forfeiture provisions are limited to federal statutes only.

Sanctions imposed by administrative authorities may be necessary to ensure expedient action in case of adverse effects. The Environmental Protection Act has several provisions for administrative orders in instances of contamination or pollution. If the definitions of contaminant and pollutant were to be expanded to include BTP's and BT wastes, these provisions could be useful. Similarly, provisions under the Environmental Protection Act permitting provincial officers to take action where the person responsible for a spill is in default, would be useful if extended to BTP's. The system for destruction of noxious weeds under the Weed Control Act also provides a useful example.

Court enforced sanctions can be useful from the point of view of deterrence. In general, a court injunction may take too long to prevent serious damage. As the risk of detection of an unauthorized release is low and the potential for damage or injuries is high, a high maximum sentence seems appropriate. Fines imposed under agricultural protection statutes may be too low. Higher fines are contained in the Environmental Protection Act especially if an offence continues for more than a day. Even higher fines are imposed under federal environmental legislation.

Imprisonment of the person responsible for an unauthorized release may be necessary as well. This would be especially effective if officers, agents or directors of corporations who directed, authorized, consented acquiesced in or participated in the commission of the relevant offence can be held personally liable. Examples of such liability

can be found in the Transportation of Dangerous Goods Act and the Environmental Contaminants Act. The Environmental Protection Act lacks this kind of provision.

CHAPTER 7. - JURISDICTIONAL FRAMEWORK

7.1 Policy Issues to be Addressed

1. Which government has jurisdiction to legislate in the field of modern biotechnology? To address this issue, the following questions should be answered:

2. Is modern biotechnology one"matter" or does modern biotechnology encompass several matters such as: agriculture, pharmaceuticals, public health, natural resource management, environmental protection, trade and commerce, property and civil rights, matters of a merely local or private nature, tort law, and/or insurance?

3. If both levels of government have passed legislation within their respective jurisdictions, is there any conflict in the legislation, its administration or its enforcement, and if so, to what extent is the provincial legislation rendered inoperative?

4. Is the risk of spreading undesirable BTP's or their waste sufficient to make the regulation of biotechnology, or certain aspects of it, a matter of national concern, because the problem cannot be adequately dealt with by the provinces?

5. In the absence of any federal legislation, could and should the provinces regulate one or more of the following activities as they relate to modern biotechnology:

(a) production;
(b) storage;
(c) use;
(d) transportation within the province and/or from or to the province;
(e) disposal of waste;
(f) spills and other accidents;
(g) statutory compensation schemes;

(h) insurance schemes;
(i) import and export from the province;
(j) licencing of all or certain BTP's with regard to production and/or use and/or sale;
(k) organizing a data bank; and
(l) imposition of sanctions.

6. In the absence of provincial legislation, could the federal government regulate one or more of the following activities as they relate to modern biotechnology:

(a) production;
(b) storage;
(c) use;
(d) international and inter-provincial transportation or all transportation;
(e) disposal of waste;
(f) spills and other accidents;
(g) statutory compensation schemes;
(h) insurance schemes;
(i) import and export;
(j) licencing of all or certain BTP's with regard to production and/or sale;
(k) organizing a data bank; or
(l) imposition of sanctions.

7. Are there limits on the severity of the sanctions that can be imposed by provincial legislators?

8. If the federal and provincial governments were to co-operate in regulating modern biotechnology, should they:

(a) enact complementary legislation to be administered and enforced by respective federal and provincial government agencies;

(b) enact complementary legislation to be enforced by one federal agency to whom power to administer the provincial laws is delegated;
(c) enact complementary legislation to be administered by provincial bodies to whom power to administer and enforce has been delegated by the federal government; or
(d) enact complementary legislation to be administered by a new agency to which power is given under both federal and provincial legislation.

9. Should either the provincial or the federal governments or both the provincial and federal governments establish an independent body to either administer or enforce legislation with regard to modern biotechnology?

10. If the federal government were to enact legislation what department would be best equipped to administer and enforce such legislation?

(a) Environment Canada;
(b) the Department of Agriculture;
(c) Ministry of State for Science and Technology;
(d) Consumer and Corporate Affairs;
(e) Department of National Health and Welfare;
(f) any other Department;
(g) a newly established department or interdepartmental commission or board; or
(h) a combination of existing departments.

11. If the provincial government passes legislation, what Ministry would be best equipped to administer and enforce such legislation?

(a) Ministry of the Environment;
(b) Ministry of Agriculture;
(c) Ministry of Natural Resources;

(d) Ministry of Education;
(e) other Ministry;
(f) Inter-Ministerial Agency or board; or
(g) a combination of Ministries.

12. Should any legislation concerning modern biotechnology specifically prohibit activity on the local level by municipal councils and similar institutions?

13. Should certain functions be delegated to local authorities, such as the issuance of permits for releases, including experimental testing?

14. If a compensation fund were to be established for damage and injury caused by the release of BTP's and/or BT wastes into the environment, what would be the best format:
(a) a provincial fund for each province;
(b) a joint fund established by all provinces;
(c) a fund established by the federal government; or
(d) a joint fund established by the federal government and all the provinces.

15. Could the federal government enact legislation attaching consequences within Canada for actions occurring abroad, such as field tests in the U.S. causing damage in Canada and if so, would such provisions be enforceable:
(a) against the person causing the damage if he or she is present in Canada;
(b) against the person causing the damage if he or she has assets in Canada;
(c) against the person causing the damage if he or she is not in Canada and has no assets in Canada;

(d) under international law against the state from which such damage arose; or

(e) under international law against the state of which such person was a national.

16. To what extent can the federal government enter into binding obligations in the area of modern biotechnology especially with regard to:

(a) exchange of information;

(b) liability and compensation;

(c) uniform safety requirements, including worker protection, packaging and labelling, environmental protection, and requirements for transportation.

17. Should legislation consider the extra-jurisdicitonal effects of releases?

7.2 Allocation of Powers Between Federal and Provincial Governments

7.2.1 Distribution of Powers

The division of powers between the federal and provincial governments is contained in the Constitution Act, 1867 as interpreted by various judicial decisions. Biotechnology, as such, has not been assigned to any level of government. Certain aspects of the regulation of modern biotechnology could be included in regulations dealing with the protection of health, agriculture, and the environment. As each of these three subject matters are the responsibilities of both provincial and federal governments, classification under either of them would not solve the issue as to which government is responsible.

If one considers the Constitution Act, 1867[1] the following heads of powers contained in section 91, giving jurisdiction to the federal government could be relevant:

1A. The Public...Property.
2. The Regulation of Trade and Commerce.
3. The Raising of any Money by any Mode of System of Taxation.
6. The Census and Statistics.
10. Navigation and Shipping.
11. Quarantine and the Establishment and Maintenance of Marine Hospitals.
12. Sea Coast and Inland Fisheries.
22. Patents of Invention and Discovery.
27. The Criminal Law, ...
29. Such Classes of Subject as are expressly excepted in the Enumeration of the Classes of Subjects by this Act assigned exclusively to the Legislatures of the Provinces.

In addition, the opening words of section 91 confer on the federal government the power:

> To make Laws for the Peace, Order, and good Government of Canada, in relations to all Matters not coming within the Classes of Subjects by this Act assigned exclusively to the Legislatures of the Provinces.

The federal government has the prerogative power to manage and dispose of its own property. For example, it may place conditions in leases of its property, which deal with matters that fall outside the ambit of its legislative powers. This proprietory power is supplemented by Parliament's legislative power over the property it owns, granted in paragraph 91(1A).[2] The Dominion's public property rights extend to certain tracts of forest lands, and the right to fish in non-tidal and non-navigable waters on or bordering federal lands.[3]

The federal trade and commerce power is limited to:

(a) regulation of trade in matters of interprovincial or international concern, and:

(b) general regulation of trade affecting the whole Dominion.[4]

The federal trade and commerce power has been significantly restricted by judicial interpretation because the provincial power of property and civil rights in the province has been held to include intra-provincial trade and commerce.[5] The federal power to regulate "general" trade and commerce affecting the whole country, is vague and obscure. The only unequivocal example of legislation being upheld under this branch is that establishing a federal mark, known as "Canada Standard", which would be applied to products meeting the federal standards under the Act.[6] The federal trade and commerce power does not entitle Parliament to establish a licencing scheme for a particular trade, such as the insurance industry " in which Canadians would otherwise be free to engage in the provinces." Nor can the federal government regulate or prohibit "individual forms of trade confined to the provinces", such as the manufacture and sale of margarine.[7]

The federal power to regulate inter-provincial or international trade and commerce may in certain instances influence intra-provincial trade. A number of federal marketing schemes which impact on intra-provincial trade have been upheld.[8] Of interest to the area of bio-technology may be the case in Re Agricultural Products Marketing Act[9] concerning a federal marketing statute.

The federal and provincial governments had agreed upon a scheme to rationalize the national market in eggs which was implemented by both federal and provincial statutes. The federal Statute:

(i) established national and provincial egg marketing agencies and provided powers for the national one;

(ii) imposed egg quotas on provinces and producers;

(iii) provided for the disposal of surplus eggs; and

(iv) imposed levies on egg producers.

The federal agency was elected by egg producers, including

The federal agency was elected by egg producers, including local ones: federal quotas were based on volumes of production, not on volumes of inter-provincially traded eggs and surplus disposal applied to local eggs as well as interprovincially traded ones. Although 90% of Canadian eggs were traded within the provinces, the Supreme Court upheld both the federal and the complementary Ontario Statutes. The court may well have upheld the scheme because it was based on federal-provincial co-operation. As Pigeon, J. said: "... it was a sincere cooperative effort, and it would be unfortunate if this was all brought to naught".[10]

However, it should be kept in mind that subsequently, two federal statutes concerning consumer protection were struck down being the Agricultural Products Standards Act providing for the establishment of grades with appropriate grade names for agricultural products [11], and federal legislation establishing composition of standards for beer under the federal Food and Drugs Act.[12]

The Federal taxation power could be used to promote research and development of biotechnology, to impose taxes or levies upon the release of BTP's and to promote protection of agricultural resources or the environment either through a system of exemptions or deductions. However, no all inclusive regulatory scheme could be justified under the taxation power.

The census and statistics power could be used to establish a federal resource inventory,[13] but would not be sufficient to establish

a general regulatory scheme.

The power over navigation and shipping enables the federal government to regulate the transportation of BTP's by ships and to control marine pollution, but is not sufficient to establish a general regulatory scheme.

Federal powers over sea coast and inland fisheries enable the federal government to regulate research and development of BTP's relating to fisheries and to protect and preserve the fisheries.

The federal power over patents and invention of discovery could be used to promote research and development of BTP's and modern biotechnological processes. (see Chapter 5).

The criminal law may be used to set some standards in relation to a public purpose such as public peace, order, security, and health. Therefore, the criminal power could be used in the areas of food and drugs, protection of general public health and protection of competition among industries.[15] In Reference re Validity of s.5(a) of the Dairy Industry Act (Margarine Case), [16] Rand,J. defined a crime in the following words.

> A crime is an act which the law, with appropriate penal sanctions, forbids; but as prohibitions are not enacted in a vacuum, we can properly look for some evil or injurious or undesirable effect upon the public against which the law is directed. That effect may be in relation to social, economic or political interests; and the legislature has had it in mind to supress the evil or safeguard the interest threatened.[17]

Is the prohibition then enacted with a view to a public purpose which can support it as being in relation to criminal law? Public peace, order, security, health, morality: these are the ordinary though not exclusive ends served by that law.[18]

The protection of the public from the adulteration of foods in the Food and Drugs Act is a valid exercise of the criminal law power, since its main purpose is the protection of public health and safety.[19] However, this power does not enable Parliament to set standards relating to the production and content of light beer.[20] The Hazardous Products Act has been upheld as valid federal legislation in this field as it is aimed at the protection of public health and safety.[21] It is clear that Parliament cannot use its criminal law powers to invade areas within provincial competence.[22] For example, the federal government cannot prohibit the manufacture and distribution of margarine under the criminal law power, because the "pith and substance" of such is the protection of the dairy industry.[23]

The criminal law power allows Parliament to prevent activities which could harm public health and safety through a system of prohibitions and penalties. Some regulatory effect could be achieved by allowing certain exemptions from the prescribed behaviour. (For example, s.251 of the Criminal Code prohibits abortions, but exempts those approved by a hospital's therapeutic abortions committee.) Yet, the criminal law power cannot be used to establish an extensive regulatory scheme.[24].

Classes of subjects excepted from provincial jurisdiction as referred to in subsection 91(29) would include works declared by the federal parliament to be for the general advantage of Canada or for the advantage of two or more provinces. This provision was used to establish a regulatory scheme with regard to atomic energy and might be used to regulate modern biotechnology as well. However, the Supreme Court of Canada has not yet rendered an opinion on the validity of the regulation in the field of atomic energy.[25]

Even if a general regulatory scheme with regard to modern biotechnology could not be justified under any of the specific heads of power, it could be justified under the so-called peace, order and good government clause in the introduction to section 91 of the Constitution Act, 1867.

The peace, order and good government clause; or p.o.g.g. clause, will support federal legislation in three instances:

1. Where there in an incomplete assignment of power in the Constitution Act, 1867 and the subject matter does not come within property and civil rights in the province or within matters of a merely local or private nature; referred to as the "gap test",

2. Where the inherent nature of the subject matter makes it a concern of the nation as a whole, rather than a local or provincial concern, referred to as the "national concern test" and,

3. Where a national emergency exists.

   An unlikely fourth instance would be where the subject matter is genuinely new.

Legislation will only come under the "gap branch" of p.o.g.g. if part of the matter has been dealt with in section 91 and 92 but the matter has not been dealt with completely. For instance, subsection 92(11) assigns the power over incorporation of companies with provincial objects to the provinces. Incorporation of companies with objects other than provincial objects will classify under the "gap branch."[27] (Citizen's Insurance Co. v. Parsons(1881), 7 App. Cas.96)(P.C.).To come under the "gap branch" it is not sufficient to describe the subject matter of legislation with a name which does not appear to come within any of the enumerated heads of power. There must be some incomplete assignment of power within section 91 and 92 to (Hogg 373-4) which the matter of legislation may be attached.[28]

A necessary but insufficient condition for coming within the "national concern branch" is that a topic is distinct and specific.[29] (Hogg @ p. 380 and 394). In addition, the matter must attain a national dimension as was mentioned in the Local Prohibitions Case [30](1896):

"...some matters in their origin local and provincial, might attain such dimensions as to affect the body politic of the Dominion, as to justify the Canadian Parliament in passing laws for the regulation or abolition in the interest of the Dominion. But great caution must be observed in distinguishing between that which is local or provincial and that which has ceased to be merely local or provincial, and has become a matter of national concern, in such sense and to bring it within the jurisdiction of the Parliament of Canada" (A.G. Ont. v. A.G. Can. (Local Prohibition) [1896] A.C.348 @ p. 361) (P.C.).

The importance of the subject matter alone is not enough.[31] Also, the desirability of uniform legislation is insufficient. For instance, the federal government is not allowed to regulate the insurance industry under the 'national concern branch.'[32] Yet, where uniformity of law throughout the country is not merely desirable, but essential in the sense that the problem "is beyond the power of the provinces to deal with it", the subject matter will come within the "national concern branch" p.o.g.g. clause[33]. For instance, the federal government could regulate in the case of an epidemic.[34] The most important element of national concern is a need for one national law which cannot realistically be satisfied by cooperative provincial action because the failure of one province to cooperate would carry with it great consequences for the residents of other provinces. A subject-matter oflegislation which has this characteristic has the necessary national concern to justify invocation of the peace, order and good government power.[35].

Where the federal parliament has a rational basis to determine that an emergency exists, the peace, order and good government clause can be used to enact temporary legislation.[36] The court has upheld legislation under the "emergency branch" in a situation of war or post-war crisis.[37] Double digit inflation combined with high unemployment was also sufficient to allow legislation under the emergency branch.[38] No permanent legislation has ever been upheld under the emergency branch.[39]

In the Queen v. Hauser, the Narcotic Control Act was upheld as legislation enacted under the peace, order and good government

clause, because it was essentially legislation adopted to deal with a genuinely new problem which did not exist at the time of confederation and clearly cannot be put in the class of "matters of a merely local or private nature". However, Hogg, concludes that Hauser was wrongly decided and that the newness reasoning might have been introduced to prevent classification under the criminal power so as to avoid addressing another issue.[41]

It is unlikely that the regulation of modern biotechnology could be classified under the "gap branch".

In determining whether the "national concern branch" of the p.o.g.g. clause would apply, the issue arises whether the subtopic of modern biotechnology is sufficiently distinct and specific, especially in light of its various applications and processes. Secondly, it should be kept in mind that the importance of the matter or the desirability of uniform legislation is not sufficient to justify federal legislation. Only if the problems caused by the application of modern biotechnology are beyond the power of the provinces to deal with because the failure of one province to cooperate would carry with it grave consequences for the residents of other provinces, would federal legislation under the "national concern branch" be justified. This will depend on the perception by the federal Parliament of the risks involved in the application of modern biotechnology.

The application of modern biotechnology has not resulted in any emergency of a national scale. Although the courts have been deferential toward the federal Parliament, a federal scheme based on the emergency branch of the p.o.g.g. power may not survive a court challenge. The only basis for application of the emergency branch would be the potential for an epidemic or emergency due to the release of BTP's, but in the absence of proven dangers such legislation may be difficult to justify. The emergency branch of the p.o.g.g. power is unlikely to sustain an emergency response scheme, which would become effective only when an actual emergency arises. Whether permanent preventative measures would be upheld remains to be seen.[42]

If genuine newness of subject matter would be an acceptable reason to uphold legislation under the p.o.g.g. power, legislation regulating biotechnology might be upheld. However, the newness criterion as expressed in [1979] The Queen v Hauser[43] has been seriously criticized.[44]

The federal government may want to justify regulation of biotechnology on the same basis as it regulated atomic energy: Peace, order and good government and works declared by Parliament to be for the general advantage of Canada. An environmental disaster caused by a disastrous application of a recombinant organism would be difficult to contain

could result in economic benefits and increased international power. Improper use of this technology could lead to the creation of new pathogens with enhanced virulence, which could be applied in military or terrorist uses. It may be argued that the preamble to the Atomic Energy Control Act[45] is equally applicable to biotechnology and the preamble to a new "Biotech statute" could read as follows:

"Whereas it is essential in the national interest to make provision for the control and supervision of the development, application and use of modern biotechnology, and to enable Canada to participate effectively in measure of international control of modern biotechnology which may be hereafter agreed upon;"

It is arguable that modern biotechnology, like atomic energy, is a matter "which from its inherent nature is of concern to the national as a whole."[46] A comprehensive scheme for biotechnology regulation could possibly be justified on the same grounds as the scheme set forth in the Atomic Energy Control Act, being national concern and the need to represent Canada in the development of international regulations. Assuming that the Nuclear Liability Act is valid federal legislation, the insurance of the biotechnology industry could be dealt with under this head as well. If the federal government were to use this clause to occupy the field of biotechnology regulation, it would be prudent to declare all works or undertakings related to biotechnology to be "works

or a work for the general advantage of Canada". [48]

The Clean Air Act was held to be properly enacted federal legislation under the peace, order and good government clause (and the criminal law power), because air crossed provincial boundaries.[50] Genetically engineered organisms released outdoors may also cross these boundaries. Yet, the question remains whether BTP's are as mobile as air pollutants. Also, the Clean Air Act has not ousted provincial legislation concerning air pollution.

7.2.1.2 Provincial Powers

Section 92 assigns the following powers to the provinces:[51]

2. Direct Taxation within the Province in order to the Raising of a Revenue for Provincial Purposes.
5. The Management and Sale of the Public Lands belonging to the Province of the Timber and Wood thereon.
8. Municipal Institutions in the Province.
9. ...and other Licences in order to the raising of a Revenue for Provincial, Local or Municipal Purposes.
10. Local Works and Undertakings other than such as are of the following Classes: (c) Such works as, although wholly situate within the Province are before or after their Execution declared by the Parliament of Canada to be for the general Advantage of Canada or for the Advantage of Two or more of the Provinces.
13. Property and Civil Rights in the Province.
15. The Imposition of Punishment by Fine, Penalty, or Imprisonment for enforcing any Law of the Province made in relation to any matter coming within any of the Classes of Subjects enumerated in this Section.
16. Generally all Matters of merely a local or private Nature in the Province.

Under subsection 92(2) the provinces are limited to imposing direct taxes. The province could use this provision to tax products which cause pollution, such as materials used for confinement . Regulatory charges may be both direct or indirect and are imposed under other heads of power.[52]

A province has both proprietary and legislative rights with respect to its public lands. In a lease of Crown lands, the province may include conditions that the lessor comply with future provincial laws, and agree to pay a variable royalty based upon the amount prescribed from time to time by provincial law. These conditions would be an exercise of the province's proprietary rights. In addition the province has power to legislate concerning its own property, under 92(5).[53]

The powers of municipal institutions will be described below. It should be remembered that, as creatures of a provincial legislature, they must restrict themselves to provincial objects.

The provinces could use their licensing power under subsection 92(9) to charge fees for the disposal and/or treatment of wastes generated by modern biotechnology and the provision of other services to the modern biotechnology industries.

The most important head of provincial power is that over property and civil rights in the province. Under subsection 92(13) the province may regulate traditional common law matters within the provinces such as contracts, torts and property. As a consequence, the province could enact a liability and compensation scheme in the modern biotechnology area. It also has jurisdiction over land use and planning. The province has jurisdiction over intra-provincial trade and marketing, even if the regulation is applied to goods produced outside of the province[54] or to goods shipped out of the province.[55] However, there are limits on this provincial power, and a discriminating marketing scheme will be struck down.[56] As a consequence, provinces could regulate the sale of BTPs and transfer of BTPs within the province, but they could not regulate importation or exportation as such. Under subsection 92(13) provinces can regulate industries over which the federal government lacks jurisdiction such as the insurance industry.[57] It

should be kept in mind that incidental aspects of these industries could be regulated under other federal heads of power such as trade and commerce, criminal law power, especially where health is affected, and the peace, order and good government clause. As jurisdiction over the modern biotechnology industry has not been specifically assigned to the federal government and the government has not assumed jurisdiction under the peace, order and good government clause or by declaring biotechnology a work for the general advantage of Canada the field is open for regulation by the provinces.[58] Although the jurisdiction of the provinces under subsection 92(13) is broad it should be kept in mind that this power is limited by specific allocation of jurisdiction to the federal government under section 91 and 92(10) of the Constitution Act, 1867, including the peace, order and good government clause and by the lack of extra-territorial competence of provinces.[59]

The provinces may use penalties for the enforcement of the legislatic as long as the "pith and substance" of the provisions is not criminal law. Although the Courts tend to uphold legislation containing provincial offences, in all the decisions in which provincial laws were upheld the penalties were upheld in respect of matters over which the provinces ordinarily have legislative jurisidiction. Section 92(15) confers a power that is merely ancillary to other provincial heads or power.[60]

The provincial power over all matters of a merely local or private nature in the province could cover a broad field but has in fact been limited because of the broad interpretation of subsection 92(13).[61] Also, some local matters are regulated by the federal government under the p.o.g.g. clause because of national dimension or emergency concerns. The courts often refer to section 92(16) as a possible alternative for jurisdiction in subsection 92(13).[62] General jurisdiction over health matters within the province falls under provincial control under subsection 92(16),[63] unless they are of a national concern and are regulated federall

under the p.o.g.g. power or the criminal law power.[64]

Section 92(A) gives the provinces the following powers over non-renewable natural resources and forestry resources:

1. In each province, the legislature may exclusively make laws in relation to:

   (a) exploration for non-renewable natural resources in the provinces;

   (b) development, conservation and management of non-renewable natural resources and forestry resources in the province, including laws in relation to the rate of primary production therefrom;[65]

The provinces also have a corresponding power to raise money through the taxation of such resources, provided that exported resources are treated the same as provincially consumed resources.

This head of power could be used to regulate applications of biotechnology in this field, such as microbial leaching in mines and the use of biological pesticides to control forest pests.

7.2.1.3. Powers over Agriculture

Section 95 give concurrent powers of legislation respecting agriculture to the federal and provincial governments as follows:

"In each province the Legislature may make Laws in relation to Agriculture in the Province....; and it is hereby declared that the Parliament of Canada may from Time to Time make Laws in relation to Agriculture in all or any of the Provinces...;and any law of the Legislature of a Province relative to Agriculture...shall have effect in and for the Province as long as and as far only as it is not repugnant to any Act of the parliament of Canada".

The power to legislate with respect to agriculture has been narrowly interpreted by the courts. For instance a provincial statute providing that the principal amount due under a farm load would be reduced by the amount of interest payable in the event of a crop failure was found to be invalid because its "pith and substance" was the regulation of interest, and not agriculture. Viscount Simon pointed out:

"there is a distinction between legislation 'in relation to' agriculture and legislation which may produce a favourable effect on the strength and stability of that industry. Consequential effects are not the same thing as legislative subject-matter.[66]

Moreover, it was held that the prohibition against the sale and use of margarine, in an effort to protect the dairy industry was not legislation concerned with agriculture, but rather an attempt of the federal government to interfere with civil rights within a province. In limiting the scope of section 95, Lord Morton wrote:

"the prohibition might well 'produce a favourable effect on the strength and stability of the dairy industry; but this fact alone is not sufficient to make it legislation 'in relation to agriculture' within s. 95;[65]

Therefore it appears that it will be difficult to support a federal scheme regulating the applications of biotechnology in the field under this power. The courts are reluctant to find a law to be in relation to agriculture, if such a finding would limit the scope of property and civil rights within a province.[69]

7.2.2. Limits on Provincial Power

The provincial jurisdiction is limited to its territory, as ascertained by the documents creating or defining the province.[70] Such territory does not include the territorial sea and the continental shelf and jurisdiction over air space is at best limited.[71]

The province cannot impair extra-provincial contractual rights.[72] However, legislation in relation to a matter territorial within the province and within a head of provincial legislative powers may incidentally impair extra-provincial rights or have other extra-provincial consequences.[73]

Clearly, a province may not regulate an extra-provincial activity. Yet provincial legislation may have an incidental effect outside the borders of the province. In the area of environmental law, the Supreme Court of Canada has held that one province, Manitoba, cannot create a statutory right of action against out-of-province firms who introduce pollutants into rivers flowing into Manitoba from Ontario and Saskatchewan and thereby destroy Manitoba fisheries. The discharges occurred under licences issued by the Ontario and Saskatchewan governments. In light of this case, the Ipco case[74], a provincial statute cannot confer a right of action against those who release BTP's outside of provincial boundaries.

7.2.3. Regulation by both the Federal and Provincial Governments

It is likely that both the federal and the provincial governments will want to regulate some or all aspects of modern biotechnology. If both governments were to regulate within their assigned powers, and the two laws were not inconsistent, the courts would enforce both laws. The Courts have recognized that certain laws may have a so-called "double aspect"; in other words, they may have both a federal and provincial "matter".[75] For instance, certain provincial highway traffic offences are very similar to certain offences contained in the Criminal Code. Yet, both were upheld by the Supreme Court[76] The provincial law may be more onerous than the federal law, as long as there is no conflict between the two. However, if there is a conflict between a valid federal law and a valid provincial law, the federal law will be considered paramount and the provincial law must yield to the federal law to the extent of the inconsistency. The provincial law will remain in abeyance until such time as the federal parliament repeals the inconsistent federal law.[77]

7.2.4. Inter-delegation

If the federal and provincial governments decide to co-operate in regulating modern bio-technology, they may decide to establish a joint agency or board which could perform regulatory and/or administrative functions.

It is clear that a legislative body may delegate some of its lawmaking power to the executive branch of government, or other body. However, in Attorney General of Nova Scotia v. Attorney General of Canada it was held that the federal[78] government cannot delegate its legislative authority to a provincial legislature; nor can a province delegate a portion of its law-enacting power to Parliament. Such "legislative inter-delegation" would have

the effect of altering the distribution of powers contained in the constitution.[79] Nonetheless in P.E.I. Potato Marketing Board v. Willis,[80] the Supreme Court of Canada decided that the Governor General acting under the authority of a federal act could delegate regulatory powers related to the interprovincial marketing and export of potatoes giving the board full power to regulate potatoes produced within the province. This amounted to a valid administrative inter-delegation. However, this type of inter-delegation will be valid only when the federal and provincial statutes conferring powers upon the board properly fall within the legislative spheres of the enacting bodies. In Re Agricultural Products Marketing Act,[81] it was confirmed that:

> The Willis case permits delegation by Parliament of administrative authority to a provincial board to exercise like regulatory authority in an area of federal competence as it exercises in the provinical area.[82]

Thus administrative inter-delegation is an accepted constitutional method to create a body having complete regulatory power in an area of overlapping federal and provincial jurisdiction.

Parliament may give broad powers to a provincial board, enabling the board to in effect regulate a matter entirely within federal jurisdiction. For example, in Coughlin v. Ontario Highway Transport Board,[83] legislation gave provincial licencing boards the power to licence extra-provincial carriers as if they were local carriers. The legislation was upheld as "the adoption by Parliament, in the exercise of its exclusive power, of the legislation of another body as it may from time to time exist".

7.2.5. Spending Power

A government can influence behaviours of its subjects through legislation, but also by providing conditional grants or by entering into contracts containing certain conditions. Thus the federal government could influence certain activities within provincial jurisdiction by the province through use of its spending power. Similarly, the federal government can influence the provinces legislation with regard to health through the Canada Health Act.[84] To the extent that research and development depend either directly or indirectly on federal funding, the federal government could regulate through conditional grants in this area.

7.3. Allocation of Responsibilities within Government

The Canadian constitution allows each level of government to allocate responsiblities for a specific subject matter over the different departments or ministries. Currently responsibilities which are relevant to the regulation of modern bio-technology are allocated as follows:

7.3.1. Ontario[85]

The Ministry of the Environment is responsible for maintaining the quality of the environment within the province, and hence would most probably have jurisdiction to regulate field releases of BTP's confined to the province and disposal of BT wastes. Its jurisdiction includes the regulation of the sale and use of pesticides within the province.

Other Ontario ministries could hold responsibilities with respect to different aspects of biotechnology. For example, the Ministry of Agriculture and Food sets standards and develops marketing schemes for agricultural products in Ontario. It also regulates persons who supply laboratory animals, sell livestock pharmaceuticals, or provide artificial insemination services for livestock.

The Ministry of Health is responsible for ensuring the health of Ontario residents. Legislation directed toward the protection and promotion of health or the prevention of disease would likely be administered by this body. Escaped pathogenic organisms could fall within the ambit of such legislation.

The Ministry of Labour is responsible for promoting occupational health and safety. Thus it can be expected to regulate the production of pharmaceuticals, enzymes and fine chemicals manufactured using recombinant DNA techniques.

The powers of local municipalities, including any capacity to regulate biotechnology is determined by the Ministry of Municipal Affairs.

Ontario's natural resources are managed by the Ministry of Natural Resources. These resources include: Crown lands, forests, fisheries, wildlife, fuel and industrial minerals. Where applications of biotechnology affect these resources, this Ministry is properly equipped to administer legislation for their protection and conservation.

The Ministry of Northern Development and Mines administers mineral resource policies, and hence would administer legislation regulating microbial mineral leaching.

Finally, the Ministry of Transportation and Communication could regulate the transportation of dangerous goods, including genetically engineered organisms which should not be released to the environment.

7.3.2. Canada[86]

The Department of Environment (or Environment Canada), is responsible for preserving and enhancing the natural environment in matters that have either interprovincial or international dimensions. (The provinces are responsible for the management of most environmental matters within their boundaries). The federal programs include: fisheries management, management of long-range air pollution, monitoring and scientific research, migratory bird protection, and management of boundary waters.

The Department of Agriculture researches agricultural issues, sets programs to protect agricultural products from pests and diseases, inspects and grades farm products, and regulates the sale of feeds, fertilizers and pesticides.

The Canadian Transport Commission administers laws and regulations relating to the safe transportation of dangerous goods.

The Department of Consumer and Corporate Affairs protects consumers by regulating agricultural food products at the retail level, and administering the Hazardous Products Act. Patents are also administered by this department.

The Department of Energy, Mines and Resources is responsible for fostering national policies concerning the development of Canada's mineral and energy resources.

The Department of Fisheries and Oceans manages fisheries resources.

The Department of Labour is responsible for occupational health and safety in enterprises which are national, interprovincial or international in character, such as those dealing with rail transport, highway transport, telephone, shipping, and grain elevators.

The Department of National Health and Welfare is responsible for the protection of the health of the general public in matters which fall under federal jurisdiction, such as the Food and Drugs Act.

Several scientific research corporations have been formed by the federal government: The Medical Research Council, The National Research Council of Canada, and The Natural Sciences and Engineering Research Council. In addition, the Ministry of State for Science and Technology provides advice and sets policy direction in the areas of science and technology.

7.4. The Role of Municipal Government

Any municipality in which releases of BTP's are anticipated is likely to take an interest in any such release and may want to regulate or prohibit releases. The issue arises as to whether municipalities can do so in the absence of federal and provincial prohibtions or even in the face of express authorization from these higher levels of government.

The Municipal Act[87] contains provisions which enable municipalities to pass by-laws relating to the operation of modern biotechnology companies within its boundaries. The powers of a municipality are generally confined within municipal boundaries, and are exercised by by-law. The general power to make by-laws reads as follows:

> "Every council may pass such by-laws and make such regulations for the health, safety, morality and welfare of the inhabitants of the municipality in matters not specifically provided for by this

Act as may be deemed expedient and are not contrary to law."[88]

However, this power has been severely limited by judicial interpretation. In Morrison v. Kingston,[89] Middleton J.A. described the following limitations upon the use of section 104:

> "The first and most obvious limitation is found in the limitations imposed upon the power of the Province itself by the B.N.A. Act (now the Constitution Act). The Province has not itself universal power of legislation, and its creature the municipality can have no higher power.
>
> A second and for many purposes a limitation of equally practical importance is that where the Provincial Legislature has itself undertaken to deal with a certain subject-matter in the interest of the inhabitants of the Province all legislation by the municipality must be subject to the provincial enactment.
>
> A third limitation is I think to be found in the express enactments of the Municipal Act. Very few subjects falling within the ambit of local government are left to the general provisions of s. 259 (now s. 104). Almost every conceivable subject proper to be dealt with by a municipal council is specifically enumerated in the detailed provisions in the Act, and in some instances there are distinct limitations imposed on the powers of the municipal council. These express powers are, I think, taken out of any power included in the general grant of power in s.259 (now s. 104)." [90]

Fourthly, he goes on to state that the by-laws passed under this section must not be "contrary to law." The many provincial and federal enactments relating to health, safety, morality, and welfare of inhabitants thus serve to greatly restrict the general by-law power.[91]

Specific heads of municipal power include by-laws:

1. For regulating establishments for the breeding or boarding of animals, or any class thereof, within the municipality or defined areas thereof;[92]

2. For regulating the keeping, storing and transporting of, other dangerous or combustible, inflammable or explosive substances;[93]

3. For appointing inspectors, and for providing for the inspection of meat, poultry, fish and natural products offered for sale for human food;[94]

4. For authorizing the seizing and destroying of tainted and unwholesome articles of food;[95]

5. For providing blank forms for recording and reporting cases of contagious or infectious diseases, for placarding houses wherein such cases exist, and for taking such measures as may be considered necessary for preventing the spread of such diseases.[96]

6. For making any other regulations for sewage or drainage that may be considered necessary for sanitary purposes. (Sewage is defined to include commercial and industrial wastes),[97]

7. For requiring owners, lessees and occupants of land in the municipality or any defined area of it to close or fill up water closets, privies, privy vaults, wells or cesspools, the continuance of which may, in the opinion of the council or the medical health

officer, be dangerous to health, [98]

8. For regulating manufactures and trades that in the opinion of the council may prove to be or may cause nuisances of any kind, and without restricting the generality of the foregoing, for prohibiting or regulating the continuance of works, tanneries or distilleries or other manufacturing s or trades that, in the opinion of the council, may prove to be or may cause nuisances and;[99]

9. For prohibiting and abating public nuisances.[100]

By-laws passed by municipalities will be quashed if they conflict with provincial or federal legislation, or even if they are inconsistent with the policies inherent in those statutes.[101] A by-law may provide more stringent standards than a provincial statute so long as there is no operative conflict between the by-law and the statute.[102] In Re Attorney General for Ontario and City of Mississauga,[103] Weatherstone J.A. reasoned that,

> "A by-law is ultra vires if, notwithstanding an apparent statutory authority for its enactment, the same subject-matter is dealt with in a comprehensive way in a statute passed in the interest of all inhabitants of the Province, and this is true even in the absence of repugnancy.[104]

However, in the same case, Howland C.J.O. and Morden J.A. felt that an operative conflict was needed to render the by-law invalid.[105] Nonetheless, all three justices agreed that a by-law prohibiting the storage or burning of chlorinated hydrocarbons (including PCB's) within a municipality could not stand, where a company had obtained a certificate of approval for a test burn of PCB's under the Ontario Environmental Protection Act. The municipality's complete prohibition

conflicted with the policy in the Ontario legislative scheme permitting the burning of PCB's in certain circumstances. Therefore, a municipal by-law will be quashed if it conflicts with the legislative scheme of a provinical or federal enactment.[106]

Where there is a conflict with provincial or federal legislation the by-law would be ultra vires. Interesting legal issues will arise if certain aspects of modern biotechnology have been regulated by either the federal or the provincial governments but no comprehensive scheme has been enacted. In such an uncertain environment municipal by-laws could impact on research and development on the one hand and could offer a last resort to those concerned about environmental releases.

7.5. International Framework:

Need For International Cooperation

The international context is relevant for two reasons: Firstly, once a living BTP is released into the environment and is proven to be viable and multiplying, it could spread over national boundaries. From a Canadian perspective, biotechnological pollution from the United States is the most likely, but air-borne pollution from other continents or pollution through carriers, especially tourists and agricultural imports, would be possible. Secondly, in light of the intense competition between modern biotechnology corporations, harmonized regulation may be necessary to protect the various domestic industries. The example of the labour conventions comes to mind in this area. Furthermore, exchange of information could prove extremely valuable for research and development in the modern biotechnology field. For instance, the progress made by the International Standards

Organization and the World Health Organization provide useful precedents.

7.5.2. OECD[107]

International operation has commenced within the Organization for Economic Cooperation and Development, the OECD. On December 2-5, 1985, a meeting of an Ad-Hoc Group on Safety and Regulations in Biotechnology of the OECD, was held in Paris. The meeting dealt with safety considerations arising from the application of recombinant DNA technology in industry, agriculture, and the environment. The mandate of the committee included the examination of approaches to be used in risk management of recombinant DNA technology. It is hoped that the issues discussed at this meeting will lead to an international agreement on health and protection of the environment, as well as enhance international commerce in the biotechnology field. The group recommended that a case-by-case risk assessment be carried out prior to application in agriculture and the environment.

7.5.3. Jurisdiction over International Relations

The federal government has the power to enter into treaties binding Canada[108]. Where the implementation of a treaty requires a change in the internal law of Canada, such a change needs to be accomplished by the amendment of existing law or the drafting of new legislation by the government which has jurisdiction over the relevant subject matter. Canadian courts will not give effect to a treaty unless it has been enacted into law and Canadian courts will apply Canadian statute law or common law even if it is inconsistent with an unimplemented treaty which is binding upon Canada.[109]

Although the provinces lack treaty making power, they do play a role in the international scene. Firstly, cooperation of the provinces is necessary if the subject matter of a treaty regards a provincial matter. The federal government may consult with the provinces prior to entering into the treaty or may enter into

international obligations subject to the consent of the provinces. In addition, the provinces can make international arrangements which fall short of binding instruments in international law. For instance, reciprocal arrangements have been made between Canadian provinces and U.S. states with respect to enforcement of maintenance orders where spouses are in different jurisdictions.[110], and also with regard to succession duties motor vehicle registration, drivers' licences, fire-fighting and tourist information[111]. The provinces have also entered into contracts with governments in foreign jurisdictions, for example, to lease property or to acquire telephone services or electricity.[112] The issues as to which government should participate if international arrangements are being made will largely depend on the classification of the relevant matter under Canadian constitutional law. In all likelihood, the cooperation of the federal government and the provinces will be required.

The Provinces have the constitutional power to prohibit the release of BTP's and BT wastes except in accordance with a provincial licence under subsections 92(13) and 92(16) of the Constitution Act 1867. The same provisions enable the provinces to set waste disposal standards. If the risk of large scale damage by the release of BTP's and/or BT wastes is considered too serious to be dealt with by the Provinces, the federal government could regulate in this area under the "national concern branch" of the p.o.g.g. power. An example of federal legislation in a related area is legislation to prevent air pollution under the Clean Air Act. If both the federal and provincial governments were to regulate the release of BTP's and BT wastes or set waste disposal standards the provinicial laws would be inoperative to the extent they were in conflict with the federal law. A provincial licence would be of no avail if a federal licence were refused. Provincial legislation may be more onerous than federal legislation. A federal licence is likely to be ineffective in the absence of the provincial one. Yet if the province were to use its licencing power to frustrate the purposes of a federal statute the courts might find the provincial legislation to be in conflict with the federal provisions. As a consequence, a federal licence would suffice. The authors are not aware of any precedents on this issue.

The provinces could issue legislation establishing some form of data sharing or data collection within the province, as this would be considered a local matter under subsection 92 (16). However, the federal government could also establish a data-sharing network under either subsection 91 (6) or section 91 (22). Federal and provincial data sharing networks could co-exist as they are unlikely to create conflicting regulation.

Transportation of BTP's and BT wastes could be regulated by both levels of government. Current regulation of transportation of dangerous goods could be extended to cover all BTP's and BT wastes. If so, the federal government could regulate interprovinical and international transport and the provinces could adopt similar legislation for transportation within the province.

Subsection 92(13) empowers the Provinces to regulate civil liability and insurance and to establish a compensation scheme or a fund within each province. Regulation of liability across provincial boundaries and the establishment of an inter-provincial fund or scheme may be problematic. Presumably a province could give the right to compensation to non-residents for adverse effects resulting from releases within the province. It could compensate its own residents for damage suffered due to out of province releases, but it could not create liabilities arising from out of province events. A compensation scheme covering all of Canada might be established through co-operation between the provinces. For instance, each province could have identical schemes and inter-provincial compensation could be agreed upon. As an alternative, a Federal scheme could be established but, it may be held invalid if a court finds that the power to deal with liability and compensation is within provincial power.

The Canadian Constitution enables the federal government to enact legislation and attach consequences within Canada for events occurring abroad. Yet, the enforcability of such legislation against foreign defendents will depend on international co-operation. The provinces cannot enact legislation which attaches consequences to out-of-province occurrences.

The federal government could regulate the effects of modern biotechnology on federal public lands and federal and inter-provincial waters under sub-sections 91 (1A), 91 (10), and 91 (12).

If the sale of BTP's is regulated to ensure compliance with production and licencing requirements, the provinces would have the power to regulate intra-provincial sales whereas the federal government would be empowered to regulate inter-provincial and international sales. Also, where regulation of importation is necessary, the federal government would have that power.

In cases of national emergency, such as the spreading of a pathogenic BTP, the federal government could issue temporary regulations under the "emergency branch" of the p.o.g.g. clause. It could regulate under its powers with respect to quarantine under subsection 91 (11).

The Province would be able to finance regulation of modern biotechnology and compensation of funds schemes by direct taxation, or by charging licence fees under subsection 92 (2) and 92 (4). Royalties could be charged for testing on provincial lands or for otherwise using provincial lands under subsection 92 (5). The federal government has a broader range of taxing powers which could be used to raise revenues necessary to finance its regulatory schemes under subsection 91 (3).

Both the federal and provincial government can use sanctions to enforce the legislation they may enact. In addition, where health is seriously endangered, the federal government could set sanctions under the criminal law power. The relevant provisions are subsection 92 (15) and subsection 91 (27).

The use of the spending power by the Federal government to "regulate" modern biotechnology is unlikely, as provincial regulation does not depend on federal transfer payments. Municipal governments are restricted to provincial objects. Therefore, if there is a conflict between a municipal provision and valid federal legislation were to arise, the federal legislation would prevail. Also where

there is a conflict between provincial legislation and municipal regulation, the municipal regulation is "invalid". Municipal regulation may be more stringent than provincial legislation only if the provincial legislation. Therefore, if the Province were to issue a licence approving of the release of BTPs, a municipality cannot prevent such a release. Municipal by-laws could impact on the release of BTPs where both the federal and provincial legislation leaves a vacuum.

The federal government has the power to represent Canada in the international arena. However, if subjects are discussed which fall under provincial heads of power and Canadian legislation will be necessary to implement any results of international consultations, consultation with and co-operation from the provinces will be necessary. Although the provinces lack treaty making power, they may enter into international arrangements which fall short of binding instruments in international law. For instance, they could make arrangements with U.S. states to exchange information or to harmonize legislation concerning modern biotechnology.

There are no legal limitations on the allocation of responsiblities within the federal government or the Ontario government. Where environmental concerns are the main reason for regulation, Environment Canada had the Ministry of the Environment appear to be the appropriate regulating agencies.

In summary, in the absence of federal legislation, the Provinces could regulate modern biotechnology within the province. Where issues arise which could not adequately be dealt with at the provincial level, the federal government could regulate and, in case of conflict, the Provincial regulation would be inoperative. Co-operation between both levels of government may be optional in addressing all concerns raised. The federal government could also regulate certain aspects of modern biotechnology under specific heads of power.

8. CONCLUSIONS

8.1. Policy Issues to be Addressed

In establishing a policy with regard to modern biotechnology, the following policy issues should be addressed. They are listed in order of priority.

1. What should be the subject of regulation?
2. What activities should be regulated?
3. Is current legislation sufficient to deal with development issues or is additional regulation necessary? If additional regulation is opted for what regulation is required?
4. We need to know more about modern biotechnology and its possible impact on the environment. How can information be obtained, analyzed and shared and how can confidentiality concerns be addressed?
5. How can one prevent adverse effects, in other words: how can one ensure that no releases of hazardous BTP's or BT wastes will occur due to intentional releases, improper waste treatment, illegal use and accidents?
6. How can human health and the environment be restored in case of unanticipated adverse effects of releases, illegal use or accidents?
7. Which government has jurisdiction to regulate and which government and government department and ministry is most suitable to regulate?
8. How can compliance with any regulatory system be ensured, either through voluntary compliance or enforcement?
9. Should under a new regulatory system compensation be given to those who suffer physical injury and/or damage to property due to the release of BTP's or BT wastes?
10. How can one evaluate long term effects of releases of BTP's and BTP wastes.

11. Should ethical concerns be addressed and reflected in the regulation?

12. Should anticipated socio-economic effects impact on the regulation?
13. How can regulation be drafted so as to promote research and development?
14. How can regulation be drafted so as to promote the development of Ontario modern biotechnology industries?
15. What resources are or could become available for the regulation in terms of finances, expertise and manpower and how can they be used most efficiently and effectively?
16. What format should the regulation take. Should there be one modern biotechnology statute or amendments to existing statutes; should only prescribed released be prohibited?

8.2 The Subject of Regulation

If all BTP's and BT wastes were to be regulated the following two questions would arise: why are living BTP's different from other exotic living organisms and why are killed and inanimate BTP's different from other chemicals? What is the concern necessitating specific regulation of BTP's and /or BT wastes? If the concern is that released substances may multiply, change or combine with other living organisms, regulation of killed BTP's and inanimate BTP's may not be necessary. On the other hand, regulation may not be restricted to living BTP's and could also include other living organisms, either all other living organisms or only living organisms exotic to the ecosystem into which they are released. Another issue is what organisms need be regulated. Need we be concerned only about viruses and bacteria, which can spread rapidly and cannot be discerned with the naked eye, or are we also concerned with genetically manipulated plants and/or animals? Another issue is the true nature of killed BTP's. Is it possible that properties of killed BTP's are transmitted into other organisms or that some allegedly killed BTP's could remain alive by accident?

8.3 Need for Additional Legislation

Current environmental legislation has been drafted to deal with chemical and nuclear contamination, not with biological contamination. At the very least it needs to be amended to cover biological contamination.

A number of agricultural protection statutes and product oriented statutes provide for pre-release evaluation. Under these statutes the production or use of a limited number of BTP's requires a licence, a permit or registration. However, the mandate of the relevant agencies does not include environmental assessment and they are likely to lack sufficient information and expertise to thoroughly evaluate ecological effects. This may result in unnecessary denial of licences or permits, as appears to occur in the fertilizers area and on the other hand it could result in potentially dangerous releases. In addition, not all BTP's are subject to a licencing, permit or registration requirement. Therefore, additional legislation requiring environmental assessment by an informed and properly staffed agency is necessary.

Current legislation contains provisions for inspection and reporting, especially of potential harmful or dangerous substances or occurrences. Yet, a comprehensive monitoring system is lacking.

Environmental protection legislation, especially the Ontario Environmental Protection Act supplements common law with regard to liability and compensation. Yet, chances are that these provisions are inadequate to deal with liability and compensation issues arising from unexpected adverse effects of releases of BTP's or BT wastes. Also, it is unclear as to whether current common law and environmental legislation will be sufficient to deal with liability issues arising from illegal use and spills. Agricultural protection legislation and product oriented legislation, as well as federal environmental legislation do not address the issue of liability and compensation at all. These are the main reasons for either expanding existing legislation or enacting

an entirely new regulatory scheme with regard to modern biotechnology.

8.4 The Need for Information

Lack of sufficient information to evaluate and assess consequences of releases into the environment lies at the heart of many of the issues raised with regard to modern biotechnology. Information is needed to determine what should be regulated and to assess the risks of releases either in general or on a case-by-case basis which is necessary if a licencing, permit or registration system is established. Information is also needed for proper responses to emergencies. More knowledge may be needed as well to regulate civil liability and insurance schemes. In addition, the public wants information which is necessary for the proper functioning of the political system. At the same time, information concerning modern biotechnology, BTP's and even BT wastes can be extremely valuable to industry and concerns about competitive position are legitimate. On the other hand, industry may well benefit from an exchange of information. It should be kept in mind that education of government officials and the public may assuage fears and could lead to deregulation.

A number of current statutes requires submission of information to government. Submission of information is part of an approvals process under many agricultural protection statutes and product oriented statutes. Environmental legislation as such does not require pre-release approvals, but once it has been determined that contamination occurs, program approvals for certain works may be required under the Environmental Protection Act. Environmental legislation contains a number of monitoring and inspection provisions. Yet, no comprehensive information gathering system exists under current legislation.

8.5 Prevention of Undesirable Releases

The issue of prevention raises a number of issues with regard to the desirability of regulation, enforcement and information. As long

as producers or users are informed about the nature of the BTP or BT waste they are dealing with, undesirable releases are unlikely. But, the public will not be satisfied to leave the judgment as to what is safe and desirable to those involved in production and use. Legislation requiring pre-release evaluation and/or post-release monitoring may be necessary. The issue of enforcement and voluntary compliance is dealt with below.

8.6 Restoration

Unanticipated effects of environmental releases of BTP's and BT wastes are conceivable. If this issue is not addressed in legislation the costs of unanticipated effects are likely to be borne by the direct victims and cost of restoration may also be borne by the taxpayers. In addition, legislation should address emergency response plans and continuing monitoring and evaluation so that unanticipated adverse effects can be remedied as soon as possible, and maybe even prevented.

8.7 Compliance

Because detection may be problematic, voluntary compliance with any regulatory system or scheme is very important. Voluntary compliance may flow from an inherently fair and useful regulatory scheme. Concerns about safety by producers and users will also greatly assist in compliance with any sensible regulatory scheme. Because of the potential of severe damage from illegal releases or even negligent releases, combined with the low probability of detection, substantial sanctions may be necessary for enforcement.

8.8 Liability and Compensation

Current common law is inadequate to provide compensation to those who suffer physical injury and/or property damage as a consequence of environmental releases of BTP's or BT wastes. The Ontario Environmental Protection Act facilitates relief for those affected by spills of

pollutants, but these provisions may not apply to BTP's and BT wastes. Also, even if certain BTP's and BT wastes qualify as pollutants, the Environmental Protection Act provisions may not be sufficient to provide compensation, especially where adverse effects are extremely remote and delayed in time. If it is decided that the burden of future and potential damage and/or injuries should be borne by current producers and/or users, a compensation fund or insurance scheme should be established.

8.9 Long-term Effects

At present there is no forum to evaluate the long term effects of environmental releases of BTP's or BT wastes. Some possible long term effects are environmental in their nature such as the impact on the soil of enhanced animals and genetic variety. Others would be biological or medical in nature, such as the impact on human health of using BTP's, such as the use of fructose instead of sugar or the use of milk from genetically altered cows. Long term environmental concerns could be taken into account if the Ministry of the Environment were to assess the consequences of releases of BTP's or BT wastes. However, some potential long term effects may be too remote to be included in their decision, such as the impact of using milk from genetically altered cows. Public education as to long term adverse effects or potential long term adverse effects may prevent the use of certain BTP's or certain processes producing BT wastes. It could also lead to public pressure on the political decision making process.

8.10 Ethical Concerns

Modern biotechnology raises a number of ethical concerns. Firstly, the issue arises as to whether we could tamper with any life form at all. Secondly, a number of animal rights issues arise; for instance, modern biotechnology is used to produce turkeys with such

large breasts that they are unable to reproduce in a normal fashion. Does this amount to unethical animal suffering? Certainly, where genetic engineering is practiced, the possibility to genetically manipulate human beings becomes feasible. Fourthly, is there an obligation to use the benefits of modern biotechnology for the development of poorer areas in the world? Many of these issues would be too remote to address in the context of environmental legislation. However, were a more exclusive regulatory scheme were enacted, these issues might become relevant.

8.11 Socio-Economic Effects

If the regulation of the release of BTP's or organisms is issued from an environmental perspective socio-economic effects may be too remote to be addressed. However, if a general regulatory scheme for the modern biotechnology industry is decided upon, socio-economic effects, such as potential unemployment, might be addressed.

8.12 Research and Development

Research and development will be important from an environmental point of view, as it will furnish information as to the nature of BTP's and BT wastes and their impact on the environment. In addition, research and development in the area of modern biotechnology may be of great importance to the Ontario or Canadian economy. Consideration should be given to exemptions from the regulations for research and development or facilitating the issuance of permits or licences. Also, obligatory patenting or other forms of ensuring disclosure of information should be considered.

8.13 Promotion of Industry

Regulation of environmental releases of BTP's or BT wastes is not primarily concerned with the fostering of Ontario or Canadian industries. However, industrial development will benefit from clarification of regulation. The reality of international competition may dictate international or interprovincial cooperation and harmonization of regulation. On the other hand, if an all encompassing regulatory scheme is designed the fostering of local industries could be part of such a scheme.

8.14 Jurisdiction

The decision as to which government agency should be in charge of administering the legislation concerning either the release of BTP's or organisms or the enabling biotechnology industry as such depends inter alia on the scope of the legislation. If only the release of BTP's or BT wastes and the restoration or the environment or health were to be addressed the Ministry of the Environment would be the appropriate agency. It has the constitutional power to deal with local releases, regulation of local industries and the establishment of a compensation scheme. If an all encompassing scheme is designed, not only the Ministry of the Environment would be involved, but also Environment Canada, the Ministry or the Department of Agriculture, the Ministry of Health, and Health and Welfare Canada and possibly the Ministry of Consumer and Corporate Affairs and government agencies responsible for mining. Because of the many aspects of modern biotechnology an inter-departmental, an inter-ministerial and/or an inter-governmental agency might be a solution. In the short term it may be impossible to establish an all encompassing regulatory scheme. As the concern of adverse effects of unsupervised environmental releases is legitimate, regulation by the Ontario Ministry of the Environment in the short term seems necessary. At a later stage, such regulation could be superceded by a more encompassing regulatory scheme for the industry.

8.15 Resources

Regulation is costly. The regulating government agency will have to allocate manpower and money to the testing and evaluating of BTP's or BT wastes. Inspection and other compliance activities are again time consuming and potentially costly. Industry may need to spend a substantial amount of time and scarce resources on the preparation of applications and the answering of questions. Whatever formal regulation is decided upon, it should be practically possible to implement both from the point of view of government and from the point of view of those regulated. It should be kept in mind that clear regulation is required to foster research and development in the modern biotechnology industry.

8.16 Format of Regulation

If the consensus exists that the release of BTP's or BT wastes into the environment without any further knowledge is too risky, a general prohibition to release unless a permit has been obtained appears the logical solution. However, as our knowledge increases, certain types of releases may become known to be safe. If so, a general exemption should be provided for such releases. In theory it would be possible to establish statutory or regulatory criteria for release of BTP's or organisms.

Yet, because our knowledge of the ecological impacts of BTP's or BT wastes is limited, a case-by-case analysis of potential releases will be necessary in the near future.

Chapter 1: Footnotes

1. Environmental Contaminants Act, S.C. 1974-75, c.72, as amended.
2. Clean Air Act, S.C. 1970-71-72, c.47, as amended.
3. Canada Water Act, R.S.C. 1970 (1st Supp.), c.5, as amended.
4. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended.
5. Environmental Assessment and Review Process Guidelines Order, S.O.R./84-46.
6. Environmental Assessment Act, R.S.O. 1980, c.140.
7. Environmental Protection Act, R.S.O. 1980, c.141, as amended.
8. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended.
9. Dangerous Goods Transportation Act, S.O. 1981, c.69.
10. Fisheries Act, R.S.C. 1970, c. F-14, as amended
11. Migratory Birds Convention Act, R.S.C. 1970, c.M-12, as amended.
12. Animal Disease and Protection Act, R.S.C. 1970, c.A-13, as amended.
13. Plant Quarantine Act, R.S.C. 1970, c. P-13, as amended.
14. Livestock Pedigree Act, R.S.C. 1970, c. L-10, as amended.
15. Artificial Insemination of Livestock Act, R.S.O. 1980, c. 29.
16. Plant Diseases Act, R.S.O. 1980, c. 380.
17. Animals for Research Act, R.S.O. 1980, c. 22.
18. Weed Control Act, R.S.O. 1980, c. 530.
19. Hazardous Products Act, R.S.C. 1970, c. H-3, as amended.
20. Food and Drugs Act, R.S.C. 1970, c.F-27, as amended.
21. Pest Control Products Act, R.S.C. 1970, c.P-10, as amended.
22. Pesticides Act, R.S.O. 1980, c.376, as amended.
23. Feeds Act, R.S.C. 1970, c.F-7, as amended.

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

25. Seeds Act, R.S.C. 1970, c.S-7, as amended.

26. Canada, Medical Research Council of Canada, Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells (Ottawa: Department of Supply and Services, December, 1980).

27. Canada, Occupational Health and Safety Regulations, S.O.R./ 86-304.

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

29. Canada Shipping Act, R.S.C. 1970, c.S-9, as amended.

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

31. Canada Wildlife Act, S.C. 1973, c. 21.

32. Northern Inland Waters Act, R.S.C. 1970, c.28 (1st Supp.), as amended.

33. Arctic Waters Pollution Prevention Act, R.S.C. 1970, c.2 (1st Supp.), as amended.

34. Department of Agriculture Act, R.S.C. 1970, c.A-10.

35. Agriculture Products Marketing Act, R.S.C. 1970, c.A-7, as amended.

36. Livestock and Livestock Products Act, R.S.C. 1970, C.L-8, as amended.

37. Meat Inspection Act, R.S.O. 1980, c. 260.

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

39. Atomic Energy Control Act, R.S.C. 1970, c. A-19, as amended.

40. Health Protection and Promotion Act, S.O. 1983, c. 10, as amended.

41. Milk Act, R.S.O. 1980, c. 266, as amended.

42. Mining Act, R.S.O. 1980, c. 268.

43. Live Stock Medicines Act, R.S.O. 1980, c. 247.

44. Insurance Act, R.S.O. 1980, c. 218, as amended.

45. Forest Tree Pest Control Act, R.S.O. 1980, c. 174.

46. Public Lands Act, R.S.O. 1980, c. 413.

47. Access to Information Act, S.C. 1980-81-82-83, c. 111, Schedule I, as amended.

48. Nuclear Liability Act, R.S.C. 1970, c. 29 (1st Supp.), as amended.

49. Patent Act, R.S.C. 1970, c. P-4, as amended.

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

51. Forestry Development and Research Act, 1970, c. F-30, as amended.

52. Fisheries and Ocean Research Advisory Council Act, S.C. 1978-79, c. 13, as amended.

53. Industrial and Regional Development Act, S.C. 1980-81-82-83, c. 160.

54. Agricultural Research Institute of Ontario Act, R.S.O. 1980, c. 13.

55. Experimental Farm Sations Act, R.S.C. 1970, c. E-14, as amended.

Chapter 2: Footnotes

1. Environmental Contaminants Act, S.C. 1974-75, c. 72, as amended, subsection 2(1).
2. Clean Air Act, S.C. 1970-71-72, c. 47, as amended, subsection 2(1).
3. Ibid.
4. Canada Water Act, R.S.C. 1970 (1st Supp.), c. 5, as amended, subsection 2(1).
5. Ibid., section 17.
6. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, subsection 5(1).
7. Ibid., section 13.
8. Ibid., paragraph 1(1)(c).
9. Ibid., paragraph 79(1)(f).
10. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, section 14 - 19.
11. Ibid., paragraph 1(r).
12. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 2.
13. Transportation of Dangerous Goods Regulations, S.O.R./85-77, paragraphs 3.19(f) and 3.20(b).
14. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, Schedule, as amended.
15. Dangerous Goods Transportation Act, S.O. 1981, c. 69, paragraph 1(c).
16. Dangerous Goods Transportation Act, S.O. 1981, c. 69, Schedule, as amended.
17. Ibid.
18. Fisheries Act, R.S.C. 1970, c. F-14, as amended, subsection 33(11).
19. Migratory Birds Regulations, C.R.C. 1978, c. 1035, as amended, section 35.
20. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, as amended, section 2.

21. Plant Quarantine Act, R.S.C. 1970, c. P-13, as amended, subsection 3(1).

22. Ibid., section 2.

23. Ibid.

25. Artificial Insemination of Livestock Act, R.S.O. 1980, c. 29, section 1.

26. Plant Diseases Act, R.S.O. 1980, c. 380, paragraph 1(i).

27. Ibid., paragraph 1(h).

28. Weed Control Act, R.S.O. 1980, c. 530, section 4.

29. Ibid., paragraph 1(h).

30. Ibid., section 20.

31. Hazardous Products Act, R.S.C. 1970, c. H-3, as amended, section 2.

32. Food and Drugs Act, R,S,C, 1970, c. F-27, as amended, section 2.

33. Ibid.

34. Food and Drug Regulations, C.R.C. 1978, Vol. VIII, c. 870, section B.01.001, as amended.

35. Pest Control Products Act, R.S.C. 1970, c. P-10, as amended, section 2.

36. Ibid.

37. Judith Miller, "Canada: Building a Regulatory Framework" (March, 1986), 4 Biotechnology.

38. Pesticides Act, R.S.O. 1980, c. 376, as amended, paragraph 1(l)(t).

39. Ibid., paragraph 1(l)(s).

40. Feeds Act, R.S.C. 1970, c. F-7, as amended, section 2.

42. Fertilizers Act, R.S.C. 1970, c. F-9, as amended, section 2.

43. Ibid.

44. Seeds Act, R.S.C. 1970, c. S-7, as amended, section 2.

45. Canada, Medical Research Council of Canada, Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells (Ottawa: Department of Supply and Services, December, 1980).

46. Canada Occupational Health and Safety Regulations, S.O.R./86-304.

47. Occupational Health and Safety Act, subsections, 3(1) and 3(2).

48. Ibid., section 1.6.

Chapter 3: Footnotes

1. Environmental Contaminants Act, S.C. 1974-75, c. 72, as amended, subsection 4(6).

2. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, sections 6 and 7.

3. Pest Control Products Act, R.S.C. 1970, c. P-10, as amended, section 3.

4. Fisheries Act, R.S.C. 1970, c. F-14, as amended, subsections 33.1(1) and 33.1(2).

5. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c. 1273, section 8.

6. Animals for Research Act, R.S.O. 1980, c. 22, sections 2 and 4.

7. Ibid., section 2.

8. Ibid., section 13.

9. Animal Disease and Protection Regulations, C.R.C. 1978 Vol. III, c. 296, as amended, section 123.

10. Ibid., section 124.

11. Ibid., subsection 122(1) and section 126.

12. Ibid., section 128 - 135.

13. Ibid., sections 115 - 119.

14. Food and Drugs Act, R.S.C. 1970, c. F-27, as amended, section 11.

15. Ibid., section 12; Food and Drug Regulations, C.R.C. 1978, Vol. VIII, c. 870, Part C, Division 4, as amended.

16. Food and Drug Regulations, supra footnote 15.

17. Ibid., section C.08.002.

18. Ibid., section C.04.007.

19. Ibid., section C.08.009.

20. Ibid., section C.08.001.

21. Ibid., section C.04.012.

22. Food and Drugs Act, R.S.C. 1970, c. F-27, as amended, section 7.

23. Pest Control Products Act, R.S.C. 1970, c. P-10, as amended, section 3.

24. Feeds Act, R.S.C. 1970, c. F-7, as amended.

25. Ibid., section 3; Feeds Regulations, S.O.R. /83-593, as amended, section 4, and Schedule IV.

26. Feeds Act, supra, footnote 25, section 3; Feeds Regulations, supra footnote 25, section 5.

27. Feeds Regulations, supra footnote 25, section 3(a).

28. Feeds Regulations, supra footnote 25, section 30.

29. Feeds Act, supra footnote 25, section 3; Feeds Regulations, supra footnote 25.

30. Feeds Act, supra footnote 25, sections 7 and 11; Feeds Regulations, supra footnote 25, section 36.

31. Food and Drug Regulations, C,R,C, 1978, Vol. VIII, c. 870, sections C.01.014 - C.01.014.7.

32. Pest Control Products Act, R.S.C. 1970, c. P-10, as amended, paragraph 5(d).

33. Pest Control Products Regulations, C.R.C. 1978, Vol. SIII, c. 1253, section 6.

34. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 8 and 9.

35. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 3.19 - 3.23.

36. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, as amended, paragraphs 3(m) and 3(n)(i).

37. Artificial Insemination of Livestock Act, R.S.O. 1980, c. 29, section 17.

39. Pest Control Products Act, R,S,C, 1970, c. P-10, as amended, section 3.

40. Pest Control Products Regulations, C.R.C. 1978, Vol. XIII, c. 1253, section 26.

41. Pesticides Act, R.S.O. 1980, c. 376, as amended, section 20.

42. Ibid., subsection 21(1) and section 13.

43. Ibid., section 24(2).

44. Food and Drugs Act, R.S.C. 1970, c. F-27, as amended, sections 8 and 11.

45. Ibid., section 7.

46. Ibid., section 4.

47. Canada Occupational Health and Safety Regulations, S.O.R./86-304, sections 10.8 - 10.10.

48. Environmental Contaminants Act, S.C. 1974-75, c. 72, as amended, subsection 8(2).

49. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 6,7,9 and 10.

Vol. 2, supra footnote 38, p. 8.

51. Pest Control Products Regulations, supra footnote 3.

52. Pest Control Products Regulations, supra footnote 40, sections 3 - 6 and 45.

53. Ibid., section 18.

54. R.R.O. 1980, Regulation 751, as amended, section 21(1).

55. Ibid., section 20.

56. Ibid., section 21.

57. Animal Disease and Protection Regulations, C.R.C. 1978, Vol. III, c. 296, as amended, section 133 and 134.

58. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, as amended, section 15.

60. Artificial Insemination of Livestock Act, supra footnote 37, subsection 16(1).

61. Ibid., subsection 16(2).

62. Plant Diseases Act, R.S.O. 1980, c. 380, section 3.

63. Occupational Health and Safety Act, R.S.O. 1980, c. 321, as amended, subsection 21(1).

64. Hazardous Products Act, R,S,C, 1970, c. H-3, as amended, section 3.

65. Food and Drugs Act, R.S.C. 1970, c. F-27, as amended, section 8.

66. Ibid., section 10.

67. Ibid., section 12.

68. Food and Drug Regulations, C.R.C. 1978, Vol. VIII, c. 870, as amended, Part C, Division 4.

69. Ibid., section C.08.002.

70. Ibid., section C.08.005.

71. Food and Drugs Act, R,S,C, 1970, c. F-27, as amended, section 4.

72. Pest Control Products Act, R.S.C. 1970, c. P-10, as amended, subsection 4(1).

73. Pest Control Product Regulations, C.R.C. 1978, Vol. XIII, c. 1253, section 26.

74. Ibid., section 5.

76. Pesticides Act, R.S.O. 1980, c. 376, as amended, section 6.

77. Feeds Act, R.S.C. 1970, c. F-7, as amended, section 3; Feeds Regulations, S.O.R./83-593, as amended.

78. Feeds Act, supra footnote 77, section 3; Feeds Regulations, supra footnote 77.

79. Feeds Regulations, supra footnote 77, section 14 - 22.

80. Ibid., section 34.

81. Ibid., section 26 - 30.

82. Ibid., subsection 22(2).

83. Fertilizer Act, R.S.C. 1970, c. F-9, as amended, section 3.

84. Ibid., section 9.

85. Fertilizers Regulations, C.R.C. 1978, Vol. VI, c. 666, as amended, section 3 and 3.1.

86. Seeds Regulations, C,R,C, 1978, Vol. XV, c. 1400, sections 5 - 8.

87. Ibid., section 10 - 18.

88. Ibid., sections 19 25; Seeds Act, R.S.C. 1970, c. S-7, as amended, subsection 3(1).

89. Environmental Contaminants Act, S.C. 1974-75, c. 72, as amended, subsection ~~4~~(6).

90. Ibid., subsection 8(2).

91. Ibid., subsection 8(4) and section 18.

92. Clean Air Act, S.C. 1970-71-72, c. 47, as amended, section 22.

93. Canada Water Act, R.S.C. 1970 (1st Supp.), c. 5, as amended, section 18.

94. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, as amended, section 15.

95. Animal Disease and Protection Regulations, C.R.C. 1978, Vol. III, c. 296, as amended, section 7 and 8.

96. Ibid., Part II.

97. Ibid., Part III.

98. Ibid., Part IV.

99. Ibid., section 32.

100. Ibid.

101. Ibid., subsection 51(1).

102. Ibid., subsection 51(2).

103. Ibid., section 35.

104. Ibid, section 121.

105. Ibid., sections 71 and 72.1.

106. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c. 1273, section 5.

107. Ibid., section 7.

108. Ibid., section 3.

109. Ibid., section 6.

110. Ibid., section 9.

111. Ibid., section 19.

113. Ibid., at 8.

114. Artificial Insemination of Livestock Act, R.S.O. 1980, c. 29, subsection 16(2).

115. Animals for Research Act, R.S.O. 1980, c. 22, section 14.

116. Hazardous Products Act, R.S.C. 1970, c. H-3, as amended, section 3.

117. Food and Drug Regulations, C.R.C. 1978, Vol. VIII, c. 870, sections A.01.040 and A.01.044.

118. Food and Drugs Act, R.S.C. 1970, c. F-27, as amended, section 32.

119. Food and Drug Regulations, C,R,C, 1978, Vol. VIII, c. 870, sections A.01.040 and A.01.044.

120. Food and Drugs Act, R.S.C. 1970, c. F-27, as amended, section 32; Food and Drug Regulations, C.R.C. 1978, Vol. VIII, c. 870, section A.01.045.

121. Pest Control Products Act, R.S.C. 1970, c. P-10, as amended, subsection 4(1).

122. Pest Control Products Regulations, C.R.C. 1978, Vol. XIII, c. 1253, sections 55 57.

123. Pest Control Products Act, R,S,C, 1970, c. P-10, as amended, subsection 4(2).

124. Environmental Contaminants Act, S.C. 1974-75, c. 72, as amended, section 18.

125. Ibid., subsection 8(1), and section 18.

126. Clean Air Act, S.C. 1970-71-72, c. 47, as amended, subsection 33(1). Note: The Act states "Minister" means Minister of Fisheries and Forestry. In practice, this means Minister of the Environment.

127. Ibid., section 4.

128. Ibid., section 8.

129. Ibid., section 7.

130. Ibid., sections 11 - 13.

131. Ibid., section 20.

132. Ibid., sections 21.1. and 21.2.

133. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, subsection 5(1).

134. Ibid., sections 26 and 27.

135. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, paragraph 44(1)(h).

136. Ontario, Ministry of the Environment, Water Management - Goals, Policies, Objectives and Implementation Procedures of the Ministry of the Environment (Toronto: the Ministry, November, 1978, Revised May, 1984).

137. Fisheries Act, R.S.C. 1970, c. F-14, as amended, subsections 33(4) and 33(13).

138. Migratory Birds Regulations, C.R.C. 1978, Vol. XI, c. 1035, as amended, section 35.

139. Animal Disease and Protection Regulations, C.R.C. 1978, Vol. III, c. 296, as amended, sections 117 and 118.

140. Ibid., subsection 128(1).

141. Ibid., paragraph a28(1)(e).

142. Ibid., paragraph 128(1)(j).

143. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c. 1273, section 8.

145. Plant Diseases Act, R.S.O. 1980, c. 380, subsection 14(1).

146. Pest Control Products Regulations, C,R,C, 1978, Vol. XIII, c. 1253, section 5.

147. Ibid., paragraph 27(2)(j).

148. Pest Control Products Act, R.S.O. 1980, c. 380, subparagraphs 9(2)(a)(i) and 9(2)(a)(viii).

149. Ibid., section 4.

150. Ibid., section 20.

151. Ibid., section 21.

152. Clean Air Act, S.C. 1970-71-72, c. 47, as amended, subsections 7(3) and 21(3).

153. Environmental Contaminants Act, S.C. 1974-75, c. 72, as amended, subsection 2(1) and section 8.

154. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 17.

155. Ibid., section 18.

156. Transportation of Dangerous Goods Regulations, S.O.R./ 85-77, section 7.16 and 4.8.1.

157. Environmental Protection Act, R.S.O. 1980, s. 141, as amended, paragraph 79(j).

158. Ibid., subsection 79(4).

159. Ibid., subsection 80(1).

160. Ibid., subsection 81(1).

161. Ibid., section 82.

162. Ibid., sections 84 and 85.

163. Ibid., subsection 87(2).

164. Ibid., section 14.

165. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, subsection 16(3).

166. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, subsection 16(3).

167. Ibid., subsection 18(1).

168. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c. 1273, subsection 4(2).

169. Ibid, subsection 4(3).

170. Ibid, section 22; Plant Quarantine Act, R.S.C. 1970, c. P-13, as amended, section 9.

171. Fisheries Act, R.S.C. 1970, c. F-14, as amended, subsections 33.2(4) and 33.2(5).

172. Plant Diseases Act, R.S.O. 1980, c. 380, section 14.

173. Ibid., section 17.

174. Canada, Medical Research Council of Canada, Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells (Ottawa: Department of Supply and Services, December, 1980), section 1, no. 3.g.

175. Canada Occupational Health and Safety Regulations, S.O.R./86-304, section 10.8.

176. Pest Control Products Regulations, C.R.C. 1978, Vol. XIII, c. 1253, section 46.

177. Ibid., sections 27 - 41.

178. Ibid., paragraph 27(2)(i) and sections 31 and 45.

179. Ibid., section 46.

180. Pesticides Act, R.S.O. 1980, c. 376, as amended, section 22.

181. Ibid., section 23.

182. Ibid., sections 20 and 21.

183. R.R.O. 1980, Regulation 751, section 27.

184. Transportation of Dangerous Goods Regulations, S.O.R./ 85-77, sections 7.16 and 7.17.

185. Ibid., sections 9.1 - 9.7.

187. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 25.

189. Transportation of Dangerous Goods Regulations, S.O.R./ 85 - 77, Part IV.

191. R.R.O., 1980, Regulation 309, as amended.

192. Animal Disease and Protection Regulations, C.R.C. 1978, Vol. III, c. 296, as amended, section 85.

193. Plant Quarantine Act, R.S.C. 1970, c. P-13, as amended, subsection 3(1).

194. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c. 1273, section 10.

195. Ibid., subsection 11(1) and Schedule III, and subsection 11(2) and Schedule III.1.

196. Ibid., section 6 and Schedule II.

197. Plant Diseases Act, R.S.O. 1980, c. 380, section 2.

198. Pest Control Products Act, R.S.C. 1970, c. P-10, as amended, subsection 4(2).

199. Pesticides Act, R.S.O. 1980, c. 376, as amended, section 28; R.R.O. 1980, Regulation 751, sections 105 - 109.

Chapter 4: Footnotes

1. Clean Air Act, S.C. 1970-71-72, c. 47, as amended, subsection 15(1).

2. Environmental Assessment Act, R.S.O. 1980, c. 140, sections 3 and 5.

3. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, sections 9 and 10.

4. Ibid., section 37.

5. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, subsections 23(1) and 24(1).

6. Fisheries Act, R.S.C. 1970, c. F-14, subsection 33(14) as amended by S.C. 1976-77, c. 35, subsection 7(4).

7. Animal Disease and Protection Regulations, C.R.C. 1978, Vol. III, c. 296, as amended, sections 122 and 126.

8. Ibid., subsection 128(2).

9. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c. 1273, section 4.

10. Ibid.; Plant Quarantine Act, R.S.C. 1970, c. P-13, as amended, section 8.

11. Pest Control Product Regulations, C.R.C. 1978, Vol. XIII, c.1253, section 57.

12. Feeds Regulations, S.O.R./ 83-593, as amended, section 8.

13. Fertilizers Regulations, C.R.C. 1978, c. 666, section 5, as amended by S.O.R./ 79-365, section 5; amended S.O.R./ 85-558, section 4; amended S.O.R./ 85-688, section 1.

14. Ibid.

15. Ibid., subsection 10.2(5), as amended by S.O.R./ 79 - 365, section 9.

16. P.C. 1984-2132.

17. Ibid., sections 11, 12, and 13.

18. Ibid., section 7; Financial Administration Act, R.S.C. 1970, c. F-10, as amended, Schedule D.

19. P.C. 1984-2132, section 6.

20. Clean Air Act, S.C. 1970-71-72, c. 47, as amended, section 3.

21. Ibid., section 5.

22. Ibid., section 6.

23. Environmental Contaminants Act, S.C. 1974-75, c. 72, subsection 4(6), as amended by S.C. 1983-84, c. 40, subsection 25(2).

24. Ibid., subsection 3(1).

25. Ibid., subsection 3(3).

26. Ibid., subsection 3(4).

27. Ibid., subsection 3(5).

28. Ibid., subsection 3(7) and section 18.

29. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 23.

30. Environmental Protection Act, R.S.O. 1980, c. 141, section 136, as amended by S.O. 1983, c. 52, subsections 23(1), (2),(3) and (4).

31. Ibid., section 113, as amended by S.O. 1983, c. 52, subsections 15(1) and (2).

32. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, subsection 23(6) and section 31.

33. Fisheries Act, R.S.C. 1970, c. F-14, subsection 33(14), as amended by S.C. 1976-77, c. 35, subsection 7(4).

34. Ibid., section 33.1, as amended by R.S.C. 1970 (ist Supp.), c, 17, subsection 3(2); amended S.C. 1976-77, c. 35, sections 8 - 10; amended S.C. 1985, c. 26, section 41.

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

36. Animals for Research Act, R.S.O. 1980, c. 22, section 15.

37. Hazardous Products Act, R.S.C. 1970, c. H-3, as amended, subsection 10(1).

38. Environmental Contaminants Act, S.C. 1974-75, c. 72, sections 10, 10.2, and 10.3, as amended by S.C. 1985, cl 26, section 40.

39. Canada Water Act, R.S.C. 1970 (1st Supp.), c. 5, sections 23 - 25, as amended by S.C. 1985, cl 26, subsection 34(1).

40. Environmental Assessment Act, R.S.O. 1980, c. 140, section 22.

41. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, subsection 33(3), and sections 105, 127, and 128.

42. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, subsection 1-(1).

43. Fisheries Act, R.S.C. 1970, c. F-14, section 33.2, as amended by R.S.C. 1970 (1st Supp.), c.17, section 3(2); amended S.C. 1976-77, c. 35, sections 8 - 10; amended S.C. 1985, c.26, section 41.

44. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, sections 18,19,20 and 21, as amended by S.C. 1975-75-76, c. 86, section 6.

45. Plant Quarantine Act, R.S.C. 1970, c. P-13, as amended, section 6.

46. Plant Diseases Act, R.S.O. 1980, c. 380, section 13.

47. Animals for Research Act, R.S.O. 1980, c. 22, section 18.

48. Food and Drugs Act, R.S.C.1970, c. F-27, section 22, as amended by S.C. 1985, c. 26, subsection 12(1).

49. Pest Control Product Act, R.S.C. 1970, c. P-10, section 7, as amended by S.C. 1985, c. 26, subsections 21(1) and (2); Pest Control Products Regulations, C.R.C. 1978, Vol. XIII, c. 1253, section 52.

50. Pesticides Act, R.S.O. 1980, c. 376, as amended, sections 17 and 18.

51. Feeds Act, R.S.C. 1970, c. F-7, section 7, as amended by S.C. 1985, c. 26, subsections 9(1) and (2).

52. Fertilizers Act, R.S.C. 1970, c. F-9, sections 6 and 7, as amended by S.C. 1985, c. 26, section 10.

53. Seeds Act, R,S,C, 1970, c. S-7, sections 6 and 7, as amended by S.C. 1985, c. 26, subsections 26(1) and (2); amended S.C. 1985, c. 47, subsection 6(1).

54. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, sections 13 and 14, as amended by S.C. 1983-84, c. 40, section 73; amended S.C. 1985, c. 26, section 30.

55. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 80.

56. Ibid., subsection 127(3).

57. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, subsection 16(3).

58. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 17.

59. Ibid., section 20, as amended by S.C. 1980-81-82-83, c. 165, subsections 43(1) and (2).

60. Transportation of Dangerous Goods Regulations, S.O.R./ 85-77, subsection 7.16(1), as amended by S.O.R./ 85-609, section 78.

61. Ibid., subsections 7.16(2) and (3).

62. Fisheries Act, R.S.C. 1970, c. F-14, subsection 33.2(4), as amended by R.S.C. 1970 (1st Supp.), c. 17, subsection 3(2); amended S.C. 1976-77, c. 35, sections 8 - 10; amended S.C. 1985, c. 26, section 41.

63. Animal Disease and Protection Regulations, C.R.C. 1978, Vol. III, c. 296, section 135.1, as amended by S.O.R./ 79 - 839.

64. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, section 9, as amended by S.C. 1974-75-76, c. 86, section 6.

65. National Research Council Act, R.S.C. 1970, c. N-14, section 13, as amended by R.S.C. 1970,(2nd Supp.), c. 14, section 12.

67. Agricultural Research Institute of Ontario Act, R.S.O. 1980, c. 13, section 3.

68. Ibid., sections 9 and 10.

69. Environmental Assessment Act, R.S.O. 1980, c. 140, section 7.

70. Ibid., section 19.

71. Ibid., section 31.

72. Canada Water Act, R.S.C. 1970 (1st Supp.), c. 5, as amended, subsection 13(2).

73. P.C. 1984-2132, section 15.

74. Ibid., section 18.

75. Ibid., section 28.

76. Ibid., section 29.

77. Ibid., section 31.

78. Environmental Assessment and Review Process Guidelines Order, S.O.R./ 84-467, section 32.

79. Ibid., section 33.

80. Ibid., section 33.

81. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, section 20, as amended, by S.C. 1980-81-82-83, c. 165, subsections 43(1) and (2).

82. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 109.

83. Patent Act, R.S.C. 1970, c. P-4, as amended, section 27.

84. Tranportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 30.

85. Clean Air Act, S.C. 1970-71-72, c. 47, as amended, section 41.

86. Canada Water Act, R.S.C. 1970 (1st Supp.), c. 5, as amended, section 36.

87. Access to Information Act, S.C. 1980-81-82-83, c. 111, as amended.

88. Ibid., section 18.

89. Ibid., section 20.

90. Ibid., section 20.

91. Bill 34, An Act to Provide for Freedom of Information and Protection of Individual Privacy, second session, 333rd Legislature, Ontario, 1986.

92. Ibid., section 11.

93. Ibid., section 17.

94. Patent Act, R.S.C. 1970, c. P-4, as amended.

95. Ibid., section 10.

96. Ibid., section 27.

97. Department of National Health and Welfare Act, R.S.C. 1970, c. N-9, as amended, paragraph 5(g).

98. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, paragraph 3(f).

99. Canada Water Act, R.S.C. (1st Supp.), c. 5, as amended, section 27.

100. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, paragraphs 26(b) and (c).

101. National Research Council Act, R.S.C. 1970, c. N-14, paragraph 13(j).

102. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, subsection 7(1).

103. Pesticides Act, R.S.O. 1980, c. 376, as amended, paragraph 2(e).

104. Environmental Assessment Act, R.S.O. 1980, c. 140, paragraph 32(e).

105. Ibid., subsection 27(1).

106. Ibid., section 27.

107. Ibid., section 30.

108. Ibid., section 19.

109. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 130.

110. Ibid., section 130.

111. Ibid., section 106.

112. Environmental Assessment Act, R.S.O. 1980, c. 140, section 19.

113. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 23.

114. Hazardous Products Act, R.S.C. 1970, c. H-3, as amended, subsection 10(3).

115. Note: A trade secret is a plan or process, tool, mechanism or compound known only to its owner and those of his employees to whom it is necessary to confid it. The term "trade secret" means a secret formula or process not patented but known only to certain individuals using it in compounding some article of trade having a commercial value and does not denote the mere privacy with which an ordinary business is carried on. A trade secret may consist of any formula, device or compilation of information which is used in a business and which gives the owner an opportunity to obtain an advantage over a competitor who does not know how to use it. A trade secret is a property right and as soon as the secret is discovered, the discoverer has the full right of using it. A trade secret is a process of device for continuous use in the operation of the business. The subject matter of a trade secret must be secret,. Once a patent has issued, the secrecy has ceased and, therefore, no trade secret exists anymore. Yet, a trade secret need not be patentable to be a trade secret. From: Hughes and Woodley on Patents (Toronto: Butterworths)(Looseleaf), 83.

116. Patent Act, R.S.C. 1970, c. P-4, as amended, subsection 28(1).

117. Ibid., section 41(1).

118. Ibid., section 2.

119. Ibid., section 35.

120. Ibid., subsection 36(1).

121. Ibid., subsection 36(1).

122. Ibid., subsection 36(2).

123. Ibid., section 47.

124. Ibid, section 67; se also: Hughes and Woodley on Patents (Toronto: Butterworths) (looseleaf), 528.

125. Patent Act, R.S.C. 1970, c. P-4, as amended, subsection 67(3).

126. Ibid., section 68.

127. Ibid., paragraph 68(c).

128. Ibid., paragraph 68(d).

129. Ibid., section 19. Note: His decision is subject to the appeal of the Federal Court of Canada.

130. Jorge A. Goldstein, "From Pseudomonas to the Birds are Animals Patentable", (June 1983), 6 Recombinant DNA, 57-62, at 57 and 61.

131. Re Application of Abitibi Co., 62 C.P.R. (2d) 81 (PAB).

132. Ibid., at 89.

133. Ibid., at 90.

134. Re Application for Patent of Connaught Laboratories, 82 C.P.R. (2d) 32 (PAB).

135. Patent Act, R.S.C. 1970, c. P-4, as amended, subsection 41(1).

136. Dairy Foods Inc. v. Co-operative Agricole the Granby, [1976] 2 S.C.R. 651, at 664.

137. Laboratoire Pentagone Ltee v. Parke, Davis and Company, [1968] S.C.R. 307, at 311.

138. Willow Creek Laboratories Ltd. v. Commonwealth Scientific and Industrial Research Organization of Australia (1983), 4 C.P.R. (3d) 202, at 208; Hughes and Woodley on Patents, (Toronto: Butterworths) (looseleaf), 381 - 382.

139. Patent Act, R.S.C. 1970, c. P-4, as amended, subsections 41(3) and (4).

140. Ibid., subsection 41(8).

141. Eli Lilly and Co. v. S. and U. Chemicals Ltd. [1977] 1 S.C.R. 536; 26 C.P.R. (2d) 141; and Syntax Corp. v. Apotex Inc. (1984), 54 N.R. 309 (FCA).

142. Patent Act, R.S.C. 1970, c. P-4, as amended, subsection 41(16).

Chapter 5: Footnotes

1. A.M. Linden, Canadian Tort Law, 3rd ed. (Toronto: Butterworths, 1982), 84.

2. Palmer v. Nova Scotia Forest Industries (1983), 2 D.L.R. (4th) 397, at 491-2 (N.S.S.C.) applying The Queen v. Saskatchewan Wheat Pool, [1983] 143 D.L.R. (3d.) 9, at 24-25 (S.C.C.).

3. McGhee v. National Coal Board, [1972] 3 All E.R. 1008 (H.L.).

4. Rylands v. Fletcher,]1868] L.R. 3 (H.L.) 330.

5. Ibid., at 340.

6. Linden, supra. footnote 1, at 514.

7. Ibid., at 515.

8. Gersten v. Metropolitan Toronto, 43 D.L.R. (3d.) 504 (O.H.C.).

9. Linden, supra. footnote 6, at 527; Canadian Environmental Law (Toronto: Butterworths) (looseleaf), 3.2.

10. Linden, supra. footnote 6, at 537; Palmer et. al. v. Nova Scotia Forest Industries (1983), 2 D.L.R. (4th) 397 (N.S.S.C. - T.D.); at 492-493; Canadian Environmental Law, supra. footnote 9 at 3.1.

11. Palmer et. al. v. Nova Scotia Forest Industries, supra. footnote 10, at 493.

12. Linden, supra. footnote 6, at 533.

13. Canadian Environmental Law, supra. footnote 9, at 3.1.1.3.

14 P.S. Elder, "Environmental Protection Through the Common Law" (1973), 12 Western Ontario Law Review 107-171.

15. Canadian Environmental Law, supra. footnote 9 at 3.1.2.2.

16. P.S. Elder, supra. footnote 14, at 152.

17. Young v. Bankier Distillery Co., [1893] A.C. 691, at 698 (H.L.).

18. Canadian Environmental Law, supra. footnote 9, at 3.9.1. Note: These rights have been qualified by permit requirements under section 20 of the Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended.

19. P.S. Elder, supra. footnote 14 at 136.

20. Canadian Environmental Law, supra. footnote 9, at 3.9.1.

21. Ibid., at 3.9.3.

22. R.T. Franson, A.R. Lucas, Canadian Environmental Law, Volume 1 (Toronto, Butterworths, 1982) (looseleaf), 3.6.

23. Palmer et. al. v. Nova Scotia Forest Industries, supra. footnote 10, at 493.

24. P.S. Elder, supra. footnote 14 at 115.

25. Palmer et. al.v. Nova Scotia Forest Industries, supra. footnote 10, at 493.

26. P.S. Elder, supra. footnote 14, at 115.

27. Franson and Lucas, supra. footnote 22, at 3.8.1., 3.8.2.

28. Ibid., at 3.9.3.

29. Shelfer v. Electric Lighting Co. (1985) 1 Ch. 28 @ 322.3 (CA).

30. Franson and Lucas, supra. footnote 22, at 3.8.2.

31. Palmer et. al. v. Nova Scotia Forest Industries, supra. footnote 10, at 495-496.

32. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, subsection 87(2).

33. Ibid., subsection 87(3), but see also subsection 87(4).

34. Ibid., subsection 87(8).

35. Ibid., subsections 89(1) and (2).

36. Ibid., subsections 89(4) - (7); see also subsection (10) with regard to the impact on the rights of insurers..

37. Ibid., sections 99 and 103.

38. Ibid., section 91.

39. Ibid., section 98.

40. Pesticide Residue Compensation Act, R.S.C. 1970, c. P-11, as amended, section 3.

41. Ibid., subsection 3(2).

42. Ibid., section 5.

43. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 46.

44. Ibid., section 46.

45. Canada Water Act, R.S.C. 1970 (ist Supp.), c. 5, as amended, paragraph 7(1)(d).

47. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 44.

48. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, section 11, as amended by S.C. 1974-75-76, c. 86, section 8.

49. Ibid., section 19.

50. Ibid., sections 10 and 12, as amended, by S.C. 1980-81, sections 1 and 2.

51. Plant Quarantine Act, R.S.C. 1970, c. P-13, as amended, subsection 9(4).

52. Ibid., subsection 3(2).

53. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 81.

54. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, subsection 17(2).

55. Fisheries Act, R.S.C. 1970, c. F-14, subsection 33.2(5), as amended by R.S.C. 1970 (1st Supp.), c. 17, subsection 3(2); amended S.C. 1976-77, c. 35, sections 8-10; amended S.C. 1985, c. 26, section 41.

56. Environmental Assessment and Review Process Guidelines Order, S.O.R./84-467, section 14.

57. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, subsection 24(3).

58. Pesticides Act, R.S.O. 1980, c. 376, as amended, section 23.

59. Ibid., sections 20 and 21.

60. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 41.

61. Ibid., section 42.

62. Ibid., sections 41 and 43.

63. Fisheries Act, R.S.C. 1970, c. F-14, subsection 33(10), as amended by R.S.C. 1970 (1st Supp.), c. 17, subsection 3(2); amended S.C. 1983-84, c. 40, subsection 29(3).

64. Ibid., subsection 33 (10.1).

65. Ibid., subsection 33(10.2).

66. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 87.

67. Ibid., section 82.

68. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, subsection 18(1).

69. Ibid., subsection 18(2).

70. Nuclear Liability Act, R.S.C. 1970, c. 29 (1st Supp.), as amended, subsection 15(1).

71. Ibid., subsection 20(1).

72. Ibid., section 32.

73. Pesticides Act, R.S.O. 1980, c. 376, as amended, section 16.

74. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 140.

75. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, subsection 17(5).

76. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, section 34.

77. Pesticides Act, R.S.O. 1980, c. 376, as amended, section 9; R.R.O. 1980, Regulation 751, as amended, section 19.

78. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, subsection 19(1).

79. Ibid., subsection 19(2).

80. Seeds Regulations, C.R.C. 1978, c. 1400, sections 34 and 35.

Chapter 6: Footnotes

1. Canada, Medical Research Council of Canada, Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells (Ottawa: Department of Supply and Services, December, 1980).

2. United States, National Institute of Health, Department of Health and Human Services, Guidelines for Research Involving Recombinant DNA Molecules, 51 Federal Register 16957-16985.

3. Environmental Contaminants Act, S,C, 1974-75, c. 72, sections 10, 10.1, 10.2, and 10.3, as amended by S.C. 1985, c. 26, section 40; Clean Air Act, S.C. 1970-71-72, c. 47, section 28, as amended by S.C. 1985, c. 26, subsections 37(1) and (2); Canada Water Act, R.S.C. 1970 (1st Supp.), c. 5, sections 24 and 25, as amended by S.C. 1985, c. 26, subsections 34(1) and (2); Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 14; Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, section 10; Environmental Protection Act, R.S.O. 1980, c. 141, subsection 127(1), and sections 128 and 129, as amended by S.O. 1983, c. 52, subsections 20(1) and (2).

4. Environmental Contaminants Act, S.C. 1974-75, c. 72, as amended, subsection 3(1).

5. Ibid., subsection 4(1).

6. Ibid., paragraph 4(1)(c).

7. Transporation of Dangerous Goods Act, S.C. 1980-81-82-83, c.36, as amended, section 23.

8. Ibid., section 17.

9. Environmental Protection Act, R,S,O, 1980, c. 141, as amended, section 126.

10. Ibid., subsection 127(3).

11. Environmental Assessment Act, R.S.O. 1980, c. 140, section 26.

12. Environmental Contaminants Act, S,C, 1974-75, c. 72, as amended, section 11; Canada Water Act, R.S.C. 1970 (1st Supp.), c. 5, as amended, sections 20 and 21; Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 15.

13. Fisheries Act, R.S.C. 1970, c.F-14, subsection 33.2(4), as amended by R,S,C, 1970 (1rst Supp.), c. 17, subsection 3(2); amended S.C. 1976-77, c. 35, sections 8-10, amended S,C, 1985, c. 26, section 41; Migratory Birds Convention Act, R.S.C. 1970, c.M-12, section 11, as amended by S.C. 1985, c. 26, section 45; Animal Disease and Protection Act, R.S.C. 1970

c. A-13, section 18, as amended by S.C. 1974-75-76, c. 86, section 14; Plant Quarantine Act, R.S.C. 1970, c.P-13, section 6, as amended by S.C. 1985, c. 26, subsections 23(1) and (2); Artificial Insemination of Livestock Act, R.S.O. 1980, c. 29, section 4; Plant Diseases Act, R.S.O. 1980, c. 380, section 13; Weed Control Act, R,S,O, 1980, c. 530, section 10.

14. Fisheries Act, supra. footnote 13, subsection 33.1(1).

15. Ibid., subsection 33.2(4).

16. Animal Disease and Protection Regulations, C.R.C. 1978, vol. III, c. 296, section 121, as amended by S.O.R./80-428, section 8.

17. Ibid., subsection 128(2).

18. Ibid., section 135.1, as amended by S.O.R./79-839, section 32.

19. Ibid., section 116, as amended by S.O.R./78-69, section 35; amended S.O.R./78-205, section 5; amended S.O.R./79-295, section 18; and section 119, as amended by S.O.R./79-295, section 19.

20. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, section 9, as amended by S.C. 1974-75-76, c. 86, section 6.

21. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c.1273, subsection 4(2).

22. Ibid., section 20.

23. Animals for Research Act, R.S.O. 1980, c. 22, section 15.

24. Ibid., sections 2 and 4.

25. Fisheries Act, R.S.C. 1970, c.F-14, section 55, as amended by S.C. 1976-77, c. 35, subsection 17(1) and (2); amended S.C. 1985, c. 26, subsections 109(1) and (2).

26. Migratory Birds Convention Act, R.S.C. 1970, c.M-12, as amended, section 7.

27. Animal Disease and Protection Act, R,S,C, 1970, c.A-13, as amended, section 19.

28. Plant Quarantine Act, R.S.C. 1970, c.P-13, as amended, section 9.

29. Hazardous Products Act, R.S.C. 1970, c.H-3, as amended, section 5; Food and Drugs Act, R.S.C. 1970, c.F-27, section 22, as amended by S.C. 1985, c. 26, subsections 12(1) and (2). Feeds Act, R.S.C. 1970, c.F-7, as amended, section 7; Fertilizers Act, R.S.C. 1970, C.F-9, section 6, as amended by S.C. 1985, c.26, section 10; Seeds Act, R.S.C. 1970, c.S-7, section 6, as amended by S.C. 1985, c. 26, section 26.

30. Hazardous Products Act, R.S.C. 1970, c.H-3, as amended, section 10.

31. Pest Control Products Regulations, C.R.C. 1978, vol. XIII, c. 1253, sections 7-11.

32. Ibid., section 26, as amended by S.O.R./85-686, section 1.

33. Ibid., section 57.

34. Pesticides Act, R.S.O. 1980, c. 376, as amended, section 5, 6, and 28.

35. Ibid., subsection 17(4).

36. Feeds Act, R.S.C. 1970, c.F-7, as amended, paragraph 5(a); Feeds Regulations, S.O.R./85-593, as amended, section 6 and 8.

37. Fertilizers Act, R.S.C. 1970, c.F-9, as amended, section 4; Fertilizer Regulations, C,R,C, 1978, Vol. VI, c. 666, section 5, as amended by S.O.R./79-365, section 5; amended S.O.R./85-558, section 4; amended S.O.R./85-688, section 1.

38. Seeds Regulations, C.R.C. 1978, Vol. XV, c. 1400, section 33, as amended by S.O.R./86-429.

39. Hazardous Products Act, R.S.C. 1970, C.H-3, as amended, paragraph 5(1)(d); Food and Drugs Act, R.S.C. 1970, c.F-27, section 22, as amended by S.C. 1985, c. 26, section 12; Pest Control Products Act, R.S.C. 1970, c.P-10, as amended, section 9; Feeds Act, R.S.C. 1970, c.F-7, as amended, section 8; Fertilizers Act, R,S,C, 1970, c.F-9, as amended, section 7; Seeds Act, R.S.C. 1970, c.S-7, section 7, as amended by S.C. 1985, c. 47, subsections 6 (1) and (2).

40. Animal Disease and Protection Act, R.S.C. 1970, c.A-13, as amended, subsection 12(3).

41. Environmental Protection Act, R.S.O. 1980, c. 141, as amended, sections 9-11. N.B. This type of approval is not so much a permit to engage in a commercial or research activity, but rather a permit to engage in an otherwise prohibited activity.

42. Ibid., section 27.

43. Ontario Water Resources Act, R.S.O. 1980, c. 361, as amended, section 24.

44. Animal Disease and Protection Act, R.S.C. 1970, c.A-13, section 5; Animal Disease and Protection Regulations, C.R.C. 1978, Vol. III, c. 296, subsection 160(3), as amended by S.O.R./79-839, subsection 34(2).

45. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c. 1273, section 8.

46. Ibid., section 10.

47. Plant Diseases Act, R.S.O. 1980, c. 380, subsections 5(1) and 6(1).

48. Animals for Research Act, R.S.O. 1980, c.22, subsections 2(4) and 3(1).

49. Ibid., subsections 3(4) and section 6.

50. Ibid., subsections 4(1)and(3), subsections 5(2) and (4), and subsection 6(1).

51. Pest Control Products Regulations, C.R.C. 1978, Vol. XIII, c. 1253, sections 19-25; Pest Control Products Act, R.S.C. 1970, c.P-10, as amended, paragraph 5(d).

52. Pesticides Act, R.S.O. 1980, c. 376, as amended, subsection 11(2).

53. Ibid., subsection 11(3).

54. Ibid., section 12.

55. Feeds Act, R.S.C. 1970, C.F-7, as amended, paragraph 5(c); Feeds Regulations, S.O.R./83-593, as amended, sections 11-13.

56. Fertilizers Regulations, C.R.C. 1978, Vol. VI, c. 666, section 8, as amended by S.O.R./79-365, section 7, amended S.O.R./85-558, section 5.

57. Seeds Regulations, C.R.C. 1978, Vol. XV, c. 1400, sections 33 and 34, as amended by S.O.R./86-429.

58. Ibid., subsection 35(2).

59. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, subsection 15(3); Environmental Contaminants Act, S.C. 1974-75, c. 72, as amended, subsection 11(3) and (4). See section 12 for extension; Canada Water Act, R.S.C. 1970, (1st Supp), c.5, as amended, sections 20 and 21; Clean Air Act, S,C, 1970-71-72, c. 47, as amended, section 24; Fisheries Act, R.S.C. 1970, c.F-14, section 58, as amended by S.C. 1976-77, c. 35, subsections 17(1) and (2); amended S.C. 1985, c. 26, subsections 109(1) and (2); Migratory Birds Convention Act, R.S.C. 1970, c. M-12, as amended, implicit in section 7; Plant Quarantine Act, R.S.C. 1970, c.P-13, as amended, subsection 9(2); Hazardous Products Act, R.S.C. 1970, c.P-10, as amended, subsection 5(6) concerning storage, no limits on the provision, application for restoration is provided for under section 6; Food and Drugs Act, R.S.C. 1970, c. F-27, section 22, as amended by S.C. 1985, c. 26, section 12. Pest Control Products Act, R.S.C. 1970, c.P-10

as amended, subsection 9(2); Feeds Act, R.S.C. 1970, c.F-7 as amended, subsection 8(2); Fertilizers Act, R,S,C, 1970, c.F-9, as amended, subsection 7(2); Seeds Act, R.S.C. 1970, c.S-7, subsection 7(2), as amended by S.C. 1985, c.47, subsections 6 ~~(1)~~ and (2).

60. Clean Air Act, S,C, 1970-71-72, c.47, section 16, as amended by S.C. 1980, c.45, section 2.

61. Ibid., section 17.

62. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c. 36, as amended, section 28.

63. Environmental Protection Act, R.S.O. 1980, c.141, as amended, sections 7 and 117.

64. Ibid., sections 6 and 113, as amended by S.O. 1983, c152, subsections 15(1) and (2).

65. Ibid., section 16.

66. Ibid., section 17.

67. Ibid., section 42.

68. Ibid., section 85.

69. Ibid., section 149, as amended by S.O. 1985, c.52, subsection 25(1).

70. Fisheries Act, R.S.C. 1970, c.F-14, subsection 33(14), as amended by S.C. 1976-77, c.35, subsection 7(4).

71. Ibid., subsection 33.1(2), as amended by R.S.C. 1970 (1st Supp.) c.17, subsection 3(2); amended S.C. 1976-77, c.35, sections 8-10; amended S.C. 1985, c.26, section 41.

72. Animal Disease and Protection Act, R.S.C. 1970, c.A-13, as amended, section 21.

73. Animal Disease and Protection Regulations, C.R.C. 1978, Vol. III, c.296, section 104.

74. Plant Quarantine Regulations, C.R.C. 1978, Vol. XIV, c.1273, section 22.

75. Plant Diseases Act, R.S.O. 1980, c. 380, subsection 14(1).

76. Ibid., subsection 14(2).

77. Animals for Research Act, R.S.O. 1980, c.22, subsection 17(4).

78. Weed Control Act, R,S,O. 1980, c.530, section 11.

79. Pesticides Act, R.S.O. 1980, c.376, as amended, section 23.

80. Ibid., section 21.

81. Ibid., section 20.

82. Environmental Protection Act, R.S.O. 1980, c.141, as amended, section 82.

83. Ibid., subsection 87(2).

84. Ibid., subsection 87(5).

85. Ibid., subsections 88(1),(4) and (5).

86. Fisheries Act, R.S.C. 1970, c.F-14, subsection 33.2(6), as amended by R.S.C. 1970 (1st Supp.), subsection 3(2): amended S.C. 1976-77, c.35, section 8-10; amended S.C. 1985, c.26, section 41.

87. Animal Disease and Protection Act, R.S.C. 1970, c.A-13, as amended, section 21.

88. Weed Control Act, R.S.O. 1980, c.530, as amended, section 13.

89. Ibid., section 14.

90. Pesticides Act, R.S.O. 1980, c.376, as amended, section 32.

91. Clean Air Act, S.C. 1970-71-72, c.47, as amended, section 33.

92. Environmental Contaminants Act, S.C. 1974-75, c.72, as amended, section 8.

93. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c.36, as amended, subsection 6(1).

94. Environmental Assessment Act, R.S.O. 1980, c. 140, section 39.

95. Environmental Protection Act, R.S.O. 1980, c.141, as amended, section 146.

96. Ibid., section 147.

97. Bill 112, An Act respecting the Enforcement of Statutes related to the Environment, second session, 33rd Legislature, Ontario, 1986, subsection 11(3).

98. Fisheries Act, R.S.C. 1970, c.F-14, paragraph 33(5)(b), as amended by S.C. 1983-84, c.40, subsection 29(3).

99. Animal Disease and Protection Act, R.S.C. 1970, c.A-13, as amended, paragraph 48(1)(b).

100. Animals for Research Act, R.S.O. 1980, c.22, section 21.

101. Seeds Act, R.S.C. 1970, c.S-7, section 9, as amended by S.C. 1985, c.47, section 7.

102. Pesticides Act, R.S.O. 1980, c.376, section 34.

103. Bill 112, supra. footnote 97.

104. Fertilizers Act, R.S.C. 1970, c.F-9, as amended, section 10.

105. Feeds Act, R.S.C. 1970, c.F-7, section 10, as amended by S.C. 1974-75-76, c. 94, section 3.

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

107. Environmental Protection Act, R.S.O. 1980, c.141, as amended, sections 146 and 147.

108. Environmental Assessment Act, R.S.O. 1980, c.140, section 39.

109. Ontario Water Resources Act, R.S.O. 1980, c.361, as amended, subsections 16(1) and 17(2).

110. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c.36, as amended, subsection 6(1).

111. Dangerous Goods Transportation Act, S.O. 1981, c.69, subsection 4(1).

112. Weed Control Act, R.S.O. 1980, c.530, subsection 21(1).

113. Plant Diseases Act, R.S.O. 1980, c.380, section 16.

114. Animals for Research Act, R.S.O. 1980, c.22, section 21.

115. Fisheries Act, R.S.C. 1970, c.F-14, as amended, section 33.

116. Pesticides Act, R,S,O, 1980, c.376, as amended, section 34.

117. Environmental Protection Act, R.S.O. 1980, c.141, as amended, sections 47, 72, 146, and 147.

118. Environmental Assessment Act, R.S.O. 1980, c.140, section 39.

119. Ontario Water Resources Act, R.S.O. 1980, c.361, as amended, section 16 and subsections 17(2), 18(2), 24(5), 32(2), 51(3), and 52(2).

120. Environmental Contaminants Act, S.C. 1974-75, c.72, as amended, subsection 8(7).

121. Clean Air Act, S.C. 1970-71-72, c.47, as amended, subsection 33(4).

122. Pesticides Act, R.S.O. 1980, c.376, as amended, section 34.

123. Environmental Protection Act, R.S.O. 1980, as amended, c.141, section 147.

124. Plant Diseases Act, R.S.O. 1980, c.380, section 16.

125. Animal Disease and Protection Act, R.S.C. 1970, c.A-13, as amended, paragraph 48(1)(b).

126. Feeds Act, R.S.C. 1970, c.F-7, section 10, as amended by S.C. 1974-75-76, c.94, section 3.

127. Bill 112, supra note 97, sections 4 and 12 and subsections 11(3) and 13(2).

128. Ibid., section 36.

129. Pesticides Act, R.S.O. 1980, c.376, as amended, sections 39 and 41.

130. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c.36, as amended, section 11.

131. Environmental Contaminants Act, S.C. 1974-75, c.72, as amended, section 14.

132. Feed Act, R.S.C. 1970, c.F07, subsection 10(1.1), as amended by S.C. 1974-75-76, c.94, section 3.

133. Bill 112, supra. footnote 97, sections 12, 36, and 41.

134. Ontario Water Resources Act, R.S.O. 1980, c.361, as amended, subsection 15(3).

135. Environmental Assessment Act, R.S.O. 1980, c.140, section 28.

136. Environmental Protection Act, R.S.O. 1980, c.141, as amended, section 144.

137. Clean Air Act, S.C. 1970-71-72, c.47, as amended, section 35.

138. Canada Water Act, R.S.C. 1970 (1st Supp.), c.5, as amended, section 30.

139. Fisheries Act, R.S.C. 1970, c.F-14, subsection 33(7), as amended by R.S.C. 1970 (1st Supp.), c.17, subsection 3(2); amended S.C. 1976-77, c.35, subsections 7(1)-(3); amended S.C. 1983-84, c.40, subsection 29(3).

140. Pesticides Act, R.S.O. 1980, c.376, as amended, section 37.

141. Fisheries Act, supra. footnote 142, subsection 33(9).

142. Clean Air Act, S.C. 1970-71-72, c.47, as amended, section 39.

143. Transportation of Dangerous Goods Act, S.C. 1980-81-82-83, c.36, as amended, subsection 15(5).

144. Environmental Contaminants Act, S.C. 1974-75, c.72, as amended, subsection 13(2).

145. Plant Quarantine Act, R.S.C. 1970, c.P-13, as amended, subsection 9(3).

146. Seeds Act, R.S.C. 1970, c.S-7, as amended, subsection 7(3).

147. Pest Control Products Act, R.S.C. 1970, c.P-10, as amended, subsection 9(3).

148. Fertilizers Act, R.S.C. 1970, c.F-9, as amended, subsection 7(3).

149. Feeds Act, R.S.C. 1970, c.F-7, as amended, subsection 8(3).

150. Animal Disease and Protection Act, R.S.C. 1970, c. A-13, as amended, section 44.

151. Migratory Birds Convention Act, R.S.C. 1970, c.M-12, as amended, section 7.

152. Hazardous Products Act, R.S.C. 1970, c. H-3, as amended, subsection 6(5).

Chapter 7: Footnotes

1. The Constitution Act, 1867 (UK), R.S.C. 1970, Appendix II, No. 5, section 91.

2. Ibid., paragraph 91(1A).

3. Peter W. Hogg, Contstitutional Law of Canada, 2nd ed. (Toronto: Carswell, 1985), 590 and 594.

4. Citizens Insurance Company v. Parsons (1881), 7 A.C. 96, at 113 (P.C.).

5. Hogg, supra. footnote 3, at 440.

6. Ibid., at 448-449; Stewart Ryan, "Comments on Biotechnology and the Environment", The Regulation of Biotechnology (Toronto: C.E.L.R.F.m October 9, 1984) 1-26.

7. Can. Federation of Agriculture v. A.-G. Que., [Margarine Reference], [1951] A.C. 179, at 194 (P.C.).

8. Ref re Farm Products Marketing Act, [1957] S.C.R. 198; Murphy v. C.P.R., [1958] S.C.R. 626; R. v. Klassen (1959), 20 D.L.R. (2d) 406 (Man. C.A.); Caloil v. A.-G. Can (no. 2), [1971] S.C.R. 543.

9. Re Agricultural Products Marketing Act, [1978] 2 S.C.R. 1198.

10. Hogg, supra. footnote 3, at 444 - 445.

11. Dominion Stores v. The Queen, [1980] 1 S.C.R. 844; Hogg, supra. footnote 3, at 446.

12. Labatt Breweries of Canada Ltd. v. A.-G. Can., [1980] 1 S.C.R. 914.

13. See Canadian Environmental Law (Toronto: Butterworths) (looseleaf), 2.4.5 with respect to establishing a federal resource inventory.

14. Gulf Trollers Association v. Minister of Fisheries and Oceans, [1984] 6 W.W.R. 220 (F.C.T.D.).

15. Hogg, supra. footnote 3, at 403-407.

16. Reference re Validity of Section 5(a) of the Dairy Industry Act, [1949] 1 D.L.R. 433 (S.C.C.), aff'd [1950] A.C. 179.

17. Ibid., at 472-473.

18. Ibid., at 473.

19. Standard Sausage Co. v. Lee, [1933] 4 D.L.R. 501, at 501 and 507 (B.C.C.A.).

20. Labatt Breweries of Canada Ltd. v. A.-G. of Canada, [1980] 1 S.C.R. 914, at 934.

21. R. v. Cosman's Furniture (1976), 73 D.L.R. (3d) 312 (Man. C.A.); R. v. Wetmore (1983) 2 D.L.R. (4th) 577 (S.C.C.).

22. Re Reciprocal Insurance Legislation, [1924] 1 D.L.R. 789, at 799 (P.C.).

23. Canadian Federation of Agriculture v. A.-G. Que., [Margarine Case], [1951] 1 A.C. 179, at 195 (P.C.).

24. Hogg, supra. footnote 3, at Chapter 17.

27. Citizens Insurance Company v. Parsons (1881), 7 A.C. 96 (P.C.).

28. Hogg, supra footnote 3, at 373 - 374.

29. Ibid., at 380 and 394.

30. A.-G. Ont. v. A.-G. Can. (Local Prohibition), [1896] A.C. 348, at 361 (P.C.).

31. A.-G. Can. v. A.G. Alberta (Insurance), [1916] 1 A.C. 588 (P.C.); A.-G. B.C. v. A.-G. Can. (National Products Marketing), [1937] A.C. 377 (P.C.).

32. A.-G. Ont. v. A.-G. Can. (Insurance), supra. footnote 31.

33. Hogg, supra. footnote 3, at 379.

34. Johanneson v. West St. Paul, [1952] 1 S.C.R. 292; Munro v. National Capital Commission, [1966] S.C.R. 663.

35. Labatt Breweries of Canada Ltd. v. A.-G. Can., [1980] 1 S.C.R. 914, at 945; Schneider v. R., [1982] 2 S.C.R. 112, at 112-131; The Queen v. Wetmore, [1983] 2 S.C.R. 284, at 296; Hogg, supra. footnote 3, at 379-380.

36. Re Anti-Inflation Act, [1976] 2 S.C.R. 373.

37. Fort Frances Pulp and Power Co. v. Man. Free Press Co., [1973] A.C. 695 (P.C.); Wartime Leasehold Regulations Reference, [1950] S.C.R. 124; Co-op. Committee on Japanese Canadians v. A.-G. Can., [1947] A.C. 87 (P.C.).

38. Re Anti-Inflation Act, supra. footnote 36.

39. Hogg, supra. footnote 3, at 391.

40. R. v. Hauser, [1979] 1 S.C.R. 984.

41. Hogg, supra. footnote 3, at 381-383.

42. Lovibond v. Grand Trunk Ry. Co., [1939] O.R. 305 (Ont. C.A.), quoted in Hogg, supra. footnote 3, at 391.

43. R. v. Hauser, supra. footnote 40.

44. Hogg, supra. footnote 3, at 383.

45. Atomic Energy Control Act, R.S.C. 1970, c.A-19, as amended.

46. Pronto Uranium Mines v. Ontario Labour Relations Board, [1956] O.R. 862, at 869 (Ont. H.C.).

47. Nuclear Liability Act, R.S.C. 1970 (1st Supp.), c.29, as amended.

48. The Constitution Act, supra. footnote 1, at subsection 91(29) and paragraph 92(10(c).

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

50. Re Canada Metal and the Queen (1982), 144 D.L.R. (3rd.) 124 (Man.Q.B.).

51. The Constitution Act, supra. footnote 1, at section 92.

52. Hogg, supra. footnote 3, at 613-615.

53. The Constitution Act, supra. footnote 1, at subsection 92(5).

54. Shannon v. Lower Mainland Dairy Products Bd., [1938] A.C. 708 (P.C.); Home Oil Distributors v. A.-G. B.C., [1940] S.C.R. 444.

55. Carnation Co.v. Quebec Agricultural Marketing Board, [1968] S.C.R. 238.

56. See, Ref. re Farm Products Marketing Act, [1957] S.C.R. 198; Central Canada Potash Co. v. Government of Saskatchewan, [1979] 1 S.C.R. 42.

57. Citizens Insurance Co. v. Parsons, supra. footnote 4; A.-G. Can. v. A.-G. Alta. (Insurance), supra. footnote 31; Canadian Indemnity Co. v. A.-G. B.C. [1977] 2 S.C.R. 504; and Labatt Breweries of Canada Ltd. v. A.-G. Can., [1980] 1 S.C.R. 914, with respect to the food industry.

58. Subsection 92(13) also provides the province with jurisdiction over labour relations within the province. This would enable the province to establish safety procedures within the work place as has been done under the Occupational Health and Safety Act.

59. See section 7.2.1.1 of this chapter.

60. Hogg, supra. footnote 3, at 417-420.

61. Ibid., 456.

62. Ibid.

63. Schneider v. R., [1982] 2 S.C.R. 112.

64. Hogg, supra. footnote 3, at 405-406.

65. The Constitution Act, supra. footnote 1, at 6th Schedule.

66. A.-G. Sask. v. A.-G. Can (Sask. Farm Security), [1949] A.C. 110, at 123 (P.C.).

67. Can. Fed. of Agriculture v. A.-G. Que. [Margarine Reference], [1951] 1 A.C. 179 (P.C.)

68. Ibid., at 200.

69. Hogg, supra. footnote 3, at 574.

70. Ibid., at 267-268.

71. Ibid., at 268-269; The Queen v. Air Canada, [1980] 2 S.C.R. 303; Ref. re Offshore Mineral Rights B.C., [1967] S.C.R. 792; Ref. re Continental Shelf Offshore Newfoundland, [1984] 1 S.C.R. 86.

72. Royal Bank of Canada v. The King, [1913] A.C. 283 (P.C.); Credit Foncier Franco v. Ross, [1937] 3 D.L.R. 365 (Alta.S.C., App. Div.); Beauharmois Light, Heat and Power Co. v. Hydro Electric Power Commission, [1937] O.R. 796 (Ont. C.A.).

73. Ladore v. Bennett, [1939] A.C. 468 (P.C.); Re Upper Churchill Water Rights, [1984] 1 S.C.R. 294; Hogg, supra. footnote 3, at 271.

74. Interprov. Co-op. v. R., [1976] 1 S.C.R. 477.

75. Hodge v. The Queen (1883), 9 App. Cas. 117, at 130 (P.C.).

76. Hogg, supra. footnote 3, at 317.

77. Ibid., at 318.

78. A.-G. Nova Scotia v. A.-G. Can, (N.S. Interdelegation), [1951] S.C.R.31.

79. Ibid., at 34.

80. P.E.I. Potato Marketing Bd. v. Willis, [1952] 2 S.C.R. 392.

81. Re Agricultural Products Marketing Act, [1978] 2 S.C.R. 1198.

82. Ibid., at 1223.

83. Coughlin v. Ontario Highway Transport Bd. (1968), 68 D.L.R. (2d) 384, at 388 (S.C.C.).

84. Canada Health Act, S.C. 1983-84, c.6.

85. Ontario, Ministry of Government Services KWIC Index (Toronto: Queen's Printer, 1986).

86. Canada, Treasury Board, The Access Register (Ottawa: Canadian Government Publishing Centre, 1986).

87. Municipal Act, R.S.O. 1980, c.302, as amended.

88. Ibid., 104.

89. Morrison v. Kingston, [1937] 4 D.L.R. 740 (Ont.C.A.).

90. Ibid., at 743-744.

91. Ibid., at 744.

92. Municipal Act, R.S.O. 1980, c.302, as amended, subsection 210.2.

93. Ibid., paragraph 210.8(d).

94. Ibid., subsection 210.47.

95. Ibid., subsection 210.48.

96. Ibid., subsection 210.71.

97. Ibid., subsection 210.77.

98. Ibid., subsection 210.128.

100. Ibid., subsection 210.134.

101. A.-G. Can. v. City of Toronto (1892), 23 S.C.R. 514, at 521; Re Regional Municipality of Ottawa-Carleton (1974), 2 O.R. (2d) 297.

102. R. v. Morin (1965), 52 D.L.R. (2d) 644.

103. Re Attorney-General for Ontario and City of Mississauga (1981) 33 O.R. (2d) 395.

104. Ibid., at 402.

105. Ibid., at 407.

106. Ibid., at 415, Note that Re A.-G. Ont. and City of Mississauga has been distinguished by Minister of the Environment v. Township of Tilbury West (1984), 16 O.M.B.R. 486 (Ont.Div.Ct.).

107. OECD, Safety in Biotechnology, (press release, Paris, December 9, 1985), 1 - 56.

108. Letters Patent constituting the office of the Governor General of Canada, R.S.C. 1970, Appendix II, No. 35.

109. Francis v. The Queen, [1956] S.C.R. 618; Capital Cities Communications v. C.R.P.C, [1978] 2 S.C.R. 141, at 173.

110. A.-G. Ont. v. Scott, [1956] S.C.R. 137.

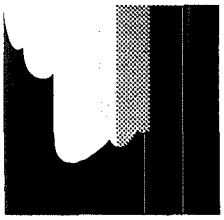
111. Hogg, supra footnote 3, at 254-255.

112. Ibid., at 255.

4. AGENDA AND PARTICIPANTS: OCTOBER 15, 1986, SEMINAR

Canadian Environmental Law Research Foundation

La Fondation canadienne de recherche du droit de l'environnement



BIOTECHNOLOGY POLICY SEMINAR

120 Adelaide Street West (between Bay and York) Suite 1000

9:00 - 4:30 October 15, 1986

AGENDA

1. The CELRF biotechnology policy program
2. Purpose of this seminar: discussion of issues not substance
3. Focus of discussion: modern genetic engineering, not traditional environmental releases, not contained applications
4. Summary presentation of the background paper - Irene Courage
5. Policy issues
   (a) Are there any issues which are not discussed in the background paper but which must be considered?
   (b) Are there any issues discussed in the background paper which can be ignored?
   (c) In what order of priority should these issues be addressed?
6. Consensus statement by participants on Canadian regulatory issues which most urgently require clarification.

243 Queen Street West, 4th Floor, Toronto, Ontario, M5V 1Z4 (416) 977-2410

PARTICIPANTS LIST - SEMINAR ON BIOTECHNOLOGY

October 15, 1986.

Mrs. B. Allen
Director of Policy
Association of Municipalities of Ontario
Toronto, Ontario

Mr. Martin Boddington
Biotechnology Centre
Commercial Chemicals Branch - DOE
Hull, Quebec

Mr. Terry Burrel
Victor and Burrel
Toronto, Ontario

Mr. Dirk Buth
Policy Advisor,
Ontario Ministry of Agriculture
Toronto, Ontario

Dr. Penny Chan
Research Officer
Advisory Council on Occupation Health and Safety
Toronto, Ontario

Ms. Irene Courage
Canadian Environmental Law Research Foundation
Toronto, Ontario

Mr. Jack Elliott
Crop Protection Institute of Canada
Willowdale, Ontario

Mr. D. Paul Emond
Associate Professor
Osgoode Hall Law School,
York University
Downsview, Ontario

Mr. John Evans
President, Allelix
Mississauga, Ontario

Dr. Clare Franklin
Chief, Environmental and Occupational Toxicology Division
Environmental Health Directorate
Health and Welfare Canada
Ottawa, Ontario

Mr. Joe Gilhooly
Consultant
Law Reform Commission of Canada
Ottawa, Ontario

Dr. Bernard Glick
University of Waterloo
Waterloo, Ontario

Ms. Sheri Glover
Research Management Office
Corporate Policy and Planning
Ministry of the Environment
Toronto, Ontario

Dr. Neil Gray
Corporate Biotechnology Advisor
C-I-L Inc.
Mississauga, Ontario

Ms. Doreen Henley
Environment Canada
Conservation and Protection
Service
Hull, Quebec

Mr. Goff Jenkins
Ontario Ministry of the Environment
Toronto, Ontario

Ms Sally Lerner
Associate Professor
Department of Man/
Environment
University of Waterloo
Waterloo, Ontario

Mr. Don Lush
Beak Analytical Services Ltd.
Mississauga, Ontario

Mr. Doug Macdonald
Canadian Environmental
Law Research Foundation
Toronto, Ontario

Mr. Terry McIntyre
Biotechnology Centre
Commercial Chemicals Branch
Environment Canada
Hull, Quebec

Mr. Simon Miles
President
Conservation Council
of Ontario
Toronto, Ontario

Mr. Paul Muldoon
Canadian Environmental Law
Research Foundation
Toronto, Ontario

Ms. Jane Pagel
Ontario Ministry of the
Environment
Toronto, Ontario

Dr. Jack Pasternak
Department of Biology
University of Waterloo
Waterloo, Ontario

Dr. Ann E. Robinson
Assistant Deputy Minister
Occupational Health and
Safety Division
Toronto, Ontario

Dr. Francis Rolleston
Medical Research Council of
Canada
Ottawa, Ontario

Dr. David Shindler
Senior Analyst - Biotechnology
Strategic Technologies Branch
Ministry of State, Science
and Technology Canada
Ottawa, Ontario

Ms. Yvonne Skof
Canadian Environmental Law
Research Foundation
Toronto, Ontario

Ms. Marcia Valiante
Canadian Environmental Law
Research Foundation
Toronto, Ontario

Ms. Toby Vigod
Canadian Environmental Law
Association
Toronto, Ontario

Dr. Martin Walmsley
Science Advisor and Energy
Coordinator
Toronto, Ontario

Mrs. Ivy Wile
Ontario Ministry of the
Environment
Toronto, Ontario

Mr. Jack Donnan
Ministry of the Environment
Toronto, Ontario

Mr. Mike Allen
Allelix
Mississauga, Ontario