APPENDIX 3

REGULATION OF GENE TECHNOLOGY – INTERNATIONAL COMPARISONS

- European Community
- United Kingdom
- Germany
- New Zealand
- Japan
- South Africa
- United States of America
- Canada

Document provided by the IOGTR

Regulation of Gene Technology in the

EUROPEAN COMMUNITY

SUMMARY

- The EC has issued a number of directives that relate to different uses with GMOs and GM products.
- In relation to the use of GMOs, there are three relevant directives:
  - contained use of GM micro-organisms;
  - deliberate release of GMOs into the environment and placing on the market; and
  - protection of workers from the risks of exposure to biological agents.
- In relation to GM products, there are also a number of relevant directives:
  - additives in feeding stuffs;
  - medicinal products; and
  - novel food.

Contained work with GMOs	
Responsible agency	• The Council of the European Communities.
Legislation	• Council Directive 90/219/EEC for contained use of genetically modified micro-organisms.
Intentional releases of GMOs in the environment	
Responsible agency	• The Council of the European Communities.
Legislation	• Council Directive 90/220/EEC regulates the deliberate release of GM microorganisms into the environment.
Coverage of the legislation	• The deliberate release of GMOs into the environment.

Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• Member states must ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise form the deliberate release or placing on the market of GMOs. • Member states shall designate a competent authority responsible for carrying out the requirements of the Directive. • A person must submit notification about the proposed release including a technical dossier with all of the information annexed to the Directive and an evaluation of the impacts. • The competent authority must examine the application for compliance with the directive and evaluate the risks posed by the release – this must be a science based consideration. • The competent authority may consult on any aspect of the proposed deliberate release. • A notification may only proceed with the release having received written consent and in conformity with any conditions required in the consent. • The competent authority shall send to the commission the results of the decision and the Commission shall forward summaries to other Member States.
Consideration of ethical issues	• The Directive does not make any reference to the need for ethical matters to be considered.
Public consultation on applications	• The Directive provides that the competent authority may consult on any application in relation to a deliberate release. There is not, however, any express or mandatory requirement for public consultation.
Conditions that may be applied	• The Directive provides that competent authorities may grant approvals subject to conditions.
Monitoring, surveillance and enforcement powers	• The Directive provides that Member States shall ensure that the competent authority organises inspections and other control measures as appropriate to ensure compliance with the Directive.
Penalties	• The Directive does not include any penalties as it is up to individual Members States as to how they implement the Directive (through legislation) and the penalties imposed.

Liability for contamination	• The EC directive does not deal explicitly with liability, including liability for contamination. • To ascertain liability, the general law in each jurisdiction would need to be applied. However, the EC has published a White Paper on Environmental Liability which is relevant.
Policy and Governance issues	
Expert Committees	• Not applicable
Research	• Not applicable
Other	
The precautionary principle	• The Directive does not explicitly reference the precautionary principle
Cost recovery	• Not applicable
Moratorium	• Not applicable
Other	• Amendments to the Directive have recently been proposed. The EC is yet to vote on the amendments.

REGULATION OF GENE TECHNOLOGY IN THE

UNITED KINGDOM

<table>
<tr><td colspan="2">SUMMARY

• The UK has implemented EC Directive 90/110/EC through Part VI of the Environment Protection Act 1990 and the issuance of the following regulations:
- Genetically Modified Organisms (Contained Use) Regulations 1992, as amended in 1996 and 1998;
- Genetically Modified Organisms (Deliberate Release) Regulations 1992 (SI 1992/3280); and
- Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304).
• There appears to be no statutory requirements for an interface between the regulation of GMOs and GM products.</td></tr>
<tr><td colspan="2">Contained work with GMOs</td></tr>
<tr><td>Responsible Agency</td><td>• The Health and Safety Executive (HSE). The HSE shapes and implements policy for the Health and Safety Commission, whose members are appointed by the Secretary of State for the Environment.</td></tr>
<tr><td>Legislation</td><td>• Genetically Modified Organisms (Contained Use) Regulations 1992, as amended in 1996 and 1998.

• Contained use is defined as any operation in which organisms are genetically modified or in which GMOs are cultured, stored, used, transported, destroyed or disposed of and where physical barriers (possibly combined with chemical and/or biological barriers) are used to limit their contact with the general population and the environment. General release includes field trials for research purposes, and commercial releases of GMOs.

• The Contained Use Regulations require persons who intend to carry out any act in which organisms are genetically modified, or intend to culture, store or use GMOs to:
(a) carry out (and keep records of) risk assessments beforehand, where specified; and
(b) notify the Health and Safety Executive of their proposals and;
(c) for certain activities, to obtain written consent.</td></tr>
</table>

Intentional releases of GMOs in the environment	
Responsible agency	• The Department of the Environment, Transport and the Regions (DETR) for consent for marketing or release of a GMO.
Legislation	• Part VI of Environment Protection Act 1990: Genetically Modified Organisms (Deliberate Release) Regulations 1992 (SI 1992/3280) and the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304). • The regulations implement EC Directive 90/110/EC.
Coverage of legislation	• The culturing storage, use, transport, destruction, disposal, release (field trials for research purposes and commercial releases) into the environment or marketing of GMOs. GMO is defined as an organism that has been altered by genetic modification.
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• The Deliberate Release Regulations requires that everyone who intends to release GMOs to the environment, or to sell products consisting of or containing GMOs, must first obtain a consent from the Department of the Environment. • Application must be made to the Department of the Environment. • Application must include a risk assessment prepared by the applicant. • The Department audits the application to ensure that the risk to human health and the environment has been minimised. • The Department seeks the advice of expert committees. Various advisory committees have been set up to examine the risk assessment and management procedures set out in applications and advise whether the work/release should proceed or work procedures amended. For example: - higher risk contained use applications are reviewed by the Advisory Committee on Genetic Modification; and - general release applications are reviewed by the Advisory Committee on Releases to the Environment (ACRE). ACRE carries out an assessment of the application and advises on the risks posed to human health and the environment, whether a consent should be granted and whether any risk management of the release should be required as a condition of consent. Once the assessment of the application is complete, the final decision rests with the Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food. Release may only take place with the consent of both the Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food.

Consideration of ethical issues	• Ethics issues are not directly considered in relation to each application, however, ethicists have been placed on advisory committees.
Public consultation on applications	• There appear to be no statutory requirements for public consultation.
Conditions that may be applied	• Conditions can be placed on general releases. • Requirements for post-release monitoring and reporting can be imposed as a condition of release.
Monitoring, surveillance and enforcement powers	• Auditing of research and marketing releases is undertaken by specialist inspectors of the HSE on behalf of DETR, to ensure conditions of consent are complied with. Inspectors can take action where breaches are detected (including fines).
Penalties	• Information is not available at this time
Liability for contamination	• Liability for environmental damage is generally imposed by general statute, and examples include land contamination, waste disposal, and water pollution. However, there is no specific statute dealing with liability for contamination by GMOs, and plaintiffs must look to the common law or general statutes for remedies.
Policy and Governance issues	
Expert Committees	• Following a review on biotechnology regulation in 1999, the UK Government decided to establish two new bio-technology specific bodies in order to create a more strategic advisory structure. The Human Genetics Commission is to advise on gene technology and its impact on humans, and the Agriculture and Environment Biotechnology Commission is to advise on all other aspects of biotechnology except food.
Research	• DETR contracts out specific research projects investigating the risks associated with GMOs.
Other	
The precautionary principle	• There is no direct reference to the precautionary principle in the Regulations.
Cost recovery	• There is a level of cost recovery – further information is being sought on the precise level of cost recovery imposed.
Moratorium	• The UK Government initially entered into a voluntary agreement with industry that no GM crops will be grown commercially in the UK for at least 2 years. In the mean-time, farm-scale field trials will be conducted to assess the safety of GMOs. Until these tests demonstrate that the risk is minimal, no GMOs will be allowed to be released in the UK. In November 1999, companies agreed to wait until the end of a 3.3 million pound government-funded experiment to see if GM crops damage wildlife more than conventional crops before growing crops commercially. The trial ends in 2002, delaying the commercial growing of GM crops in Britain for another 3 years.

REGULATION OF GENE TECHNOLOGY IN
GERMANY

SUMMARY

- Research with GMOs and release of GMOs into the environment in Germany is regulated under one piece of legislation – the *Genetic Engineering Act.*
- There appears to be no statutory link (or one-stop shop) between legislation to regulate GMOs and GM products (such as GM therapeutics and agricultural and veterinary chemicals).
- Note: It was not possible to obtain a copy of the *Genetic Engineering Act* in English and as such all of the information contained in this report is based on summary information including that published on Biotrack Online by the relevant German authorities.

Contained work with GMOs and intentional releases of GMOs into the environment

Responsible agency	• Federal Ministry of Health (the Robert Koch-Institut - RKI) – for the licensing of and release of GMOs and the marketing of products containing them. • The Federal States (for contained work).
Legislation	• The Genetic Engineering Act.
Coverage of the legislation	• Recombinant micro-organisms, viruses, cells, plants, animals and plasmid vectors. • This Act regulates GMOs in closed systems (laboratory and production areas), field experiments with GMOs and the placing on the market of products containing GMOs. Reproductive medicine and the use of somatic-genetic therapeutic procedures in humans are not covered by the legislation.
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• Regulation is risk-based – the law divides work with rDNA into four safety levels (class one being the lowest level of risk), with activities considered to be of higher risk subject to more stringent requirements. For example: - commercial work in class one need only be notified to the authorities (no permissions needed); - academic research in all four classes need only be notified to the authorities (no permissions needed); and - commercial work in classes 2, 3 or 4 requires permission.

	• Applications for release of a GMO (including field trials) must be made to the RKI. • The RKI seeks advice from: - the Federal Environment Agency and Federal Biological Research Centre for Agriculture and Forestry and, in the case of releases of animals, the Federal Research Centre for Virus Diseases of Animals; - the Advisory Committee for Biological Safety; and - the competent authority of the State in which the GMO is proposed to be used. • The RKI makes decisions in agreement with: the Federal Environmental Agency (Federal Ministry of Environment); the Federal Biological Research Center for Agriculture and Forestry (Federal Ministry of Food, Agriculture and Forestry) and the Federal Research Center for Virus Diseases of Animals (in the case of GM vertebrates or GM micro-organisms that are applied to vertebrates). • In relation to contained uses of GMOs, the States are responsible for assessing applications under the legislation. The responsible authorities of the States seek advice from the Central Advisory Committee for Biological Safety and inform the RKI of their decisions.
Consideration of ethical issues	• On the basis of the information available, it does not appear that ethics are taken into account as part of the decision making process on individual applications.
Consultation on applications	• On the basis of the information available, it does not appear that there is any statutory requirement for public consultation on individual applications.
Conditions that may be applied	• A series of regulations have been issued under the Genetic Engineering Act specifying requirements, procedures and safety precautions to be observed. For example: - Regulations on Containment Levels and Safety Measures for Genetic Operations in Genetic Engineering Installations; - Regulations on the Advisory Committee for Biological Safety; - Regulations on the Keeping of Records for Genetic Operations; and - Regulations on Hearing Procedures and Regulations on Application and Notification Documents.
Monitoring, surveillance and enforcement powers	• There are significant monitoring and enforcement powers available under the legislation.
Penalties	• A maximum fine of $1,000,000 or a prison term of 3 years.

Liability for contamination	• The Act imposes a strict liability regime for any damage caused by the deliberate release of GMOs. • On the basis of secondary sources, it is understood that the legislation provides that the producer of a GMO is strictly liable for any damage caused by the release of the GMO. Liability is limited to DM 160 million (AUD 127 million).
Policy and Governance issues	
Expert Committees	• The **Central Advisory Committee for Biological Safety** (Zentrale Kommission für die Biologische Sicherheit - ZKBS) was established in 1978, in conjunction with the development of guidelines on the protection against hazards from in-vitro recombinant nucleic acids. After the Genetic Engineering Act came into force, the Central Advisory Committee for Biological Safety was constituted as an institution. The Committee consists of thirty scientific or technical experts and experts from other relevant fields (15 members and 15 deputy members) who work on an honorary basis. The members are either experts in the fields of microbiology, cell biology, virology, genetics, hygiene, ecology and technical safety which are, in most cases, familiar with the methods of genetic engineering or experts from trade unions, occupational safety, economy, research-promoting organizations and environmental protection. • The Committee undertakes safety evaluation of GMOs, and provides advice to the States and other institutions dealing with GMOs. This applies to experimental research in the laboratory, operations for production purposes in industrial fermentation facilities, and also the release and the placing on the market of GMOs. • Work of the Central Advisory Committee for Biological Safety is supported by its Secretariat at the Centre for Gene Technology at the RKI.
Research	• No information available at this time.
Other	
The precautionary principle	• No information available at this time.
Cost recovery	• No information available at this time.
Moratorium	• Chancellor Schroeder recently proposed a 3-year program to explore the possible environmental and health impacts of gene technology and to increase consumer trust in gene products Industry would be required to give an undertaking only to use genetically modified seed and plants and to cooperate with the scientific and government sector.

REGULATION OF GENE TECHNOLOGY IN
NEW ZEALAND

SUMMARY

- One piece of legislation covers research with GMOs and release of GMOs into the environment in New Zealand – the *Hazardous Substances and New Organisms Act 1996* (HSNO Act).
- There appears to be no statutory link (or one-stop shop) between legislation to regulate GMOs and GM products (such as GM therapeutics and agricultural and veterinary chemicals).

Contained work with GMOs and intentional releases of GMOs in the environment

Responsible agency	• Environmental Risk Management Authority (ERMA)
Legislation	• *Hazardous Substances and New Organisms Act* (HSNO Act)
Coverage of the legislation	• The legislation covers the importation, development, field testing and release from containment of new organisms. • A new organism includes any organism in which any of the genes or other genetic material: (a) Have been modified by *in vitro* techniques; or (b) are inherited, or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques. The term *in vitro* is not defined.
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• Any person importing or releasing a 'new organism' into the environment must apply to the ERMA for approval. Approval may be given if the new organism is not likely to cause: - any significant displacement of any native species within its natural habitat; - any significant deterioration of natural habitats; - any significant adverse effects on New Zealand's inherent genetic diversity; and - disease, become parasitic or become a vector for human, animal or plant disease. • In addition, the positive effects of the GMO must outweigh the adverse effects of the GMO.

	For release of GMOs into the environment
	• The HSNO Act describes a specific procedure which must be followed in relation to each application. When ERMA receives an application it must:
	- inform the Minister for the Environment and any government department or crown entity that is likely to express an interest in the application;
	- in relation to applications involving new organisms, inform the Department of Conservation and any regional council that is likely to express an interest;
	- if the application is to field test or release a GMO (ie if the GMO is not to be used in containment), publicly notify the application (in relation to an application for contained work, ERMA may publicly notify the application if it considers that there is likely to be significant public interest). The public notice invites people to make submissions on the application. All submissions must be received by the date specified in the public notice, and this date must be no longer than 30 working days after the public notification was advertised. ERMA may also call a hearing to consider the application and any submissions made;
	- Consider the application and any submissions made in accordance with documented assessment methodology;
	- Consider the following principles:
	  - safeguarding the life supporting capacity of air, water and ecosystems; and
	  - maintaining and enhancing the capacity of people and communities to provide for their own economic, social and cultural well being, and for the reasonable foreseeable needs of future generations;
	- consider:
	  - the sustainability of all flora and fauna;
	  - the intrinsic value of ecosystems;
	  - public health;
	  - the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga;
	  - economic and related values; and
	  - New Zealand's international obligations.
	
	For low risk contained work
	• The Act allows ERMA to delegate assessment decisions in these cases. For example, approval decisions may be delegated to approved biological safety committees attached to research institutions. The definition of "low risk" in this case is set out in regulations made under section 41.

Consideration of ethical issues	• No specific mention is made of ethical concerns, except in relation to Maori concerns. However, it is possible that ethical concerns could be addressed when weighing up the positive and adverse effects of an application, especially as section 5 provides that persons exercising functions under the Act should recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural wellbeing. However, harm (or adverse effects) would need to be established.
Public consultation on applications	• Refer to assessment process. ERMA must publicly consult on all applications for release into the environment for a period of no longer than 30 days. • ERMA may consult on applications for use of GMOs in contained settings if ERMA considers that there is likely to be significant public interest on the issue.
Protection of confidential commercial information	• Provides some protection for commercial in confidence information
Conditions that may be applied	• There is no provision for conditions to be imposed on general release approvals in relation to GMOs. • Persons with approvals to undertake contained GMO research and field trials can have monitoring and inspection controls placed on them. It is also an offence for a manufacturer, developer or importer of a GMO to knowingly fail to report any significant adverse effect of a GMO.
Monitoring, surveillance and enforcement powers	• Enforcement officers can be appointed under the Act to promote and monitor compliance with the provisions of the Act. • Enforcement officers have powers of entry for inspection without consent to monitor the conditions in a premises or to determine the nature of any organism in the premises. Officers have extensive seizure powers and powers to take samples, open containers, conduct examinations and inquiries, and to require the production of documents. Enforcement officers can issue compliance orders to require persons to cease, or prohibit persons from commencing, anything which will, or is likely to, contravene the Act.
Offences/Penalties	• One of the key offences under the Act is manufacturing or developing a GMO in contravention of the Act (maximum penalty of $500,000 or up to 3 months imprisonment and $50,000 for every day on which the offence continues). • Similar penalties for offences such as failing to comply with any controls in relation to an approval.

Liability for contamination	• The *HSNO Act* does not address the issue of liability for contamination by GMOs and therefore it would be necessary for plaintiffs to seek relief under common law. • Tort law in New Zealand operates in a similar fashion to Australian law. To establish the tort of negligence a plaintiff would need to show the existence of a duty of care, a breach of that duty, causation of damages, proximity, and damage.
Policy and Governance issues	
Expert Committees	• The Act does not establish any overarching expert scientific, community or ethics committees. The legislation does however acknowledge the roles of Institutional Biosafety Committees. The IBCs can be approved by ERMA and delegated authority to approve low risk containment work. • ERMA has appointed a non-statutory advisory committee, Nga Kaihautu Tikanga Taiao, to provide ERMA, on request, with information on Maori issues in relation to individual applications.
Research undertaken by Regulator	• It is not a statutory function of ERMA to conduct, or commission, research.
Other	
The precautionary principle	• Section 7 of the Act states that all persons exercising functions, powers and duties under this Act shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.
Cost recovery	• ERMA applies cost recovery and levies charges for services such as searching the register, submitting applications, auditing and conducting public hearings.
Moratorium	• On 17 April 2000, the Government announced a four-person Royal Commission headed by former Chief Justice, Sir Thomas Eichelbaum, to inquire into genetic modification. • The Royal Commission's chief objective is to inquire into and report on the strategic options available to enable New Zealand to address genetic modification now and in the future. It may also recommend any changes in the current legislative, regulatory, policy or institutional arrangements for addressing genetic modification technologies and products in New Zealand. • The Commission will have 12 months to report. • The Government also announced that a voluntary moratorium on all applications for the release of genetically modified organisms is to be negotiated between the government and relevant industry and research groups (with industry groups already expressing agreement with this approach). The moratorium will also apply to field testing of GMOs, but with some exemptions (to be determined on a case by case basis by the Minister for the Environment). The moratorium will be in force for the length of the Commission's inquiry.

REGULATION OF GENE TECHNOLOGY IN
JAPAN

SUMMARY

- Controls on gene technology are essentially voluntary and different aspects of gene technology are overseen by different portfolios:
- Ministry of Agriculture Forestry and Fisheries – oversee GMOs for use in agriculture;
- Science and Research Agency – oversees experimentation in all research facilities other than University research facilities;
- Monbusho (Ministry of Education, Sports and Culture) - oversees experimentation in University research facilities; and
- In relation to GM products, the Ministry for Health and Welfare approves GM products such as pharmaceuticals, medical treatments and foods.

For contained work with GMOs	
Responsible agency	• Science and Research Agency - for experimentation in all research facilities other than University research facilities. • Monbusho (Ministry of Education, Sports and Culture) - for experimentation in University research facilities.
Guidelines (no legislation)	• Voluntary guidelines: - "Guidelines for rDNA Experimentation" (for experimentation in facilities other than university facilities) and; - "Guidelines for rDNA Experimentation in University Research Facilities".
For intentional releases of GMOs in the environment	
Responsible agency	• Ministry of Agriculture, Forestry and Fisheries (MAFF).
Guidelines (no legislation)	• "Guidelines for application of recombinant DNA organisms in Agriculture, Forestry, Fisheries, the Food Industry and other related industries". • The system is based on administrative guidance with no underpinning legislation.
Coverage of the guidelines	• The release, production and use in agro-industries of rDNA organisms in both open systems (without specific measures of containment) and simulated model environments (e.g. experimental applications of rDNA in a

	restricted area).
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• Any person who wishes to utilize rDNA crop plants in agriculture must conduct safety assessments in accordance with the guidelines. • Before organisms can be applied to open systems or a simulated model environment, the developer may request the approval of the MAFF to confirm that the safety assessments satisfy the requirements of the Guidelines. Safety assessments undertaken by proponents are examined by scientific advisory committees underpinning MAFF. • The guidelines set out how safety is to be confirmed. For example the guidelines set out: - the way of conducting simulations (including requirements for facilities, experimental equipment, cultivation, storage, transport etc); - the information required for a safety evaluation of an organism (conducted by the proponent); and - the institution of management systems including appointment of a safety officer, an operations administrator, a safety operations manager and a safe operations committee. • When a safety assessment has been conducted in accordance with the guidelines, a person may request the Minister of Agriculture, Forestry and Fisheries to approve the safety criteria regarding safety assessment and procedures utilised to ensure compliance with the guidelines.
Consideration of ethical issues	• No reference to ethics in the guidelines.
Public consultation on applications	• Not required.
Protection of confidential commercial information	• Information not available.
Conditions that may be applied	• The guidelines set out the requirements for various releases (eg education, handling, reporting etc).
Monitoring, surveillance and enforcement powers	• The system is a voluntary one and as such there are no enforcement provisions.
Penalties	• No penalties as the system is a voluntary one.

Liability for contamination	• Plaintiffs must seek redress for contamination by GMOs under general law.
Policy and Governance issues	
Expert Committees	• Information not available at this time.
Research undertaken by the Regulator	• There is no statutory provision for research to be undertaken on risks posed by GMOs. • However, significant research budgets across various portfolios. For example in 1998 in the Ministry of International Trade and Industry alone, over AUD$100m was dedicated to biotechnology R&D, AUD$500,000 to bioindustry safety assurance measures, AUD$2.2m to research into conservation and biodiversity.
Other	
The precautionary principle	• No reference to the precautionary principle in the Guidelines.
Cost recovery	• Information not available – but as the system is based on voluntary compliance with guidelines it is unlikely that there is a cost recovery regime.
Moratorium	• No moratorium.

REGULATION OF GENE TECHNOLOGY IN
SOUTH AFRICA

<table>
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• One piece of legislation regulates the contained use of GMOs, trial releases of GMOs and general releases in South Africa.
• The relationship with GM product regulators is not clear.</td></tr>
<tr><td colspan="2">Contained work with GMOs and intentional releases of GMOs in the environment</td></tr>
<tr><td>Responsible agency</td><td>• The Minister’s delegate (the Registrar) on the advice of the Executive Council for GMOs</td></tr>
<tr><td>Legislation</td><td>• Genetically Modified Organisms Act 1997</td></tr>
<tr><td>Coverage of the legislation</td><td>• The Act covers GMOs, the development, production, release, use and application of GMOs (including viruses and bacteriophages) and the use of gene therapy (but not human gene therapy).
• A GMO is defined as an organism, the genes or genetic material of which have been modified in a way that does not occur naturally through mating or natural recombination or both. ‘Organism’ means a biological entity, cellular or non-cellular, capable of metabolism, replication, reproduction or of transferring genetic material and includes a microorganism.</td></tr>
<tr><td>Assessment process for intentional releases of a GMO into the environment
(field trials and general releases)</td><td>• Distinctions are drawn between ‘contained use’, ‘trial use’ and ‘general release’ of GMOs.
• A permit is required to use facilities for the development, production, use or application of GMOs, or to release such organisms into the environment.
• Permit applications must be submitted to the Registrar.
• The registrar seeks advice from the Executive Council on GMOs.
• The Council, through the Registrar, may request the applicant to submit a risk assessment and, where required, an assessment of the impact on the environment of the activity for which a permit is being sought.
• The Council, after consideration of the submitted assessments, authorises the Registrar to issue a permit.
• In coming to its decision, the Council must consult the Advisory committee (discussed below).</td></tr>
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Consideration of ethical issues	• Ethical issues are not addressed in the legislation.
Public consultation on applications	• There is no public consultation requirement in the legislation
Protection of confidential commercial information	• No person shall disclose information acquired by them in performance of duties under the Act, except in certain circumstances. • The Council will decide, after consultation with an applicant, which information will be kept confidential, but this cannot include descriptions of GMOs, the purpose of contained use or release, the location of use (although it is not clear what level of detail is necessary), methods and plans for monitoring of GMOs and for emergency measures, and the risk assessment. • However, the information can be withheld if it is in order to protect the intellectual property of the applicant.
Conditions that may be applied	• The Executive Council may approve permit applications subject to such terms and conditions as the Council may deem necessary.
Monitoring, surveillance and enforcement powers	• Under the Act, the Executive Council can require the Registrar to arrange for the inspection of facilities where activities with or release of GMOs are being undertaken, or the inspection of all activities which the Registrar deems necessary to ensure that the terms and conditions attached to a permit are being complied with. • Inspectors may conduct an investigation to determine whether the provision of the Act are being complied with. However, they can only do so on the authority of a warrant. • During working hours, inspectors may also, without a warrant, enter any place or facility registered in terms of the Act in order to open containers, examine GMO material and inspect activities and records in connection with GMOs (monitoring power). • The Registrar may also authorise inspectors to destroy GMOs where the registrar has ascertained or suspects on reasonable grounds that GMOs are being imported, used or produced contrary to the provisions of the Act or the conditions of a permit.
Penalties	• It is an offence under the Act to contravene or fail to comply with any condition, restriction, prohibition, reservation or directive imposed or issued in terms of the Act, or to obstruct and hinder an inspector, or to refuse or fail to furnish information or give an explanation or reply to the best of your ability. • Penalty for first conviction is a fine (no maximum limit prescribed) or maximum imprisonment period of 2 years. • Penalty for subsequent offences is a fine or maximum imprisonment of 4 years.

Liability for contamination	• Section 17 of the Act provides that the liability for damage caused by the use or release of a GMO shall be borne by the user concerned. Clarification of the impact of this provision is currently being sought.
Policy and Governance issues	
Expert Committees	• **Executive Council for Genetically Modified Organisms:** consists of no more than eight members appointed by the Minister. It is essentially a bureaucratic committee established under the legislation and comprising one member from the Departments of Agriculture, Arts, Culture, Science and Technology, Environmental Affairs and Tourism, Health, Labour, and Trade and Industry who has knowledge of the implications of GMOs for their respective Departments, and any 2 other persons. The Council advises the Minister on all aspects concerning the development, production, use, application and release of GMOs, and ensures that such activities are performed in accordance with the provisions of the Act • **National advisory body:** advises, on request or of its own accord, the Minister, Executive Council, other Ministries and appropriate bodies on matters concerning genetic modification of organisms. This includes advice on all aspects relating to the introduction of GMOs into the environment and the contained use of GMOs, and on proposals for specific activities or projects concerning the genetic modification of organisms and the import and export of GMOs, and advice on proposed guidelines. The Committee must also liaise through relevant Departments, with international groups and organisations concerned with biosafety. The Committee may invite written comments from knowledgeable persons on any aspect that is within the Committee's brief. The Committee is to consist of no more than 10 persons appointed by the Minister (on recommendation of the Council, and for a period not exceeding 5 years), with no more than eight being knowledgeable persons in those fields of science applicable to the development and release of GMOs, and two being from the public sector with a knowledge of ecological matters and GMOs.
Research	• No information available at this time.
Other	
The precautionary principle	• The Precautionary Principle is not referred to in the Act
Cost recovery	• There is provision in the Act for regulations to provide for application fees. No confirmation has been received at this stage regarding whether fees have been prescribed.
Moratorium	• No moratorium.

REGULATION OF GENE TECHNOLOGY IN THE UNITED STATES

SUMMARY

- Several pieces of legislation regulate GMOs:
  - *Federal Plant Pest Act – 7 USC 7B;*
  - *Federal Insecticide, Fungicide, and Rodenticide Act – 7 USC 136;*
  - *Federal Food, Drug and Cosmetic Act – 21 USC 9;*
  - *Toxic Substances Control Act – 15 USC 53.*
- The system requires permits to be issued by the relevant regulatory authority. Depending on the nature of the GMO, permits may be required from more than one authority. In general:

- the US Department of Agriculture Animal and Plant Health Inspection Service (APHIS) - has the broadest authority over transgenic plants and has responsibility for determining whether such a plant poses a threat directly or indirectly as a plant pest;
- the US Environmental Protection Agency (EPA) regulates microbial and plant pesticides, new uses of existing pesticides and novel microorganisms; and
- the US Food and Drug Administration (FDA) is responsible for ensuring the safety of all food (by enforcing tolerances in food set by EPA), feed, and human and veterinary drugs.

- *There is no statutory link between each of the regulators.*

Contained work with GMOs

Responsible Agency	• National Institute of Health (NIH).
Legislation	• There is no special regulatory system for ensuring the safe use of biotechnology in the laboratory or factory where the organism is not to be released into the environment (ie: contained use). Voluntary guidelines - the NIH's *Guidelines for Research Involving Recombinant DNA Molecules* - are implemented by most users of the technology.

Intentional releases of GMOs in the environment	
Responsible agency	• The US Department of Agriculture Animal and Plant Health Inspection Service (for plant pests, plants and veterinary biologics). • The U.S. Environmental Protection Agency (for microbial/plant pesticides, new uses of existing pesticides and novel micro-organisms).
Legislation	• *Federal Plant Pest Act*; and • *Federal Insecticide, Fungicide and Rodenticide Act* • *National Environment Protection Act*
Coverage of the legislation	• Field testing, moving, importing and commercial release of organisms and products altered or produced through genetic engineering which are plant pests or may become plant pests • 'Genetic engineering' is defined as the genetic modification of organisms by recombinant DNA techniques. There is no definition of 'recombinant DNA techniques'.
Assessment process for intentional release of a GMO into the environment (field trials and general releases)	• Developer submits data to the APHIS (notification to APHIS of an environmental release must be at least 120 days prior to release). • Data must demonstrate that the plant is safe to release and is not itself a plant pest or potential noxious weed. • The APHIS conducts an assessment in accordance with the *National Environmental Protection Act.* • APHIS has a two tiered level of risk – lower risk GMOs need only be notified to the agency, while other releases require a permit. • In assessing an application for a permit, the APHIS: - examines the results of any field trial (field trial results must be submitted to APHIS within 6 months of the termination of a field trial); - must be satisfied that the benefits of the proposal outweigh the costs; - may require the preparation of an environmental impact statement in addition to an environmental assessment; - must seek public comment on a proposal if a person has submitted to the APHIS a petition to seek a determination that a particular GMO should not be regulated under the legislation. APHIS then makes a decision to approve the petition in whole or in part, or to deny the petition; and - must consult Departments of Agriculture in the States where release is planned.

	• If the GMO is also a plant pesticide then EPA approval is also required under the *Federal Insecticide, Fungicide and Rodenticide Act* as pesticide is broadly defined to include plants modified by biotechnology to resist disease. The EPA may also treat micro-organisms as subject to the *Toxic Substances Control Act* • A "determination of non-regulated" status is issued by APHIS if the crop is not a plant pest allowing the crop to be released without restriction. EPA would also issue approval.
Consideration of ethical issues	• The only matter considered by APHIS is whether the plant is a plant pest or has the potential to be a plant pest. Ethics, trade and social issues are not taken into account.
Public consultation on applications	• The APHIS must only seek public comment on a proposal if a person has submitted to the APHIS a petition to seek a determination that a particular GMO should not be regulated under the legislation. APHIS then makes a decision to approve the petition in whole or in part, or to deny the petition.
Protection of confidential commercial information	• Each of the relevant pieces of legislation provide for the protection of confidential commercial information. • Proponents applying to APHIS for a permit must provide two copies of their application, one with confidential business information passages marked and the other with these passages removed.
Conditions that may be applied	• APHIS permits are subject to several conditions prescribed in the regulations, including: - Separation of the GMO from other organisms; - Treatment of material accompanying the GMO; - Compliance with measures prescribed by APHIS which are necessary to prevent the accidental or unauthorized release of the GMO; - the requirement that the GMO be subject to the application of remedial measures determined by APHIS to be necessary to prevent the spread of plant pests; - the maintenance of the GMO only in the areas prescribed in the permit; and - inspectors must be allowed access, during regular business hours, to places where the GMO is located, and to records relating to the introduction of the GMO. • In addition, the permit holder can be subject to any other conditions APHIS deems as necessary to prevent the dissemination and establishment of plant pests. Permit can be withdrawn if non-compliance with these conditions is identified.
Monitoring, surveillance and enforcement powers	• Once permission for the cultivation of a transgenic crop has been granted, progress is monitored. The system does not rely on significant enforcement powers as the regulatory system is based on 'permits, testing and tolerance setting'
Offences/Penalties	• Violations relating to plant pests can incur criminal or civil penalties. • Any person who violates the regulations, or who forges or counterfeits any permit can be punished criminally by

	a fine not exceeding $5000 or by imprisonment not exceeding 1 year, or both. Such violations may also be dealt with civilly with the maximum fine being $1000.
Liability for contamination	• There is no strict liability regime for recovery by third parties; third parties must rely on the common law or remedies available under general environment protection legislation.
Policy and Governance issues	
Committees	• Information about Committees is currently being clarified but there are no statutory committees that examine GMOs specifically.
Research	• Information about research is currently being clarified but there is no statutory requirements for the Regulator to undertake research on GMOs.
Other	
The precautionary principle	• The legislation does not reference the Precautionary Principle.
Cost recovery	• There is capacity for some cost recovery – For example, permit applications carry a charge but the services of inspectors during regular assigned hours and at usual places of duty are furnished without cost while overtime for inspectors does carry a cost.
Moratorium	• No moratorium.

REGULATION OF GENE TECHNOLOGY IN
CANADA

SUMMARY

- Canada does not have a single piece of legislation that regulates GMOs. Most of the legislation applicable to biotechnology addresses specific product categories, and pertains both to biological and non-biological processes and products.
- The main agencies involved in the regulation of GMOs are Agriculture Canada, Environment Canada and Health and Welfare Canada. The relevant legislation includes:
  - *Canadian Environment Protection Act 1999 (CEPA)* (covers those uses not covered by other legislation);
  - *Feeds Act* (feeds);
  - *Fertilisers Act* (supplements);
  - *Health of Animals Act* (veterinary biologics);
  - *Seeds Act* (plants with novel traits);
  - *Pest Control Products Act* (microbial pest control agents); and
  - *Food and Drugs Act* (drugs, cosmetics, medical devices, and novel foods).
- Environment Canada oversee all intentional releases of GMOs into the environment and as such this summary will focus on this.

Contained work with GMOs	
Type of regulation	• Contained research involving GMOs is not covered by the Environment Protection Act. • Laboratory research in Canada is covered by the US NIH's *Guidelines for Research Involving Recombinant DNA Molecules*.
Intentional releases of GMOs in the environment	
Responsible Agency	• Environment Canada.
Legislation	• Canadian Environment Protection Act 1999 (CEPA).

Coverage of the legislation	• Substances that are new (ie not on the list of Domestic Substances) cannot be manufactured or imported unless approval is granted from the Minister. • Substance is defined as any distinguishable kind of organic or inorganic matter, whether animate or inanimate, and includes any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformation in the environment. 'Living organism' is defined as a substance that is an animate product of biotechnology.
Assessment process for intentional releases of a GMO into the environment (field trials and general releases)	• The Minister must be notified if someone wishes to manufacture or import a new substance that is not on the Domestic Substances List (if it is on the list no approval is necessary). • Information relevant to the assessment must be provided to the Minister. • All proposals undergo a single 60-day public consultation period where interested parties may bring forward additional scientific evidence to support or refute the Minister's decision. • After taking into account any advice provided, the Minister must decide whether the substance is toxic or capable of becoming toxic. • If the Minister decides that the organism is not toxic or capable of becoming toxic, the Minister can place the organism on the Domestic Substance Register but cannot impose any conditions. • If the Minister decides that the organism is toxic or capable of becoming toxic, then the Minister can: (a) permit its manufacture or importation subject to any conditions the Minister may specify; or (b) can prohibit its import or manufacture. • The final decision of the Minister must be published.
Consideration of ethical issues	• In making a decision Ministers may only determine whether the substance is toxic or capable of becoming toxic. Ethics, trade, social and other issues may not be taken into account.
Public consultation on applications	• All proposals for release of a GMO into the environment undergo a single 60-day public consultation period where interested parties may bring forward additional scientific evidence to support or refute the Minister's decision.
Protection of confidential commercial information	• An applicant may request that information be treated as confidential. • The Minister must not disclose any information in respect of which a request for confidentiality has been made unless: - it is in the public interest; or - it is disclosed under an agreement between the Government of Canada and any other government of Canada or government of a foreign state etc and the agency agrees to keep the information confidential.
Conditions that may be applied	• Where the Minister suspects that a living organism is toxic or capable of being toxic, the Minister for the

	Environment may permit the manufacture or import of the living organisms subject to any conditions that the Minister may specify.
Monitoring, surveillance and enforcement powers	• Enforcement officers may be appointed under the CEPA. • Enforcement officers have the power to enter and inspect premises where a substance can be found, for the purposes of the Act. Officers have been given wide powers of inspection, including opening receptacles and packages, examining records, taking samples and conducting tests. CEPA also allows officers to act without warrants in emergencies. Officers may seize or detain anything which caused a contravention to occur, or which will provide evidence of the contravention, however they can only do so if it is required for evidence, analysis or it is in the public interest to do so. • Officers may also issue environmental protection compliance orders to owners and managers and persons contributing to contraventions which must be complied with (orders can include reporting requirements, and to cease operating).
Penalties	• A maximum fine of $1,000,000 or a prison term of 3 years exists (if convicted on indictment) for persons who contravene a provision of the Act or regulations, an order or direction under the Act or an obligation or a prohibition arising from the Act or regulations, or who knowingly provide false or misleading information. • For summary conviction it is $300,000 or 6 months. • If, in committing the offence, a person intentionally or recklessly causes a disaster that results in loss of the use of the environment, or shows wanton disregard for the lives or safety of other persons and thereby causes a risk of death or harm to another person, the maximum prison term increases to 5 years and there can be an unlimited fine imposed. • Each day the offence is committed is a separate offence. The CEPA also sets down criteria which the Court must look at when sentencing, including harm caused, the costs of any remedy actions, intention, and any property, benefit or advantage to the offender. • Despite the maximum amount of any fine under the legislation, a court may impose an additional fine equal to the court's estimation of the amount of property, benefit or advantage derived by the offender from their actions. Instead of convicting an offender, or in addition to other punishments, a court may make an order requiring the offender to do or refrain from doing certain action (eg: requiring the offender to take any action to remedy or avoid harm, prepare and implement a pollution prevention plan, carry out environmental effects monitoring, compensate the Minister, pay an amount to environmental, health or other groups or to scholarships for students enrolled in environmental studies, or publish the facts relating to the incident).

Liability for contamination	The CEPA provides for two types of action: (1) <u>Environmental Protection Actions.</u> Any Canadian citizen can apply for an investigation of an alleged offence in contravention of the legislation – this is called an "Environmental Protection Action" (EPA). An EPA can only be bought if: (a) the Ministers investigation was inadequate or non-existent; and (b) there was an alleged breach of the Act; and (c) the alleged breach is causing significant harm to the environment. An EPA may not be bought if the alleged conduct was: (a) taken to correct or mitigate harm or risk of harm to the environment or human plant or animal life; (b) taken to protect national security; or (c) was reasonable and consistent with public safety. Defences to an EPA include: (a) due diligence; (b) authorisation by another act of parliament; (c) an officially induced mistake of law; and (d) any other defences available under general law. In addition, an action may be dismissed if it is not in the public interest. The only relief that is available if an EPA is successful is an injunction (stopping the defendant from doing something or forcing them to do something) or an order to the parties to negotiate a plan to correct or mitigate the harm to the environment etc, costs of the action. There can be no award of damages in the event of a successful EPA. This action does not assist individuals effected by contamination to seek damages for loss suffered; rather it enables them to bring an action if there has been a breach of the Act, to stop the activity continuing. (2) <u>Common law actions</u> The Act explicitly reiterates the common law right for a third party who has suffered damage to go to court to seek damages for such loss. The action that may be brought (and the damages able to be recovered) will depend entirely on the application of ordinary principles of law (nuisance, negligence etc). The Canadian Environment Protection Act does not establish any statutory right to recover for loss or damage or any strict liability regime. At the time of preparing this document, no successful actions for contamination have been brought under common law in Canada.

Policy and Governance issues	
Committees	• **Canadian Biotechnology Advisory Committee (CBAC):** is a non-statutory committee established by the federal government to provide advice to a Coordinating Committee of federal ministers on broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. CBAC is made up of 21 members drawn from the scientific, business, general public, ethics and environmental communities. • The CEPA establishes a **National Advisory Committee** that can provide both technical and policy advice to the Minister on: - proposed regulations for toxic substances; - proposed regulations on environmental emergencies; - a co-operative coordinated approach to the management of toxic substances; and - any other matter or mutual interest. • This Committee looks at all environmental issues not just biotechnology.
Research	• The Minister for the Environment and Minister for Health must both undertake research and studies into environmental contamination arising from disturbances of ecosystems by human activity, and the role of substances in illnesses or health problems, respectively.
Other	
The precautionary principle	• The preamble to CEPA states that 'whereas the Government of Canada is committed to implementing the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental damage.
Cost recovery	• Fees are attached to notifications to CEPA. The Canadian Government may also recover all costs of, and incidental to, taking reasonable measures to prevent releases that endanger the environment and public safety, or to remedy any dangerous situation or reduce or mitigate any danger to the environment or to human life that results, or may result, from the release of a toxic substance in breach of conditions (although there is a 5 year limitation period).
Moratorium	• No moratorium.