APPENDIX 5

APPROVAL PROCESSES FOR THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED PLANTS INTO THE ENVIRONMENT

Attachment C

COMPARISON OF REGULATION IN RELATION TO THE APPROVAL PROCESS FOR THE INTENTIONAL RELEASE OF GENETICALLY MODIFIED PLANTS INTO THE ENVIRONMENT

	United States	**Canada**	**New Zealand**	**EU**	**United Kingdom**
Relevant legislation	Federal Plant Pest Act and Federal Insecticide, Fungicide and Rodenticide Act	Canadian Environmental Protection Act	The Hazardous Substances and New Organisms Act	Council Directive 90/220/EEC	Environment Protection Act 1990 Part VI, the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (SI 1992/3280) and the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (SI 1995/304).
Relevant Regulatory authority	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).	Environment Canada	Environmental Risk Management Authority (ERMA)	The Council of the European Communities Member states must designate a competent authority responsible for carrying out the requirements of the Directive.	The Department of the Environment, Transport and Regions
Coverage	Field testing, moving, importing and commercial release of organisms and products altered or produced	Manufacture or import of new substances (i.e. that are not on the list of Domestic Substances). Substances include living	Importation, development, field testing and release of new organisms. All GMOs are considered to be new	The deliberate release of GM micro-organisms into the environment	The culturing storage, use, transport, destruction, disposal, release (field trials for research purposes and commercial releases) into the environment or

	through genetic engineering which are plant pests or may become plant pests	organisms that are an animate product of biotechnology.	organisms.		marketing of GMOs.
Assessment process	Developer submits data to the USDA Animal and Plant Health Inspection Service Data must demonstrate that the plant is safe to release and is not itself a plant pest or potential noxious weed. The USDA conducts an assessment in accordance with the *National Environmental Protection Act.* 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	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. Assessment is undertaken by Environment Canada who may utilise external advice	Any person importing or releasing a 'new organism' into the environment must apply to the ERMA for approval. The organism is assessed according to whether it is likley 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. The positive effects of the	A person must submit notification about the proposed release including all of the information required by 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.	Application must be made to the Department of the Environment. Application must include a risk assessment prepared by the applicant. The Advisory Committee on Releases to the Environment (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.

	Substances Control Act		organism must outweigh the adverse effects of the organism and any inseparable organism.		
Approvals	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.	Minister decides whether the substance is toxic or capable of becoming toxic. If 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 organism is toxic or capable of becoming toxic, the Minister can permit its manufacture or importation subject to conditions or can prohibit its import or manufacture.	Approval for release can only be granted without conditions.	Consent to release may be granted with conditions The competent authority must send to the commission the results of the decision and the Commission must forward summaries to other Member States.	Release may only take place with the consent of the Secretary of State for the Environment and the Minister of Agriculture, Fisheries and Food. Consent may be subject to risk management conditions.

Enforcement	Once permission for the cultivation of their transgenic crops 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'.	The Minister can appoint enforcement officers to investigate alleged offences against the Act. The enforcement officers have broad powers including to search, seize etc.	Considerable powers of enforcement and inspection including search and seizure powers.	Member states shall ensure that the competently authority organises inspections and other control measures as appropriate to ensure compliance with the Directive.	Specialist inspectors may be appointed on behalf of DETR.