

<p>SUMMARY — continued</p> <ul style="list-style-type: none"> • The Economic Research Service (ERS) conducts research on the economic aspects of the use of genetically engineered organisms, including the rate of and reasons for adoption of biotechnology by farmers. • The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labelled and packaged including animals involved in biotechnology. • The National Agricultural Statistics Service (NASS), as the fact finder for agriculture, provides information on the adoption of biotechnology crops (specifically corn, cotton, and soybeans). 	
<p>Contained work with GMOs</p>	
Responsible agency	<ul style="list-style-type: none"> • National Institute of Health (NIH).
Legislation	<ul style="list-style-type: none"> • 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 (i.e. contained use). Voluntary guidelines — the NIH's Guidelines for Research Involving Recombinant DNA Molecules — are implemented by most users of the technology.
<p>Intentional releases of GMOs in the environment</p>	
Responsible agency	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Federal Plant Pest Act; Federal Insecticide, Fungicide and Rodenticide Act; National Environment Policy Act; Plant Protection Act; Federal Food, Drug and Cosmetic Act; Food Quality Protection Act; Endangered Species Act.

<p>Coverage of the legislation</p>	<ul style="list-style-type: none"> • 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. Under the Plant Protection Act, APHIS regulates plants that may pose such a risk. Organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering are called 'regulated articles'. • Intentional confined release into the environment of regulated articles require notification to the relevant authority under the relevant legislation. • 'Genetic engineering' is defined as the genetic modification of organisms by recombinant DNA techniques. There is no definition of 'recombinant DNA techniques'. • The Federal Food, Drug and Cosmetic Act, Food Quality Protection Act and Endangered Species Act are also considered by the EPA when evaluating the risks that biopesticides (including those that either are, or result from, GMOs or GM techniques) may pose to the environment or human health. • The Federal Food, Drug and Cosmetic Act governs the FDA in assessing the safety of foods/ feeds from novel plant varieties (including genetically engineered plants); the Food Quality Protection Act imposes standard tolerances for allowable levels of pesticides in food; whereas the Endangered Species Act ensures that any pesticides (including those derived from GMOs or techniques) do not pose a risk to endangered species.
<p>Assessment process for intentional release of a GMO into the environment (field trials)</p>	<ul style="list-style-type: none"> • The developer submits a notification to the APHIS (notification to APHIS of an environmental release must be at least 120 days prior to release, but this can be extended if an environmental impact statement is required in addition to an environmental risk assessment, and in the case that additional information is subsequently required, the 120 day period will start upon the receipt of the additional information). • Data must demonstrate that the plant is safe to release and is not itself a plant pest or potential noxious weed.

<p>Assessment process for intentional release of a GMO into the environment (field trials) (continued)</p>	<ul style="list-style-type: none"> • The APHIS conducts an assessment. APHIS has a two tiered level of risk — lower risk GMOs (for example, plants that are altered with common agronomic traits such as pest or herbicide resistance) need only be notified to the agency, while other releases that pose an elevated risk (such as plants that produce pharmaceutical or industrial compounds and GMOs other than plants) require a permit. • There are six criteria that a plant has to meet before being considered by APHIS for notification: it is either corn, cotton, potato, soybean, tobacco, tomato or any additional plant species that BRS has determined may be safely introduced; the introduced genetic material is stably integrated; the function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease; the introduced genetic material does not (1) cause the production of an infectious entity, (2) encode substances that are known or likely to be toxic to non-target organisms known or likely to feed or live on the plant species, or (3) encode products intended for pharmaceutical use; the introduced genetic sequences derived from plant viruses do not pose a significant risk of the creation of any new plant virus; the plant has not been modified to contain certain genetic material derived from an animal or human pathogen. • Notifications are required to contain: specific information on the genetic trait introduced, including its origins; how the expression of the trait differs to the non-modified counterpart; information on proposed procedures and safeguards to prevent escape, dissemination and contamination; proposed method of final disposition. • While there are no size restrictions on field trials, APHIS officials take into consideration the size of the field trial when they determine the significance of the impact on the environment. • APHIS forwards the notifications on to relevant state agencies for comment within five days of receipt of the notification. State authorities can comment at their discretion, but comments from state authorities are not required for the progression of the assessment process.
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<p>Assessment process for intentional release of a GMO into the environment (field trials) (continued)</p>	<ul style="list-style-type: none"> • In assessing an application for a permit, the APHIS: 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; field trial results must be submitted to APHIS within 6 months of the termination of a field trial; . 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 (plant-incorporated protectant; PIP) 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. • In the case of PIPs or GM micro-organisms for pesticide use, the EPA does an evaluation to assess the risk: to human health and the environment; to non-target organisms; for potential gene flow.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • 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. • However, under the National Environmental Policy Act the Council on Environmental Quality takes into account the scientific, economic, social, aesthetic, and cultural needs and interests of the nation.

<p>Public consultation on applications</p>	<ul style="list-style-type: none"> • The APHIS only seeks 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. A period of 60 days is given for public consultations on the petition. • In conducting risk assessments, the data used by the EPA undergoes extensive public comment and peer review by scientific experts.
<p>Protection of confidential commercial information</p>	<ul style="list-style-type: none"> • 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.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • 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 unauthorised 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. • Unusual occurrences (to those specified in the application, such as higher rates of morbidity or mortality) and suspected accidental or unauthorised release of a regulated article must be notified to APHIS within the timeframes specified in the regulations.

<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • 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’. • Any regulated article introduced not in compliance with the requirements shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests. (Under the Federal Plant Pest Act, the Secretary of Agriculture is authorised to order prompt removal from the United States or to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of, in such manner as the Secretary deems appropriate, certain regulated articles which are believed to be infested or infected by or contain a plant pest.) • Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test site and any records necessary to evaluate compliance with the provisions. • Field test reports must be submitted within 12 months of the start of a field trial and then every 12 months through the duration of a field trial.
<p>Penalties</p>	<ul style="list-style-type: none"> • 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 US\$5000 or by imprisonment not exceeding 1 year, or both. Such violations may also be dealt with civilly with the maximum fine being US\$1000. However, depending on the nature of the violation criminal penalties can range up to a fine of US\$50,000 or a year in jail or both. • Failure to adhere to BRS regulations, permit conditions and requirements can result in serious penalties, including fines up to US\$500,000 per adjudication.

<p>Assessment process for unrestricted intentional release of a GMO into the environment</p>	<ul style="list-style-type: none"> • When an applicant has field tested a transgenic crop and accumulated enough data to show that this crop is free from any risk (compared to its unmodified counterpart), the applicant can petition APHIS that the transgenic crop should no longer be considered a regulated article (and thus free from any monitoring or restriction). Depending on the product and its intended purpose, reviews by the FDA (if intended for food use) and the EPA may also be required. • The petition is required to include data such as: a description of the biology of the plant before it was genetically engineered; extensive data from tests designed to detect differences between the GE plant and the original plant; characterisation of genetic changes; plant pest-risk characteristics; disease and pest susceptibilities; expression of gene products; new enzymes; effects on non-target organisms; changes in plant metabolism; weediness of the GE plant; impact on the weediness of relatives of the GE plant; impacts on agricultural practices or on other agricultural products; field-test reports for all trials conducted under permit or notification procedures involving the GE plant. • Completed petitions are published on the Federal Register and public comment can be accepted for 60 days from the date of the publication on the Federal Register.
<p>Assessment process for unrestricted intentional release of a GMO into the environment (continued)</p>	<ul style="list-style-type: none"> • The administrator will, within 180 days of receiving a completed petition, either: approve the petition in whole or in part; or deny the petition. • APHIS announces its decision on the Federal Register but he decision does not become final for another 30 days during which time APHIS may alter its decision should additional information become available.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • Under the National Environmental Policy Act the Council on Environmental Quality shall have account of scientific, economic, social, aesthetic, and cultural needs and interests of the nation.

Public consultation on applications	<ul style="list-style-type: none"> Completed petitions are open to public comment for a period of 60 days.
Protection of confidential commercial information	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> After a petition for deregulation is granted, there are no restrictions on the GMO for which the petition was approved.
Monitoring, surveillance and enforcement powers	<ul style="list-style-type: none"> None
Penalties	<ul style="list-style-type: none"> No penalties apply, as once a regulated item has been petitioned and becomes a deregulated item, it can be freely moved and planted without BRS regulatory control and therefore is no longer subject to the APHIS or BRS regulations.
<p>Placing on the market GMOs intended for food or feed</p>	
Assessment procedure for placing on the market GMOs intended for food or feed	<ul style="list-style-type: none"> Applicants should consult with the USDA before submitting a notification for placing foods derived from novel plant varieties (including those genetically engineered) on the market. The consultation is a two-step process. Initial consultations should start early in the development of the novel food or feed and are designed to resolve potential safety, nutritional, and regulatory issues. Such issues may include, but are not limited to, significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food or feed of an unapproved food/feed additive.

<p>Assessment procedure for placing on the market GMOs intended for food or feed (continued)</p>	<ul style="list-style-type: none"> • Final consultations involve the submission to the USFDA of a summary of the safety and nutritional assessment that has been conducted and, if necessary, a meeting of the applicant's scientists with FDA scientists to discuss the data and results contained in the submission. • The safety and nutritional assessment should contain information on: the particulars of the GE food/feed and plant derivative; the intended use of the product (including if it is intended for feed use); the particulars of the introduced genetic material; the purpose or intended technical effect of the modification; the modification's expected effect on the composition or characteristic properties of the food or feed; the identity and function of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product in the bioengineered crop or derived food/feed; allergenicity and toxicity; the basis for concluding that foods containing the expression products can be safely consumed; comparing the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties.
	<ul style="list-style-type: none"> • During the consultation process, the USFDA does not conduct a comprehensive scientific review of data generated by the developer. Instead, the USFDA considers, based on agency scientists' evaluation of the available information, whether any unresolved issues exist regarding the food derived from the new plant variety that would necessitate legal action by the agency if the product were introduced into commerce. • During the early consultation process, an applicant may submit an early food safety evaluation. The evaluation is intended to be done prior to the stage of development where the new proteins might inadvertently enter the food supply. The information requirements are similar to the above safety and nutritional assessment. A guidance document on the evaluation process states that the evaluation is to be acknowledged within 15 days of receipt by the USFDA and a response to the applicant is given within 120 days of receipt (which is considered short). A response may: extend the review time for another 120 days; request further information; conclude that there is no safety risk and that it satisfies the requirements of the Federal Food, Drug and Cosmetic Act.

<p>Assessment procedure for placing on the market GMOs intended for food or feed (continued)</p>	<ul style="list-style-type: none"> Once the consultation process has been completed, the applicant should then submit a pre-market notification. This notification should be submitted to the USFDA at least 120 days before the planned commercialisation date. The USFDA has drafted a document on the proposed rules for pre-market notification. In this document, it is proposed that plants modified to contain a pesticide substance come under the USEPA's jurisdiction via the Federal Insecticide, Fungicide and Rodenticide Act. Food derived from plants whose genetic transformation has already been assessed by the USFDA will be exempt from the proposed regulation. Proposed information to be included in the notification includes: the particulars of the genetic modification; the identity and function of these substances; the level of these substances in the bioengineered food; dietary exposure to these substances; the potential that the food will be an allergen; and a discussion of other safety issues that may be associated with these substances. Information, data and results from earlier evaluations (such as in the early food safety evaluation) may be submitted as part of the notification.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> No mention of ethical issues was found in the relevant guidelines or legislation.
<p>Public consultation on applications</p>	<ul style="list-style-type: none"> The application for notification will become public when the USFDA files it, but there was no specific mention of public consultation during the consultative or notification process.
<p>Protection of confidential commercial information</p>	<ul style="list-style-type: none"> The USFDA treats submitted information in accordance with the United States Freedom of Information Act, which contains provisions to exempt information related to 'trade secret' and commercial information. The proposed guidelines allow the applicant to submit two versions of the notification: one has the information deleted that the applicant considers exempt from public disclosure. The application for notification will become public when the USFDA files it. However, there is provision for USFDA to evaluate applicant claims for confidentiality according to the exemption criteria under the proposed notification guidelines.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> Not applicable. Once the GMO intended for food/feed use is found to be safe for human and animal consumption, it can be entered into the market without restriction.

<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • If a bioengineered food/feed is commercialised without prior approval, the USFDA has the power under the Federal Food, Drug and Cosmetic Act to conduct inspections and investigations, collect samples and perform analyses, as well as to engage in publicity and public education. • The Federal Food, Drug and Cosmetic Act states that all food additives receive USFDA approval before commercialisation. Foods/feeds derived from or containing genetically engineered plants (or products thereof) would be considered as food/feed additives by the proposed notification guidelines.
<p>Penalties</p>	<ul style="list-style-type: none"> • The Federal Food, Drug and Cosmetic Act contains provisions for penalties (criminal and civil), including seizure of the product or proceeds thereof. • Penalties exist for contravening specified sections of the Federal Food, Drug and Cosmetic Act. These may include: imprisonment for not more than one year or fined not more than \$1000, or both; imprisonment for not more than three years or fined not more than \$10,000 or both if a person commits another violation while a conviction of him is pending, or the person commits a violation with the intent to defraud or mislead; a civil money penalty of not more than \$50,000 for an individual and \$250,000 for any other person, but not exceeding \$500,000 for all violations in a single proceeding for any person who introduces or delivers, for commercialisation, an article of food/feed with unapproved food/ feed additives (this would include additives derived from or that are genetically engineered plants).
<p>Policy and Governance issues</p>	
<p>Liability for contamination</p>	<ul style="list-style-type: none"> • 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.

Expert committees	<ul style="list-style-type: none"> Information about committees is currently being clarified but there are no statutory committees that examine GMOs specifically.
Research	<ul style="list-style-type: none"> The National Environmental Policy Act states that the President appoints members of the Council on Environmental Quality and that part of its role is to research and collect data on the environment and ecosystems and monitor emerging trends, and to have account of scientific, economic, social, aesthetic, and cultural needs and interests of the nation. There are government agencies that are able to research various aspects of GMOs. For example: <ul style="list-style-type: none"> The Agricultural Research Service (ARS) is USDA's in house science agency. The agency's biotechnology research includes introducing new traits and improving existing traits in livestock, crops, and micro-organisms; safeguarding the environment; and assessing and enhancing the safety of biotechnology products. The Cooperative State Research, Education, and Extension Service (CSREES) administers the Biotechnology Risk Assessment Research Grants Program (BRAG) which supports the development of science-based information regarding the safety of introducing into the environment genetically-modified plants, animals, and micro-organisms.
Other	
Liability for contamination	<ul style="list-style-type: none"> No reference to a strict liability regime or no-fault scheme was found.
The precautionary principle	<ul style="list-style-type: none"> The legislation does not reference the precautionary principle.

<p>Cost recovery</p>	<ul style="list-style-type: none"> • 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, whereas overtime for inspectors does carry a cost.
<p>Moratorium</p>	<ul style="list-style-type: none"> • No moratorium.
<p>Other</p>	<p>The pre-market notification guidelines were made in 2001 and at the time of compiling this information, it did not appear that the guidelines had been enacted into legislation.</p>

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 and Agri-Food 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 from both plant and animal sources); Plant Protection Act (importation of unapproved plants with novel traits).
- The release of novel substances (this includes GMOs) into the environment is governed by the above-mentioned Acts. There are also directives that provide guidelines for applying for the release of novel substances into the environment. In addition, there are directives for the release of novel plant and animal organisms for both confined and unconfined releases. The Canadian Food Inspection Agency, under the Agriculture and Agri-Food Portfolio, is the main agency responsible for the release of novel substance into the environment and is divided into Sections. One of the sections, the Plant Biosafety Office has carriage of assessing applications for the confined and unconfined release of novel substances (plant) into the environment. If the novel plants could be used as a feed (for livestock or laboratory animals), then the Feed Section of the Canadian Food Inspection Agency assesses the application for release. Applications for release of novel substances that could be used as food for humans are assessed by the Department of Health. Where necessary, approval for release of a novel substance may require approval from more than one authority/agency.

Contained work with GMOs	
Responsible agency	<ul style="list-style-type: none"> • Canadian Medical Research Council. • Guidelines of the United States of America's National Institute of Health (NIH).
Legislation	<ul style="list-style-type: none"> • Contained research involving GMOs is not covered by CEPA. • Laboratory research in Canada is covered by the US NIH's Guidelines for Research Involving Recombinant DNA Molecules. All scientists working with GMOs must adhere to the guidelines established by the Medical Research Council, as well as codes of practice established by their own institution.
Intentional releases of GMOs in the environment	
Responsible agency	<ul style="list-style-type: none"> • Environment Canada.
Legislation	<ul style="list-style-type: none"> • CEPA. • Directive 2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada. • Seeds Act and amendments. • Directive 95-03: Guidelines for the Assessment of Novel Feeds: Plant Sources. • Feeds Act and amendments. • Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits.
Coverage of the legislation	<ul style="list-style-type: none"> • Substances that are new (i.e. not on the list of Domestic Substances) cannot be manufactured or imported unless approval is granted from the Minister.

<p>Coverage of the legislation (continued)</p>	<ul style="list-style-type: none"> • 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. • The Canadian Food Inspection Agency’s Plant Biosafety Office is responsible for regulating the intentional introduction into the environment in Canada of plants with novel traits (PNTs). The procedures and guidelines for applying to release PNTs into the environment are outlined in Directive 2000–07. • The Feeds Act governs the use of feed within Canada and ensures that it is safe to use. Novel feeds, including those with a novel trait require a notification of intended release to be approved by the relevant minister before they can be released. The Act and its Regulations refer to the release of novel feeds, including those with novel traits, for research purposes only. • Directive 95-03 applies to novel feeds from plants, or parts or products thereof, that have not been previously used as livestock feed in Canada, and/or have a novel trait. The application requires information on the novel trait, techniques used, the breeding history, nutritional data, toxicology data and dietary exposure, allergy data, animal/livestock trial data, an environmental risk assessment, detection methods. The guidelines appear as though they can be used for applying for release of novel feed (plant source) for eventual commercialisation.
<p>Assessment process for confined intentional releases of a GMO into the environment (field trials), including for experiments on GMOs intended for feed</p>	<ul style="list-style-type: none"> • 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.

<p>Assessment process for confined intentional releases of a GMO into the environment (field trials), including experiments on GMOs intended for feed (continued)</p>	<ul style="list-style-type: none"> • 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. • Under Directive 2000–07 (which provides guidelines to the applicant on how to apply for the confined release of a PNT) the application for a confined research field trial: puts the onus on the applicant to ensure that the PNT will not negatively affect any other trial or non-PNT crops; requires the applicant to consider contingency plans in the event of accidental release of material or inadvertent breakdown of reproductive isolation. If the applicant intends on feeding the material from the confined research field trial to livestock for research purposes, the application is given to the Feed Section of the Canadian Food Inspection Agency. The applications are sent to provincial governments where the trials will occur, who then have 30 days to provide comment. The comments are considered by the Plant Biosafety Office when making a decision on the application. To ensure that the trials are for research purposes only: each trial site must be no larger than 1 Ha; there are no more than 10 trial sites per submission, per province; trial site locations are no larger than 5 Ha cumulative per submission, per province. The applicant is responsible for reproductive isolation or other isolation methods (such as bags and nets over flowering plant parts, harvest of plant before flowering, removal of flowers before pollen maturity).
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<p>Assessment process for confined intentional releases of a GMO into the environment (field trials), including for experiments on GMOs intended for feed (continued)</p>	<ul style="list-style-type: none"> • Under the Feeds Act and its amendments and regulations a written notification of the proposed release must be made to the Minister, including information such as: the particulars of the release; confinement and monitoring procedures; methods for safe disposal; contingency plans to mitigate adverse effects on humans and the environment in the event of accidental release; the particulars of the novel trait; any results from data or research done to identify risks to the environment or human health. The Minister for Agriculture and Agri-foods can then either authorise or refuse to authorise the release of the novel feed and shall consider the magnitude of exposure of the release, the effects on the environment and whether the novel feed is toxic. The application shall be accompanied with evidence (such as scientific research) to permit an assessment or evaluation of the safety and efficacy of the feed in respect of livestock and its potential effect on humans and on the environment. • Directive 95-03 provides the guidelines for the completion of an application for the unconfined release of a novel feed from plant sources. Applications should contain: sufficient data about the novel trait; information about the modification history; characterisation of the DNA inserted, if any; nutritional data, allergenicity data; toxicology data; dietary exposure; laboratory animal/livestock feeding trial data; environmental risk assessment; method of detection. A decision is then made on the information provided in the application. • The application procedure and information requirements for releasing a novel feed of an animal origin is similar to that for a novel feed from a plant source and is outlined in the Feeds Act and regulations. • There is a draft document that outlines the application requirements for notification of a release of biotechnology-derived livestock animals. This draft appears to apply to confined and unconfined releases. Information requirements include information: on the organism; on the organism's manufacture or import; on the introduction of the organism; on the environmental fate of the organism; on the organism's environmental effects; on potential adverse effects on human health; on test data that assists in the identification of hazards to human health and environment. If the organism is confined, information on the possible mechanisms for escape and possible dispersal is also required.
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<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • In making a decision Ministers may only determine whether the substance is toxic or capable of becoming toxic. No specific mention of ethics or trade is made. However, the Minister may take into account factors such as, but not limited to social, economic and technical matters when determining preventative or control action in relation to a substance or in plans for virtual elimination of the substance.
<p>Public consultation on applications</p>	<ul style="list-style-type: none"> • 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.
<p>Protection of confidential commercial information</p>	<ul style="list-style-type: none"> • 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.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • 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.
<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • 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.

<p>Monitoring, surveillance and enforcement powers (continued)</p>	<ul style="list-style-type: none"> • 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). • Under Directive 2000-07, the Canadian Food Inspection Agency requires the applicant to keep records regarding the management of the site (including monitoring, harvesting, cleaning of harvesting machinery, transportation and storage of the plant material) and the records must be made available upon request. Regional Food Inspection officers have the power to inspect trial sites during the growing season at random and without notification. • Under the Feeds Act and Seeds Act, there are provisions for inspections and inspectors to seize and detain articles, open packages and take samples, where an inspector believes on reasonable grounds that the Act or the regulations have been contravened.
<p>Penalties</p>	<ul style="list-style-type: none"> • A maximum fine of CA\$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 CA\$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 remedial actions, intention, and any property, benefit or advantage to the offender.

<p>Penalties (continued)</p>	<ul style="list-style-type: none"> • 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 (e.g. 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). • Penalties for contravening the Feeds Act or the Seeds Act include: a fine of up to CA\$50,000 or six months imprisonment or both for an offence punishable by summary conviction; a fine of up to CA\$250,000 or two years imprisonment or both.
<p>Placing GMOs (or products containing GMOs) on the market</p>	
<p>Responsible agency</p>	<ul style="list-style-type: none"> • Environment Canada. • The Canadian Food Inspection Agency's Plant Biosafety Office is responsible for regulating the intentional introduction into the environment in Canada of plants with novel traits (PNTs).
<p>Legislation</p>	<ul style="list-style-type: none"> • Feeds Act and amendments. • Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits.
<p>Coverage of the legislation</p>	<ul style="list-style-type: none"> • Directive 94-08 provides guidance regarding the submission of an application for the authorisation of the unconfined release of a PNT. An unconfined release involves the release of a PNT into the environment with no restrictions, with a view towards commercialisation.

<p>Application process for unconfined release of GMOs into the environment (usually for the purpose of commercialisation)</p>	<ul style="list-style-type: none"> • 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. • Directive 94-08 specifies that applications contain information that allows the Plant Biosafety Office to conduct an environmental risk assessment. • The criteria for the assessment include: potential of the PNT to become a weed of agriculture or be invasive of natural habitats; potential for gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive; potential for the PNT to become a plant pest; potential impact of the PNT or its gene products on non-target species, including humans; potential impact on biodiversity. In considering the environmental safety, the Plant Biosafety Office may consult with scientific experts.
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<p>Application process for unconfined release of GMOs into the environment (usually for the purpose of commercialisation) (continued)</p>	<ul style="list-style-type: none"> • In addition, and before authorisation for release can be granted, information on the following is also required: the identity and origin of the PNT; the properties of the novel gene and gene products; the relative phenotypic expression of the PNT compared to a similar counterpart, where differences are anticipated; anticipated or known relative effects on the environment resulting from the release. • The applicant can also submit other scientific research as part of the application. Upon becoming aware of new information regarding the environmental safety of the PNT (e.g. enhanced weediness characteristics), including the risk to human health (e.g. exposure to allergens) that could result from the release, the applicant must immediately provide the Plant Biosafety Office with the new information. • The Plant Biosafety Office may maintain, change, or remove existing conditions respecting the release; impose additional conditions; or refuse or cancel the authorisation and require the applicant to stop the release and take any appropriate action necessary to eliminate from, or minimise the risk to, the environment. • There is a draft document that outlines the application requirements for notification of a release of biotechnology-derived livestock animals. This draft appears to apply to confined and unconfined releases. Information requirements include information: on the organism; on the organism's manufacture or import; on the introduction of the organism; on the environmental fate of the organism; on the organism's environmental effects; on potential adverse effects on human health; on test data that assists in the identification of hazards to human health and environment.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • In making a decision Ministers may only determine whether the substance is toxic or capable of becoming toxic. No specific mention of ethics or trade is made. However, the Minister may take into account factors such as, but not limited to social, economic and technical matters when determining preventative or control action in relation to a substance or in plans for virtual elimination of the substance.

<p>Protection of confidential commercial information</p>	<ul style="list-style-type: none"> • 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.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • 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. • The Plant Biosafety Office may maintain, change, or remove existing conditions respecting the release; impose additional conditions; or refuse or cancel the authorisation and require the applicant to stop the release and take any appropriate action necessary to eliminate from, or minimise the risk to, the environment.
<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • Monitoring and enforcement powers are the same as those described above because unconfined releases are governed by the same legislation as confined releases.
<p>Penalties</p>	<ul style="list-style-type: none"> • Penalties that may be imposed in relation to unconfined release are the same as those described for the Feeds Act for confined releases because unconfined releases are governed by the same legislation as confined releases.
<p>Placing on the market GMOs for food or feed</p>	
<p>Legislation</p>	<ul style="list-style-type: none"> • Food and Drugs Act. • Feeds Act and amendments and regulations. • Directive 95-03.

<p>Coverage of legislation</p>	<ul style="list-style-type: none"> • The Food and Drugs Act regulates the use of GMOs (derived from plant and animal sources) that are intended for use as novel foods. • The Feeds Act governs the use of feed within Canada and ensures that it is safe to use. • Directive 95-03 appears as though it can be used for applying for release of novel feed (plant source) for eventual commercialisation.
<p>Application process for unconfined release of GMOs into the environment for use as feed for livestock and laboratory animals (usually for the purpose of commercialisation)</p>	<ul style="list-style-type: none"> • Under the Feeds Act and its amendments and regulations a written notification of the proposed release must be made to the Minister, including information such as: the particulars of the release; confinement and monitoring procedures; methods for safe disposal; contingency plans to mitigate adverse effects on humans and the environment in the event of accidental release; the particulars of the novel trait; any results from data or research done to identify risks to the environment or human health. The Minister for Agriculture and Agri-foods can then either authorise or refuse to authorise the release of the novel feed and shall consider the magnitude of exposure of the release, the effects on the environment and whether the novel feed is toxic. The application shall be accompanied with evidence (such as scientific research) to permit an assessment or evaluation of the safety and efficacy of the feed in respect of livestock and its potential effect on humans and on the environment. • Directive 95-03 provides the guidelines for the completion of an application for the unconfined release of a novel feed from plant sources. Applications should contain: sufficient data about the novel trait; information about the modification history; characterisation of the DNA inserted, if any; nutritional data, allergenicity data; toxicology data; dietary exposure; laboratory animal/livestock feeding trial data; environmental risk assessment; method of detection. A decision is then made on the information provided in the application. • The application procedure and information requirements for releasing of a novel feed of an animal origin is similar to that for a novel feed from a plant source and is outlined in the Feeds Act and regulations.

<p>Application process for unconfined release of GMOs into the environment for use as feed for livestock and laboratory animals (usually for the purpose of commercialisation) (continued)</p>	<ul style="list-style-type: none"> • There is a draft document that outlines the application requirements for notification of a release of biotechnology-derived livestock animals. This draft appears to apply to confined and unconfined releases. Information requirements include information: on the organism; on the organism’s manufacture or import; on the introduction of the organism; on the environmental fate of the organism; on the organism’s environmental effects; on potential adverse effects on human health; on test data that assists in the identification of hazards to human health and environment.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • In making a decision Ministers may only determine whether the substance is toxic or capable of becoming toxic. No specific mention of ethics or trade is made. However, the Minister may take into account factors such as, but not limited to social, economic and technical matters when determining preventative or control action in relation to a substance or in plans for virtual elimination of the substance.
<p>Protection of confidential commercial information</p>	<ul style="list-style-type: none"> • 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.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • The Plant Biosafety Office may maintain, change, or remove existing conditions respecting the release; impose additional conditions; or refuse or cancel the authorisation and require the applicant to stop the release and take any appropriate action necessary to eliminate from, or minimise the risk to, the environment.

<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> Monitoring and enforcement powers are the same as those described in the above table because unconfined releases are governed by the same legislation as confined releases.
<p>Penalties</p>	<ul style="list-style-type: none"> Penalties that may be imposed in relation to unconfined release of GMOs intended for feed use are the same as those described for the Feeds Act for confined releases because release of GMOs intended for feed use are governed by the same legislation as confined releases.
<p>Application process for unconfined release of GMOs into the environment for use as food for human consumption (usually for the purpose of commercialisation)</p>	<ul style="list-style-type: none"> No novel food may be sold or advertised without first submitting a notification for the intention to do so to the decision maker. The notification requires the following information: details of the food, including information concerning its development; details of the method by which it is manufactured, prepared, preserved, packaged and stored; details of the major change, if any; information concerning its intended use and directions for its preparation; information concerning its history of use as a food; information relied on to establish that the novel food is safe for consumption; the estimated consumption level of the novel food. Upon receiving the information, the decision maker shall, within 45 days, notify the applicant that the information provided is sufficient if the food is safe, or request further information. Upon receiving the additional information, the decision maker shall notify the applicant within 90 days that the information was sufficient if the food is safe. The novel food must undergo numerous safety assessments before being approved for use as food. This may include using data from animal studies or trials regarding its toxicity and allergenicity. In evaluating GM foods for safety, government scientific evaluators may consider the following: how the food crop was developed, including the changes in the plant's/animal's molecular structure; how the GM food compares with its conventional counterpart; whether the GM food contains new toxins (to animals, humans and the environment); whether the GM food may cause allergies.

<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • No specific mention of this was found in the relevant legislation.
<p>Protection of confidential commercial information</p>	<ul style="list-style-type: none"> • No specific mention of this was found in the Food and Drugs Act or its regulations, or in the draft guidelines for notification for the intended release of biotechnology-derived animals.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • There was no mention of specific conditions required to be met other than those required when an application/notification for the novel food to be placed on the market is made.
<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • The Food and Drugs Act has provisions that allow an inspector from the Canadian Food Inspection Agency to conduct inspections. An inspector may, at any reasonable time, enter grounds where the inspector believes on reasonable grounds any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged or stored to: examine and take samples of articles; open and examine receptacles or packages; examine or make copies of documents that contain information relevant to the enforcement of the Act; seize and detain articles.
<p>Penalties</p>	<ul style="list-style-type: none"> • Persons who contravene the Food and Drugs Act: on a summary conviction for a first offence may face a fine of no more than CA\$500 or a prison term no more than three months or both; for a subsequent offence, a fine no more than CA\$1000 or a prison term of no more than six months or both; for a conviction on indictment, a fine no more than CA\$5000 or a prison term no more than three years or both.

<p>Policy and Governance issues</p>	<p>The CEPA provides for two types of action: (1) Environmental Protection Actions.</p> <p>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 brought if:</p> <ul style="list-style-type: none"> (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. <p>An EPA may not be brought if the alleged conduct was:</p> <ul style="list-style-type: none"> (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. <p>Defences to an EPA include:</p> <ul style="list-style-type: none"> (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. <p>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.</p> <p>This action does not assist individuals affected 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.</p>
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<p>Liability for contamination (continued)</p>	<p>(2) Common law actions</p> <p>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 (for example, nuisance, negligence). The Canadian Environment Protection Act does not establish any statutory right to recover for loss or damage. There is a strict liability arrangement in the CEPA 1999 where the person who owns or has the charge, management or control of a substance immediately before an environmental emergency is liable:</p> <ul style="list-style-type: none"> – for restoring any part of the environment damaged by or during the emergency; and – for costs and expenses incurred by a public department in respect of measures taken to prevent, repair, remedy or minimise the damage to the environment resulting from the emergency, including measures taken in anticipation of the environmental emergency; as the person's liability does not depend on proof of fault or negligence. <p>However, the person's strict liability may be reduced or nullified if the person can show that the emergency was caused by: an act of war; an exceptional, irresistible and inevitable natural phenomenon; a third party with the intent to cause damage; negligence or wrongful act of government, public department or authority.</p>
<p>Expert committees</p>	<ul style="list-style-type: none"> • 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 12 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 of mutual interest. • This Committee looks at all environmental issues not just biotechnology.

<p>Research</p>	<ul style="list-style-type: none"> • 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. The Minister for the Environment and the Minister for Health may collect or generate data and conduct investigations respecting any matter in relation to a substance when assessing whether a substance is toxic.
<p>Other</p>	
<p>The precautionary principle</p>	<ul style="list-style-type: none"> • 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. • In giving advice and recommendations to the Minister, the National Advisory Committee shall use the precautionary principle.
<p>Cost recovery</p>	<ul style="list-style-type: none"> • Fees are attached to notifications to the relevant government departments for proposed use of novel plants, feed or food. 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).
<p>Moratorium</p>	<ul style="list-style-type: none"> • No moratorium.
<p>Other</p>	<ul style="list-style-type: none"> • Canada is currently proposing a regulation under the CEPA (1999) that would allow Canada to implement the Cartagena protocol. However, living modified organisms that are pharmaceuticals for human use are excluded from the regulation. • A novel feed from a PNT that could reasonably be expected to be released into the environment or used as food will not be authorised for livestock feed use until: the Plant Biosafety Office, CFIA, is ready to authorise the PNT for environmental release; the Novel Foods Section, Health Canada, is ready to provide notification of no objection for human food use of the novel food.

REGULATION OF GENE TECHNOLOGY IN ARGENTINA

SUMMARY — The Secretaria de Agricultura, Ganaderia, Pesca y Alimentos (SAGPyA)/Secretary of Agriculture, Livestock, Fisheries and Food is responsible for granting licences to dealings with GMOs. SAGPyA bases its decisions on the recommendation of an expert committee: Comisión Nacional Asesora de Biotecnología Agropecuaria (CONABIA)/The National Advisory Committee on Agricultural Biosafety.

- These rules are part of the general regulatory system governing the agricultural existing regulations in Argentina related to plant protection (Decree-Law of Agricultural Production Health Defense, N° 6704/66 and its amendments), seeds and phylogenetic creations (Seed and Phylogenetic Creations Law, N° 20.247/73 and its regulatory Decree), and animal health (Law of Veterinarian Products. Supervision of the creation and commercialisation. N° 13.636/49).

Contained work with GMOs

Responsible agency	<ul style="list-style-type: none"> • CONABIA/SAGPyA.
Legislation	<ul style="list-style-type: none"> • Resolution N°31/03 of SAGPyA 11 July 2003 specifies the application procedure for the issue of licences for Experimentation on and/ or Release into the Environment of Genetically Modified Micro-organisms and/or their products for use in animals; the release of genetically modified animals are regulated by Resolution N°656 of SAGPyA 11 July 2003.

Intentional releases of GMOs in the environment

Responsible agency	<ul style="list-style-type: none"> • CONABIA/SAGPyA. Commercial releases are also assessed by Health, Trade and Seed agencies.
Legislation	<ul style="list-style-type: none"> • Field trials are governed under Resolution N°57 of SAGPyA 18 July, 2003; commercial releases are also subject to SAGPyA Regulation No. 511/98 as well as general seed and health laws.
Coverage of the legislation	<ul style="list-style-type: none"> • The deliberate release of GMOs into the environment.

<p>Assessment process for intentional releases of a GMO into the environment (field trials)</p>	<ul style="list-style-type: none"> • Information requirements for applications are based on the US Department of Agriculture's experience. CONABIA's technical staff make a preliminary review of the applications for completeness and data quality. The CONABIA committee then undertakes a risk assessment analysis. The risk assessment includes: <ul style="list-style-type: none"> – assessment of the biosafety of the released organisms; – assessment of the agro-ecological features of the site where they are intended to be released; and – suitability of the person(s) responsible for conducting the field trial. • Authorisations for field trials are then issued by SAGPyA based on CONABIA's recommendation. • After at least one field trial and the safety of the GMO has been demonstrated, an applicant can apply for more flexible field trial conditions for that GMO referred to as 'flexibilización' (SAGPyA Resolution 131/98). After SAGPyA grants flexibilización, further releases into the environment of that GMO will only need the applicant to submit information on: <ul style="list-style-type: none"> – the area sown; – the date of sowing; and – the site of release and the harvest date.
<p>Procedure for the placing of GMOs or products containing GMOs on the market</p>	<ul style="list-style-type: none"> • A flexibilización permit is also the first stage to get approval for a commercial release. In addition, seed commercialisation is subject to the following terms and conditions: • National Service of Agrifood Health and Quality approval for use as food or feed. This is assessed by analysis of: (1) natural toxins; (2) new forms of toxins; (3) homology of the newly expressed proteins with other known allergens; (4) nutritional changes; (5) nutritional changes and nutritional characterisation resulting from processing methods; (6) modifications in the bioavailability of macronutrients and/or micronutrients; (7) characterisation of the modified foodstuff with regard to its safety for human and animal health.

<p>Procedure for the placing of GMOs or products containing GMOs on the market (continued)</p>	<ul style="list-style-type: none"> • Approval for marketing by the National Division of Agrifood Markets of the Secretariat, which assesses the trade and marketing impacts. This assessment seeks to avoid any potential negative impact on Argentine exports. • Compliance with the requirements set forth by the INASE for registration of the material in the National Cultivar Registry and in the Official Certification regulations. • As with field trials the final approval is made by SAGPyA.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • There is no specific mention made of consideration of ethical concerns.
<p>Public consultation on applications</p>	<ul style="list-style-type: none"> • There is no specific mention of public consultation on applications. Annual reports and details of GMOs approved are listed on CONABIA's web site.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • The Resolution provides that competent authorities may grant approvals subject to conditions.
<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • Monitoring of the field trials is the responsibility of the National Seeds Institute and of the National Service of Agrifood Health and Quality. The purposes of the monitoring are the on-site verification of compliance with the trial conditions as approved in the application and that the measures taken to avoid adverse effects on the environment have been followed. The fields are also inspected after the trials, in order to prevent any possible gene transfer from transgenic volunteer plants or harvest residues to other organisms. For field trials under flexibilización CONABIA will only recommend that inspections be made at harvest and of the measures taken for the final disposition of the material. • At the end of the period for which the authorisation was granted, the applicant must submit to CONABIA a final report. CONABIA will not evaluate any further application from a public or private institution which had failed to present a final report.

Penalties	<ul style="list-style-type: none"> • Not known at this stage.
Liability for contamination	<ul style="list-style-type: none"> • There is no mention of liability for contamination.
Policy and Governance issues	
Expert committees	<ul style="list-style-type: none"> • CONABIA is a multidisciplinary and inter-institutional group whose members are representatives of the public and private sectors working in Agricultural Biotechnology.
Research	<ul style="list-style-type: none"> • CONABIA requests that applicants perform research but does not conduct the research.
Other	
The precautionary principle	<ul style="list-style-type: none"> • The whole department operates under the 1992 Rio Declaration on Environment and Development version of the precautionary principle.
Cost recovery	<ul style="list-style-type: none"> • Not applicable.
Protection of confidential commercial information	<ul style="list-style-type: none"> • Parts of applications that contain trade secrets or confidential information are protected. • There is no data exclusivity.
Moratorium	<ul style="list-style-type: none"> • Not applicable.
Other	

REGULATION OF GENE TECHNOLOGY IN CHINA

SUMMARY — The Ministry of Agriculture appears to be mainly responsible for the formulation and implementation of regulations in relation to biotechnology and biosafety.

- Other interested government agencies include the State Environmental Protection Agency, the Ministry of Public Health, the Inspection and Quarantine Agency, the Ministry of Foreign Economy and Trade and the Ministry of Sciences and Technologies.
- All these agencies' views are represented on State Ministerial Council.
- Day-to-day regulation of GMOs is administered by the Office of Agricultural Genetic Engineering Biosafety Administration. However, in late 2005, the Chinese Government formed a new body to administer GMO regulation.
- The Ministry of Public Health is responsible for food safety in relation to GMOs intended for that purpose.
- The Ministry for Sciences and Technologies is responsible for biotechnology research.
- Genetic engineering work is classified into four classes of risk to human health and ecological environment: none; low; intermediate; and high.
- The risk classification is determined by the relevant agencies on the State Ministerial Council.

Contained work with GMOs

Responsible agency	<ul style="list-style-type: none"> • This may depend on the classified level of risk for the type of work being done, but generally no or low risk, contained experimental work would normally require approval from the administration of the institution in which the work is conducted. However, higher risk work requires additional approval from the relevant departments under the State Council and the National Genetic Engineering Safety Committee.
Legislation	<ul style="list-style-type: none"> • Safety Administration and Regulation on Genetic Engineering Regulations (1993).

<p>Assessment process for contained work involving GMOs</p>	<ul style="list-style-type: none"> • Institutions carrying out genetic experimental research should conduct evaluation on DNA donors, vectors, hosts and genetic engineered organisms. Factors considered should include pathogenicity, carcinogenicity, chemical resistance, transfer possibility, and effects on environment of target genes, vectors, hosts and genetically engineered organisms, and on determining biological control and physical control classes. • For intermediate risk work, the institution's administration should consider the application and then submit the application to the relevant departments under the State Council for consideration. For high risk work, the application is submitted to the National Genetic Engineering Safety Committee for approval after being submitted to the relevant department under the State Council. • Institutions carrying out genetic engineering work should go through the following application procedures: the chief of the planned genetic engineering project should evaluate the safety of the project and fill in the application form; the academic committee of the institution should conduct technical evaluation on the application; applications should be submitted along with technical documentation. • Safety measures include: development of safety control measures appropriate for the class of risk; waste management procedures (GMOs should be killed and disposed of to prevent dissemination and environmental pollution); development of measures to prevent accidents; appropriate storage and transportation provisions; maintaining a written safety control record for a minimum of ten years; requirement for institutions taking immediate measures to restrict and alleviate harm if it is discovered that the institution's work is causing environmental damage or harm.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • There was no specific requirement for ethical issues to be considered.
<p>Public consultation on applications</p>	<ul style="list-style-type: none"> • There was no specific mention for the requirement for public consultation.

<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • No specific mention of the conditions to be applied were mentioned, but relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violations.
<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • Laws and regulations introduced in 2002 and 2003 contain provisions for monitoring and surveillance to ensure environmental safety from use of GMOs.
<p>Penalties</p>	<ul style="list-style-type: none"> • Relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violation when: the genetic engineering project begins operation without approval; equipment, apparatus, laboratories which do not fit in with regulations have been used; violation of safety operation regulations of genetic engineering work has occurred; violation of other rules under the regulations occur. • Both individuals and the institution conducting the work can be liable for any damages resulting from the work. • Responsible institutions of those violating any relevant legislation and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses: causing serious environment pollution; causing damage or harm to the public health; causing severe damage to ecological resources and ecological balance. Criminal charges can also be laid subject to the appropriate legislation.
<p>Intentional releases of GMOs in the environment</p>	
<p>Responsible agency</p>	<ul style="list-style-type: none"> • Departments under the State Council; Department of Agriculture; Department of Science and Technology; State Environmental Protection Administration; National Genetic Engineering Safety Committee.

<p>Legislation</p>	<ul style="list-style-type: none"> • Safety Administration and Regulation on Genetic Engineering Regulations (1993). • Regulations on Administration of Agricultural GMOs Safety (2001).
<p>Coverage of the legislation</p>	
<p>Assessment process for intentional releases of a GMO into the environment (field trials and general releases)</p>	<ul style="list-style-type: none"> • Institutions carrying out genetic engineering pilot experiments or industrial production should conduct safety evaluation on the physical barriers of the equipment and facilities of the culture, fermentation, separation and purification processes according to genetic engineered organisms safety class, to determine the safety class of pilot experiments or industrial production. • Institutions carrying out the release of genetic engineered organisms should conduct evaluation on the safety of genetic engineered organisms, the purpose of the release, ecological environment conditions of the release site, releasing methods, monitoring means and control measures, to determine the safety class of the release. Approval for work classified as no risk should be obtained from the chief administrators of the institution; approval for work classified as low risk requires approval by relevant State Council departments; intermediate risk work also requires approval from relevant State Council departments with the application recorded by the National Genetic Engineering Safety Committee; applications for high risk work is examined by the relevant State Council departments and submitted for approval to the National Genetic Engineering Safety Committee. • Institutions carrying out genetic engineering work should go through the following application procedures: the chief of the planned genetic engineering project should evaluate the safety of the project and fill in the application form; the academic committee of the institution should conduct technical evaluation on the application; applications should be submitted along with technical documentation.

<p>Assessment process for intentional releases of a GMO into the environment (field trials and general releases) (continued)</p>	<ul style="list-style-type: none"> • Safety measures include: development of safety control measures appropriate for the class of risk; waste management procedures (GMOs should be killed and disposed of to prevent dissemination and environmental pollution); development of measures to prevent accidents; appropriate storage and transportation provisions; maintaining a written safety control record for a minimum of ten years; requirement for institutions taking immediate measures to restrict and alleviate harm if it is discovered that the institution's work is causing environmental damage or harm.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • There was no specific requirement for ethical issues to be considered.
<p>Public consultation on applications</p>	<ul style="list-style-type: none"> • There was no specific mention for the requirement for public consultation.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • No specific mention of the conditions to be applied were mentioned, but relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violations.
<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • Laws and regulations introduced in 2002 and 2003 contain provisions for monitoring and surveillance to ensure environmental safety from use of GMOs.

<p>Penalties</p>	<ul style="list-style-type: none"> • Relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violation when: the genetic engineering project begins operation without approval; equipment, apparatus, laboratories which do not fit in with regulations have been used; violation of safety operation regulations of genetic engineering work has occurred; violation of other rules under the regulations occur. • Both individuals and the institution conducting the work can be liable for any damages resulting from the work. • Responsible institutions of those violating any relevant legislation and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses: causing serious environment pollution; causing damage or harm to the public health; causing severe damage to ecological resources and ecological balance. Criminal charges can also be laid subject to the appropriate legislation.
<p>Assessment process for intentional releases of a GMO for commercialisation</p>	<ul style="list-style-type: none"> • Use of finished genetic engineering products (intended for release) should be accompanied by biological tests for the purposes of a safety evaluation, which will determine the possible impact of the product on the public health and the ecological environment. • For work classified between no risk and intermediate risk, applications should be submitted to the relevant departments under the State Council for approval and to the National Genetic Engineering Safety Committee for their record. • For releases classified as high risk, the application should be examined by the relevant departments under the State Council and submitted to the National Genetic Engineering Safety Committee for approval.

<p>Assessment process for intentional releases of a GMO for commercialisation</p>	<ul style="list-style-type: none"> • Institutions carrying out genetic engineering work should go through the following application procedures: the chief of the planned genetic engineering project should evaluate the safety of the project and fill in the application form; the academic committee of the institution should conduct technical evaluation on the application; applications should be submitted along with technical documentation. • Safety measures include: development of safety control measures appropriate for the class of risk; waste management procedures (GMOs should be killed and disposed of to prevent dissemination and environmental pollution); development of measures to prevent accidents; appropriate storage and transportation provisions; maintaining a written safety control record for a minimum of ten years; requirement for institutions taking immediate measures to restrict and alleviate harm if it is discovered that the institution's work is causing environmental damage or harm.
<p>Consideration of ethical issues</p>	<ul style="list-style-type: none"> • There was no specific requirement for ethical issues to be considered.
<p>Public consultation on applications</p>	<ul style="list-style-type: none"> • There was no specific mention for the requirement for public consultation.
<p>Conditions that may be applied</p>	<ul style="list-style-type: none"> • No specific mention of the conditions to be applied were mentioned, but relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violations.
<p>Monitoring, surveillance and enforcement powers</p>	<ul style="list-style-type: none"> • Laws and regulations introduced in 2002 and 2003 contain provisions for monitoring and surveillance to ensure environmental safety from use of GMOs.

<p>Penalties</p>	<ul style="list-style-type: none"> • Relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violation when: the genetic engineering project begins operation without approval; equipment, apparatus, laboratories which do not fit in with regulations have been used; violation of safety operation regulations of genetic engineering work has occurred; violation of other rules under the regulations occur. • Both individuals and the institution conducting the work can be liable for any damages resulting from the work. • Institutions responsible for violating any relevant legislation and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses: causing serious environment pollution; causing damage or harm to the public health; causing severe damage to ecological resources and ecological balance. Criminal charges can also be laid subject to the appropriate legislation.
<p>Policy and Governance issues</p>	
<p>Liability for contamination</p>	<ul style="list-style-type: none"> • Institutions are responsible for any clean-up requirements and providing compensation for losses. • Criminal charges can also be laid subject to the appropriate legislation.
<p>Expert committees</p>	<ul style="list-style-type: none"> • National Genetic Engineering Safety Committee. • National Agricultural GMO Biosafety Committee participates in biosafety management.
<p>Research</p>	<ul style="list-style-type: none"> • At the national level, the Ministry of Agriculture, the Chinese Academy of Sciences, the State Forestry Bureau and the Ministry of Education are the major authorities responsible for agricultural biotechnology research. • Under the Ministry of Agriculture, there are three large academies: the Chinese Academy of Agricultural Sciences; the Chinese Academy of Tropical Agriculture; and the Chinese Academy of Fisheries.

Other	
The precautionary principle	<ul style="list-style-type: none"> No specific mention of the precautionary principle was found in any of the information found on the Chinese gene technology regulation regime.
Cost recovery	<ul style="list-style-type: none"> Institutions whose work with GMOs has caused environmental damage are responsible for taking remedial action and for compensation costs.
Protection of confidential commercial information	No reference was found to this.
Moratorium	No specific mention of a moratorium was found; however, China introduced more restrictive biosafety regulations in 2002.
Other	<ul style="list-style-type: none"> China has ratified the Cartagena protocol on biosafety. As of 2003, China was in the process of introducing new/updating existing laws and regulations governing work involving GMOs. The information in this table may soon be superseded. GM labelling guidelines took effect from 2002. Information was sourced from http://www.ebnic.org (http://www.ebnic.org/detailsc.htm#hapter%20T wo:%20Safety%20Classes%20and%20Safety%20Evaluation) and http://www.china.org.cn/english. Institute of Developmental Studies working paper 195, Jikun Huang and Qinfang Wang, Biotechnology policy and regulation in China (2003).