



Research Guideline: OR-RR-G-004.0

# Agricultural Biotechnology – Plant with Novel Traits (PNTs)

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**Office of Administrative Responsibility:** Office of Research Services, Research Risk

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## **Purpose**

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The purpose of this guideline is to:

- promote compliance with federally prescribed requirements for human and animal health protection, environmental protection, and safety performance concerning biotechnology-derived plants, novel feeds, and related novel agricultural products;
  - provide reference and information regarding appropriate plant biosafety levels and containment/confinement guidelines for PNT research
  - publicize University requirements and resources for due diligence and performance of best agricultural practices
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## **Scope**

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University PNT research involving field crop, horticultural and ornamental plants, turf grasses, fruit and forest trees including indoor research and development involving experimental PNTs, and outdoor confined research field trials with experimental PNTs.

## Guideline

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### General Guidelines

1. Research involving plants with novel traits (PNTs), including confined research field trials of experimental PNTs, and field work with PNTs approved for unconfined release, shall be conducted in compliance with federal and provincial requirements, and in an environmentally responsible manner.
2. The Principal Investigator shall plan the research accordingly to anticipate and address the following issues (as applicable):
  - novel traits of the product and the containment/confinement level required
  - documentation needed for regulatory authorities
  - permissions to use growth facilities and/or field sites including formalized agreements for private properties
  - physical security and biological containment
  - reproductive isolation for indoor experiments
  - field site confinement and reproductive isolation for outdoor experiments
  - presence of endangered species at the field trial site
  - orientation and training for all associated personnel
  - potential need for dedicated facilities and equipment
  - need for detection methods and quality control procedures for experimental PNTs
  - need for biosecurity and standard operating procedures
  - restrictions concerning harvested seeds and PNT biomass
  - monitoring, surveillance and stewardship commitments
  - prescribed record-keeping requirements

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- labeling, transportation, secure segregated storage, devitalization and destruction (by approved methods) of all experimental PNT biomass
  - management plans for herbicide-tolerant or insect resistant experimental PNTs
  - reporting obligations, for e.g., annual reporting to Canadian Food Inspection Agency (CFIA) for confined research field trials, sponsor reporting, etc.
  - compliance with any third-party agreements/contracts
  - compliance obligations, commitments and costs related to prescribed post-harvest land-use restrictions and field site monitoring and surveillance
  - contingency plans for accidental releases
  - reporting obligations and communication strategies for unplanned events
  - responsibility for costs to remedy any situation associated with incidents and accidental releases (as prescribed).
3. Experimental PNT research proposals may be reviewed by the Manager, Research Risk as required. PNT risk issues should be identified and the Plant Biosafety Level of containment determined before proposals are submitted to sponsors. Further information regarding appropriate selection of plant biosafety can be found:
- [Appendix P of the National Institutes of Health \(NIH\) NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, 2016](#), provides guidance on selecting the appropriate Plant Biosafety Level of containment required at growth facilities
  - [Plant Biosafety and Containment](#) (section within this guideline)
4. Containment levels for laboratory research (e.g., for plant microorganisms, plant pathogens, media protection) shall be determined in accordance with the [Canadian Biosafety Standard and Guidelines](#) facility containment features and operational procedures (e.g., requirements for PNT inventories, seed logs, transit logs, waste logs) as summarized within this document describe the University's performance standards for experimental PNT research.

5. The Principal Investigator, the Manager, Research Risk, and the departmental growth facility coordinator should assess any new greenhouse/growth chamber space intended for PNT research, i.e., for containment features and physical security. Current growth facilities for PNT research include:
  - [Plant Agriculture - Crop Science and Bovey growth facilities](#)
  - [Phytotron, Science Complex](#)
6. Experimental PNT research requiring Plant Biosafety Level 2 shall be documented for the University's Biosafety Committee whenever potential exists for human allergenic response.
7. The Vice-President Research may convene an ad hoc Biotechnology Review Committee to make recommendations about research proposals that involve issues such as transgenic plant research ethics, genetic provenance and third-party rights, utilization of genetic resources and derivatives, biodiversity, outstanding concerns about safety performance, containment or confinement, etc. This Biotechnology Review Committee shall include at least two members who are non-stakeholders.
8. For confined research field trials conducted on private lands, formalized agreement(s) outlining appropriate landowners' permissions and postharvest field site monitoring must be established through Research Support Services. It is preferable to plan confined research field trials such that the isolation distance is confined within University property. If not possible, property owners whose lands lie within the isolation distance from a confined research field trial must be notified and formalized agreements established as required.
9. Copies of letters of authorization issued by CFIA for confined research field trials are to be provided to the Manager, Research Risk. The Manager, Research Risk is available to assist Principal Investigators with import permit applications for PNTs, confined research field trial applications, standard operating procedures, inspections, audits and other CFIA compliance-related matters.

10. Principal Investigators are responsible for ensuring all personnel involved in experimental PNT research are provided with project-specific orientation and training prior to commencement of the research. For confined research field trials, the Principal Investigator must ensure mandatory orientations for research personnel regarding CFIA-prescribed terms and conditions for experimental PNT research are provided. Topics should include:

- nature of the PNT
- laboratory containment or field confinement requirements
- transfer and confinement protocols related to:
  - seeding
  - cultivation
  - harvesting
  - seed collection
  - equipment clean-up
- labelling and storage requirements
- post-harvest surveillance
- record-keeping requirements
- contingency plans for unauthorized releases
- incident notification
- devitalization/destruction methods for all PNT biomass

11. Principal investigators must retain trial protocols, field maps, seed logs, site activity and monitoring records, contingency plans and corrective action reports at or near the field site. PNT research personnel shall accommodate CFIA and other inspectors to enable authorities to carry out their duties. The Principal Investigator and the Manager, Research Risk are to be notified about all external (e.g., CFIA) field site inspections.

12. Experimental PNT research laboratory records, confined research field trial site records, PNT biomass destruction records and other prescribed documentation are subject to internal

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and external audits. The Principal Investigator is to notify the Manager, Research Risk about all external (e.g., CFIA, or sponsor) laboratory and/or growth facility audits.

13. Accidental or unauthorized releases, breaches of containment and removals of PNTs must be reported immediately by the Principal Investigator to his/her Department Chair and College Dean and to the Manager, Research Risk who will in turn notify the Associated to the Vice-President Research Services. If applicable and in accordance with CFIA requirements, CFIA (613-773-5000) and/or Environment Canada shall be notified by phone and in writing within 24 hours. If required, written corrective action reports may be faxed to CFIA at 613-773-7144.
14. Experimental PNT research facilities (laboratories, growth chambers, greenhouse spaces) must be cleaned upon completion or termination of PNT research projects. All PNT biomass must be destroyed as prescribed by CFIA and in accordance with University disposal procedures for PNT waste
15. Research planned with PNTs intended for plant molecular farming (PMF) should be discussed with the Manager, Research Risk. Containment standards, management protocols and disposal of all PMF biomass will be determined in accordance with directions from [CFIA Guidelines for Plant Molecular Farming](#).
16. Research involving plant pests should be discussed with the Manager, Research Risk. Facilities must be assessed for compliance with the [CFIA Containment Standards for Facilities Handling Plant Pests](#).
17. Research trials with novel feeds require standard operating procedures (e.g., security of the novel feed, management of animal manure and by-products, disposition of all animals, record keeping). For more information see [CFIA's guidance documents on Novel Feeds](#).



### **Additional Information and Background:**

Before being approved, all biotechnology-derived products must undergo pre-market science-based safety assessments to investigate potential harms to the environment and to animal and human health. The novelty of the agricultural product, not its method of production (e.g., recombinant DNA technology, mutagenesis, selective breeding techniques), triggers the extent of the regulatory scrutiny. Researchers and product developers are responsible for submitting all data requested by federal authorities for their reviews.

The regulatory agencies responsible for plant biotechnology in Canada are the Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada. CFIA serves as the lead agency for plant biosafety and involves Health Canada and Environment Canada for any necessary concurrent approvals. As experimental agricultural products progress through the stages of research and development, confined research field trials, assessments for environmental, animal and human safety, variety registration, commercialization and marketing, the regulatory agencies apply stage-related controls.

The CFIA is responsible for regulating PNTs, novel animal feeds and feed ingredients, fertilizers, and veterinary biologics. CFIA will assess the potential risks of environmental effects and risks to animal and human health, issue import permits for experimental PNTs, administer the confined research field trial process, conduct safety approval assessments, oversee variety registration, and dictate the process for unconfined release of approved PNTs. (See [CFIA's Plants with Novel Traits website](#) ).

Health Canada is responsible for assessing the human health and safety of consumer products derived through biotechnology including novel foods, drugs, cosmetics, medical devices and pest control products. The [Pest Management Regulatory Agency \(PMRA\)](#) of Health Canada regulates biological control agents used in food production.

Environment Canada administers the New Substances Notification Regulations (NSNR) for organisms and chemicals and polymers pursuant to the Canadian Environmental Protection Act (CEPA). New products of biotechnology that are not assessed by CFIA or Health Canada under

other legislation, are evaluated by Environment Canada for potential harm to human health or the environment prior to approval for commercialization. Further information is available in the [Guidance documents for notification and testing of new substances](#).

## 1. Research and Development

It is the responsibility of the plant breeder or plant developer to determine the range of selected trait of cultivated populations of the plant species in Canada and to determine if the product is a PNT.

PNTs are initially produced in research laboratories or tissue culture facilities and are propagated in growth chambers or greenhouses under controlled conditions with physical and biological isolations to protect the natural environment. The containment and operational procedures outlined herein are intended to help promote due diligence and best agricultural practices for research involving plants with novel traits.

Pursuant to the Plant Protection Act, the import into Canada of experimental (unapproved) PNTs, seeds, plant-associated organisms, and novel livestock feeds derived from plants (for research and development) requires an import permit from the Plant Health and Production Division of CFIA. [Directive D-96-13: Import Permit Requirements for Plants with Novel Traits and their Products](#) gives guidance and [CFIA's Import Procedures](#) provides further instructions and the application form.

For information about phytosanitary certificates for exotic plants, seeds, cuttings or bare roots please see [D- 95-26: Phytosanitary requirements for soil and related matter, and for items contaminated with soil and related matter](#).

## 2. Plant Biosafety and Containment

Plant Biosafety Levels for indoor containment of experimental PNTs and associated organisms (that may contain recombinant DNA) are based upon recommendations in



Appendix P of the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules 2016](#), Recommended containment standards for plant biosafety minimize the likelihood of accidental releases and unanticipated deleterious effects on organisms and ecosystems.

In general:

Plant Biosafety Level 1 - provides a low level of containment for PNTs, transgenic plants and associated organisms for which there is no evidence that the modified organism would survive and spread uncontrolled in the environment;

Plant Biosafety Level 2 - provides a moderate level of containment for PNTs, transgenic plants and associated organisms that, if released, could be viable in the surrounding environment with negligible or manageable biological impact;

Plant Biosafety Level 3 - provides an even higher level of containment for PNTs, transgenic plants, plant pathogens and other organisms that have recognized potential for detrimental impacts on organisms and ecosystems beyond the containment facility;

Plant Biosafety Level 4 - provides the highest level of containment for experiments on exotic readily transmissible infectious agents that are potentially serious pathogens of Canadian crops, and that are performed in the presence of their arthropods.

### 2.1. Risk Assessments for PNTs

Criteria for risk assessment and the identification of appropriate containment for PNTs (which are flexible given species-specific information), should include:

- source of the novel trait (i.e. whether pathogenic or infectious, whether derived from a fragment of DNA, or from a complete genome)

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- recipient organism (i.e. mode and ease of dissemination, invasiveness, whether a noxious weed or capable of interbreeding with noxious weeds; potential for outcrossing with related species)
- nature of novel trait (i.e. toxicity, biological activity, stability)
- potential for release into the natural environment (i.e. reproductive limitations, regulated gene expression)
- local environment (i.e. nature of nearby crops, presence of sexually compatible wild or weedy species)
- likelihood of fitness and survival in the natural environment
- possibilities for multiplication in the environment
- potential for detrimental impact on managed or natural ecosystems and probability of harm (toxicities) to non-target species.

Other factors for consideration include:

- ease of detection of the novel trait (i.e. phenotypic characteristics or laboratory detection; see [CFIA Detection and Identification Method Criteria](#))
- complexity of procedures needed to manage the transfers of plant materials;
- scale of the experiment (i.e. number of plants cultivated).

For experimental (unapproved) PNTs, control must be maintained over the entire life cycle of the novel plant wherever they are grown i.e., in containment or confinement. Minimizing the likelihood of accidental releases of viable PNT material or (waste) biomass negates the overall ecological risks of transgene escape. Potential environmental risks (e.g. novel weed phenotypes) could be difficult to mitigate after-the-fact if accidental releases occurred.

## 2.2. Recommended Containment Levels for Experimental PNTs

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Progressively stringent requirements for containment and biosafety are warranted as the risk potential of the experimental PNT increases. See Appendix 1.

The highest Plant Biosafety Level associated with a risk criterion will determine the containment required for the experimental PNT.

### 2.3. Facilities for Experimental PNT Research

The University of Guelph has laboratory and growth facilities suitable for Plant Biosafety Level 1 and Level 2 containment. Higher-level containment facilities do not exist at the University. Access to research spaces must be arranged via growth facility coordinators.

- [Plant Agriculture - Crop Science and Bovey growth facilities](#)
- [Phytotron, Science Complex](#)

It may be desirable for security reasons to accommodate Level 2 greenhouse research, supervised by different principal investigators, in separate compartments.

Greenhouse research, supervised by different principal investigators at different Plant Biosafety Levels may be accommodated concurrently in the same compartment if the higher-level plant biosafety precautions are exercised by all personnel using this same space and there is no concern of outcrossing.

### 2.4. Plant Biosafety Level 1 – Physical Containment Features

#### **Laboratory Features**

As Plant Biosafety Level 1 involves little or no plant, pest or environmental risk, no special containment features are required beyond those features suitable for a well-designed, functional and secure microbiology laboratory. Noteworthy features include:

- locks on doors and on any openable windows;

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- proximity hand-washing facilities;
- separate spaces for hanging street clothing and lab coats;
- an autoclave available at or near the laboratory;
- screens with 30-mesh size or higher are recommended on all openings (window and ventilation openings) to preclude the transit of arthropods.

**Growth Chamber and Greenhouse Features**

- locks on growth chamber access doors;
- locks on greenhouse access and compartment doors;
- self-closures on greenhouse access and compartment doors;
- galvanized or stainless steel (easily cleanable) work surfaces;
- proximity hand-washing or hand sanitization facilities;
- separate spaces for hanging street clothing and lab coats;
- an autoclave available at or near the growth facility;
- screens with 30-mesh size or higher are recommended on all openings (window and ventilation openings) to preclude the transit of arthropods.

2.5. Plant Biosafety Level 1 – Recommended Operational Procedures

In addition to good research practices (e.g., planning, record keeping, performance, termination), recommended Biosafety Level 1 operational procedures are appropriate:

- provide orientations for staff and students that focus on managing containment for environmental protection;
- provide departmental Greenhouse Manual/SOPs to all personnel;
- restrict greenhouse access to a minimum number of authorized users;
- limit the number of locations where PNT biomass is developed, cultivated or stored; keep these locations locked when unattended and restrict third-party access as/when appropriate;

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- maintain location-specific inventories of PNT materials;
- use distinctive colour labeling or identification codes to differentiate PNT and non-PNT materials;
- record re-locations of PNTs;
- prohibit transfers of PNT materials to persons outside your research group, unless approved by the Principal Investigator;
- maintain chronological laboratory notes to document experimental PNT work and results;
- restrict PNT bench-top work to designated workstations;
- wear personal protective equipment including lab coat, gloves and eyewear as appropriate;
- decontaminate and clean workstations each day;
- prevent the release of germplasm or novel product using physical containment, reproductive isolation from cross-fertile plants, separation distances, and appropriate procedural precautions;
- inspect plants for insect damage and implement an integrated pest management program in co-operation with the greenhouse facility manager;
- identify seed from PNTs in clearly marked containers with labels that identify the Principal Investigator's name and date;
- segregate PNT seed from all other seed and store it in a locked laboratory or greenhouse cabinet; maintain 'seed logs';
- use closed non-breakable containers when transporting PNT seed, transgenic material and associated microorganisms outside of the containment area;
- contain waste PNT biomass for safe transport to the treatment area and ensure that exterior surfaces of waste containers are clean before removal from containment;

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- destroy (autoclave or chemically devitalize) all PNT biomass when research is finished; record details (name, date, description of PNT biomass, method of treatment) and results of autoclave quality control indicator tests;
- prepare contingency plans for spills (i.e., employ effective chemical disinfectants, consider required concentrations and contact times);
- prepare contingency plans for breaches of containment;
- decontaminate skin with an alcohol/ethanol hand sanitizer;
- report loss or theft of PNT material immediately

Experiments involving organisms requiring no prescribed containment may be conducted concurrently with those requiring Plant Biosafety Level 1 containment if all work is conducted with Level 1 protocols.

## 2.6. Plant Biosafety Level 2 – Physical Containment Features

Further to the physical features for Level 1 containment, mandatory Plant Biosafety Level 2 security and containment features include:

### **Laboratory Features**

- a Plant Biosafety Level 2 warning sign (re: potential environmental risk) is to be posted at the laboratory entrance (as described in 2.10 Signs and Labelling)
- easily cleanable work surfaces such as galvanized steel or stainless steel
- a Class I or Class II biological safety cabinet for manipulations of agents with potential to create aerosols.

### **Growth Chamber and Greenhouse Features**

- 24-hour environmental monitoring and alarm systems to signal mechanical malfunctions, loss of environmental conditions, and/or loss of containment

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- a Plant Biosafety Level 2 warning sign (re: potential environmental risk) posted on the growth chamber door or at the greenhouse compartment entrance (as described in Signs and Labelling)
- a Contingency Plan for Breach of Containment must be posted
- galvanized or stainless steel (easily cleanable) work surfaces
- screening (30-mesh size or higher for the size, shape and morphology of the arthropods to be excluded) is required on all ventilation openings not otherwise screened/filtered.
- a sealed (impervious) concrete greenhouse floor is required.

## 2.7. Plant Biosafety Level 2 – Recommended Operational Procedures

In addition to the procedures recommended for Plant Biosafety Level 1 containment, the following procedures are appropriate for Level 2:

- seek Biosafety Committee review and approval whenever the work involves the potential for human allergenic response
- use biological safety cabinets whenever manipulations produce aerosols
- conduct pre-experiment inspections of the growth chamber and/or greenhouse compartment to confirm suitability for Plant Biosafety Level 2 containment
- discuss all growth chamber or greenhouse uses of arthropods and other motile macro-organisms with the departmental facility coordinator to determine appropriate protocols and precautions
- grow experimental plants and microbes at a time of year when susceptible plants are not growing
- choose microorganisms that have an obligate association with the host plant
- conduct experiments at a time of year when survival of any escaped organism (arthropod) is impossible

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- provide written SOPs to personnel concerning regular facility inspections, reproductive isolation techniques, PNT biomass waste management, disinfection and cleaning of surfaces, spills and incident (loss) reporting
- avoid taking unnecessary personal effects into containment areas
- clean or contain personal protective equipment before removing from the containment area; decontaminate as required
- autoclave or devitalize all detritus from screens prior to disposal
- inspect shoes and clothing before leaving the containment area
- sanitize the growth chamber or greenhouse after the completion of projects with experimental PNTs
- conduct inspections after any event that may damage the containment structure
- maintain growth facility maintenance records.

When Plant Biosafety Level 2 and Level 1 (or lower) experiments are performed concurrently in the same growth facility, operational procedures for all experiments must conform to Level 2 containment standards.

In summary, containment for plant biosafety is achieved via appropriate physical containment combined with plant-specific reproductive isolation techniques and good microbiological, horticultural, pest control and operational practices.

#### 2.8. Containment Standards for Plant Pests

The level of containment required for plant pests depends on the pest's biology and the potential environmental impact. CFIA's [Containment Standards for Facilities Handling Plant Pests, First Edition](#) outline associated requirements and are intended for laboratories, greenhouses and screen-houses where plant pests and/or plants infected or infested are grown.



## 2.9. Screening

Screens can keep pests and pollinators out of the growth cabinet, growth room or greenhouse. The mesh-size refers to the number of threads per linear inch (e.g., a 30-mesh screen has 30 threads per inch). Mesh size will greatly affect airflow, cooling efficiency, humidity and light transmission. Thread diameter and mesh material will affect insect exclusion properties. The following mesh sizes will generally restrict certain insect species:

Adult Insect	Insect Screen Size
leafminers	40-mesh
silverleaf whiteflies	52-mesh
melon aphids	78-mesh
Western flower thrips	132-mesh

For further information about screens and related issues, see:

- [Rutgers Cooperative Extension – Greenhouse Screening for Insect Control](#)
- [OMAF – Fact Sheet – Screening of Greenhouses for Insect Exclusion](#)

Consult the facility supervisor about the screening provided at the facility you plan to use.

## 2.10. Signs and Labeling

No special warning signs are required for Plant Biosafety Level 1 experiments.

For Level 2 experiments, the Principal Investigator is to post a “Caution – Experiment in Progress” sign on the growth cabinet and/or at the entrance to his/her growth room or greenhouse compartment. The sign is to indicate:

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- the researcher's name
- Plant Biosafety Level 2
- plant (PNT) species
- potential environmental risk
- whether any viable microorganisms or motile macro-organisms are being used
- specific precautionary requirements, and
- 24-hour emergency contact information.

Any risk to human health must be identified with a separate Biohazard Warning sign indicating the nature of the risk. Pursuant to CFIA recommendations, a Contingency Plan for Breach of Containment must be posted on your growth chamber and at the growth room or greenhouse compartment door.

2.11. Biological Containment - Reproductive Isolation

CFIA-approved strategies for reproductive isolation of experimental PNTs in growth facilities or confined research field trials include, as appropriate:

- geographic isolation
- spatial isolation
- temporal isolation of flowering plants
- physical isolation:
  - isolation cages
  - bags over flowering parts to prevent dispersal of pollen or seeds
  - physical removal of flowers prior to pollen maturity
  - harvesting of plants before flowering
  - guard rows (pollen traps)

Plant-specific reproductive isolation techniques are used to prevent the movement of plant material, particularly pollen, from the containment or confinement area into

the natural environment. (See the [Directive Dir2000-07: Conducting Confined Research Field Trials of Plant with Novel Traits in Canada](#))

### 3. Confined and Unconfined Releases of PNTs

For experimental transgenic plants, the main ecological concerns are escape and establishment in the ecosystem, outcrossing with related species to produce more competitive species, and toxicities to non-target species. CFIA regulates the confined and unconfined environmental releases of PNTs and their uses as ingredients in livestock feeds. Each type of release is subject to environmental safety assessments and, if approved, to applicable restrictions. The process to research, develop, test and assess the safety of a new novel product may take from seven to ten years. For more information about data needed, see the [Directive 94-08 \(Dir 94-08\) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits](#).

Note that current fees for confined and unconfined release approvals are available [CFIA fee schedule](#).

#### 3.1. Confined Research Field Trials

Confined research field trials, which are permitted only upon approval by CFIA, enable evaluations of experimental PNTs in the natural environment under confined and strictly controlled conditions. The conditions for field confinement are based on prescribed performance standards for reproductive isolation (to prevent the transfer of pollen), field site monitoring, the management of seed and harvested material, and post-harvest land use restrictions. CFIA audits records and inspects research laboratories and field sites to enforce all terms and conditions for authorized confined research field trials. General information about confined research field trials is available at [Confined Research Field Trials for Plants With Novel Traits \(PNTs\)](#).

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Performance standards (i.e., plant-specific terms and conditions) for confined research field trials (pursuant to the Seeds Regulations, Part V) and the Confined Research Field Trial Application Form are found with [CFIA Directive 2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada](#). 30-60 days are required to process applications. As such recommended application deadlines for submission are March 15<sup>th</sup> for spring planting and June 15<sup>th</sup> for fall planting. Confined research field trials are normally limited to one hectare per site and to a maximum of five sites per province. CFIA regards field trial locations as confidential business information. Web-based information concerning various aspects of field trial work will assist with the Application process. For example, the CFIA prescribes crop-specific isolation distances for PNTs in confined trials, post-harvest land use restrictions and frequencies for field site monitoring and surveillance.

Information about plant and animal species at risk near a field trial is available at the [Species at Risk Public Registry](#) and at the [Species at Risk section of the Parks Canada website](#). Also, see the schedules pursuant to the [Species at Risk Act](#).

Plant protection information is available at on the [Plant Protection section of the CFIA website](#)

If the trial requires the use of an unregistered pesticide or the unregistered use of a registered pesticide, a research permit must be obtained from the [Pest Management Regulatory Agency of Health Canada](#). Warning signs at all four corners of a trial site must indicate pesticide use each time the site is chemically treated.

Unless explicitly exempted, all seeds and plant material harvested from confined field trials must be destroyed via CFIA-approved methods (e.g., incineration, autoclaving, deep burial).

[Annual summaries of all confined research field trials approved by CFIA, and their corresponding terms and conditions](#) are available online.

### 3.2. Unconfined Releases

CFIA environmental safety assessments are a prerequisite for approvals of unconfined releases of PNTs and for approvals of novel livestock feeds derived from plants. Data from confined research field trials must address the following criteria for environmental safety:

- altered weediness potential
- potential for outcrossing
- altered plant pest potential
- impact on non-target organisms
- impact on biodiversity.

Other data to be evaluated concerns impacts on human and animal health.

Approval for unconfined release (pursuant to the Seeds Regulations, Part V) is an essential step towards the registration and commercialization of experimental novel plants. For guidance on the approval process for PNTs, see [CFIA Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits](#).

As the CFIA approval process is subject to on-going development, applicants are advised to consult the Plant Biosafety Office early.

[CFIA biology documents](#) provide reference information on stable species with no novel traits. They are helpful for completing applications for unconfined releases of related PNTs.

Management plans must be included with applications for approval of herbicide-tolerant PNTs.

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Environmental safety assessments are evaluated on a case-by-case basis. After completing their safety assessment process for environmental and biodiversity impacts (which can take 6 to 12 months), [CFIA posts notices about every PNT approved for unconfined release](#).

[Novel product-specific decision documents](#) are posted online. Any new post-approval information about an approved PNT or novel livestock feed derived from plants must be communicated to CFIA. The decision document will be re-evaluated. Post-approval monitoring and inspection programs may be imposed by CFIA.

Information about [variety registration](#) is available online.

#### 4. Novel Foods and Feeds

Pursuant to the Food and Drugs Act and the Novel Food Regulations, [Health Canada](#) is responsible for assessing novel human foods that have no previous history of safe use. HC is also responsible for nutritional, allergenicity and environmental assessments of novel foods.

Health Canada [Guidelines for Safety Assessment of Novel Foods](#) are based on international scientific standards.

A [listing of all Health Canada-approved novel food products](#) is found online.

Information from CFIA about the [regulation of novel feeds](#) is found online.

For guidance on the approval process for novel feeds pursuant to the Feeds Regulations, see [Guidelines for the Assessment of Novel Feeds, Plant Sources](#) and [Novel Feeds from Microbial Sources](#).

[Notices of submission](#) for approval of experimental PNTs and novel livestock feeds derived from plants that are under review by CFIA are posted online.

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Research trials with novel feeds involve extraordinary strategies for operations management (e.g. security of the novel feed, management of animal manure and by-products, disposition of all animals, record keeping). These matters should be discussed with the Animal Facility Manager and the Manager, Research Risk.

5. PNTs for Plant Molecular Farming

Since PNTs for PMF produce pharmaceutical (or industrial) biocompounds which may potentially be active in humans, livestock animals or non-target organisms, may prescribe additional standards for containment and confinement.

6. Ornamental Plants with Novel Traits

Ornamental plants that express novel traits also come under the CFIA regulatory framework for environmental protection (due to physical or genetic invasiveness, weediness, etc.). Generally, environmental concerns are no different from those associated with exotic ornamentals. University guidelines for physical containment and operational procedures for PNTs are also appropriate for ornamental PNTs.

## References

For further information about agricultural biotechnology, see:

- [BiotecCanada](#)
- [Biotechnology at the Canadian Food Inspection Agency](#)
- [National Agricultural Biotechnology Council](#)
- [United States Department of Agriculture](#)

Adair, D., Irwin, R., Traynor, P.L., "[A Practical Guide to Containment, Greenhouse Research with Transgenic Plants and Microbes](#)

## Definitions

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### *biodiversity*

number and types of organisms in a region or environment; includes species and genetic diversity.

### *biotechnology*

application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms in their natural and modified forms. Techniques of biotechnology include gene mapping, DNA sequencing, genetic modification, functional genomics, diagnostics and cloning.

### *confined release*

under conditions intended to minimize the release establishment and spread in the environment of seed, or genetic material from plants derived from seed, and the interaction of the seed or genetic material with the environment.

### *confined research field trial*

tests the ability of an experimental PNT to perform under normal field cultivation conditions; the CFIA- sanctioned release of an experimental (unapproved) PNT for research purposes under terms and conditions of confinement designed to minimize any impact that the PNT may have on the environment. The terms and conditions may include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions. Plant materials grown in a confined research field trial shall not be permitted to enter the marketplace.

### *ecosystem*

a dynamic complex of plant, animal and microorganism communities and their non-living environment interacting as a functional unit.



*environment*

components of the earth including the atmosphere, land, water, all organic and inorganic matter and living organisms, and all interacting natural and managed (e.g., agricultural) ecosystems.

*exotic*

non-native, refers to an organism that has been introduced into an area.

*microorganism*

any bacteria, mycoplasma, Chlamydia, rickettsia, protozoa, fungi, algae, viruses, parts of these microorganisms and any combination thereof.

*novel trait*

a new characteristic or attribute scientifically introduced to a plant, a food or food ingredient

*New Substances Notification Regulations (NSNR)*

pursuant to the Canadian Environmental Protection Act; regulate genetically engineered living organisms and microorganisms not regulated by other legislation (e.g., Seeds Act).

*plants*

includes but not limited to mosses, liverworts, macroscopic algae and vascular plants including crops, forest, weed and ornamental species.

*plant molecular farming (PMF)*

the cultivation of plants for industrial, medicinal or scientifically useful biomolecules (e.g., vaccines, antibodies, pharmaceuticals, industrial enzymes) rather than traditional uses as foods, feeds or fibres.

*plant with novel trait (PNT)*

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a plant with a characteristic not normally found in that species or a trait expressed outside the normal range of similar existing characteristics in that species. Novel traits are introduced via genetic modification techniques including conventional selective breeding, biotechnology or mutagenesis. Most genetically engineered plants are PNTs but not all PNTs are created by genetic engineering. A livestock feed (including feeds from non-traditional sources and feeds used or approved in other countries) is also considered novel until listed in Schedule IV or V of the Feeds Regulations. Experimental PNTs (e.g., unapproved novel human or animal food crops, horticultural and marine plants, trees) are subject to regulatory controls by CFIA and extensive safety assessments before approval for unconfined release.

*reproductive isolation*

the means used to prevent movement of plant material, particularly pollen, from experimental containment or confinement. There are four principal methods to achieve reproductive isolation: geographic isolation, spatial separation, temporal isolation and physical isolation.

*submission*

refers to each plant species/genetic modification combination documented for CFIA.

*transgenic material*

biological material that incorporates genetic material from completely unrelated organisms in order to exhibit or enhance desired characteristics.

*unauthorized release*

any release of any genetic material, seeds or plant propagules of an experimental PNT into the environment without authorization by CFIA.

*unconfined release*

the unrestricted use of a CFIA-approved PNT in the environment, i.e., the PNT is no longer experimental.

*weed*

any plant that poses a major threat to agriculture or to natural ecosystems in Canada;  
See the OMAF Guide to Weed Control 2014.

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**Related External Legislation or Policy**

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Administered by the Canadian Food Inspection Agency (CFIA):

- [Feeds Act](#)
- [Fertilizers Act](#)
- [Health of Animals Act](#)
- [Plant Protection Act](#)
- [Seeds Act](#)

Administered by Health Canada:

- [Food and Drugs Act](#)
- [Pest Control Products Act](#)

Administered by Environment Canada:

- [Canadian Environmental Protection Act](#)

Administered through Excellence through Stewardship:

[Guide for Maintaining Plant Product Integrity of Biotechnology-Derived Plant Products](#)

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**Related University Policy, Procedures or Guidance**

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- [University's Biosafety Safety Policy 851.11.01](#)



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### **Location of Research Guideline**

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This guideline is published at: [www.uoguelph.ca/research](http://www.uoguelph.ca/research)

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### **Review Frequency**

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It is the responsibility of the Office of Administrative Responsibility to initiate review of this policy. This guideline is to be reviewed every 5 years.

**Appendix**

Table 1. Recommended Plant Biosafety Levels Based on Specific Risk Criteria

<b>Risk Criteria</b>	<b>Description</b>	<b>Plant Biosafety Containment Level</b>
<b>Weediness</b>	Not a noxious weed, cannot outcross with one	1
	Noxious weed or can interbreed with weeds	2
<b>Dissemination</b>	Not easily disseminated	1
	Can outcross with other populations or related species	2
<b>Environmental Risk</b>	No detriment from PNT or associated DNA-modified common microorganism	1
	Release would have predictable minimal environmental impact	2
	Transgenic plant-associated microorganisms are indigenous, or exotic but presenting no harm to natural ecosystems	2
	Plant-associated transgenic insects that present no threat to ecosystems	2
	Potential for detrimental impact on organisms or ecosystems beyond the containment facility	3

Risk Criteria	Description	Plant Biosafety Containment Level
<b>Transgenic origin</b>	Contains the complete genome of a non-exotic indigenous infectious agent or pathogen	2
	Contains genome of an exotic infectious agent	3
	Treated with an exotic infectious agent	
	Involves an exotic infectious agent with detriment to the environment	3
	Genome of the infectious agent may be reconstituted in planta	3
	Contains vertebrate toxin	3
	Involves an exotic readily transmissible pathogen	4
<b>DNA Used</b>	Non-coding DNA (not part of any organism or virus)	1
	Segments are from a single non-chromosomal or viral source	1
	From a particular organism propagated only in that organism	1
	From species that exchange DNA by well-established physiological means (natural exchangers)	1
	In vitro work with transiently transformed tissues	1