



CANADIAN FOOD INSPECTION AGENCY 59 Camelot Drive Ottawa, Ontario K1A 0Y9 (Tel: 225-2342; FAX: 613-228-6602)	D-96-13
	(EFFECTIVE DATE) July 26, 2010 (2nd Revision)
TITLE: Import Requirements for Plants with Novel Traits, including Transgenic Plants and their Viable Plant Parts	

SUBJECT:

This directive outlines the requirements for the importation into Canada of all plants with novel traits (PNTs) including transgenic plants and viable plant parts derived from them, such as fruit, tubers, seed and grain.

The current revision clarifies the import permit requirements for plants with novel traits (PNTs). A number of definitions were also updated.

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Review

This directive will be reviewed every 5 years unless otherwise needed. For further information or clarification regarding the content of the directive, please contact the Plant Biosafety Office of the Canadian Food Inspection Agency (CFIA) at <http://www.inspection.gc.ca/english/tools/feedback/commene.shtml?pbo>.

Endorsement

Approved by:

Chief Plant Health Officer

Amendment Record

Amendments to this directive will be dated and distributed as outlined in the distribution below.

Distribution

1. Directive mail list (Regions, PHRA, USDA)
2. Provincial Government, Industry Organizations (determined by Author)
3. National Industry Organizations (determined by Author)
4. Internet

Introduction

Transgenic plants and other plants with novel traits (PNTs) including viable plant parts derived from them such as fruit, tubers, seed and grains are subject to the import requirements outlined in this directive. The import of a PNT into Canada will require an import permit issued under section 43 of the *Plant Protection Regulations*, if the PNT's plant pest potential has not yet been assessed by the CFIA.

Requirements of an import permit will include maintenance of the PNT in conditions of containment until such time as a release from containment is authorized by the Director of the CFIA's Field Crop Division, e.g. in a confined research field trial or an unconfined environmental release.

PNTs may also be subject to commodity-specific phytosanitary requirements. These phytosanitary conditions are applied to prevent the entry and spread of pests in Canada and apply regardless of whether the imported product is a PNT. Figure 1 illustrates how

commodity-specific phytosanitary and PNT-specific phytosanitary requirements are applied to an import permit request.

For more information on determining if a non-transgenic plant is a PNT, please see D-2009-09: Plants with novel traits regulated under Part V of the *Seeds Regulations: Guidelines for determining when to notify the CFIA*, at <http://www.inspection.gc.ca/english/plaveg/bio/dir/dir0909e.shtml>.

For more information on import requirements for PNTs, contact the PBO of the CFIA through email at: pbo@inspection.gc.ca or through the CFIA contact information website at: <http://www.inspection.gc.ca/english/tools/feedback/commene.shtml?pbo>.

Scope:

This directive is intended for use by importers, the Canadian Food Inspection Agency (CFIA), the Canada Border Services Agency (CBSA), other government departments and the public. This directive outlines the Canadian import requirements for PNTs.

This directive supersedes D-96-13 (1st Revision).

Definitions, Abbreviations and Acronyms

Definitions for terms used in the present document can be found in the Plant Health Glossary of Terms.

<http://www.inspection.gc.ca/english/plaveg/protect/dir/glosterme.shtml>

1.0 General Requirements

1.1 Legislative Authority

The Plant Protection Act, S.C. 1990, c.22

The Plant Protection Regulations, SOR/95-212

Canadian Food Inspection Agency Fees Notice, Canada Gazette, Part I (05/13/2000)

Seeds Act, R.S., 1985 c.S-8

Seeds Regulations, Part V, C.R.C., c. 1400

1.2 Fees

The CFIA is charging fees in accordance with the *Canadian Food Inspection Agency Fees Notice*. For information regarding fees associated with imported product, please contact the Import Service Centre (ISC) at

<http://www.inspection.gc.ca/english/imp/importe.shtml>. Anyone requiring other information regarding fees may contact any local CFIA office

<http://www.inspection.gc.ca/english/directory/offbure.shtml>

or visit our Fees Notice Web Site:

<http://www.inspection.gc.ca/english/reg/cfiaacia/feesfrais/feesfraise.shtml>.

1.3 Regulated Commodities

PNTs, transgenic plants (including transgenic cut flowers) and viable plant parts derived from them such as fruits, tubers, seed and grain, are regulated commodities under the *Plant Protection Act*. For the purposes of this document, PNTs, transgenic plants and/or viable plant parts derived from them will be referred to inclusively as PNTs.

The import of any viable transgenic seed or plants intended for environmental release will require an import permit in accordance with this directive, and will also trigger regulation under Part V of the *Seeds Regulations*

1.4 Exempt Commodities

Although other phytosanitary requirements may still apply, **PNT-specific import requirements do not apply** to commodities conforming to the following exemptions:

1.4.1 PNTs authorized for unconfined release in Canada

PNTs that have been authorized for unconfined release into the Canadian environment under Part V of the *Seeds Regulations* have already undergone a safety assessment that includes an evaluation of their plant pest potential.

For a list of PNTs that have been authorized for unconfined release in Canada, please see <http://active.inspection.gc.ca/eng/plaveg/bio/pntvcne.asp>.

1.4.2 Plants derived from those PNTs authorized for unconfined release

Plants that are further developed from, and are considered substantially equivalent to, PNTs identified in exemption 1.4.1, are also exempted from PNT-specific import requirements provided that the intended use is similar, the plants do not contain any additional novel traits, and have not been subject to interspecific breeding.

Stacks of previously authorized single events are also exempted from PNT-specific import requirements. For more information on the regulatory requirements for stacks please see section 2.5.5.

1.4.3 Non-viable PNTs

PNTs that are incapable of sexual or asexual propagation, i.e., have been processed in some way to render them non-viable, such as by grinding or freezing (e.g. freeze-dried leaves), are exempted from PNT-specific import requirements.

1.4.4 Stand-alone DNA or RNA preparations

DNA or RNA preparations free of (not in or associated with) any living host organisms.

1.4.5 Select taxa of transgenic cut flowers

Transgenic cut flowers specifically of the taxa

Rosa spp.,
Chrysanthemum x morifolium,
Dianthus caryophyllus,
Dendranthema spp.,
Gerbera hybrida.,
Lilium spp., and
Tulipa spp.,

That are not intended for environmental release (i.e. are not intended for propagation, field cultivation, or other planting outdoors), are exempted from the requirements of this directive.

Importers should note the following:

- Any phytosanitary measures which apply to non-transgenic cut flowers would also apply to transgenic cut flowers. Importers are advised to contact their local CFIA Import Service Centre for more information or utilize the automated import reference system (AIRS) of the CFIA found at: <http://www.inspection.gc.ca/english/imp/airse.shtml>
- The intentional planting or propagation of transgenic cut flowers such that they persist or spread in the Canadian environment requires prior authorization under Part V of the *Seeds Regulations*.

1.5 Regulated Areas

All origins.

2.0 Specific Requirements

2.1 Import Requirements for PNTs

Importation into Canada of all PNTs that have not been previously authorized for unconfined release into the Canadian environment under the *Seeds Act* and Part V of the *Seeds Regulations* require a permit issued under Section 43 of the *Plant Protection Act* and *Plant Protection Regulations*. See Figure 1: Relationship between PNT-specific import requirements and commodity-specific phytosanitary requirements for import.

Due to the presence of a novel trait, all PNTs are considered to pose a potential pest risk to the Canadian environment. As such, PNT-specific phytosanitary requirements are applied to all PNTs until the PNT's plant pest potential has been assessed by the CFIA.

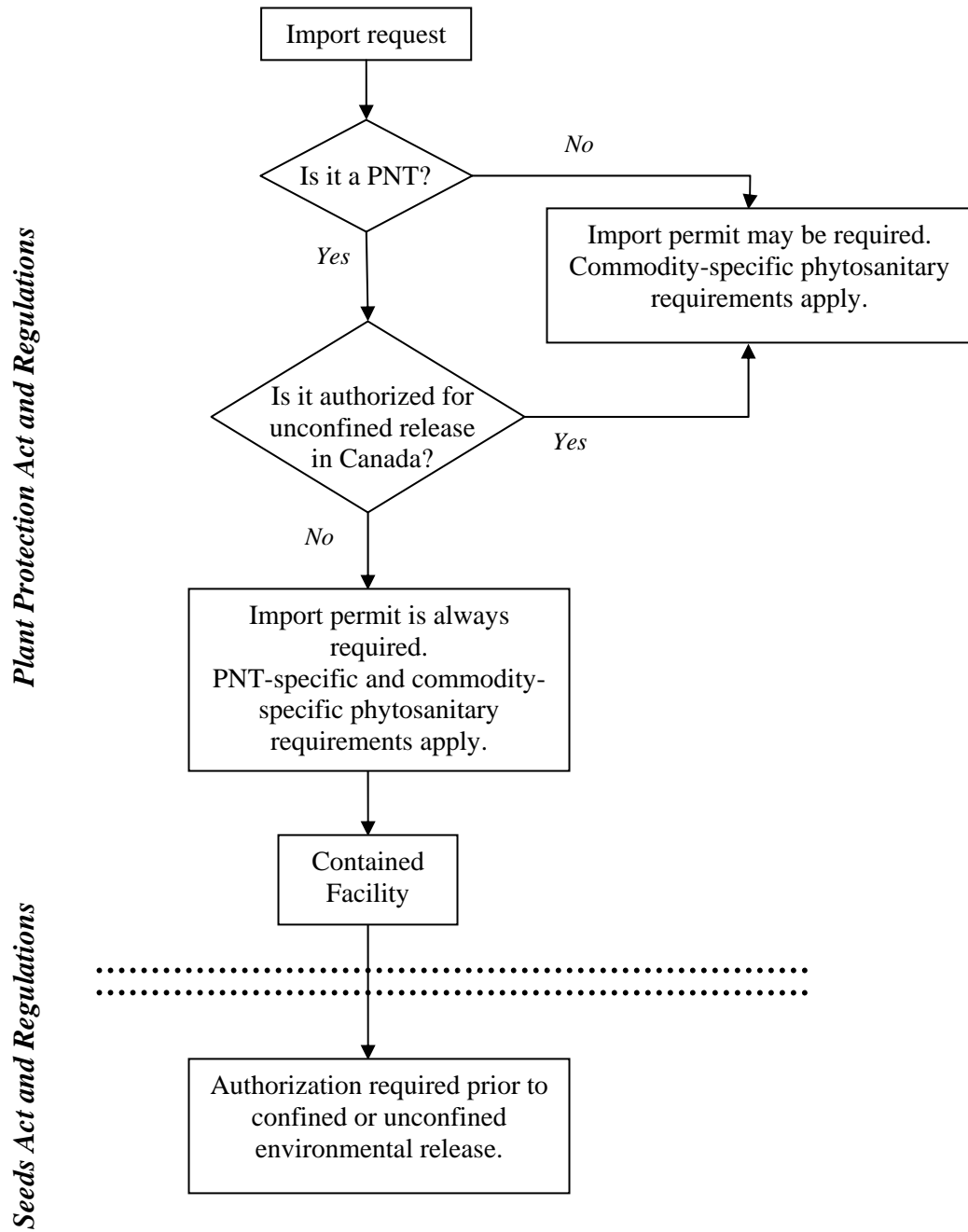


Figure 1: Relationship between PNT-specific import requirements and commodity-specific phytosanitary requirements for import.

2.1.1 Application for an import permit

Importers must complete an Application for a Permit to Import (CFIA/ACIA 5256), which can be obtained from any local office of the CFIA or downloaded from the CFIA website at:

<http://www.inspection.gc.ca/english/for/mpppe.shtml#C5256>.

For guidance on how to apply for a Permit to Import, information requirements, including the issuance and amending of Permits to Import or the *Plant Protection Regulations*, please see the directive D-97-04 “Application, procedures, issuance and use of a Permit to Import under the *Plant Protection Act*” at the following website:

<http://www.inspection.gc.ca/english/plaveg/protect/dir/d-97-04e.shtml>

2.1.2 Additional information required for the evaluation of PNTs

Please note that the information requirements for the evaluation of PNTs are in addition to those listed in the directive D-97-04. When completing an application form, the description of the material must be complete. The description fields of the application form must include as much of the following information as is available. If the information is unknown, this should be explicitly stated. If the information is too large for the form to accommodate, please attach the remainder of the information as a separate document (e.g. construct map).

- the scientific name (genus and species) and common names
- the type of material (e.g. seeds, plants, tubers, etc.). Note: an application may include more than one type of material, if the material comes from the same country of origin
- a clear description of the novel traits and genetic modifications
- the construct/plasmid name
- a map of the construct/plasmid including description of genes and their sources must be provided for the first submission. This information may be referenced in subsequent submissions
- OECD Unique Identifier and the transformation event (a name or designation associated with the specific PNT)
- the intended end use (e.g. research in a contained facility, confined field release, for processing, etc.)
- Permit numbers of permits previously issued for the same PNT or event

Applicants should note that certain information which is provided to the CFIA for the purposes of issuing an import permit may be protected under the provisions of the *Access to Information Act* or *Privacy Act*. For example, confidential business information, which may include information on specific constructs and events under development, may be exempt from disclosure pursuant to section 20(1) of the *Access to Information Act*. For additional information, please contact the CFIA’s Access to Information and Privacy Office at (613) 773-5557.

2.2 Other Phytosanitary Requirements

All PNTs, like their conventional counterparts, could serve as vectors for the introduction of plant pests such as molluscs, insects, or pathogens into Canada. Therefore, all imported PNTs are subject to the same phytosanitary requirements as their conventional counterparts.

Please note that all material entering Canada is subject to inspection or audit by CFIA inspectors.

2.3 Inspection of Receiving Facilities

Before an import permit is issued, facilities intended to receive PNTs may be inspected by a CFIA inspector to confirm that the importer will be able to comply with import permit conditions.

2.4 Inspection for Compliance with Permit Condition

After importation, facilities where imported PNTs are contained may be inspected to determine whether the importer is in compliance with import permit conditions.

2.5 Other Regulatory Requirements

PNTs that are imported into Canada may be subject to other regulations depending on the intended use. Please note that the list below is not exhaustive. The importer has the responsibility to determine that they have met all other regulatory requirements before and after import.

2.5.1 Environmental Release

PNTs imported into Canada must be maintained in contained facilities unless release into the environment is authorized by the CFIA.

For additional information regarding applications for confined environmental release, please see Directive 2000-07: Conducting Confined Research Field Trials of Plant with Novel Traits in Canada, found at <http://www.inspection.gc.ca/english/plaveg/bio/dir/dir0007e.shtml>.

For additional information regarding applications for unconfined release, please see Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits, found at <http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml>.

2.5.2 Food Use

Depending on the end use of the imported materials, requirements may apply under Health Canada legislation (*Food and Drugs Act* or *Pest Control Products Act*).

2.5.3 Feed Use

Depending on the end use of the imported materials, requirements may apply under legislation related to animal feed (*Feeds Act* or *Health of Animals Act*).

2.5.4 Commercial Processing Use

Products of biotechnology imported for commercial processing, i.e. not for planting, may also be subject to Environment Canada/Health Canada legislation (*New Substances Notification Regulations (Organisms)* under the *Canadian Environmental Protection Act*).

2.5.5 Environmental Release of Stacks

Release into the environment of stacks (such as planting) requires authorization under the Part V of the *Seeds Regulations*.

For more information on the regulatory requirements for stacks please refer to Directive 94-08 “Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits at the following website:

<http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.shtml>

and Directive 2000-07 “Conducting Confined Research Field Trials of Plant with Novel Traits in Canada” at the following website:

<http://www.inspection.gc.ca/english/plaveg/bio/dir/dir0007e.shtml>.

3.0 Non-Compliance

Shipments that do not meet the import requirements described in this directive will be refused entry, returned to origin, or destroyed, at the expense of the importer. The importer is responsible for any and all costs relating to treatment, disposal, and removal or re-routing, including costs incurred by CFIA to monitor the action taken. Violations of the *Plant Protection Act and Regulations* may be assessed according to the Administrative Monetary Penalties (AMPS).