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<p>Title/Titre IMPORT PERMIT REQUIREMENTS FOR PLANTS WITH NOVEL TRAITS (INCLUDING TRANSGENIC PLANTS), AND THEIR PRODUCTS</p>	<p>(EFFECTIVE DATE) July 27, 1998 (1st Revision)</p>

Our File/Notre référence

I. SUBJECT

This directive contains the phytosanitary import requirements for importing into Canada plants with novel traits (PNTs), including transgenic plants, and products derived from them, such as fruit, tubers and grain.

This directive supersedes D-96-13 (Original) dated May 1, 1996.

II. BACKGROUND

The current revision reflects the additional information required to assess an application for a Permit to Import. It also includes a new provision which allows an importer to obtain a permit for multiple destinations in one province when importing from the continental United States (U.S.).

Since 1988, Agriculture and Agri-Food Canada (AAFC), now the Canadian Food Inspection Agency (CFIA) has overseen the importation and field release of plants derived through techniques often referred to as biotechnology, and through traditional plant breeding methods such as wide cross hybridization and mutagenesis. These techniques are capable of introducing novel or unfamiliar traits into a species, which are not substantially equivalent to traits already present in that species in Canada. These techniques enable the plant breeder to have access to a wide source of beneficial traits.

Although these plants may differ from presently cultivated plant species by only a few traits, all PNTs (and/or products derived from them) are subject to the CFIA regulatory review under the *Plant Protection Act and Regulations*, regardless of the process used to produce them. Pest risk assessments (PRAs) are conducted in order to evaluate the potential capability of PNTs to pose a pest risk to the agricultural and forestry environment. Potential pest risk is assessed on the basis of the novel traits coded by the novel genes.

For example, novel traits could potentially impart weedy characteristics, or, if the inserted genes are derived from plant pathogens, they may recombine with genes from other pathogens, forming new strains with unknown pathogenicity.

Prior to issuing this directive, all PNTs (and/or products derived from them) have required a Permit to Import, issued by the Plant Health and Production Division, to enter Canada, regardless of regulatory decisions by other authorities outside the plant protection program. These permits included specific conditions to limit the movement or use of PNTs upon entry into Canada, in the absence of field trial experience and greater familiarity with the novel traits.

In 1995, AAFC for the first time approved several PNTs for unconfined release. These approvals were based on satisfactory environmental assessments (EAs) that involved the evaluation of several years of field testing information and the determination through PRA that these PNTs do not pose a plant pest risk. Once approved for unconfined release, these plants are no longer considered novel.

Many more applications for unconfined release are anticipated over the next few years. In addition, some products of PNTs will be imported into Canada directly as food or feed items. These are also subject to PRAs.

The policy conveyed in this directive is to discontinue the previous blanket requirement for a Permit to Import for all PNTs. **There is now no requirement for a Permit to Import, issued under the *Plant Protection Act and Regulations* for PNTs (and/or products derived from them) that have been determined by a PRA not to pose a plant pest risk.**

III. LEGISLATIVE AUTHORITY

Plant Protection Act, s.c. 1990, c.22
Plant Protection Regulations, SOR/95-212
Plant Protection Cost Recovery Fees Order

IV. REGULATED COMMODITIES

Plants with novel traits, including transgenic plants, and products derived from them, regardless of the process used to produce them.

V. COMMODITIES EXEMPT

1. PNTs that have been determined, following a PRA, not to pose a plant pest risk by the Plant Health and Production Division. These can include PNTs that have been authorized for unconfined, release *under the Seeds Act and Regulations*, following an environmental assessment (EA).
2. PNTs or products of 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.

Plants further developed from PNTs in exemption 1. above, and plants considered substantially equivalent to PNTs in exemption 1. above, are also exempted provided that the intended use is similar, the plants do not display any additional novel traits, do not contain novel genetic elements and have not been subject to interspecific breeding.

VI. REGULATED AREAS

PNTs originating from all countries.

VII. IMPORT REQUIREMENTS

1. GENERAL

A Permit to Import, issued by the Plant Health and Production Division, is required to import PNTs including transgenic plants, and any products derived from PNTs. Permits are issued under Section 43 of the *Plant Protection Regulations*, that provides for the importation of plant material for scientific research, educational, processing, industrial or exhibition

purposes. **This requirement is in addition to other plant protection import requirements that apply to specific commodities.** Importers must complete an “Application for Permit to Import” form, which can be obtained from any local office of the CFIA.

The **exceptions** to this import requirement are the exempted commodities in **Section V**. Importers do not require a Permit to Import for these unless otherwise specified under a policy governing a specific policy.

If the importer is uncertain as to whether their material is exempt from import permit requirements, he or she should submit an “Application for Permit”. This will be reviewed to determine if the PNT requires a Permit to Import and the importer will be advised accordingly.

In completing an “Application for Permit to Import” form, it is essential that the description of the material is complete. As a minimum, information supplied in the “Description” section of the “Application for Permit to Import” form must include:

- C the scientific name (genus and species), synonyms and common names;
- C the type of material (e.g. seeds, plants, tubers, etc.). Note: a separate application must be submitted for each different type of material;
- C clear identification of the novel traits and DNA inserts or modifications;
- C construct/plasmid code. A map of the construct describing genes and their source must be provided for first submission;
- C the quantity of material to be imported;
- C the intended end use (e.g. research in a contained facility, confined field release, for processing, etc.);

To expedite the processing of an application, please provide the following information whenever appropriate:

- C previous permit number if the application is for a renewal of a Permit to Import;
- C the unique identifier that clearly identifies the material to be imported. This designation is associated with the specific PNT and corresponds to a single, or finite number of modification(s) also referred to as a transformation event(s), in a specific plant species.

All information provided in conjunction with permit applications will be held in confidence by the CFIA. **In addition, any documents associated with material that requires a Permit to Import should clearly indicate that it is a PNT, or where appropriate, that it is transgenic.**

2. PERMIT TO IMPORT ISSUED FOR MULTIPLE DESTINATIONS WITHIN ONE PROVINCE

- 2.1** Only one Permit to Import is required for plants and related things provided they originate from one source in the continental U.S. and are destined to a minimum of five locations in one province in Canada. It is the applicant's responsibility to provide a complete list of destinations to which the material may be sent. This list will be attached to the Permit to Import. The Permit Office must be notified immediately of any changes to the list of destinations.
- 2.2** Shipments originating from areas other than the continental U.S. require one Permit to Import for each destination.

VIII. INSPECTION PROCEDURES

All material passing through Customs Canada is subject to inspection or audit according to the commodity specific instructions in the Import Inspection Manual.

IX. NON-COMPLIANCE

- 1.** Shipments of regulated articles not meeting Canadian import requirements, as specified in this directive or as part of the permit conditions, may either be confiscated and destroyed or ordered removed from Canada at the importer's expense.
- 2.** Records of importation must be maintained by the importer and may be reviewed by CFIA on a regular basis.

X. OTHER REQUIREMENTS

PNTs that are intended for import and release into the environment (e.g., for field testing under confined conditions), may also be subject to other regulations under such CFIA Acts as the *Feeds Act*, *Fertilizer Act*, *Seeds Act*, and *Health of Animals Act*. In addition there may be import requirements under Health Canada legislation (*Food and Drug Act* or *Pest Control Products Act*) or provincial jurisdiction.

Any importer wishing more information may contact local offices of the CFIA.

XI. DEFINITIONS

PLANT WITH NOVEL TRAITS (PNTs) - A plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of cultivated plant species in Canada and that has been intentionally selected, created or introduced into a population of that species through a specific genetic change.

BIOTECHNOLOGY - *"Biotechnology is the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms"*. In general, biotechnology can include the processes of: genetic modification through the insertion of modified genes or genes transferred from foreign sources; and modifying existing genes by mutagenesis.

TRANSGENIC PLANTS - Plants containing one or more new genes introduced by genetic engineering.

SUBSTANTIAL EQUIVALENCE - The equivalence of a novel trait within a particular plant species, in terms of its specific use and plant pest potential, to those in that same species, that are in use and generally considered safe in Canada, based on valid scientific rationale.

PEST RISK ANALYSIS - Pest risk assessment and pest risk management.

PEST RISK ASSESSMENT - Determination of whether a pest is a quarantine pest and evaluation of its introduction potential.

PEST RISK MANAGEMENT - The decision-making process of reducing the risk of introduction of a quarantine pest.

V. FEES

The CFIA is charging fees in accordance with the *Plant Protection Cost Recovery Fees Order*. For information regarding fees associated with imported product, please contact the Import Service Centres (ISC) at the following phone numbers: Eastern ISC -1-877-493-0468; Central ISC - 1-800-835-4486; Western ISC - 1-888-732-6222. Anyone requiring other information regarding fees may contact any local CFIA office.

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