Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

D-15-01: Import and domestic movement requirements for prohibited or restricted propagative plant material for scientific research

Effective date: TBD

(1st revision)

Subject

This directive outlines the criteria that must be met to import or move certain types of prohibited or restricted propagative plant material into or within Canada for the purpose of scientific research.

This document formalizes the D-15-01 pilot program which was launched in May 2015. The following amendments have been made to the original pilot program:

- The scope of the directive has been expanded to include domestic movement of prohibited or restricted material within Canada;
- A third category of research end-use has been added for pre-screening and provisional release of prohibited or restricted material; and
- Extensive formatting and editorial changes have been made to improve the clarity of the text.

This document supersedes directive D-15-01 (pilot - unpublished).

Canada

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1.0 Legislative authority

Plant Protection Act (S.C. 1990, c. 22)

Plant Protection Regulations (SOR/95-212)

Canadian Food Inspection Agency Fees Notice, *Canada Gazette, Part I* (as amended from time to time)

Agriculture and Agri-Food Administrative Monetary Penalties Act (S.C. 1995, c. 40)
Agriculture and Agri-Food Administrative Monetary Penalties Regulations (SOR/2000-187)

2.0 Definitions, abbreviations and acronyms

Definitions of terms used in this document can be found in the International Standard for Phytosanitary Measures 5: Glossary of phytosanitary terms the North American Plant Protection Organization Glossary of Phytosanitary Terms, and/or the Canadian Food Inspection Agency's (CFIA's) Plant Health Glossary of Terms.

For the purposes of this directive:

- **Certified** material refers to plant material which has been virus-tested and originates from a CFIA-accepted certification program. **Uncertified** material refers to plant material which does not originate from a CFIA-accepted certification program, regardless of any available virus test results at time of import.

- **Containment** measures are reviewed on a case by case basis, and must be approved by the CFIA as part of the facility's preventive control plan (PCP). Containment of material may be accomplished by using a suitable enclosure (e.g. growth chamber, greenhouse or screenhouse), a planting location that ensures adequate isolation from major production zones of the commodity in question, or a combination of measures determined to sufficiently mitigate all identified risks associated with the material in question.

3.0 Introduction

Under the authority of the *Plant Protection Act* and *Plant Protection Regulations*, the Canadian Food Inspection Agency (CFIA) establishes import and domestic requirements to prevent the introduction and spread of plant pests in Canada. Material regulated under this directive is considered to pose a high phytosanitary risk either due to the identification of specific risk(s) through the Pest Risk Analysis (PRA) process or because a PRA has not yet been conducted and the phytosanitary risk is unknown.

As such, plant material may be prohibited entry into or movement within Canada for several reasons, including:

- The material is considered to be a pest,

- The material is or could be infested with a pest,
- The material could constitute a biological obstacle to the control of a pest, or
- The material does not otherwise meet the requirements of the *Plant Protection Act* or cannot be certified to meet Canada's import requirements.

Under sections 43 and 54 of the *Plant Protection Regulations,* permission may be granted to import or move things that are otherwise prohibited entry into or movement within Canada, for special purposes including scientific research. This permission is specifically granted by the CFIA by means of either a **Permit to Import** or a **Domestic Movement Certificate**.

It is important to note that while this directive provides the general guidelines that will be followed in the review of permission applications and development of conditions for the import and movement of high-risk material which would otherwise be prohibited, each application is assessed on a case-by-case basis to ensure that the potential phytosanitary risks associated with the material in question can be sufficiently mitigated.

4.0 Scope

4.1 Regulated pests

See the List of pests regulated by Canada.

Note: the CFIA may take action on material found to be infested with pests of potential quarantine concern even if the pests are not yet included on this list.

4.2 Material regulated under this directive

Any plant or plant part which meets **all** of the following criteria:

- is prohibited entry into, or movement within, Canada or cannot be certified to meet Canadian phytosanitary import or domestic requirements; and
- is being imported or moved for the purposes of scientific research at a research laboratory owned and operated by a chartered academic institution; a federal, provincial, municipal or indigenous self-government; or a research and development section of a corporation; and
- will be grown on or further propagated during the research period.

4.3 Material outside the scope of this directive

- Plant propagative material permitted entry to Canada under section 32 of the *Plant Protection Regulations* (see directive D-08-04)
- Plants designated as pests (see directive D-12-01)
- Plants known or found to be infested with a pest regulated by Canada (see directives D-12-02 and D-12-03)
- Restricted or prohibited plant material which will not be grown on or further propagated (e.g. plant material intended for destructive analysis only)
- Restricted or prohibited plant material imported for uses other than scientific research
- Soil (see directive D-95-26)
- Propagative material of *Solanum tuberosum* (see directive D-98-01)
- Plant material imported for the sole purpose of traditional post entry quarantine testing and release via the CFIA Centre for Plant Health – Sidney Laboratory , such as fruit trees (see directive D-22-01), grapevines (D-22-03), and small fruit plants (D-18-01).

4.4 Regulated areas

- All origins

5.0 Research categories

There are three categories of scientific research which may be considered under this directive. Each category is based on the intended end use of the regulated material:

5.1 Material intended for eventual destruction

This category is for material which will undergo destructive analysis or otherwise be destroyed at the end of the research period.

The material must remain contained at all times, and must be destroyed at the end of the analysis or research trial. No further propagation of the material or its progeny is permitted beyond the scope of the research period.

Material to be destroyed includes all residual material and its progeny, and may also include articles associated with the regulated material, such as seeds, soil, pots, etc. These activities will occur at the expense of the importer and in consultation with and/or under the supervision of a CFIA inspector.

5.2 Material intended for eventual release from research conditions

This category is for material that will potentially be released from its conditions at the end of the research period. The suitability of this category depends on whether the specific risk(s) identified for the commodity in question can be sufficiently mitigated, as determined by the CFIA.

This material must remain contained at all times until officially released by the CFIA. To be eligible for release, material must meet the conditions outlined in Section 8.

It should be noted that some material, such as uncertified fruit trees and grapevines, may not be eligible for direct release or export certification at the end of the research period. For example, samples of fruit tree and grapevine material intended for release must be sent to the CFIA Centre for Plant Health – Sidney Laboratory for post entry quarantine (PEQ) testing either at import or later in the research process with advanced CFIA approval. Only material released from CFIA Centre for Plant Health – Sidney Laboratory, and its direct progeny, may enter the relevant CFIA export certification programs or be eligible for distribution and/or propagation beyond the research parameters.

For more information on the CFIA's fruit tree and grapevine export certification programs, please see directives D-08-05: Canadian Fruit Tree Export Program (CFTEP) for *Malus, Pyrus, Chaenomeles, Cydonia* and *Prunus* spp. and D-97-06: Plant Protection export certification program for grapevine nursery stock, *Vitis* spp.

5.3 Material intended for pre-screening and provisional release

This category is for material which requires reduced containment measures, such as outdoor growth of uncertified fruit tree or grapevine material, where there is a risk of virus transmission through pollen, insect, or nematode vectors. The eligibility of material imported for this intended end use also depends on whether the specific risk(s) identified for the commodity in question can be sufficiently mitigated, as determined by the CFIA.

This material must be imported or moved directly to the CFIA Centre for Plant Health – Sidney Laboratory where it will undergo screening for viruses and other pests of concern associated with the commodity in question using appropriate methods, including high throughput sequencing (HTS) technologies. Upon successful completion of this preliminary screening (i.e. no viruses or pests of concern are detected) a portion of the material will be eligible for provisional release to the research facility for restricted use as identified in the preventive control plan until full post-entry quarantine testing is complete.

Material received and released under this option may be eligible for eventual certification and export, but only upon successful completion of full diagnostic testing of the material remaining at CFIA Centre for Plant Health – Sidney Laboratory. If material is intended for eventual certification and export then all applicable requirements of the appropriate certification program must be followed throughout the provisional release period.

6.0 Program requirements

The import or movement of material regulated under this directive may only proceed once **all** of the following requirements have been met:

- The appropriate permission application (i.e. permit to import or domestic movement certificate) has been submitted by the researcher; and
- A preventive control plan (PCP) has been developed by the research facility receiving the regulated material; and
- All submitted documentation has been reviewed and accepted by the CFIA, including any required facility inspections; and
- The permit to import or domestic movement certificate has been issued by the CFIA.

Additional details about each of these requirements can be found below. It is recommended that researchers contact their local CFIA office several months prior to their planned importation or domestic movement to discuss their particular request. The local CFIA office will be able to provide information regarding fees and timelines associated with the process.

6.1 Permission application

The movement of any regulated material imported or moved under this directive requires written permission from the CFIA. The type of permission required depends on the origin and destination of the material, as outlined below.

6.1.1 Permit to import

For regulated material being imported from outside of Canada, a permit to import (issued pursuant to section 43 of the *Plant Protection Regulations*) is required. The importer must be the individual who is overseeing the scientific research and must be associated with a formal research organization (see section 4.2). In the case of colleges and universities, only a faculty member or department head can apply for a permit to import on behalf of the institution. This does not include emeritus personnel.

For detailed information on how to apply for a permit to import, as well as the criteria under which regulated material may be imported for scientific research, please see CFIA directive D-97-04: Application, procedures, issuance and use of a Permit to Import under the Plant Protection Act.

Each application for a permit to import regulated material for scientific research must include the information outlined in section 2.3.2 of D-97-04. It must also contain a brief description of the phytosanitary aspects of the research, such as where the plants will be contained or grown, the length of time of the research project, and the long-term plans or applicable research category (section 5) of the imported material.

6.1.2 Domestic movement certificate

For regulated material being moved within Canada, a domestic movement certificate (issued pursuant to section 54 of the *Plant Protection Regulations*) is required. Please contact your local CFIA office for information on how to obtain a domestic movement certificate.

6.2 Preventive control plan

Any researcher or facility that will be receiving, handling, or storing material regulated under this directive is required to develop, implement, and maintain a Preventive Control Plan (PCP). The PCP is a written document that describes how the risk(s) posed by the import or movement of regulated material are identified and controlled. It must be submitted to the local CFIA office for review and acceptance prior to the issuance of a permission referenced in Section 6.1.

The PCP must:

- Be relevant to the specific regulated material and the activities for which it will be used;
- Outline the containment area where the regulated material will be handled and stored, and the biosecurity measures that will be taken by the importer/researcher to prevent the movement of regulated material, or any associated pests, outside of this authorised containment area;
- Describe the intended use of the regulated material and address the risks at every stage of the research, including receipt, handling, storage, and destruction (when applicable); and
- Describe the training that will be provided to all employees who may handle the material including how documentation of this training, and any other required records, will be maintained. This documentation must be made available to the CFIA upon

request.

For a more detailed list of the required elements, and how they should be incorporated into the PCP, please see Appendix 1.

6.3 Inspections

There are a number of different inspection activities that may be carried out by the CFIA in order to verify compliance with legislative and policy requirements. These inspections are explained in further detail below and are in alignment with the CFIA's Integrated Agency Inspection Model (iAIM) and Standard Inspection Process (SIP).

6.3.1 Pre-permission inspection

Once the PCP has been reviewed by the local CFIA office, and confirmed to meet the requirements outlined in Appendix 1, the research facility where the material is to be maintained will be subject to a pre-permission inspection by the CFIA to ensure that all of the risk mitigation measures outlined in the PCP can be met. Successful completion of this inspection is required prior to the issuance of a permit to import or domestic movement certificate.

6.3.2 Commodity inspection

Upon receipt of material imported or moved under a permit to import or domestic movement certificate, the local CFIA office must be contacted and material held unopened until either (a) the material has undergone a commodity inspection by the CFIA and/or (b) permission is granted by the local CFIA office to open or unpack the imported material without a commodity inspection. The facility may be subject to inspection any time regulated material is imported or moved.

6.3.3 Preventive control inspections

Depending on the length of the research project, the research facility may be subject to preventive control inspections to verify continued compliance with the conditions of the PCP. The facility may be subject to inspection on an annual basis until the restricted material has either been officially released by the CFIA or destroyed.

6.4 Notice of Prohibition or Restriction of an Activity

Upon issuance of the permit to import or domestic movement certificate, the importer or researcher will also receive a Notice of Prohibition or Restriction of an Activity issued by the CFIA. This notice will state that the imported material must be used and maintained in

accordance with the associated preventive control plan throughout the duration of the research period.

7.0 Non-compliance

Imported material may be subject to inspection by the CFIA and must meet all requirements outlined or otherwise addressed in the permit to import and preventive control plan (PCP) when reaching their first point of arrival in Canada.

If the regulated material is found to have additional risk or be infested with pests of quarantine concern that are not addressed by the preventive control plan (PCP) it may be ordered removed from the country, treated, or destroyed; or the PCP may need to be updated to sufficiently mitigate the newly identified risk. This decision will be at the discretion of the CFIA, and the importer will be responsible for all costs relating to treatment, disposal or removal of the material, including costs incurred by the CFIA to monitor the action taken.

8.0 Release of material from containment conditions

Regulated material may only be released from some or all of the containment conditions outlined in the permit to import and/or Notice of Prohibition or Restriction of an Activity when official written notice has been provided to the importer by a CFIA inspector.

Material may only be released when the following conditions have been met:

a) For material that is considered Not Authorized Pending Pest Risk Analysis (NAPPRA) or of unknown risk status, a pest risk analysis (PRA) has been completed for the material in question and the CFIA has determined that the material is eligible for release; and/or
b) For material with identified risk(s), the material has undergone appropriate risk mitigation measures (e.g. CFIA inspection, appropriate treatment, testing or virus indexing at a CFIA accredited laboratory) and the CFIA has determined the material to be free of pests and diseases of concern to Canada.

In some cases, only material that has undergone testing will be released to the importer for further propagation, such as for uncertified fruit trees or grapevines. In this case, any untested material and its progeny must either remain under official control or be destroyed.

For more information on the PRA process visit www.inspection.gc.ca/PRAprocess.

8.1 Denial of release of material from containment conditions

If the results of the PRA or testing have concluded that the material does not meet the conditions for release the CFIA will inform the importer of the results and present alternative options, which may include treatment or destruction.

9.0 References

9.1 Fees

The CFIA charges fees in accordance with the *Canadian Food Inspection Agency Fees Notice*. For information regarding fees, please contact your local CFIA office or visit the CFIA's *Fees Notice* website.

9.2 Supporting documents

- Automated Import Reference System (AIRS)
- D-08-04: Plant protection import requirements for plants and plant parts for planting
- D-08-05: Canadian Fruit Tree Export Program (CFTEP) for Malus, Pyrus, Chaenomeles, Cydonia and Prunus spp.
- D-12-01: Phytosanitary Requirements to Prevent the Introduction of Plants Regulated as Pests in Canada
- D-12-02: Import Requirements for Potentially Injurious Organisms (Other than Plants) to Prevent the Importation of Plant Pests in Canada
- D-12-03: Domestic Requirements for Potentially Injurious Organisms (Other than Plants) to Prevent the Spread of Plant Pests Within Canada
- D-18-01: Phytosanitary requirements for imported small fruit propagative material
- D-22-01: Phytosanitary requirements for the importation of fruit tree material for propagation or decorative use as fresh cut branches
- D-22-03: Phytosanitary requirements for the importation and domestic movement of grapevine material for propagation or decorative use.
- D-95-26: Phytosanitary Requirements for Soil and Soil-Related Matter, and for Items Contaminated with Soil and Soil-Related Matter
- D-97-06: Plant Protection Export Certification Program for Grapevine Nursery Stock, Vitis spp.
- D-98-01: Import Requirements for Seed Potatoes and Other Potato Propagative Material
- Pest Risk Analysis: How we evaluate fruits, vegetables and plants from new countries of

origin

Appendix 1: Elements of a preventive control plan

Any researcher or facility that will be receiving, handling, or storing regulated material must develop, implement, and maintain a preventive control plan (PCP) that includes the following elements, as appropriate. Please note that not all of the elements listed below will be applicable to every PCP. Annex B of the Integrated Agency Inspection Model (iAIM) has been used to develop this guide and can be consulted for more details.

For additional guidance on how to develop your PCP, visit the CFIA National Farm-Level Biosecurity Planning Guide.

Criteria	What the PCP must include (as appropriate)
General information	- Name and job title of the principal researcher overseeing the research activity - Name and job title of the facility employee who will be responsible to ensure that the PCP is followed throughout the entire process, if different from the principal researcher - Full scientific name and description of the regulated material - Brief description of the phytosanitary aspects of the research, including: • What the material will be used for; • Expected duration of the research project; • Identification of the research category of the regulated material, as per Section 5.0; • For material intended to be destroyed, the approximate date and description of the means by which the material will be destroyed; and • For material intended for eventual or provisional release, details of any testing or other measures being carried out prior to release.
Element 1: Process and import controls	- Identification of the plant health risk(s) associated with the regulated material, if known (i.e. why the material does not meet standard import or movement requirements). This may also be discussed with the CFIA and added during the PCP review process, if required - Description of how the regulated material will be identified and tracked through all steps of the research process - Description of any risk mitigation measures performed at the point of origin prior to import or movement - Details of the specific permission associated with the regulated material (i.e. permit to import or domestic movement certificate), including the source of the regulated material and exporter information. Note: the actual permit or domestic movement certificate number may not be available during the development of the PCP and can be added after it is issued.

Element 2: Biosecurity and pest control	- Description of the operational procedures for receiving, handling, storage, and disposal of the regulated material to prevent the spread of pests - Description of any measures in place for prevention, control, and monitoring of plant pests, including vectors of plant pests
Element 3: Employee training	- Details of the training that will be provided to every employee who may handle the regulated material and how this training will be documented and maintained. Note: training records must be made available to the CFIA upon request.
Element 4: Equipment design and maintenance	- Details of any equipment used to store, move, manipulate, process, or dispose of the regulated material. Equipment must be maintained in a manner to prevent cross-contamination and the spread of pests
Element 5: Physical structure, surroundings and maintenance	- Description of measures in place to mitigate the risk of external contamination and alternative pest hosts - Description of any required isolation or buffer zones, if required - General description and/or map of the authorized containment area, including areas where regulated material will be stored - Description of the measures to be taken to prevent the movement of the regulated material, or any associated quarantine pests, outside of this authorized containment area throughout the stages of the project - Description of the method(s) used to dispose of the regulated material, and how risks will be mitigated prior to disposal to prevent the spread of pests
Element 6: Receiving, transportation and storage	- Description of how material is handled and safeguarded during receiving, transport, and storage to prevent the spread of pests; including how packing material will be disposed of - Identification of any known or potential movement requirements outside of the containment area (e.g. movement of regulated material to another facility or disposal site)
Element 7: Traceability, control and complaints	- Copies of any record templates used in the implementation of the preventive controls described in the plan. These include, but are not limited to, records for: • Receipt and tracking of regulated material (e.g. storage, processing, movement, disposal) • Permissions, i.e. permit to import or domestic movement certificates • Training • Equipment maintenance and/or calibration (e.g. autoclave) • Pest monitoring and/or treatment records • Deviations and corrective actions taken - Details on how internal audits (i.e. those conducted by the facility and not the CFIA) will be conducted to ensure that all aspects of the PCP are being carried

	out consistently. This should include: • Internal audit schedule; • audit checklist; and • the name(s) of the employees responsible for conducting the internal audits - Description of the response action that will be taken in the event of a pest detection - Record of any amendments made to the PCP since its initial approval

Amendment procedure for the PCP

The facility staff should review the PCP on an ongoing basis to ensure that it properly details the procedures and processes in place, and that it effectively addresses the risk associated with the regulated material. Minor changes to the PCP may be done at any time, however major changes to the PCP that impact the integrity of the program must be submitted to the CFIA for review and approval prior to their implementation. All procedures identified as mandatory in the PCP must be followed.