ORGANISATON NORD AMERICAINE POUR LA PROTECTION DES PLANTES
NORTH AMERICAN PLANT PROTECTION ORGANIZATION
ORGANIZACION NORTEAMERICANA DE PROTECCION A LAS PLANTAS
CANADA UNITED STATES MEXICO

# NAPPO Regional Standards for Phytosanitary Measures (RSPM)



## RSPM No. 14
## Importation and Release (into the environment) of Transgenic Plants, in NAPPO Member Countries

Module 1: Importation Into Contained Facilities (attached)

Module 2: Confined Release into the Environment (attached)

Module 3: Unconfined Release into the Environment (attached)

Module 4: Importation for uses other than Propagation (in preparation)

The Secretariat of the North American Plant Protection Organization
Observatory Crescent Bldg. # 3, Central Experimental Farm
Ottawa, Ontario K1A 0C6
20 October, 2003

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**Review**

NAPPO Standards for Phytosanitary Measures are subject to periodic review and amendment. The next review date for this NAPPO standard is 2007. A review of any NAPPO Standard may be initiated at any time upon the request of a NAPPO member country.

**Endorsement**

This Standard was approved by the North American Plant Protection Organization (NAPPO) Executive Committee on August 12, 2002.

Approved by:

Robert Carberry
Executive Committee Member
CANADA

Richard Dunkle
Executive Committee Member
UNITED STATES

Jorge Hernandez Baeza
Executive Committee Member
MEXICO

**Effective Date**

This standard will become effective on the date of endorsement.

**Amendment Record**

Amendments to this Standard will be dated and filed with the NAPPO Secretariat. The most recent version will be posted on the NAPPO website at: www.nappo.org/stds_e.htm

**Distribution**

This standard is distributed by the Secretariat of the NAPPO within NAPPO, including Sustaining Associate Members and Industry Advisory Groups, to the FAO IPPC Secretariat, to the ICGPP, and to the Administrative Heads of the Regional Plant Protection Organizations (RPPOs). Copies are available upon request to the NAPPO Secretariat and are available on the NAPPO web page: www.nappo.org

## Introduction

## Scope

This standard is designed to provide guidance on the criteria for evaluating potential direct or indirect risks to plants and plant health posed by importation and release into the environment of transgenic plants associated with the transgenic plant itself. In addition, this standard provides guidance on appropriate authorization requirements and will encourage consistency in terms of implementing authorization systems for transgenic plants in NAPPO member countries.

Requirements for importation and release of transgenic plants pertaining to the potential pest risks associated with transgenic plants themselves do not replace other phytosanitary requirements for imports.

The standard is set out in four modules. Module 1 (this document) focuses on regulatory requirements for the importation into contained facilities. Module 2 (also this document) addresses assessment for confined release into the environment. Module 3 will cover assessment for unconfined release into the environment, and Module 4 will focus on assessment for the importation of transgenic plants for uses other than propagation. An overview of the regulatory framework in the three NAPPO member countries is also provided in appendix 1.

The development of this standard on transgenic plants does not preclude the development of additional NAPPO guidelines to assess the pest risk potential associated with other genetically-engineered products/Living Modified Organisms, such as arthropods or microorganisms, as the need arises.

Issues relating to the potential adverse impact of transgenic plants on human and animal health or on biological diversity and the environment beyond direct and indirect impacts on plants and plant health are not relevant to plant pest issues and fall outside the scope of this NAPPO standard. Authorization for importation and/or release of transgenic plants may also depend on analyses performed by other regulatory authorities to evaluate environmental and/or human health impacts. The type and extent of the analysis required will depend on the particular plant/trait combination and the intended use of the product, i.e., for production, for food/feed only, or for production of pharmaceutical or industrial compounds. Under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Codex Alimentarius Commission is the standard setting body for food safety issues including any food safety issues related to transgenic plants. The SPS Agreement cites Codex standards, guidelines and recommendations as the preferred international measures for facilitating international trade in food. Similarly, the Office International Des Epizooties (OIE) has as one of its objectives harmonization of regulations for trade in animals and animal products among Member Countries.

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**Definitions, Abbreviations and Acronyms**

Definitions of phytosanitary terms used in the present standard can be found in ISPM 5 and RSPM 5.

**Outline of Requirements**

Authorization for the importation and/or release of a transgenic plant into the environment may require:

1) Provision of sufficient information by the applicant to identify the transgenic plant material, the type of action proposed and the available risk management measures;
2) An assessment of the pest risk potential associated with the transgenic plant itself;
3) A determination that specific assessment criteria, and any risk management measures intended to minimize potential pest risk associated with the transgenic plant, have been met.

## General Requirements

## Background

Applications of modern biotechnology may have the potential to adversely affect plant resources in the environment, including as pests of plants and plant products. NAPPO member countries have had considerable experience with the importation of transgenic plants for research purposes, and with the environmental release of transgenic plants under confined and unconfined conditions. NAPPO member countries, therefore, have identified the need to develop standards for transgenic plants that identify our common approaches to the regulatory review of agricultural biotechnology products. In developing a standard for the safety assessment of transgenic plants, NAPPO has identified common risk assessment criteria, including the potential for pest risk associated with the transgenic plant itself, even though the regulations of NAPPO's individual member countries may not be directly promulgated under plant pest statutes. For example, Canada regulates all plants with novel traits, whatever the process used to introduce the traits.

Specific plant pest risk concerns related to transgenic plants include the potential for the plant to become a weed or to spread to, establish in and displace other species in natural habitats, including through gene flow from the plant to weedy or wild relatives. Concerns related to the potential for negative impacts on non-target organisms beneficial to plants, e.g. pollinators have also been raised. In addition, many transgenic plants have been developed using biological vectors from phytopathogenic sources, or with the use of genetic material from pathogenic sources, therefore, it may be appropriate for regulatory agencies to evaluate these plants to assure that there is no significant potential pest risk associated with the transgenic plant itself.

The NAPPO standard for review of transgenic plants identifies the information required to assess pest risk potential and outlines the assessment criteria required for making decisions regarding the importation of transgenic plants into member countries for use in contained facilities, for confined and unconfined release into the environment, and for importation for uses other than propagation, such as for food, feed, or for processing.

## MODULE 1: IMPORTATION TO CONTAINED FACILITIES

Transgenic plants may be imported into contained facilities for a variety of reasons including growth under contained conditions i.e. a specific laboratory, growth chamber, or greenhouse for research or commercial development purposes. In addition, transgenic plants imported for other purposes such as for confined field release, for unconfined environmental release, or for food and feed or for processing, may be initially imported into contained facilities.

NAPPO countries have implemented authorization systems for the importation of transgenic plants in order to assess whether a proposed importation presents any potential pest risk, and to make decisions on any requirements for the transit and use of transgenic plants following importation.

Importation requirements should allow for a determination that the transgenic plant is adequately characterized, that the transgenic plant can be considered to be contained in the contained facility, that dissemination into the environment will be prevented, and therefore, that the transgenic plant poses no significant pest risk. Information requirements necessary for making decisions regarding importation are defined below.

Note that the assessment of the potential pest risk associated with the importation of transgenic plants for uses other than for in contained facilities requires information in addition to that addressed in Sections 1.1.1 and 1.1.2.

When applicable, the following material is exempted from importation requirements specific to transgenic plants:

- transgenic plants that are incapable of sexual or asexual propagation following a treatment that renders them non-viable, and
- transgenic plants that have been determined, following a previous pest risk analysis (PRA) by the regulatory authority of the respective country, not to pose a pest risk due to the transgenic plant itself. These may include transgenic plants that have been authorized for unconfined release in the importing country.

### 1. Information requirements

Information provided by the applicant should address the proposed action, characterize the transgenic plant material, and indicate, when applicable, that acceptable containment measures will be taken to prevent dissemination into the environment during transit and while in the contained facility.

### 1.2 Proposed action

The following information should be provided:

- names, complete addresses and telephone numbers of the importer and the exporter;
- proposed date(s) or period of the importation
- means of transportation and place of entry into the importing country;
- country or place of origin of the plant material;
- intended use of the plant material and description of the contained facility (ies);
- signature of the applicant (must be a resident of the country into which the material

will be imported) and the date of application.

### 1.2.1 Description of the transgenic plant material

The following information should be provided:

- scientific name, synonyms and common names of the species to which the transgenic plant material belongs;
- type of material being imported, e.g., seeds, grains, plants, tubers, etc.;
- description of novel trait(s);
- name of the genetic construct/plasmid and a detailed description of the genes including marker genes, regulatory sequences, and their source (donor organisms);
- when applicable, method of transformation and name of the transformation vector (if any); and
- quantity being imported

### 1.2.2 Risk management measures

Where required, information related to risk management measures should include:

- adequate identification, packaging and segregation measures to prevent and/or minimize mixing, spillage and dissemination of viable transgenic plant material, including as necessary, the flow of fertile transgenic pollen to sexually compatible plants during transit and within and outside the contained facility, except for the purposes of controlled breeding within the contained facility.
- devitalization when no longer in use or authorized. Means of devitalization could include, but are not limited to, dry heat, steam heat, crushing, deep burial and/or chemical treatment.

Guidance documents on acceptable containment measures, such as the NIH Guidelines for Research Involving Recombinant DNA Molecules (1999), Appendix P, or the Health Canada Laboratory Biosafety Guidelines (1996), can also provide useful information on risk management.

## 1.3 Assessment criteria

The information required in Section 1.1 provides the basis for an assessment of potential pest risk associated with the transgenic plant itself that may be presented by the proposed import. The regulatory authority in each NAPPO country should review the information submitted on a case-by-case basis for its completeness and acceptability. When applicable, this can be done by an expert advisory group.

When applicable, contained facilities may require an inspection, depending on prior inspections by regulatory authorities and/or the nature of the transgenic plant, to determine whether the contained facilities are appropriately designed and managed to minimize dissemination of fertile pollen (including exclusion of pollinators) to other sexually compatible plants outside or within the facility, in order to prevent the dissemination of viable material from the transgenic plants, and/or to address any other plant pest issues that may be posed by the use of the transgenic plants.

## 1.4 Authorization requirements

Authorization to import should generally be granted when a determination can be made as per Section 1.2 that the proposed importation of the transgenic plant does not pose a significant pest risk.

Authorizations are to be conditional on the use of the transgenic plant material at specific location(s) stipulated on the application, and**,** when applicable, to appropriate segregation, containment and disposal of the transgenic plant material to prevent mixing, escape and dissemination of the transgenic plant material, and to any inspections to ensure regulatory compliance.

- Authorization to import should be conditional on clear identification of the transgenic plant material during transit and in the receiving facility.
- When applicable, authorizations to import are to be valid for a fixed date or period of time from the date of issue.

The importer must be responsible for reporting any information promptly to the regulatory authority relating to significant changes in pest risk potential, including accidental releases. The regulatory authority must consider, and where appropriate, ensure that corrective action is taken.

All material passing through Customs should also be subject to inspection or audit according to the commodity specific instructions. Records of imports must be maintained by the importer and must be made available to the regulatory authorities upon request.

Consignment of transgenic material not meeting plant protection regulatory requirements and/or conditions of entry, should be either confiscated and destroyed or ordered removed from the country into which it is imported, at the importer's expense.

## MODULE 2: CONFINED RELEASE INTO THE ENVIRONMENT

Transgenic plants are cultivated under confined conditions for a variety of reasons including, the evaluation of yield or effectiveness of the introduced novel trait, the generation of safety data required for unconfined release into the environment, and/or the use of confined conditions as an effective means to segregate the harvested product (e.g. modified oil qualities) from that produced by conventional crops. In addition, transgenic plants may be cultivated under confined conditions because the plants or products thereof are of particularly high value (e.g. producing pharmaceuticals or other biologics). Confined conditions are intended to minimize any interaction between the transgenic plant (including its progeny, products, and the inserted genetic material) and the exposed environment.

Requirements related to confined release should allow for a determination that the transgenic plant is adequately characterized, that no transgenic plant material will persist in the environment, and that any unintentional or unanticipated effects, if any, can be restricted to the confined field site and can be managed in such a way that there are no potential significant pest risk after the confined field release is terminated.

### 2.1 Information Requirements

Information provided by the applicant should describe the proposed action, characterize the plant material, and when applicable, describe relevant details about the confined field site. In addition, the applicant should demonstrate that acceptable risk management measures have been and/or will be taken to confine the transgenic plant to the field site during its release and to prevent persistence of the plant or its progeny in the environment after completion of the field release.

#### 2.1.1 Proposed action

The following information should be provided:

- name, complete address and telephone number of the person and/or agency/body responsible for the proposed confined release and name of the person who will be in charge of carrying out the experimental release;
- number, size (e.g., acres, or hectares or number of plants) and location of the confined field sites and proposed dates or period of the confined releases;
- purpose, (e.g., research, such as evaluation of disease, insect or herbicide resistance or commercial purposes, such as production of pharmaceuticals or specialty oilseeds);
- when applicable, government agencies that have been notified of the development of the transgenic plant, and purpose for which the information was provided (e.g., importation, field testing, commercial cultivation, etc.);
- signature of the applicant and the date of application (must be a resident of the country where the confined field release will be carried out).

#### 2.1.2 Description of the plant prior to modification

The following information should be provided:

- scientific name, synonyms and common names;
- when applicable, life cycle with emphasis on reproductive biology, habitats (managed vs unmanaged), and location where it is a known weed or invasive species (if any).

### 2.1.3 Description of the modification(s) and transformation method

The following information should be provided:

- description of the novel trait(s);
- description of the transformation method and vector (when applicable), map or description of the genetic construct(s), and list of the genetic material or genes conferring the desired traits, including marker genes, associated regulatory sequences driving their expression in the plant, donor organisms for all introduced genetic material, and gene products.

### 2.1.4 Description of the transgenic plant

The following information should be provided:

- expected phenotype related to expression of the novel trait, including (if needed to address specific risk concerns) levels of expression of the novel trait in specific tissues of the plant, and the stability of the incorporation of the novel genetic material into the plant's genome;
- when applicable, information and test data relevant to identifying risk to plants (including wild and related species), and non-target organisms beneficial to plants in the exposed environment;
- when applicable, a description of the analytical methodologies used in generating any submitted data, including quality control and quality assurance procedures.

### 2.1.5 Confined field site details

When applicable, the following information should be provided:

- relevant details about sites and surroundings, including proximity to sensitive ecological areas and the presence of endangered or threatened species, or sexually compatible species, including cultivated or wild or weedy relatives;
- cultivation protocols including any monitoring of and/or challenge of plants with pests (pathogens, insects, weeds) and use of pesticides (herbicides, insecticides, fungicides, etc.). In these latter cases, special authorization may also be required for the release of regulated pests at the site

### 2.1.6 Risk management measures

For confined releases, measures are to be taken to confine the transgenic plants to the field site during the defined period of the release and to prevent the transgenic plants or their progeny from persisting in the environment in subsequent growing seasons either within or outside of the site of the confined release.

Post-harvest land use restrictions may be necessary for a certain number of years following harvest of the transgenic plant material to allow monitoring, removal and destruction of volunteers. Generally, the post-harvest periods used to ensure purity of certified seed may be adapted successfully. For certain plant species, and for certain specific cases, post-harvest land use restrictions may also be necessary for the perimeter of the confined field site itself to monitor for volunteers resulting from potential dissemination of seed, e.g., during mechanical harvesting operations.

Both the reproductive isolation measures and post harvest land use restrictions should be based on the reproductive biology and seed dormancy characteristics of the species, surrounding land use, proximity of sexually compatible plants and

presence of pollinators. Additional management measures may be necessary based on the nature of the introduced trait(s). NAPPO member countries have provided guidance on risk management measures (USDA 1997a, b, c). Information may be required on the adequacy of risk management measures, particularly if the proposed measures deviate from guidance provided.

**2.1.6.1 Information related to risk management measures employed during the growing season should include:**

- adequate site selection (considering presence of sexually compatible relatives or protected plants or other species, flood susceptibility, wind breaks, security, etc.).
- adequate methods intended to prevent contact and dissemination of viable material by foraging animals, birds, vermin, etc., as warranted.
- adequate cleaning of seeding and transplanting, harvesting, threshing or other farm machinery at the confined field site prior to removal to another location to prevent dissemination of viable transgenic plant material into the environment
- measures to achieve reproductive isolation from plants of the same species and other sexually compatible species that are not part of the confined release, whether they are cultivated, weedy or wild species
- Depending on the plant species, this can be achieved by the use of one or a combination of the following methods: isolation distance, pollen or pollination proof caging, netting or bagging of plants prior to flowering, guard rows/ border rows of plants to attract pollinators or trap transgenic pollen, flower removal prior to pollination, use of male sterile lines, use of plant growth regulators to block reproductive development, different flowering time, and/or termination of the confined field release prior to flowering.
- Generally, isolation distances that are used to ensure purity of certified seed (such as breeder seed or foundation classes of certified seed) may be adapted successfully to prevent or minimize outcrossing of transgenic pollen to sexually compatible plants that could produce viable progeny capable of persisting outside the confined field release site.
- site monitoring for timely removal and disposal of plants of related species. When isolation distances are used, these zones are also monitored for the presence of the same species, related species and for proximity of fields of the same species.

**2.1.6.2 Information related to risk management measures employed during post-harvest years should include:**

- site monitoring for removal and disposal of volunteering transgenic plants before flowering to prevent transfer of pollen to sexually compatible plants. This implies that neither the plant species, nor any sexually compatible related species is to be grown on the confined field site during the post-harvest years.
- site monitoring for removal and disposal of related plant species prior to flowering as necessary to prevent transfer of pollen from transgenic volunteers to these related species.

**2.1.6.3 Information related to handling, disposal, record keeping and other considerations should include:**

- adequate identification, packaging and segregation measures intended to prevent seed mixing, spillage and dispersal into the environment during transit.
- devitalization of surplus seed or seedlings, and any viable transgenic plant material remaining after transplantation or after harvesting at the confined field site by suitable means which could include, but are not limited to, dry heat, steam heat, crushing, deep burial, discing into the soil, burning, treatment with appropriately labeled herbicides and/or chemicals. Harvested transgenic seed and/or plant material from the confined field site may only be retained in an approved facility if requested at the time of the submission and authorized by the regulatory authority, and should be clearly identified, securely transported, and stored separately from other seed/or plant material to avoid mixing.
- a contingency plan for destruction of viable transgenic plant material in case of accidental release. The plan should include site marking and monitoring to ensure destruction of viable material and immediate notification of regulatory authorities.

## 2.2 Assessment criteria

- The information required in Section 2.1 provides the basis for an assessment of any pest risk associated with the transgenic plant itself that may be presented by the proposed confined release. The regulatory authority in each NAPPO member country should review the submitted information on a case-by-case basis for its completeness and acceptability. When applicable, this can be done by an expert advisory group.
- Authorizations to allow confined field releases into the environment should generally be granted only when a determination can be made that the proposed confined release does not pose a significant pest risk.

In order to make such a determination, the following assessment criteria must be met:

- any biological vectors associated with the plant that are able to transfer genes and/or cause a risk of disease, damage or injury to plants or plant parts have been adequately disarmed or eliminated from the plant;
- any regulated pests able to transfer genes and/or cause a risk of disease, damage or injury to plants or plant parts that are to be used in the confined release site will not be disseminated beyond the site due to appropriate confinement and monitoring measures;
- the genetic modification of the transgenic plant is unlikely to lead to disease, damage or injury to plants or plant parts and will not result in the production of an infectious agent capable of causing such effects;
- any ability of the plant to pass on new weedy or invasive characteristics or pose a risk to threatened, endangered, or protected classes of plants is eliminated or minimized by appropriate site selection, reproductive isolation and confinement measures; and
- any new harmful property of the plant has a minimal likelihood of a detrimental effect on other plants and non-target organisms beneficial to plants. Any such

effect is limited by the size of the confined field release, appropriate selection of the site, and appropriate reproductive isolation and confinement measures.

## 2.3. Authorization requirements

Authorization for confined field releases should generally be granted when the assessment criteria in Section 2.2 allow for a determination that the proposed confined field release is not considered to pose a significant pest risk.

- authorizations to conduct confined releases should be valid for a fixed period of time;
- authorizations to conduct confined releases should be conditional on the employment of applicable risk management measures listed in section 2.1.6, including any measures regarding the use of any transgenic plant material harvested or removed from the site;
- authorized confined releases should be subject to inspection by regulatory authorities during the period of the release and the post-harvest restriction years to verify that the confined release is carried out in accordance with the authorization conditions;
- A final report should be produced and be made available to regulatory authorities upon request;
- The applicant must be responsible for reporting any information to regulatory authorities relating to significant changes in pest risk. Regulatory officials must consider, and where appropriate, ensure corrective action is taken;
- Records of all activities related to confined field release compliance, including experimental data and monitoring during the year of the confined release and post-harvest restriction period, should be maintained by the applicant. Records should be made available to the regulatory authority upon request.

## Appendix 1: National regulatory framework for transgenic plants in NAPPO member countries

The national frameworks for the regulation of transgenic plants in Canada, Mexico and the U.S. are very similar. Each NAPPO member country has adapted existing laws to regulate transgenic plants. As with their traditional counterparts, transgenic plants and products derived there from are regulated by the relevant regulatory authority of each NAPPO member country.

The three North American countries have also implemented a stepwise regulatory approach to the release of transgenic plants into the environment in which the degree of environmental exposure, the plant species and the novel trait(s) are important factors in determining the extent of the data requirements.

Lastly, science-based risk assessments are the basis for regulatory decisions. Potential risks are identified in light of current scientific knowledge and are alleviated through the application of risk management measures.

In Canada, the Canadian Food Inspection Agency (CFIA) regulates the importation, environmental release, and livestock feed use of plants with novel traits (PNTs). PNTs include, but are not limited to, transgenic plants. Importation, confined release and unconfined environmental release and the use of PNTs as livestock feed are regulated under the *Plant Protection Act*, the *Seeds Act* and the *Feeds Act*, respectively. Health Canada regulates novel foods for human consumption, including food products derived from transgenic plants, under the *Food and Drugs Act*.

In Mexico, the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA) regulates the importation, interstate movement and environmental release of transgenic plants under the *Federal Plant Health Law* and the *Law for the Production, Certification and Commercialization of Seeds*. The Intersecretariat Committee for Biosafety and Genetically Modified Organisms (CIBIOGEM) conducts risk assessments and provides biosafety recommendations in support to SAGAR regulatory decisions. SAGARPA also regulates the use of transgenic plants as livestock feed under the *Federal Animal Health Law*. Food products derived from transgenic plants are regulated by the Secretary of Health under the *General Health Law*.

In the U.S., the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture (USDA/APHIS) regulates the importation, interstate movement, and environmental release of transgenic plants that contain plant pest components. These activities are regulated under the federal *Plant Protection Act*. Regulatory authority for food and livestock feed use in the United States lies with the Food and Drug Administration (FDA). The U.S. Environmental Protection Agency (EPA) regulates the sale, distribution, production, and use of pesticides, including those produced by transgenic plants, and establishes tolerances for the pesticides expressed in transgenic plants intended for food or feed.

## MODULE 3: UNCONFINED RELEASE INTO THE ENVIRONMENT

The review of transgenic plants prior to their movement into traditional unconfined breeding programs, or into agricultural production or commerce, includes an assessment of the potential pest risks associated with the plants' unconfined release into the environment. In most cases, the transgenic plant will be a well-characterized species that has been modified by the addition of one or several genes that result in the presence of one or more new traits, such as pest resistance, herbicide tolerance, abiotic stress tolerance, or the ability to synthesize and/or accumulate a new protein or other product that could affect product quality. Risk assessments should consider the pest risk potential associated with the cultivation of the corresponding plant or crop counterpart compared with the consequences of unconfined release of the transgenic variety. The assessment should emphasize changes in pest risk potential that may result from interactions among new traits of the plant, the plant itself, and the receiving environment, including both managed and unmanaged ecosystems.

The concept of familiarity, as described in the OECD document *"Safety Considerations for Biotechnology: Scale-Up of Crop Plants"*, can be used to inform and facilitate the risk assessment as it relates to unconfined release of transgenic plants (NAS, 1989; OECD, 1993). Familiarity takes into account, but need not be restricted to, knowledge and experience with the biology, cultivation, and breeding of the crop plant; the environments in which it is grown and the presence of sexually compatible relatives in those environments; the new traits or similar traits; results from previous research with plants or other organisms expressing these traits; and the scale-up, breeding and deployment of plants with similar traits (if available).

The pest risk assessment outlined in this document should allow for a determination as to the potential pest risk associated with the unconfined release of the transgenic plant. The assessment should include, but is not limited to, a determination as to whether introduced DNA sequences or expression products cause or aggravate disease symptoms in plants, cause the production of new plant pathogens, or alter the susceptibility of the plant to particular diseases or insect pests; whether the transgenic plant is more likely to become a weed than its counterpart(s); and whether introgression of the transgene into wild or cultivated sexually compatible plants increases the weediness potential of resulting progeny or the potential for that plant to become invasive in unmanaged ecosystems and/or negatively impact plant biodiversity. If a determination can be reached that unconfined environmental release of the transgenic plant does not pose an unacceptable plant pest risk as compared to its counterpart when grown in comparable ecosystems under comparable modes of agronomic practice, authorization for such action may be granted. If appropriate, conditions or restrictions may be placed on the authorization to reduce the risk to an acceptable level.

The information requirements outlined in this document are based on those described in Appendix I and Appendix II resulting from U.S.-Canada bilateral discussions in 1998-2002 designed to compare and harmonize data requirements for regulatory review of transgenic plants (CFIA/HEALTH CANADA/USDA APHIS, 1998, 2002.)

## 3.1 Information requirements for the evaluation of molecular genetic data

In order to provide a clear understanding of the impact of a new transgenic modification on a plant that could affect the potential of that plant to be a pest, information should be provided about the molecular and biochemical characteristics of the plant. Knowledge of the source, function, inheritance, and expression of the new genetic material inserted provides information to assess the environmental fate, routes and levels of exposure, and effects of the introduction and expression of the new genetic material on the plant, its relatives, and other organisms with which they interact. This information should include a description of the transformation system including: the transformation process, the vectors used during the transformation, and the genetic material intended for delivery into the recipient plant. Information provided should also characterize the genetic material inserted into the transgenic plant, indicate the source of the transgenic material, characterize its expression, as well as the possibility of unintended changes in expression of new or endogenous proteins, and demonstrate the stability and inheritance of new traits. The information may be based on data collected from field trials, greenhouse or growth chamber studies, laboratory analyses, and/or scientific literature. (Information requirements related to the recipient plant, including any prior transformation events, are described in Section 3.2.1.)

### 3.1.1 The transformation process

#### 3.1.1.1 Description of the transformation method

The following information should be provided:

- Description of, and references for, the transformation method, e.g. *Agrobacterium*-mediated transformation or direct transformation by methods such as particle bombardment, electroporation, polyethylene glycol (PEG)-mediated transformation of protoplasts.

- For direct transformation methods, the nature and source of any carrier DNA used should be described

- For *Agrobacterium*-mediated transformation, the strain designation of the *Agrobacterium* used during the transformation process should be provided. In addition, how the Ti plasmid-based vector was disarmed, and whether *Agrobacterium* was cleared from the transformed tissue should be indicated.

- For transformation systems other than *Agrobacterium*, the following information should be provided:
  - whether the system utilizes a pathogenic organism or nucleic acid sequences from a pathogen;
  - how any pathogenesis-related sequences were removed from the transformation vector prior to transformation;
  - whether the transformation process involved the use of helper plasmids or a mixture of plasmids. If so, these should be described in detail.

### 3.1.1.2 Description of the genetic components that comprise the recombinant vector

- A physical and functional description of all genetic components that comprise the recombinant vector should be provided including coding regions, and non-coding sequences of known function. A citation should be provided for each genetic component, describing where these functional sequences were described, isolated, and characterized (publicly available database citations are acceptable[1]).

  The following information should be indicated for each component:

- the portion of the functional sequence from which each genetic component was derived (as designated by relative base pair position or restriction fragments), and its size;
- the location, order, and orientation in the vector of the genetic material to be inserted into the recipient plant;
  - the intended function in the recipient plant;
  - the source (scientific and common, or trade name, of the donor organism);
- whether the genetic component is responsible for disease or injury (direct or indirect) to plants, or whether it is a known toxicant, pathogenicity factor or irritant;
- whether the donor organism is responsible for any disease or injury to plants (direct or indirect), produces toxicants, or irritants or is related to organisms that do;
  - whether there is a history of safe use of the source organism or components thereof.

- If there has been a modification that affects the amino acid sequence of proteins designed to be expressed in the plant, the citation should be provided. If the modified amino acid sequence has not been published, the complete sequence should be provided, highlighting the modifications.
  - Modifications that affect only a few amino acids of a well-characterized protein can simply be indicated without the provision of the complete sequence. Whether the modifications are known or expected to result in changes in post-translational modifications or changes in sites critical to the structure, function or cellular location of the gene product should be indicated. An example of such modifications might include addition of new glycosylation sites.

- A detailed map of the vector should be provided, with the location of sequences described above. The map should contain sufficient detail to be used in the analysis of data supporting the characterization of the DNA, including, as appropriate, the location of restriction sites and regions used as probes and/or primers for PCR (polymerase chain reaction).

[1] Four commonly used databases and their website addresses are:
GenBank: http://www.ncbi.nlm.nih.gov/Genbank/index.html
DNA Data Bank of Japan: http://www.ddbj.nig.ac.jp/fromddbj-e.html
EMBL Nucleotide Sequence: http://www.ebi.ac.uk/embl/
The SWISS-PROT Protein Sequence Data Bank: http://www.ebi.ac.uk/swissprot/index.html

### 3.1.2 Inheritance and stability of introduced traits that are functional in the plant

- For plants which are either male or female fertile or both, data should be provided that demonstrates the pattern and stability of inheritance and expression of the new transgene traits. If the new trait cannot be directly measured by an assay, it may be necessary to examine the inheritance of the DNA insert directly, and expression of the RNA.

- For plants that are either infertile or for which it is difficult to produce seed (such as male-sterile potatoes), data should be provided to demonstrate that the transgene trait is stably maintained and expressed during vegetative propagation over a number of cycles that is appropriate to the crop.

### 3.1.3 Characterization of the DNA inserted in the plant

- DNA characterization data may be presented in the form of Southern blot analyses, DNA sequence information, PCR analyses, or other appropriate information.

- For all coding regions (see definition), data should be provided that demonstrates whether complete or partial copies are inserted into the plant's genome. The number of insertion sites should be indicated as precisely as possible or within a closely defined range. The number of insertion sites may affect the inheritance pattern of the transgene and the level of transgene expression. Partial copies of coding regions could lead to the production of fusion proteins.

- For non-coding regions associated with the expression of coding regions:

- Data should be provided to demonstrate whether or not plant gene promoters are inserted intact with the coding regions whose expression they are designed to regulate.
    - When the integrity of the insert or characterization of the protein or RNA expression (Section 3.1.4) raises questions with regard to the potential for unintended gene expression or gene products, DNA analysis may be necessary for introns, leader sequences, terminators, and enhancers of plant-expressible cassettes, or for promoters or other regulatory regions associated with bacteria-expressible cassettes.

- For noncoding regions that have no known plant function and are not associated with expression of coding regions, DNA analysis is generally not required for sequences whose function in the donor organism is known (e.g., oriV and ori322, bom, and bacterial transposable elements) or for any remaining sequences of the plasmid backbone.

### 3.1.4 Protein and RNA characterization and expression in the plant

- For all complete coding regions inserted, data should be provided that demonstrates whether the protein is or is not produced as expected in the appropriate tissues consistent with the associated regulatory sequences driving its expression (e.g., if the gene is inducible, it should be determined whether the gene is expressed in the appropriate tissues under induction conditions). For virus resistant plants where the

transgenes are derived from a viral genome, in addition to transgene protein analysis, transgene RNA levels should be determined in tissues consistent with the associated regulatory regions driving expression of the transgene. This information is used to assess the potential for recombination with other RNA viruses. The following exceptions also may apply:

- If the protein concentration is below the limits of detection, mRNA data may be substituted.
- Protein analysis for products of genes used only as selectable markers may be waived under certain circumstances, e.g. when there is at least one complete copy of a selectable marker gene present and the effective expression of the selectable marker gene is verified by the process used to select the transformed tissue.
- For plants modified to express non-translatable mRNA, truncated sense constructs, antisense constructs, or constructs containing ribozymes, data on the level of the target protein only should be provided, since the function of these genetic constructs is to specifically alter the accumulation of a specific mRNA or protein present in the transgenic plant (e.g. native tomato fruit polygalacturonase would be the target protein of antisense polygalacturonase to achieve altered fruit ripening). If the target protein levels are below levels of detection, the target mRNA levels should be determined.

- When analysis indicates that the insert contains a fragment of a coding region designed to be expressed in a plant (as opposed to the complete coding region), it should be determined whether a fusion protein or other unintended protein products could be produced by processes such as read-through, and in which tissues such protein products could be located.

- Protein or RNA characterization may not be required for fragments of genetic constructs not expected to be produced or functional in the plant (e.g., fragments of selectable marker genes driven by bacterial promoters.)

### 3.2 Information requirements for the assessment of plant pest risk for environmental release of transgenic plants

Any decision to allow the unconfined release of a transgenic plant into the environment should consider whether the transgenic plant will present a hazard to plants, and the type and magnitude of any adverse effects that may result from such a hazard. The decision should also take into account the availability and effectiveness of risk mitigation measures that could be employed to decrease the risks to an acceptable level. The assessment would include potential for the transgenic plant itself to present a pest risk, that is, whether there is significant potential for that plant to have a direct or indirect adverse impact on plant health or other plants, as compared to its counterpart, including impacts on either cultivated or unmanaged populations. The phenotype of the transgenic plant that could affect the plant pest potential may be influenced by the incorporation of new genetic material and the expression of the new genes, or the suppression of endogenous traits. Thus the molecular characterization described in Section 3.1 can be used to inform the assessment process for pest risks that may be posed by transgenic plants. Information requirements for assessment of pest risks that may be posed by unconfined environmental release of transgenic plants include a description of the biology of the host plant species; a description of the phenotype of

the transgenic plant as compared to its counterpart(s), including any changes in composition or in survival or reproductive potential; information on the cultivation of the transgenic plant; potential for cross-breeding with sexually compatible relatives and possible consequences of the resulting gene transfer; and any observed unintended effects on organisms associated with plants that could directly or indirectly have an adverse impact on plants.

### 3.2.1. Description of the biology of the plant species prior to modification

The following information should be provided:

- Common name(s) and currently accepted scientific nomenclature;
- Description of the biology of the recipient plant species that has been modified. The specific information provided may vary depending on the plant under consideration, but may include the following:
  - information on the use as a crop
  - taxonomy
  - genetics (ploidy, genome composition, etc.)
  - Reproductive biology, including pollination
  - tendency for occurrence of volunteers in a field following harvest
  - tendency to weediness
  - potential modes of gene flow (e.g., mechanisms, compatible species)
- Authorization status and references related to molecular and environmental characterization, if the recipient plant is transgenic;
  The information requirement may be fulfilled completely or in part by reference to an appropriate biology document submitted to the regulatory agency. In addition, OECD consensus documents that are available for a number of species at (http://www.oecd.org or general biology documents available through the USDA (http://www.aphis.usda.gov) may partially or completely fulfill these requirements.

### 3.2.2. Description of the phenotype of the transgenic plant

- Information should be provided on the intended phenotype and the observed phenotype, including any unintended or unanticipated traits. The phenotype of plants is influenced by many factors that may or may not be associated with the insertion of the new genetic material. Unintended or unanticipated traits can be caused by many phenomena associated with insertion of the new genetic material, e.g. random DNA insertion; multiple copies of the insert; silencing, suppression, or activation of endogenous genes; perturbations of related metabolic pathways, etc. The transgenic plant should be compared to its counterpart(s), and related cultivated varieties as appropriate. A description should be provided of the breeding history of the transgenic plant population being evaluated starting at the point of introduction of the transgenic trait. A description should also be provided of the breeding history of the counterpart as relevant to its use as a suitable control. The specific plant generations used in each of the different studies should be indicated.
- Data should be obtained from plants grown in multiple sites that are representatives of

- In the case where a trait is incorporated into a transgenic plant that allows for the plant to grow in an area outside its normal growing region, data should be obtained from transgenic plants and any counterparts growing in this expanded region (see 3.2.3.1.). It may be appropriate to obtain data from other plant varieties or species in addition to the counterpart(s).
- Data from more than one growing season is generally required. However, the assessment may take into account certain crop/trait combinations for which there is prior experience, and the growth of the transgenic plants at multiple sites.
- Data may be required to evaluate the plants outside of managed ecosystems, where there may be a potential for increased weediness characteristics of the transgenic plant itself, or if the plant is an outcrossing species and will be grown in regions with known sexually-compatible wild relatives.

### 3.2.2.1 Reproductive and Survival Potential

- The plant should be compared to its counterpart(s) with respect to characteristics that influence the reproductive and survival potential. Those parameters determined to be relevant to risk assessment based on the biology of the plant and the normal cultivation conditions of the specifc plant should be reported with descriptions of the conditions under which they were determined and using appropriate statistical methods. Special consideration may be necessary for long-lived species such as trees. Characteristics that may affect reproductive and survival potential include:

    - growth habit, including changes in the basic morphology of the plant and any abnormalities;
    - life span, e.g., any changes in the plant as an annual, biennial, or perennial;
    - vegetative vigor, including plant height, crop biomass, growth rate, etc.;
    - ability to overwinter or overseason;
    - number of days to onset of flowering;
    - timing and duration of flowering;
    - number of days until maturity – depending on the plant species, this could be defined as the time to the production of mature fruit or seed (suitable for harvesting.) In many species this characteristic is dependent upon environmental factors such as day length and/or temperature.

    - seed parameters. These could include:
        - seed production - This could be measured as either yield (number of seeds or fruit per cultivated area) or the number of viable seeds per plant;
        - continuous seed/fruit production - Length of time (days) of seed/fruit production. This might include, but is not limited to, changes between determinant and indeterminant flowering;
        - seed dormancy-characterization of any changes in the ability of the seed to remain viable over time;
        - seedling emergence - Proportion of seeds planted that emerges as seedlings under field conditions and, where warranted, under unmanaged ecosystems, and a description of the various environmental conditions under which seedling emergence was observed. These data are used to evaluate emergence in variable environments.

- proportion surviving from seeding to reproduction for specific environments of the intended planting areas;
- outcrossing frequency - the percentage of total progeny produced by a plant as a result of sexual reproduction involving cross-fertilization with other plant genotypes. Other plant genotypes could include the same or related species that are sexually compatible and that occur in areas where the crop may be cultivated.
    - adverse impact on pollinator species. This may be addressed through information on whether the same pollinator species have been seen in the field or if there have been changes in pollinator species visiting the flowers. Data on changes in flower morphology, color, fragrance, etc. may also indicate that interactions with pollinators have been altered.

    - pollen parameters, including:
        - Amount of pollen produced, proportion of viable pollen, the longevity of pollen under various environmental conditions;
        - Physical parameters such as stickiness, shape, and weight that might affect the viability or performance of the pollen in leading to successful pollination.
    - fertility: Changes in fertility could be measured by test crosses, using the male parent as the test organism for outcrossing species or by self- pollination for plants with a high rate of self-pollination, and by looking at the number of viable seeds produced.
    - self-compatibility;
    - asexual reproduction, i.e. vegetative reproduction; ability of the plant material to set roots; parthenocarpy (production of fruit without fertilization);
    - seed dispersal factors - This might be addressed by considering characteristics such as seed morphology, shattering or dispersal by animals.
    - symbionts, e.g., vesicular- arbuscular mycorrhizal fungi, rhizobia;
    - stress adaptations; note should be taken as to how transgenic plants compare to their counterparts in response to specific stresses that were observed.;
        - biotic stress factors - Examples might include parasites or pathogens, competitors (e.g., weeds), and herbivores;
        - abiotic stress factors - Examples might include response to moisture stress, nutrient deficiency, or other stresses common to that species.

#### 3.2.2.2. Compositional analysis

- The compositional analysis of the transgenic plant should be compared to its counterpart(s) with respect to protein, lipid, and fiber content, as well as other parameters as appropriate. Changes in these parameters may indicate impacts on plant health.

#### 3.2.2.3. Toxicants and antinutrients

- The transgenic plant should be compared to its counterpart(s) with respect to levels of known naturally expressed toxicants and antinutrients for that species, for example, cucurbitacin in cucurbits or glycoalkaloids in solanaceous species. Changes in the levels of substances related to plant defense mechanisms may make the plant more susceptible to pests or have an adverse impact on organisms beneficial to plants.

### 3.2.3 Cultivation of the transgenic plant

#### 3.2.3.1 Description of intended planting area

- Geographic descriptions should be provided for the regions where the plant will be grown. If the new transgenic plant will be grown in areas outside the normal geographic area for that species, descriptions should be provided of the new area or ecosystems in which the transgenic plant will be grown, and consideration given to potential pest risks to this environment (see 3.2.2).

- Consideration should be given to how projected planting areas compare with the usual areas of planting, including potential changes in agronomic practices and whether there is likely to be a change in the total projected area of planting. For example, such a change could occur if the introduced trait facilitates growing of a particular plant due to increased resistance to a significant pest or abiotic stress.

#### 3.2.3.2 Description of agronomic practices

- Descriptions should be provided for the agronomic practices for the transgenic plant, such as land preparation, fertilizer usage, weed and pest control, harvest, post-harvest protocols, etc. Emphasis should be placed on how these practices compare to or differ from the practices traditionally used for the counterparts(s). Consideration should be given as to how practices might influence agro-ecosystem sustainability, crop rotations, pesticide use, development of resistance in target populations, frequency of tillage, soil erosion and consequential changes in energy and soil conservation. Consideration should also be given as to whether the appearance of volunteer plants of the transgenic variety could dictate altered agronomic practices for succeeding crops.
- Descriptions should be provided for any specific deployment strategies recommended for this transgenic plant. These deployment strategies might include geographic or temporal factors or integration with other agronomic practices. Examples include but are not limited to:
  - insect resistance management - In the case of insect resistant transgenic plants, describe any strategies developed that are intended to delay the development of resistance in target insect populations.
  - herbicide resistant crop management - In the case of transgenic plants developed for resistance (tolerance) to an herbicide or class of herbicides, describe any strategies developed that are intended to delay the development of herbicide resistant weeds and avoid significant changes in weed biotypes.

### 3.2.4 Interactions of the transgenic plant with sexually compatible relatives and effects on plant biodiversity

- Consideration should be given as to whether there are any sexually compatible relatives of the same or related species, including threatened and endangered species, in areas where the transgenic plants may be grown. If there are, then this section is applicable and the following points should be considered.

- identification of sexually compatible relatives, in areas where the transgenic plant is

intended to be grown, including any new areas of cultivation.

- characterization of the compatible relative(s) with respect to weediness in managed ecosystems and/or entry into or spread within unmanaged ecosystems.
- ways in which the introduced trait itself would be likely to change the ability of the transgenic plant to interbreed with other plant species.
- similarity of the introduced trait to traits found currently in natural populations of the compatible relatives.

In cases in which there is a potential for gene flow from the transgenic plant into sexually compatible species (e.g. same or related species as appropriate, including threatened and endangered species), consideration should be given to the consequences for the offspring of such crosses. Characterization of the crosses between wild relatives and transgenic plants could be considered using the criteria described in section 3.2.2 for transgenic plants in order to address the following issues:

- the potential of the introduced trait to increase or decrease the reproductive fitness or confer a selective advantage or disadvantage to the relative. If so, consideration should be given to whether the introduced trait could have a significant impact on the establishment and spread, weediness, or survival of populations of relatives. Consideration should be given to the presence or absence of selection pressures.
- whether the potential for the trait to change the reproductive fitness or confer a selective advantage or disadvantage is different from the potential for this to occur from a similar trait that may already exist in the recipient plant species or the sexually compatible relatives in question.

### 3.2.5 Unintended or non-target effects on organisms exposed to transgenic plants or their products

- For transgenic plants that have been engineered to produce a pesticidal substance, consideration should be given to potential direct or indirect effects on non-target organisms beneficial to plants.

- A determination should be made as to whether the introduction of the new DNA directly or indirectly leads to the production of a toxin or other biologically active product that is known to have an adverse effect on plants or effects on other organisms beneficial to plants (see section 3.2.2.4) Examples of direct effects could include production of allelochemicals or plant growth regulators; indirect effects could include production of defense compounds or other harmful effects on pollinator populations or nitrogen-fixing microbes.

- For organisms that might be unintentionally affected by a pesticidal protein, toxin, or other harmful substance as described in the points above, consideration should also be given to the potential levels and routes of exposure of appropriate organisms to the harmful substance, i.e., direct feeding or other exposure to the plant or plant part, dispersed plant parts, secretion, degradation, or leaching of the active toxic component, gene introgression, or organisms that have fed on the plant. In addition to knowledge of the environmental interactions and agronomic practices associated with the transgenic plant species, expression data may be useful in analyzing the routes

of exposure if this data is available from various plant tissues.

### 3.2.6 Other interactions

- In case of transgenic plants developed using plant viral coding regions, consideration should be given to issues of synergy, facilitated movement, transcapsidation, and viral recombination. See the 1996 OECD consensus document for a description of these terms. (OECD C*onsensus Document on General Information Concerning the Biosafety of Crop Plants Made Virus Resistant Through Coat Protein Gene-mediated Protection.* 54 pp. Paris: OECD Publications Service; http://www.olis.oecd.org)

## 3.3 Assessment criteria

- The information required in Sections 3.1 and 3.2 provide the basis for an assessment of the pest risk associated with the proposed unconfined release of the transgenic plant. Some information may not be applicable depending on the crop and the trait introduced and in such cases may be waived. The regulatory authority in each NAPPO member country should review the submitted information on a case-by-case basis for its completeness and acceptability. The national plant protection organization may convene an expert advisory group for this purpose. NAPPO member countries are encouraged to consult with each other to determine whether significant extraterritorial effects could occur from unconfined release of the transgenic plant.

- Authorisations to allow unconfined field releases into the environment should generally be granted only when a determination can be made that the proposed unconfined release does not pose an unacceptable pest risk.
- In order to make such a determination, the following criteria must be met:

    - Any vectors used to introduce the DNA into the plant that are able to transfer genes and/or create a risk of disease, damage or injury to plants or plant parts have been adequately disarmed or eliminated from the plant or pose no greater risk than those naturally occurring;
    - The genetic modification of the transgenic plant is unlikely to lead to disease, damage or injury to plants or plant parts and will not result in the production of an infectious agent capable of causing such effects.
    - Compared to plants of the same species that are currently grown, and current agricultural practices used with those plants, the following apply:

        - The transgenic plant will not increase the potential for the creation (or selection) of more virulent plant pathogens.

        - The transgenic plant does not possess characteristics that cause it to be significantly more weedy or invasive or that would increase the weedy or invasive characteristics of other plants with which it can produce natural hybrids in the country in which approval is sought and in areas in which the plants are likely to be grown. The degree of significance should take into consideration the availability of various methods to control weedy or invasive populations of these plants, should the need arise, and the plant pest or environmental risks associated with their implementation.

- Unconfined growth of the transgenic plants is unlikely to change agricultural or land use practices (such as pest and weed control, soil conservation, irrigation, crop rotations, etc.) in such a way as to have a significant adverse effect on plants, plant health, or plant biodiversity. As appropriate, this should take into consideration the likelihood of successful implementation of any proposed insect resistance or herbicide resistance management strategies.

- Any new harmful property of the transgenic plant has a minimal likelihood of a detrimental effect on the health of other plants and non-target organisms beneficial to plants in the country in which approval is sought.

- Unconfined growth of the transgenic plant will not increase the potential for adverse impacts on threatened, endangered, or protected classes of plants, or organisms beneficial to plants that are recognized in the country in which approval is sought.

### 3.4 Authorization requirements

- Authorization for unconfined releases should generally be granted when the assessment criteria in Sections 3.3 allow for a determination that the proposed unconfined release is not considered to pose an unacceptable plant pest risk. However authorization for unconfined release may also depend on analyses performed by other regulatory authorities to evaluate environmental and/or human health impacts resulting from unconfined release.

- Authorizations may be subject to pest risk mitigation measures, depending on national authority, such as:

- pest or herbicide resistance management strategies;

- restrictions on use of the transgenic plant. Examples include, but may not be limited to, planting restrictions in particular geographic regions or breeding into particular genetic backgrounds or with certain traits where a plant pest risk has been identified.

- Authorizations may be subject to oversight for compliance with risk mitigation measures, including mitigation measures to address concerns outside of the scope of pest risk (see Scope section of this standard).

- The applicant may be required to report any information to regulatory authorities relating to significant increases observed in pest risk not previously disclosed.

- Authorizations and changes to authorizations should be posted to authorized national or international databases, for example, the Biosafety Clearing House consistent with the provisions of the Cartagena Protocol on Biosafety.