



Canada

Regulatory Directive

Dir2000-07

**GUIDELINES FOR THE
ENVIRONMENTAL RELEASE OF
PLANTS WITH NOVEL TRAITS WITHIN
CONFINED FIELD
TRIALS IN CANADA**

This Regulatory Directive replaces Regulatory Directive 95-01 dated
January 6, 1995 and all amendments.

(publié aussi en français)

July 10, 2000

TABLE OF CONTENTS

1	GENERAL INFORMATION	1
1.1	INTRODUCTION	1
1.2	DEFINITIONS	2
1.2.1	<i>Applicant</i>	2
1.2.2	<i>Application</i>	2
1.2.3	<i>Confined Field Trials</i>	2
1.2.4	<i>Construct</i>	2
1.2.5	<i>Field Trial</i>	2
1.2.6	<i>Familiarity</i>	3
1.2.7	<i>Plant with Novel Traits (PNT)</i>	3
1.2.8	<i>Submission</i>	3
1.2.9	<i>Substantial Equivalence</i>	3
1.2.10	<i>Trial Site Location</i>	3
1.3	LEGAL AUTHORITY FOR THE REGULATION OF PNTs IN CONFINED TRIALS	4
2	APPLICATIONS FOR CONFINED FIELD TRIALS	5
2.1	NEW APPLICATIONS	5
2.2	RENEWALS OF PREVIOUSLY AUTHORIZED CONFINED FIELD TRIALS	5
2.3	HOW TO COMPLETE A FIELD TRIAL APPLICATION.	6
2.4	WHEN TO APPLY	6
2.5	FEES	7
2.6	MAPS	7
2.7	INFORMATION CONSIDERED CONFIDENTIAL	8
3	SUMMARY OF FIELD TRIAL REQUIREMENTS FOR PNTs	9
3.1	THE PRESENCE OF ENDANGERED SPECIES AT THE TRIAL SITE	9
3.2	RESTRICTIONS ON THE SIZE AND NUMBER OF CONFINED FIELD TRIAL SITE LOCATIONS	9
3.3	INSPECTION OF CONFINED TRIALS	10
3.4	RECORDS AND REPORTING OF CONFINED TRIALS	10
3.5	REPRODUCTIVE ISOLATION OF CONFINED FIELD TRIALS	10
3.5.1	<i>Isolation distances (Spatial Separation) and Destruction Zones</i>	10
3.5.2	<i>Alternative Methods for Reproductive Isolation</i>	11
3.6	DISPOSITION OF PLANT MATERIAL FROM CONFINED TRIALS	12
3.7	POST-HARVEST LAND USE	12
3.8	GENERAL TERMS AND CONDITIONS FOR CONFINED FIELD TRIALS	13
3.9	SPECIES-SPECIFIC TERMS AND CONDITIONS FOR CONFINED FIELD TRIALS	13
3.10	SPECIAL CASES	14
3.10.1	<i>Out crossing studies</i>	14
3.10.2	<i>Herbicide efficacy studies</i>	14
3.10.3	<i>Replanting trial sites with PNTs</i>	14
3.10.4	<i>Disease nurseries</i>	14
3.10.5	<i>Insect Resistance Management for PNTs expressing Bt endotoxins</i>	14
4	OTHER REQUIREMENTS	15

APPENDIX 1: FEE SUBMISSION FOR CONFINED AND UNCONFINED RELEASES i

APPENDIX 2: MINIMUM ISOLATION DISTANCES AND PERIODS OF POST-HARVEST LAND USE RESTRICTION ii

APPENDIX 3: A SCHEMATIC REPRESENTATION OF THE SAFETY BASED MODEL FOR THE REGULATION OF PLANTS iii

APPENDIX 4: GENERAL AND SPECIES-SPECIFIC TERMS AND CONDITIONS FOR CONFINED FIELD TRIALS iv

1. COMMON CONFINED FIELD TRIAL TERMS AND CONDITIONS iv

2. SPECIES-SPECIFIC CONFINED FIELD TRIAL TERMS AND CONDITIONS v

2.1 *Agrostis palustris* (creeping bentgrass) v

2.2 *Beta vulgaris* (sugar beet) v

2.3 *Brassica carinata* (Ethiopian mustard) vi

2.4 *Brassica juncea* (brown mustard) vii

2.5 *Brassica napus* (argentine rape) vii

2.6 *Brassica rapa* (polish rape) viii

2.7 *Capsicum annuum* (pepper). ix

2.8 *Cucurbita pepo* (squash) x

2.9 *Glycine max* (soybean) x

2.10 *Hordeum vulgare* (barley) x

2.11 *Lens culnaris* (lentil) x

2.12 *Linum usitatissimum* (flax) xi

2.13 *Lolium perenne* (perennial ryegrass) xi

2.14 *Lycopersicum esculentum* (tomato) xii

2.15 *Medicago sativum* (alfalfa) xii

2.16 *Nicotiana tabacum* (tobacco) xii

2.17 *Phalaris canariensis* (canary seed) xiii

2.18 *Pisum sativum* (pea). xiii

2.19 *Populus spp.* (poplar) xiii

2.20 *Sinapis alba* (white mustard) xiv

2.21 *Solanum tuberosum* (potato) xv

2.22 *Trifolium repens* (white clover). xvi

2.23 *Triticum aestivum* (wheat) xvi

2.24 *Vitis spp.* (grapevine) xvi

2.25 *Zea mays* (corn). xvii

APPENDIX 5: CONFINED FIELD TRIAL FORM. xviii

1 GENERAL INFORMATION

Note: Definitions of terms used in this document appear in section 1.2

1.1 INTRODUCTION

In Canada, confined field trials for research of plants with novel traits (PNTs) provides developers with the opportunity to evaluate the performance of PNTs, study the environmental safety of these modified plants, address the criteria and information requirements considered in the environmental safety assessment of PNTs¹ and generate data for variety registration purposes. PNTs may include plants derived using recombinant DNA technology or traditional plant breeding techniques, including mutagenesis, somaclonal variation, or wide crosses. Novel traits are those that when introduced into a specific plant species, result in a novel plant that may be considered unfamiliar, when compared with plants of the same species already on the market and may not be considered substantially equivalent to similar, familiar plant types already in use and regarded as safe.

The purpose of this Directive is to provide clear and concise instructions to help applicants meet the regulatory requirements of the Canadian Food Inspection Agency (CFIA) for authorization of, or renewal of previously authorized, confined field trials of PNTs for research purposes. It considers only field trials of imported or domestically developed PNTs conducted in accordance with terms and conditions of confinement, including reproductive isolation, site monitoring and post-harvest land use restrictions. This Directive summarizes the information requirements and procedures used by the Plant Biosafety Office (PBO) of the Plant Health and Production Division, CFIA, and where appropriate, other federal and provincial agencies that reserve the right to comment on the conduct of the trials. The information presented in this Directive does not preclude additional regulatory requirements from other sections of the CFIA or other government agencies (see Section 4). If in doubt, please call the PBO at (613) 225-2342 to verify if these guidelines apply to your material.

1.2 DEFINITIONS

-
1. Applicants considering future commercialization of a PNT for eventual release into the environment without confinement are encouraged to include experiments designed to meet the information requirements of *Regulatory Directive Dir 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*. Specifically, such experiments could contribute to generating data which can be used to address the five key criteria of environmental safety assessments: altered weediness potential, potential for out-crossing, altered plant pest potential, impact on non-target organisms, and impact on biodiversity. The generation of data to be considered for a determination of environmental safety under *Dir 94-08* must be produced using statistically valid experimental designs and protocols (i.e. equivalent to the standards required for inclusion in peer-reviewed research publications). In making an application for the unconfined release of a PNT, proponents will be required to submit details of field trial protocols, including experimental designs and sampling procedures. Trials must be conducted in a manner consistent with the proposed use of the PNT.

1.2.1 APPLICANT

The applicant must be a permanent resident of Canada or must designate a Canadian agent who is a permanent resident of Canada. The applicant need not be the breeder or owner of the PNT, however, if the applicant is not the breeder/owner, a signed statement is required from the breeder/owner authorizing representation by the applicant or the designated Canadian Agent. All correspondence with respect to the application, including authorization of trials, will be addressed to the applicant, or when appropriate, the Canadian Agent. The applicant/Canadian Agent must accept full responsibility for compliance with all terms and conditions of authorization.

1.2.2 APPLICATION

An application is the data package submitted for each modified plant species intended for a confined release and which meets the information requirements of this Directive. More than one submission (see definition 1.2.8) may be included in a single application.

1.2.3 CONFINED FIELD TRIALS

A confined field trial is the release of a PNT, for research purposes, under terms and conditions of confinement designed to minimize any impact the PNT may have on the environment. These terms and conditions include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions.

1.2.4 CONSTRUCT

An engineered DNA fragment (e.g. plasmid) which contains, but is not limited to, the DNA sequences to be integrated into a target plant's genome.

1.2.5 FIELD TRIAL

A field trial is an experimental trial of one submission (see definition 1.2.8), grown at one trial site location (see definition 1.2.10) for the purpose of conducting research.

For example:

- a) Two different lines of a plant species, such as canola (*Brassica napus*), one showing tolerance to the herbicide sulfonylurea, resulting from the insertion of the gene coding for an altered acetolactate (ALS) enzyme, and the other showing tolerance to certain insects by the insertion of the δ -endotoxin gene from *Bacillus thuringiensis*, both to be grown in the same field trial site location in one year will be considered as two field trials.
- b) Two different lines of tobacco, both showing tolerance to the herbicide sulfonylurea, resulting from the insertion of two different genetic constructs, both to be tested in a confined field trial site location in one year will be considered as two field trials. A separate assessment will be carried out on each of the two different genetic constructs.
- c) Flax modified to be resistant to a specific herbicide as a result of one specific gene insertion, to be tested for agronomic performance in confined field trials at six locations

will be considered as six field trials.

- d) The same modified corn to be tested at the same general location (for example, the Central Experimental Farm in Ottawa), but at six specific sites (different fields at farm) and for different purposes will constitute six field trials.
- e) The same modified soybean to be tested at the same six general locations over two growing seasons will constitute 12 field trials
- f) A perennial crop such as alfalfa, tested at one site over a period of several years, will be counted as one trial for each year it is tested.

1.2.6 FAMILIARITY

Knowledge of the characteristics of a plant species and experience with the use of that plant species in Canada. Please see Appendix 3.

1.2.7 PLANT WITH NOVEL TRAITS (PNT)

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

1.2.8 SUBMISSION

A submission refers to each plant species/genetic modification combination. For example, two lines of the same plant species transformed with different constructs constitute two submissions. Two lines of the same plant species transformed with the same construct will constitute one submission, provided the two lines express the traits encoded by the construct in a similar fashion.

1.2.9 SUBSTANTIAL EQUIVALENCE

The equivalence of a novel trait within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species, that are in use and generally considered as safe in Canada, based on valid scientific rationale. Please see Appendix 3.

1.2.10 TRIAL SITE LOCATION

A field trial or trials of a submission or submissions at a single location. Single location is defined as a single, unbroken geographical location.

1.3 LEGAL AUTHORITY FOR THE REGULATION OF PNTs IN CONFINED TRIALS

The *Seeds Act*, administered by the Plant Health and Production Division, CFIA, provides authority to regulate the quality, testing, inspection and sale of seeds in Canada. The *Seeds Regulations, Part V* defines the regulatory requirements for both confined and unconfined environmental release of PNTs in Canada.

For your information, the importation of any PNT, for whatever purpose, requires an import permit that must be obtained from the Director, Plant Health and Production Division. PNTs exempt from this requirement, are those that have been previously authorized by the CFIA for unconfined release into the environment. Import permits are issued under the authority of the *Plant Protection Act*, administered by the Plant Health and Production Division, CFIA, for the purposes of protecting Canadian agriculture and forestry from pests injurious to plants.

2 APPLICATIONS FOR CONFINED FIELD TRIALS

For an application form for new confined field trials, and renewal of previously authorized confined field trials, refer to Appendix 5 of this directive. Applications must be completed in full to ensure timely evaluation and to minimize requests for further information.

2.1 NEW APPLICATIONS

The PBO will distribute copies of received field trial applications to the Feed Section, CFIA, if a determination of safety of the PNT as a novel livestock feed is requested by the applicant.

While the PBO will exchange information with the Pest Management Regulatory Agency (PMRA), Health Canada, and the Feeds Section, CFIA, where required, it is the applicant's responsibility to ensure that all requirements of these offices are met directly (see Section 4).

Additionally, the PBO will send non-confidential information about each new trial to designated provincial government contacts in those provinces where proposed trials are to be conducted. Secondary agencies and provincial governments have a 30 day turnaround time and any comments from them are considered by the PBO in the final evaluation of the application.

General information about confined trials authorized by the PBO is made available to the public upon request from the CFIA or from the PBO's web site at:
<http://www.cfia-acia.agr.ca/english/plaveg/pbo/pbobbve.shtml>

2.2 RENEWALS OF PREVIOUSLY AUTHORIZED CONFINED FIELD TRIALS

Renewals of authorization for confined field trials, including ongoing trials of perennial PNTs, may be granted for trials that are identical (i.e. same species, construct and location) to those approved in previous years.

Gene constructs, genetic modifications, plant material, trial purposes, experimental protocols, and the trial sites (including size and location) must be identical to those reviewed and authorized in previous years. Applications for renewals must be completed in full to ensure timely evaluation and to minimize requests for further information.

The terms and conditions of authorization required in previous years still apply, however, the CFIA reserves the right to modify, add, or remove any condition of authorization upon renewal and any changes will be communicated to provincial and other federal authorities.

For perennial crops or trees, the years following the field trial's initial approval shall be considered to be renewals. The fees applicable shall be calculated and due each year that the trial exists on the basis of the renewal, and the number of trial site locations that exist. Applications for perennial crop or tree confined field trial renewals should be forwarded to the PBO prior to the deadline for spring planting (March 15).

2.3 HOW TO COMPLETE A FIELD TRIAL APPLICATION

For new or renewal applications, use the form located in Appendix 5 of this document. Applications should be mailed to:

National Manager, Plant Biosafety Office
Plant Health & Production Division
Canadian Food Inspection Agency
59 Camelot Drive
Nepean, Ontario
K1A 0Y9

If the PNT intended for use in a field trial is to be imported, then an "Application for Permit to Import" (CFIA-ACIA 5083) can be downloaded as a PDF file at:

<http://www.cfia-acia.agr.ca/english/plaveg/oper/opere.shtml>

or can be obtained from any local CFIA office. Once completed, application forms must be sent to:

The Permit Office
Plant Health & Production Division
Canadian Food Inspection Agency
59 Camelot Drive
Nepean, Ontario
K1A 0Y9
Fax (613) 228-6605.

In the case of confined trials involving unregistered pesticides, or unregistered use of registered pesticides, see Section 4 regarding the requirements of the PMRA.

2.4 WHEN TO APPLY

Applications for field trials must be received by the PBO on or before **March 15th for spring-planted trials** or **June 15th for fall-planted trials**. Applications are processed on a first-come, first-served basis. Failure to meet the application deadline may make it impossible to provide authorization in time for planting. (See also Section 4 regarding the requirements of the PMRA if applicable.)

2.5 FEES

Please see Appendix I for a schedule of fees for the review and authorization of confined trials of PNTs. The submission fee must be included with the application. Once review of an application has been initiated, the submission fee will not be refunded. Trial fees are due prior to May 15th in

the case of spring planting and August 1st for fall planting. Trial fees will not be refunded after the respective trial fee due date or after an authorization letter has been issued.

2.6 MAPS

Maps of all confined field trials are a prerequisite of authorization. The PBO recognizes that exact trial locations may not be finalized by the March 15th application deadline (spring planting) or the June 15th application deadline (fall planting). Applications without exact trial locations will be accepted if:

1. The application is received by March 15th (spring planting) or June 15th (fall planting) and includes the general location (to the nearest town), the expected planting date and the number of trial site locations within each general location.

and

2. The legal land location is subsequently submitted no later than May 15th (spring planting) or August 1st (fall planting).

The PBO will not authorize a confined trial until information detailing the legal land location of each trial site location has been given.

It is the responsibility of each applicant to provide an exact map of each confined trial site location for each submission, in an application received by the PBO, no later than 7 days after planting.

The PBO reserves the right to cancel the authorization of any confined field trial for which an accurate map has not been received seven days after planting of the trial.

Maps of confined field trials must be legible and precise. CFIA inspectors have previously encountered problems locating trials sites, particularly in post-harvest years. Maps are not to be submitted to CFIA inspectors or area staff. Maps should be on a blank page with crisp line drawings and block letters. Maps on lined or graph paper, photocopies of road or topographical maps will not be accepted.

ON EACH MAP THE FOLLOWING INFORMATION MUST BE CLEARLY PRINTED:

1. The general location of the field trial (city/town/province).
2. Compass directions, with North at the top of the page.
3. The legal land location.
4. Measurements between the trial site and permanent surrounding landmarks i.e. the exact trial location coordinates. **Permanent markers must be placed to identify the confined trial boundaries.** When this is not possible, measurements from permanent surrounding landmarks must be provided for precise location of the site, both for current year and post-harvest restriction periods.
5. Exact trial dimensions and an indication of surrounding crops, particularly those that may lie within the isolation distance. When applicable, show previous years' trial site locations on the map(s).
6. The name and phone number of the field contact.
7. The trial number designated by the PBO.
8. The planting date of the trial.

Any changes to confined field trial site locations made subsequent to authorization must be received by the PBO on or before May 15th (spring planting) or August 1st (fall planting) of the year of application. After this date trial site changes will not be accepted with the exception of cancellations. If a trial site change is made after May 15th (spring planting) or August 1st (fall planting), authorization of the trial will be revoked and the trial will have to be destroyed. This stipulation is necessary to accommodate the increasing number of applications received by the PBO for confined field trials and the corresponding increase in the number of changes to authorized trial sites that the Office has to process.

2.7 INFORMATION CONSIDERED CONFIDENTIAL

Please indicate on the application any specific information that is considered to be confidential business information (CBI). Please do not apply a confidential stamp to all pages of the application. Although information is held as confidential, the retention of this information as CBI is subject to the federal *Access to Information and Privacy (ATIP) Acts*. Please contact the CFIA's ATIP Services at (613) 225-2342 for additional information.

The PBO submits non-confidential information on authorized field trials to its own publicly available web site and to the Organization of Economic Cooperation and Development's BioTrack database.

3 SUMMARY OF FIELD TRIAL REQUIREMENTS FOR PNTs

It is the applicant's (or Canadian Agent's, as appropriate) sole responsibility to ensure compliance with the terms and conditions of authorization, including the conduct of any subcontractors. The onus is on the applicant (or Canadian Agent, as appropriate) to ensure that the confined trial will not negatively affect any other trial or non-PNT crops. The PBO requires that each applicant (or Canadian Agent, as appropriate) (i) determine what plant material, if any, will be in proximity to each trial (including within the isolation distance) before the confined trial is planted, and (ii) consider mitigation procedures in the event that the reproductive isolation inadvertently breaks down.

3.1 THE PRESENCE OF ENDANGERED SPECIES AT THE TRIAL SITE LOCATION

It is important to know if there are any endangered species at or near the trial site location which could potentially be affected by the confined field trial. To obtain information on endangered species contact:

Canadian Wildlife Service
RENEW Secretariat
351 Blvd. St-Joseph
Hull, Quebec
K1A 0H3

3.2 RESTRICTIONS ON THE SIZE AND NUMBER OF CONFINED FIELD TRIAL SITE LOCATIONS

In Canada, confined field trials of PNTs provide researchers with the opportunity to evaluate the PNTs under conditions which minimize their impact on the environment. The confined field trial system is not intended to support other activities such as seed multiplication for commercial purposes. In order to maintain the integrity of this system, confined field trials in Canada are subject to restriction in size and number, unless the applicant applies for an exemption to one or both of the following:

1. Confined field trial site locations are limited in size to no more than 1 hectare per trial location site.
2. Confined field trial site locations are limited in number to no more than 5 trial site locations per province.

These restrictions exclude small scale Variety Registration Trials provided these trials are endorsed by the respective recommending committee.

Exemptions from the restrictions on trial site location size and number may be granted under extenuating circumstances but only for research purposes. The applicant must submit a rationale

for the exemption along with their application to the PBO by March 15th (spring planting) or June 15th (fall planting) of the year of planting.

3.3 INSPECTION OF CONFINED TRIALS

CFIA regional inspectors have the authority to inspect trials during both the growing season and the period of post-harvest land use restriction for compliance with the terms and conditions under which the trials were authorized. The applicant's field managers may carry out joint inspections with CFIA inspectors. The coordination of such inspections is the responsibility of the applicant.

3.4 RECORDS AND REPORTING OF CONFINED TRIALS

Records of all confined field trials, including current season and post-harvest site monitoring, disposition of all plant material, activities related to trial site compliance (including subcontracts), and experimental data, must be maintained by the applicant and must be made available to the CFIA upon request.

3.5 REPRODUCTIVE ISOLATION OF CONFINED FIELD TRIALS

In order to minimize potential gene flow, it is necessary to reproductively isolate all PNTs from neighbouring related commercial crops, breeding nurseries, seed multiplication plots, other trials, and sexually compatible wild relatives.

3.5.1 ISOLATION DISTANCES (SPATIAL SEPARATION) AND DESTRUCTION ZONES

The most common means to achieve reproductive isolation is through the use of spatial isolation distance between the plants of the trial and neighbouring sexually compatible plants. Isolation distances have been established through consultation with academics, scientists, and other stakeholders, using regulations adapted from the Canadian Seed Growers Association (CSGA) for producing foundation seed.

It is the responsibility of the applicant to ensure that the conditions for the reproductive isolation of all trial plants are met.

Should related species be found within this isolation zone the applicant must remove and destroy these plants before seed set. Frequent monitoring of the field trials is required. If inadvertent pollination/hybridization and seed set occur, additional post-harvest restrictions and monitoring requirements may be imposed, including imposition of certain minimum isolation distances as described in Appendix 2.

Exemptions from these requirements may be approved for specific cases, but reproductive isolation from surrounding fields is still required - please refer to section 3.8 for more details.

The PBO reserves the right to increase the minimum isolation distances for specific submissions.

3.5.2 ALTERNATIVE METHODS FOR REPRODUCTIVE ISOLATION

The following alternative methods may be available to reproductively isolate specific PNTs:

1. Bags, nets or cages placed over flowering plants to prevent pollen exchange, provided that scientific rationale is provided in writing to justify the effectiveness of such measures.
2. Harvest of plants before flowering (requires close monitoring at the onset of flowering).
3. Removal of floral parts before pollen maturity.
4. Seeding of guard rows/pollen traps (border strips or buffer zones) immediately around the trials. In the case of field trials of modified *Medicago sativa*, *Brassica napus* or *B. carinata* the use of a 10 metre deep perimeter of non-modified plants of the same species is acceptable to act as guard rows and pollen traps (bee traps). For *B. rapa* a 100 metre deep perimeter of non-modified plants of the same species is acceptable to act as a guard row and pollen trap (bee trap). In all cases, the guard row plants must flower concurrently with the PNTs and no gaps can be created for machinery use. Should guard rows fail to flower concurrently with the test material, or should they be interrupted by gaps, a destruction zone corresponding to the minimum isolation distance indicated in Appendix 2 will be enforced, and this perimeter will be kept free of sexually compatible plants. Progeny from the non-modified guard rows (which may result from fertilization with modified pollen) may not be used as human food or livestock feed unless prior approval is granted by Health Canada or the Feed Section of CFIA.

If an applicant (or Canadian Agent, as appropriate) chooses an approved alternative method of reproductive isolation other than the minimum required isolation distance and if that method fails to prevent potential pollination/hybridization and seed set, then current season and post-harvest monitoring and restrictions will have to include the minimum isolation distances as described in Appendix 2. For example, if an applicant (or Canadian Agent, as appropriate) chooses to ensure reproductive isolation of a *B. rapa* trial by netting the PNTs, and if the netting fails to prevent pollen movement, a 400 m isolation distance around the *B. rapa* trial will be imposed. It is the applicant's (or Canadian Agent's, as appropriate) responsibility to ensure that all the terms and conditions related to the isolation distance, including destruction of any *B. rapa* or related species, are met.

Applicants (or Canadian Agents, as appropriate) who choose alternative methods for reproductive isolation must ensure that they will have control over the reproductive isolation distance around the trial site, should the alternative method fail to provide for reproductive isolation. This control must take into account neighbouring fields and any potential financial implications to their owners.

3.6 DISPOSITION OF PLANT MATERIAL FROM CONFINED TRIALS

No harvested material or byproduct from a confined field trial may be used as human food or livestock feed without the prior approval of Health Canada or the Feeds Section, CFIA, respectively.

Seed or other plant material harvested from confined trials (including border rows) and which is not authorized by the PBO to be retained for future research trials, or which is not approved for use in the food or feed supply, must be disposed of by an approved method (eg. incineration, roasting, grinding, deep burial, or by other means that will render the seed or plant material non-viable). Composting is not an acceptable method for the disposal of plant material. Please refer to the species-specific terms and conditions in Appendix 4.

Progeny from any PNT trial cannot be retained for future planting without prior written authorization from the PBO, and must be specifically requested in the field trial application.

3.7 POST-HARVEST LAND USE

Applicants must notify the PBO in writing of crop species planted on trial sites for each year the sites are subject to post-harvest restriction. This notification must be received every year and by June 15. Notification will no longer be required once the material has been authorized for unconfined release.

Following harvest, PNTs may arise at the field trial site in subsequent growing season(s) as volunteers. Therefore, the following precautions must be taken, to prevent volunteers crossing with crops of the same species or with sexually compatible related species:

1. monitoring of the trial site after harvest and in subsequent growing seasons each year the site is subject to post-harvest restrictions (see Appendix 2), in order to identify and ensure the destruction of volunteer plants.
2. strictly no planting of any species related to the PNT on the trial site (each year the site is subject to post-harvest restrictions), including areas where guard rows were planted, in accordance with the species-specific terms and conditions presented in Appendix 4.
3. monitoring the isolation distance zone (each year the site is subject to post-harvest restrictions), in addition to the trial site, for volunteers and for sexually compatible weed species may be required in cases when reproductive isolation has failed.
4. If harvested by combine (other than small plot combines), an additional 50-metre buffer zone around all sites must be monitored each year the site is subject to post-harvest restrictions.

In the case of flax (*Linum usitatissimum*) because of the high number of volunteers observed from previous trials, it is recommended that the flax trial site be summer fallowed (by cultivation or with herbicide application) the year following a flax trial.

Upon completion of the trial, disposal of remaining plant material must be in accordance with the stipulated terms and conditions for that plant species (see Appendix 4).

It is the applicant's (or Canadian agent's, as appropriate) responsibility to communicate with field managers precisely which material has, or has not, been authorized for unconfined release and therefore no longer subject to post-harvest land use restrictions.

3.8 GENERAL TERMS AND CONDITIONS FOR CONFINED FIELD TRIALS

See Appendix 4, section 1 for terms and conditions that are general and will be imposed on all trials.

3.9 SPECIES-SPECIFIC TERMS AND CONDITIONS FOR CONFINED FIELD TRIALS

To view the species-specific terms and conditions of authorization for confined field trials, refer to Appendix 4.

Agrostis palustris (creeping bentgrass)

Beta vulgaris (sugar beet)

Brassica carinata (Ethiopian mustard)

Brassica juncea (brown mustard)

Brassica napus (argentine rape)

Brassica rapa (polish rape)

Capsicum Annum (pepper)

Cucurbita pepo (squash)

Glycine max (soybean)

Hordeum vulgare (barley)

Lens culnaris (lentil)

Linum usitatissimum (flax)

Lolium perenne (perennial ryegrass)

Lycopersicon esculentum (tomato)

Medicago sativa (alfalfa)

Nicotiana tabacum (tobacco)

Phalaris canariensis (canary seed)

Pisum sativum (pea)

Populus (poplar)

Sinapis alba (white mustard)

Solanum tuberosum (potato)

Trifolium repens (clover)

Triticum aestivum (wheat)

Vitis (grapevine)

Zea mays (corn)

3.10 SPECIAL CASES

3.10.1 OUT CROSSING STUDIES

If an Out crossing study is being performed, non-modified related species can be deliberately planted within the isolation distance. However, PNTs must be separated from plants not included in the experiment by the recommended isolation distance. At the completion of such a study, the non-modified experimental plants must be handled in the same manner as PNTs.

3.10.2 HERBICIDE EFFICACY STUDIES

For herbicide efficacy studies, related weeds may remain within the trial site, provided they are removed and destroyed before seed set. The isolation distance must remain free from plants of the same species as the PNT and from any sexually compatible relatives of the PNT.

3.10.3 REPLANTING TRIAL SITES WITH PNTs

If applicants wish to use the same trial site location in consecutive years, a partial exemption regarding required crop rotations may be allowed for plants containing the same gene(s) in the same genetic background, tested on the same sites as the original trials. All resulting plant material will be destroyed after harvest and the land use restrictions (Appendix 2) will be observed after the last PNT trial.

3.10.4 DISEASE NURSERIES

Reduced rotation cycles are sometimes required for building up disease inoculum in the soil of trial sites. A partial exemption regarding crop sequences may therefore be allowed in the case of disease nurseries. All resulting plant material will be destroyed after harvest and the post-harvest land use restrictions (Appendix 2) will be observed after the last PNT planting.

3.10.5 INSECT RESISTANCE MANAGEMENT FOR PNTS EXPRESSING BT ENDOTOXINS

Insect resistant management plans for all plants expressing *Bacillus thuringiensis* endotoxins must be implemented for any trial exceeding 1.0 ha - see section 3.2.

4 OTHER REQUIREMENTS

1) The Feed Section of CFIA administers the *Feeds Act* which provides authority to the CFIA over the manufacture, sale or import of any substance or mixture of substances containing amino acids, anti-oxidants, carbohydrates, condiments, enzymes, fats, minerals, non-protein nitrogen products, proteins or vitamins, or pelletizing, colouring, foaming or flavouring agents and any other substance manufactured:

- a) for consumption by livestock
- b) for providing nutritional requirements of livestock
- c) for the purpose of preventing or correcting nutritional disorders of livestock, or any such substance for use in any such substance or mixture of substances.

Researchers or their agents are responsible for communicating to the CFIA if the applicant requires the notification of the Feeds Section regarding the use of any materials generated in the trial as a livestock feed. It is the applicants' responsibility to ensure that all of the requirements of the Feeds Section are met. Researchers or their agents should refer to the CFIA's regulatory directive No. 95-03 (Guidelines for the Assessment of Livestock Feed From Plants with Novel Traits) for guidelines regarding the Feed use of PNT's.

Where a trial involves the use of a novel Feed not covered by a current registration, a research permit from the CFIA will be required.

For more information concerning the feed use of PNT's, refer to the Feeds Section of the CFIA web page at: <http://www.cfia-acia.agr.ca/english/anima/feebet/feebete.shtml>.

2) The Pest Management Regulatory Agency (PMRA), Health Canada, administers the *Pest Control Products Act* which provides authority to the PMRA for regulating the use and testing of pest control products.

Researchers or their agents are responsible for communicating with the PMRA regarding registration status of pesticides, research permit applications, and notification submissions. It is the applicants' responsibility to ensure that all the requirements of the PMRA are met. Researchers or their agents should refer to the PMRA's Regulatory Directive No. 98-05 (Chemical Pesticide Research Permit Guidelines) for guidelines regarding permit applications and notification submissions.

Where a trial involves the use of a pesticide not covered by a current registration, a research permit from the PMRA may be required. Requirements for permits depend on the size of the field trial, the type of personnel who is conducting the trial and the premises where it is conducted. For small scale trials, there may be exemptions to the requirement for Permits, but a Notification of Pesticides Research in lieu of an application for Permits of Pesticides Research may be required. The PMRA requires that Applications for Permits of Pesticides Research be submitted 30 to 180 days before treatment, depending on the nature of the pesticide and trial site. Notifications must be submitted to the PMRA at least 30 days before the pesticide treatment.

Information on obtaining research permits or on the registration status of pesticides can be obtained from the PMRA's Pest Management Information Service by phone at 1-800-267-6315 (outside Canada: 1-613-736-3799; long distance charges apply), by e-mail at pminfoserv@hc-sc.gc.ca, or by fax at 613-736-3666. Regulatory directives and other general information are available on the Internet at <http://www.hc-sc.gc.ca/pmra-arla>.

Applications and Notifications regarding pesticides research should be addressed to the Submission Management and Information Division, PMRA, Health Canada (AL. 6605E1), 2250 Riverside Drive, Ottawa, Ontario K1A 0K9.

APPENDIX 1: FEE SUBMISSION FOR CONFINED AND UNCONFINED RELEASES

Payment must be made in Canadian funds. No Goods and Services Tax applies.

To be completed by the Applicant

Name of Applicant or Canadian Agent: _____

Crop species: _____

		Total cost	Project code
Number of submissions applied for confined field trials	___ x \$400 =		3820
Number of renewal submissions for confined field trials	___ x \$100 =		3824
Number of trial site locations	___ x \$100 =		3826
Number of submissions for unconfined release *	___ x \$2000 =		3822

By Cheque or Money Order

Cheque Money Order

Cheques and money orders must be payable to the Receiver General for Canada. Please ensure that all cheques are drawn from a Canadian bank.

By Credit Card

Visa Master Card OTHER CREDIT CARDS NOT ACCEPTED

Card Holder's Name (please print): _____

Company Name: _____ Telephone () _____

Card Number: _____ Expiry date ____/____

Signature: _____

Application Code: _____ Reference No.: _____

Applicant: _____

Date received _____

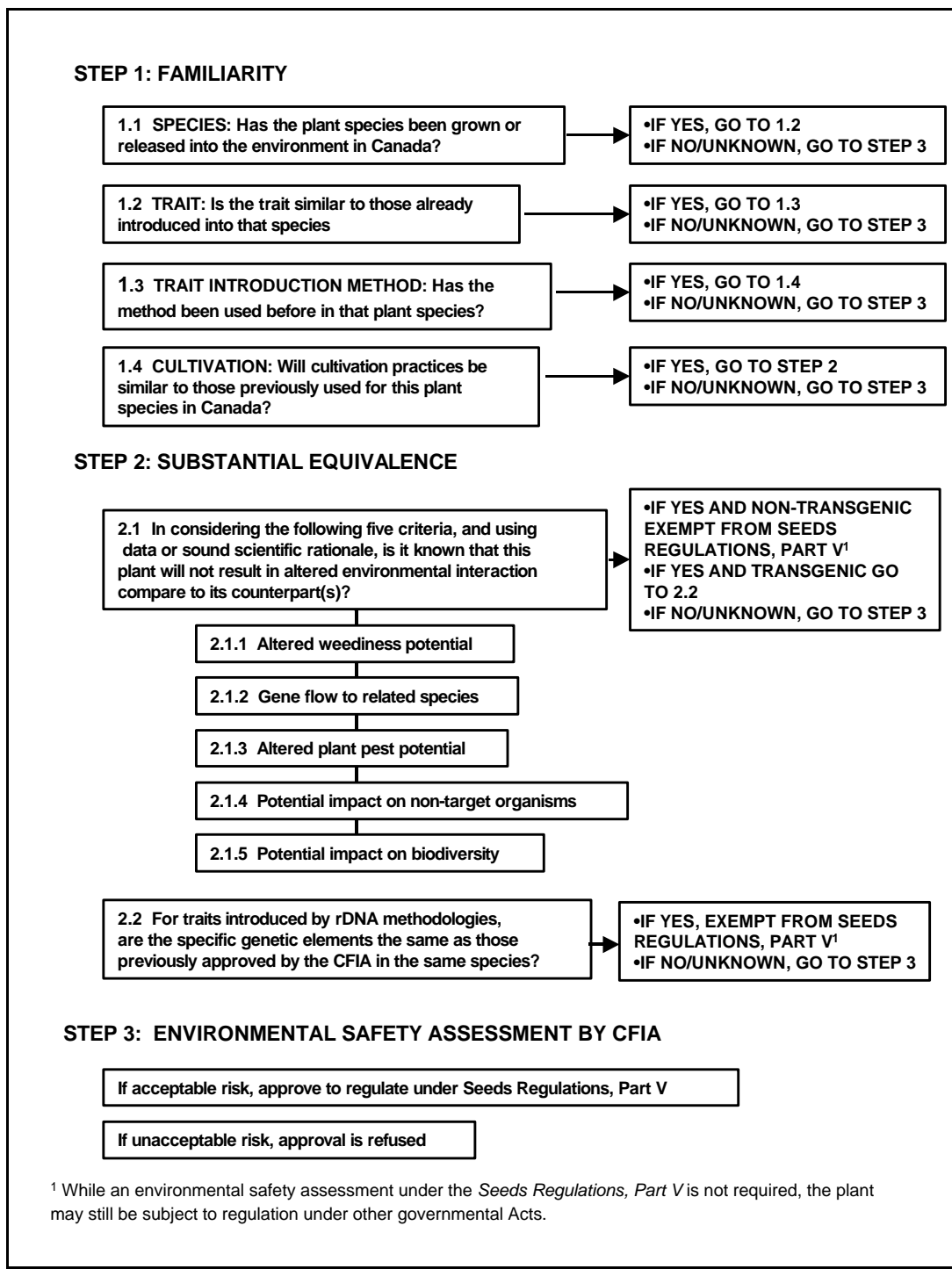
* Refer to regulatory directive 94-08; "Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits".

**APPENDIX 2: MINIMUM ISOLATION DISTANCES AND PERIODS OF
POST-HARVEST LAND USE RESTRICTION**

Note: For detailed information about isolation distances and post-harvest land use restrictions please refer to Appendix 4(2).

Crop	Minimum Isolation Distance	Period of Post-harvest Land
<i>Agrostis palustris</i> (creeping)	300 m (without cropping)	3 years
<i>Beta vulgaris</i> (sugar beet)	3 m	1 year
<i>Brassica carinata</i> (Ethiopian)	200 m from other <i>Brassica spp.</i>	3 years
<i>Brassica juncea</i> (brown mustard)	200 m from other <i>Brassica spp.</i> 50 m from weedy relatives	5 years
<i>Brassica napus</i> (argentine rape)	200 m from other <i>Brassica spp.</i> 50 m from weedy relatives	3 years
<i>Brassica rapa</i> (polish rape)	400 m from other <i>Brassica spp.</i> 50 m from weedy relatives	5 years
<i>Capsicum annuum</i> (pepper)	20 m	1 year
<i>Cucurbita pepo</i> (squash)	650 m	1 year
<i>Glycine max</i> (soybean)	3 m	1 year
<i>Hordeum vulgare</i> (barley)	3 m	2 years
<i>Linum usitatissimum</i> (flax)	3 m	3 years
<i>Lens culinaris</i> (lentil)	3 m	1 year
<i>Lolium perenne</i> (perennial)	300 m (without cropping)	3 years
<i>Lycopersicon esculentum</i>	20 m	1 year
<i>Medicago sativum</i> (alfalfa)	300 m	3 years
<i>Nicotiana tabacum</i> (tobacco)	400 m	1 year
<i>Phalaris canariensis</i> (canary seed)	3 m	1 year
<i>Pisum sativum</i> (pea)	3 m	1 year
<i>Populus spp.</i> (poplar)	2 guard rows	5 years
<i>Sinapis alba</i> (white mustard)	400 m from other <i>S. alba</i> 50 m from other <i>Brassica spp.</i>	5 years
<i>Solanum tuberosum</i> (potato)	one blank row	2 years
<i>Trifolium repens</i> (white clover)	300 m (without cropping)	3 years
<i>Triticum aestivum</i> (wheat)	3 m	2 years
<i>Vitis spp.</i> (grapevine)	Bagging of flowers	3 years
<i>Zea mays</i> (corn)	100 m	1 year

APPENDIX 3: A SCHEMATIC REPRESENTATION OF THE SAFETY BASED MODEL FOR THE REGULATION OF PLANTS



**APPENDIX 4: GENERAL AND SPECIES-SPECIFIC
TERMS AND CONDITIONS FOR CONFINED FIELD TRIALS**

1. COMMON CONFINED FIELD TRIAL TERMS AND CONDITIONS

**THE FOLLOWING TERMS AND CONDITIONS WILL BE IMPOSED ON
ALL CONFINED FIELD TRIALS:**

- 1) The applicant must ensure that the trial seed and/or plant material are transported in clearly identified, secure containers and are kept separate from other seed and/or plant material.
- 2) Seeding and transplanting machinery must be cleaned at the trial site to prevent dispersal of plant material. Surplus seed or seedlings, and any plant material remaining after transplantation, will be destroyed by autoclaving, burning, or burial at a depth of one metre. Composting of this material is not an acceptable destruction method.
- 3) In the case of accidental release, recoverable seeds or seedlings must be collected and destroyed, the site must be marked and monitored, and the PBO notified immediately. Plants from unrecoverable seed or seedlings must be controlled by spraying with a broad spectrum herbicide.
- 4) No plant material from these trials may enter the human food or animal feed chain unless approved by Health Canada or the Feeds Section, CFIA, respectively.
- 5) Planting and harvesting equipment will be cleaned of all residual plant material at the trial site prior to being moved to other locations. Plant material harvested must be destroyed by burning, autoclaving, or burial to a depth of one metre. Composting of this material is not an acceptable destruction method.
- 6) Records of all confined field trials, including current season and post-harvest site monitoring, activities related to trial site compliance, and experimental data, must be maintained by the applicant and be subject to review upon request by the PBO.
- 7) Harvested seed and/or plant material from the confined trial may only be retained if requested in the application and authorized by the PBO. Any harvested seed and/or plant material must be clearly labeled, securely transported, and stored separately from other seed and/or plant material.
- 8) Applicants must notify the PBO in writing of crop species planted on trial sites for each year the sites are subject to post-harvest restriction. This notification must be received every year by June 15.

2. SPECIES-SPECIFIC CONFINED FIELD TRIAL TERMS AND CONDITIONS

THE FOLLOWING TERMS AND CONDITIONS WILL BE IMPOSED ON SPECIES-SPECIFIC TRIALS, IN ADDITION TO THE COMMON CONFINED FIELD TRIAL TERMS AND CONDITIONS:

2.1 *Agrostis palustris* (CREEPING BENTGRASS)

1. *A. palustris* plants in trial must be reproductively isolated from *A. palustris* or any other sexually compatible species by cropping prior to pollen shed, and by an isolation distance of 20 metres. If any flowers are allowed to shed pollen, all *A. palustris* plants within a 300 metre isolation distance of the confined field trial site must be treated as part of the trial.
2. Trials must be monitored weekly during the growing season and daily at the onset of the budding stage to ensure that flowering does not occur. For the duration of the growing season, the trial site must be inspected every third day.
3. At the termination of trials, trial sites must be sprayed with a non-selective herbicide to destroy plants remaining in the field.
4. After trials are completed, trial sites must not be planted to *A. palustris* for a period of 3 years. During this 3 year, post-trial period, the site must be monitored monthly during the growing season and any volunteer plants must be destroyed prior to flowering.

2.2 *Beta vulgaris* (SUGAR BEET)

1. Sugar beet plants under trial must be separated from other beet crops by a distance of 3 metres.
2. Sugar beets under trial must not be allowed to flower and any plants that bolt and/or develop floral parts must be removed prior to any pollen shed. In the event that plants are allowed to shed pollen, all *Beta* species (i.e. sugar beets, fodder beets, red beets, Swiss Chard) within 900 metres of the trial must be destroyed.
3. All plant material remaining at the end of the trial must be soil incorporated.
4. During the trial, the trial site must be monitored weekly. The trial site must be monitored monthly during the two post-trial growing seasons, including a 20 metre zone around the plots. Any volunteer plants must be destroyed.
5. The trial site must not be used to grow beets for two years following harvest.

2.3 *Brassica carinata* (ETHIOPIAN MUSTARD)

1. Plants must be reproductively isolated from *Brassica* species by: (a) 200 metre isolation distance or a 10 metre guard row of *Brassica carinata*; or (b) being grown in cages. Trial plants must be reproductively isolated from weedy relatives by 50 metres. *Brassica* species include: *Brassica rapa* (oilseed rape, Polish rape canola, turnip, bird rape), *Brassica juncea* (brown mustard, Indian mustard), *Brassica napus* (Argentine rape canola, swede rape), *Brassica nigra* (black mustard), *Brassica hirta* [also known as *Sinapis alba* (white mustard)], *Brassica oleracea* (cabbage, cauliflower, brussel sprouts, broccoli, Chinese cabbage, kale, kohlrabi). Should the guard rows fail to flower concurrently with the modified plants or be interrupted by gaps, a 200 metre isolation distance from *Brassica* species will be required. In the case of protein products material, plants must be grown in cages, to be erected prior to flowering.
2. The following related weed species must be removed before seed set when found on the sites and, in the case of guard row failure, within 50 metres of the site (including ditches, shelterbelts and neighbouring land): *Diploaxis muralis* (sand rocket, stinking wall rocket), *Raphanus raphanistrum* (wild radish), *Erucastrum gallicum* (dog mustard). These related weeds must also be removed from the sites before flowering when found during the three years following harvest of the trial.
3. Plants must be harvested before full maturity to minimize silique shattering and seed dispersal. Plant matter remaining at the end of the trials must be soil incorporated.
4. During the trial, the trial site must be monitored weekly. The trial site must be monitored monthly for the next three post-trial growing seasons to ensure that any volunteer plants and related species are removed before flowering.
5. The trial sites must not be seeded to *Brassica* species for three years after harvest of the trial.
6. In the case of reproductive isolation distance for confined field trials of *B. carinata* containing a transformation event introgressed from a different *Brassica* species in which that event is approved for unconfined release, the isolation distance from the donor species and *B. carinata* can be reduced. For example: A novel trait “event X”, approved in *B. napus* is backcrossed into *B. carinata*. The new plant line is considered to be a novel plant and must be grown in confined field trials until unconfined release is granted by CFIA. In such cases the reproductive isolation distance between the confined *B. carinata* trials and adjacent *B. napus* can be reduced from 200 metres to 3 metres. If *B. rapa* with the same transformation event has been granted unconfined release the same principle applies with regard to isolation distance between the *B. carinata* confined trials and adjacent *B. rapa*. Note: This principal does not supercede the Canadian Seed Growers Association (CSGA) rules for the production of pedigree seed.

2.4 *Brassica juncea* (BROWN MUSTARD)

1. Plants must be reproductively isolated from other *B. juncea* and *Brassica* species by 200 m. *Brassica* species include *Brassica napus* (Argentine rape, swede rape), *Brassica rapa* (oilseed rape, Polish canola, turnip, bird rape), *Brassica carinata* (Ethiopian mustard), *Brassica nigra* (black mustard), *Brassica hirta* [also known as *Sinapis alba* (white mustard)], *Brassica oleracea* (cabbage, cauliflower, brussels sprouts, broccoli, Chinese cabbage, kale, kohlrabi).
2. The following related weed species must be removed before seed set when found on and within 50 metres of the trial site (including ditches, shelterbelts and neighbouring land): *Diploaxis muralis* (sand rocket, stinking wall rocket), *Raphanus raphanistrum* (wild radish), *Erucastrum gallicum* (dog mustard) and *Sinapis arvensis* (wild mustard). These related weeds must also be removed from the site before flowering when found during the five post-trial growing seasons.
3. Plants must be harvested before full maturity to minimize silique shattering and seed dispersal. Plant matter remaining at the end of the trial must be soil incorporated.
4. The trial site must be monitored weekly during the trial period and monthly during the five post-trial growing seasons to ensure that any volunteer plants and related species are removed before flowering.
5. The trial site must not be planted with *Brassica* species for five years following harvest of the trial and volunteer plants must be destroyed prior to flowering if found during this time.
6. In the case of reproductive isolation distance for confined field trials of *B. juncea* containing a transformation event introgressed from a different *Brassica* species in which that event is approved for unconfined release, the isolation distance from the donor species and *B. juncea* can be reduced. For example: A novel trait “event X”, approved in *B. napus* is backcrossed into *B. juncea*. The new plant line is considered to be a novel plant and must be grown in confined field trials until unconfined release is granted by CFIA. In such cases the reproductive isolation distance between the confined *B. juncea* trials and adjacent *B. napus* can be reduced from 200 metres to 3 metres. If *B. rapa* with the same transformation event has been granted unconfined release the same principle applies with regard to isolation distance between the *B. juncea* confined trials and adjacent *B. rapa*. Note: This principal does not supercede the Canadian Seed Growers Association (CSGA) rules for the production of pedigree seed.

2.5 *Brassica napus* (ARGENTINE RAPE CANOLA)

1. Plants must be reproductively isolated from *Brassica* species by: (a) 200 metre isolation distance or a 10 metre guard row of *Brassica napus*; or (b) being grown in cages. Trial plants must be reproductively isolated from weedy relatives by 50 metres. *Brassica* species include: *Brassica rapa* (oilseed rape, Polish rape canola, turnip, bird rape), *Brassica juncea* (brown mustard, Indian mustard), *Brassica carinata* (Ethiopian mustard), *Brassica nigra* (black

mustard), *Brassica hirta* [also known as *Sinapis alba* (white mustard)], *Brassica oleracea* (cabbage, cauliflower, brussel sprouts, broccoli, Chinese cabbage, kale, kohlrabi). Should the guard rows fail to flower concurrently with the modified plants or be interrupted by gaps, a 200 metre isolation distance from *Brassica* species will be required. In the case of protein products material, plants must be grown in cages, to be erected prior to flowering.

2. The following related weed species must be removed before seed set when found on any trial site and, in the case of guard row failure, within 50 metres of the site (including ditches, shelterbelts and neighbouring land): *Diploaxis muralis* (sand rocket, stinking wall rocket), *Raphanus raphanistrum* (wild radish), *Erucastrum gallicum* (dog mustard). These related weeds must also be removed from the sites before flowering when found during the three years following harvest.
3. Plants must be harvested before full maturity to minimize silique shattering and seed dispersal. Plant matter remaining at the end of the trials must be soil incorporated.
4. During the trial, the trial site must be monitored weekly. During the three post-trial growing seasons, the trial site must be monitored to ensure that any volunteer plants and related species are removed before flowering.
5. The trial site must not be seeded to *Brassica* species for three years after harvest of the trial.
6. In the case of reproductive isolation distance for confined field trials of *B. napus* containing a transformation event introgressed from a different *Brassica* species in which that event is approved for unconfined release, the isolation distance from the donor species and *B. napus* can be reduced. For example: A novel trait “event X”, approved in *B. rapa* is backcrossed into *B. napus*. The new plant line is considered to be a novel plant and must be grown in confined field trials until unconfined release is granted by CFIA. In such cases the reproductive isolation distance between the confined *B. napus* trials and adjacent *B. rapa* can be reduced from 200 metres to 3 metres. If *B. juncea* with the same transformation event has been granted unconfined release the same principle applies with regard to isolation distance between the *B. napus* confined trials and adjacent *B. juncea*. Note: This principal does not supercede the Canadian Seed Growers Association (CSGA) rules for the production of pedigree seed.

2.6 *Brassica rapa* (POLISH RAPE CANOLA)

1. Plants must be reproductively isolated from other *B. rapa* by 400 metres and from other *Brassica* species by 200 metre, or a 100 metre guard row of *Brassica rapa* flowering concurrently with the trial site. Should the guard rows fail to flower concurrently with the modified plants or should the guard rows be interrupted by gaps, a 400 metre isolation distance from other *B. rapa*, and a 200 metre isolation distance from other *Brassica* species will be required. *Brassica* species include *Brassica napus* (Argentine rape canola, swede rape), *Brassica juncea* (brown mustard, Indian mustard), *Brassica carinata* (Ethiopian mustard), *Brassica nigra* (black mustard), *Brassica hirta* [also known as *Sinapis alba* (white mustard)], *Brassica oleracea* (cabbage, cauliflower, brussels sprouts, broccoli, Chinese cabbage, kale, kohlrabi).

2. The following related weed species must be removed before seed set when found on the sites and, in the case of guard row failure, within 50 metres of the site (including ditches, shelterbelts and neighbouring land): *Diploaxis muralis* (sand rocket, stinking wall rocket), *Raphanus raphanistrum* (wild radish), *Erucastrum gallicum* (dog mustard). These related weeds must also be removed from the site before flowering when found during the five post-trial growing seasons.
3. Plants must be harvested before full maturity to minimize silique shattering and seed dispersal. Plant matter remaining at the end of the trial must be soil incorporated.
4. During the trial, the trial site must be monitored weekly. The trial site must be monitored monthly during the five post-trial growing seasons to ensure that any volunteer plants and related species are removed before flowering.
5. The trial site must not be planted with *Brassica* species for five years following harvest of the trial and volunteer plants must be destroyed if found during this time.
6. In the case of reproductive isolation distance for confined field trials of *B. rapa* containing a transformation event introgressed from a different *Brassica* species in which that event is approved for unconfined release, the isolation distance from the donor species and *B. rapa* can be reduced. For example: A novel trait “event X”, approved in *B. napus* is backcrossed into *B. rapa*. The new plant line is considered to be a novel plant and must be grown in confined field trials until unconfined release is granted by CFIA. In such cases the reproductive isolation distance between the confined *B. rapa* trials and adjacent *B. napus* can be reduced from 200 metres to 3 metres. If *B. juncea* with the same transformation event has been granted unconfined release the same principle applies with regard to isolation distance between the *B. rapa* confined trials and adjacent *B. juncea*. Note: This principal does not supercede the Canadian Seed Growers Association (CSGA) rules for the production of pedigree seed.

2.7 *Capsicum annuum* (PEPPER)

1. The peppers under trial must be reproductively isolated from other peppers or any sexually compatible relatives by a distance of 20 metres.
2. Plant matter remaining at the end of the trial period must be destroyed by cultivation and incorporated into the soil.
3. During the trial, the trial site must be monitored bi-weekly.
4. Peppers must not be grown on the trial site during the one year post-harvest period. The trial site must be monitored monthly during the post-trial growing season and any volunteer plants must be destroyed prior to pollen shed.

2.8 *Cucurbita pepo* (SQUASH)

1. Squash plants under trial must be separated by a distance of 650 metre from other squash plants or sexually compatible relatives.
2. During the trial, the trial site must be monitored weekly. The plot must be monitored monthly during the post-trial growing season and any volunteer plants must be destroyed.
3. The trial site cannot be used to grow squash for one year following harvest.

2.9 *Glycine max* (SOYBEAN)

1. Soybean plants under trial must be reproductively isolated from other soybean by a distance of 3 metres.
2. Plant matter remaining at the end of the trials must be destroyed by cultivation into the soil or by incineration.
3. During the trial, the trial site must be monitored bi-weekly.
4. The trial site must not be used to grow soybean during the one year post-harvest period. The trial site must be monitored monthly during the post-trial growing season to ensure that any volunteer plants are removed prior to flowering.

2.10 *Hordeum vulgare* (BARLEY)

1. Plant matter remaining at the end of the trial must be destroyed by cultivation or incineration.
2. Trial plants must be reproductively isolated from all sexually compatible species by 3 metres.
3. The trial site must be monitored every two weeks during the trial period.
4. The trial site must not be seeded to another cereal crop for two years after harvest of the trial. Trial sites must be monitored monthly during the two post-trial growing seasons to ensure that any volunteer plants and related species will be removed or destroyed prior to anthesis.

2.11 *Lens culinaris* (LENTIL)

1. Plants must be separated by a distance of 3 metres from other *Lens culnaris* plants that are not part of this trial.
2. Plant matter remaining at the end of the trials must be destroyed by cultivation or incineration.

3. During the trial, the trial site must be monitored bi-weekly.
4. The trial sites must not be used to grow lentil during the one year post-trial period. Trial sites must be monitored monthly during the post-trial growing season and any volunteer plants must be destroyed prior to flowering.

2.12 *Linum usitatissimum* (FLAX)

1. Plants in these trials must be reproductively isolated from all *Linum* species by 3 metres.
2. Plant matter remaining at the end of the trials must be destroyed by cultivation or incineration.
3. During the trial, the trial site must be monitored weekly.
4. Flax must not be grown on the trial site during the two-year post-harvest period. Trial sites must be monitored weekly during the two post-trial growing seasons for volunteers which must be immediately removed or destroyed.
5. Due to the high number of volunteers observed from previous trials, it is recommended that the flax trial site be summer fallowed (by cultivation or with herbicide application) the year following a flax trial.

2.13 *Lolium perenne* (PERENNIAL RYEGRASS)

1. *L. perenne* plants under trial must be reproductively isolated from other *L. perenne* or any sexually compatible species by cropping prior to pollen shed, and by an isolation distance of 20 metres.
2. If any flowers are allowed to shed pollen, all *L. perenne* plants within a 300 metre isolation distance of the confined field trial site must be treated as part of the trial.
3. The trial site must be monitored weekly during the growing season and daily at the onset of the budding stage to ensure that flowering does not occur. For the duration of the trial growing season the trial site must be inspected every third day.
4. At the termination of trial, the trial site must be sprayed with a non-selective herbicide to destroy plants remaining in the field.
5. After trials are completed, trial sites must not be planted to *L. perenne* for a period of 3 years. During this 3 year, post-trial period, the site must be monitored monthly during the growing season and any volunteer plants must be destroyed prior to flowering.

2.14 *Lycopersicon esculentum* (TOMATO)

1. Tomato plants under trial must be separated from other tomato plants by a distance of 20 metres.
2. Plant matter remaining at the end of the trials will be soil incorporated.
3. During the trial, the trial site must be monitored weekly. The trial site must be monitored monthly during the post-trial growing season and any volunteer plants must be destroyed.
4. The site cannot be used to grow tomatoes for one year following harvest.

2.15 *Medicago sativa* (ALFALFA)

- 1 *M. sativa* plants under trial must be reproductively isolated from other *M. sativa* and any sexually compatible species by cropping the PNT prior to pollen shed, and by an isolation distance of 20 metres
- 2 If any flowers are allowed to shed pollen, all *M. sativa* plants within a 300 metre isolation distance of the confined field trial site must be treated as part of the trial.
- 3 Trials will be initially monitored weekly from the time of planting and then daily at the onset of the budding stage to ensure that flowering does not occur. After budding and for the duration of the growing season the trial site will be inspected every third day.
- 4 At the termination of the trial, the trial site will be sprayed with a non-selective herbicide to destroy plants remaining in the field.
5. After the trial is completed, the trial site must not be planted to *M. sativa* for a period of three (3) years. During this three year, post-trial period, the site must be monitored semi-monthly during the growing season and any volunteer plants must be destroyed prior to flowering.

2.16 *Nicotiana tabacum* (TOBACCO)

1. Tobacco plants under trial must be reproductively isolated from other tobacco crops by a distance of 400 metres or by harvesting of the trial plants prior to flowering.
2. Plant matter remaining at the end of the trials must be destroyed by cultivation or incineration.
3. The trial site must be monitored weekly during the trial period. During the post-trial growing season, the plots must be monitored monthly and volunteers must be removed before flowering and destroyed.

2.17 *Phalaris canariensis* (CANARY SEED)

1. Plants must be separated by a distance of 3 metres from other *Phalaris canariensis* .
2. Plant matter remaining at the end of the trials must be destroyed by cultivation into the soil or by incineration.
3. The trial site must be monitored every two weeks during the trial period.
4. The trial site must not be used to grow canary grass during the two-year post-harvest period. The trial site must be monitored monthly during the two post-trial growing seasons and any volunteer plants must be destroyed prior to flowering.

2.18 *Pisum sativum* (PEA)

1. Plants must be separated by a distance of 3 metres from other *Pisum sativum* to prevent the spread of pollen.
2. Plant matter remaining at the end of the trials must be destroyed by cultivation into the soil or incineration.
3. During the trial, the trial site must be monitored bi-weekly.
4. The sites must not be used to grow peas during the one year post-harvest period. The trial site must be monitored monthly during the post-trial growing season and any volunteer plants must be destroyed prior to flowering.

2.19 *Populus spp.* (POPLAR)

1. The trial term must be limited to eight years from the date of commencement.
2. The boundaries of the trial site must be marked during the trial period and the post-harvest restriction period.
3. Two guard rows must be composed of non-transformed balsam poplar (*Populus balsamifera*) producing no or very few suckers.
4. The trial material (including the guard rows) must be separated by a distance of at least 15 metres from other trees of the same or related species. The trial site and isolation distance must be monitored regularly, at least twice a week during the period of flowering and budburst and every week during the growing season of the trial period to ensure that all suckers, precocious inflorescences and trees of the same or related species that are not part of the trial are destroyed.

5. The trees must be cut down at the end of the trial period and all precocious inflorescences (if any) must be removed each year before anthesis to prevent pollen and seed dissemination. Records must be kept of the date and number of flowering catkins removed for each genetic line.
6. In case of unexpected spread, volunteer poplar plants and plants arising from vegetative propagation must be mechanically or chemically destroyed.
7. Plant matter remaining at the end of the trials must be destroyed. Stumps on root systems must either be mechanically destroyed on site or removed and destroyed. The trial site must be tilled and any developing suckers after tillage must be destroyed.
8. The site must not be used to grow poplar trees for five years from the date of termination of the trial. The site must be monitored regularly, at least monthly, during the growing season of the post harvest restriction period to ensure that any volunteer plants and suckers are destroyed. The post harvest restriction period must be extended if suckers are still observed during the fifth year of the post harvest restriction period.

2.20 *Sinapis alba* (WHITE MUSTARD)

1. *S. alba* plants under trial must be reproductively isolated from other *S. alba* plants by 400 metres.
2. *S. alba* plants under trial must be reproductively isolated from all *Brassica* species and related weed species by 50 metres. *Brassica* species include *Brassica rapa* (oilseed rape, Polish rape canola, turnip, bird rape), *Brassica napus* (Argentine rape canola, swede rape), *Brassica juncea* (brown mustard, Indian mustard), *Brassica carinata* (Ethiopian mustard), *Brassica nigra* (black mustard), *Brassica oleracea* (cabbage, cauliflower, brussels sprouts, broccoli, Chinese cabbage, kale, kohlrabi). Weed species include *Diplotaxis muralis* (sand rocket, stinking wall rocket), *Raphanus raphanistrum* (wild radish), *Erucastrum gallicum* (dog mustard). These plants must be removed from the trial site before flowering when found during the five post-trial growing seasons.
3. Plants must be harvested before full maturity to minimize silique shattering and seed dispersal. Plant matter remaining at the end of the trial must be soil incorporated.
4. During the trial, the trial site must be monitored weekly. The sites must be monitored monthly during the five post-trial growing seasons to ensure that any volunteer plants and related species are removed before flowering.
5. The trial site must not be planted with *Sinapis* or *Brassica* species for five years following harvest.

2.21 *Solanum tuberosum* (POTATO)

1. Seeding and transplanting machinery must be cleaned at the trial site to prevent dispersal of plant material. Surplus seed or seedlings, and any plant material remaining after transplantation, will be destroyed by autoclaving, burning, or burial at a depth of two metres. Composting of this material is not an acceptable destruction method.
2. Potato plants under trial must be separated from other potato plants by a distance of one blank row (~1 metre).
3. During the trial, the trial sites must be monitored weekly. The trial site, including a 10 metre zone around the trial site, must be monitored monthly during the two post-trial growing seasons and any volunteer plants must be destroyed.
4. The trial site, including the 10 metre zone around the trial site, cannot be used to grow potatoes for two years following harvest of the trial.
5. For the disposition by burial of potatoes with novel traits produced in confined field trials and that have not received environmental, feed or food safety approvals from the CFIA and Health Canada, the following will apply:
 - a) The potatoes must be buried to a depth sufficient to allow for a minimum of 5 feet or more of soil cover.
 - b) It is recommended that applicants consult with the appropriate provincial and/or municipal authorities to determine if disposition by burial of regulated potatoes with novel traits is acceptable.
 - c) The applicant must provide the Plant Biosafety Office of the Canadian Food Inspection Agency with a record of disposition identifying the date and site of disposition, the source and line identity of the potatoes (including CFIA trial number) and the quantity of each line disposed of, no later than 48 hours after completion of the burial.
 - d) The disposition of the potatoes must be witnessed by a CFIA inspector, or an acceptable alternate (eg. provincial agronomist). In the case of an alternate, the applicant must provide an affidavit signed by the alternate attesting that the potatoes were buried in accordance with the requirements outline herein.
 - e) If all of the above conditions have been met, monitoring of the burial site will not be required by the CFIA. It is the responsibility of the applicant to determine if site monitoring is required by provincial and/or municipal authorities.

2.22 *Trifolium repens* (WHITE CLOVER)

1. Plants must be reproductively isolated from *T. repens* or any other sexually compatible species by cropping prior to pollen shed and by an isolation distance of 20 metres.
2. If any flowers in the trial are allowed to shed pollen, all *T. repens* plants within a 300 metre isolation distance of the confined field trial site must be treated as part of the trial.
3. The trial must be monitored weekly during the growing season and daily at the onset of the budding stage to ensure that flowering does not occur. For the duration of the growing season the trial site will be inspected every third day.
4. At the termination of the trial, the trial site will be sprayed with a non-selective herbicide to destroy plants remaining in the field.
6. After the trial is completed, the trial site must not be planted to *T. repens* for a period of 3 years. During this 3 year, post-trial period, the site must be monitored semi-monthly during the growing season and any volunteer plants must be destroyed prior to flowering.

2.23 *Triticum aestivum* (WHEAT)

1. Wheat plants under trial must be reproductively isolated from all *Triticum* species by 3 metres.
2. Plant matter remaining at the end of the trial must be destroyed by cultivation or incineration.
3. The trial sites must be monitored twice per month during the trial period.
4. No cereal crops may be grown on the trial site during the two-year post-harvest period. The post-harvest trial site must be monitored monthly during the two post-trial growing seasons for volunteers which must be removed or destroyed prior to anthesis.

2.24 *Vitis spp.* (GRAPEVINE)

1. Plants must be reproductively isolated by bagging of the flowers to prevent pollen dispersal.
2. The applicant must maintain control of the trial site throughout the 5 year trial period and 3 year post-trial period.
3. During the growing season the trial site must be monitored monthly for the duration of the trial and weekly during pollen shed.
4. The trial site must not be planted to grapes for 3 years post trial and any volunteer plants must be removed and destroyed prior to flowering.

2.25 *Zea mays* (CORN)

1. Plants must be reproductively isolated from non-modified corn by removal of tassels prior to pollen shed, or 100 metre isolation from other *Zea mays* plants. In the event that some tassels are allowed to shed pollen, all non-modified corn within 100 metres of the trials must be destroyed.
2. Plant matter remaining at the end of the trials must be soil incorporated.
3. During the trial, the trial site must be monitored weekly.
4. Corn must not be grown on the trial sites for one year after harvest. The sites must be monitored monthly during the next post-trial growing season and all volunteer plants must be destroyed prior to pollen shed.



Confined Field Trial Form

(All sections must be completed.)

1. Personnel Involved

PBO Trial No.

1.1 Applicant 1.1.1 Name		1.2 Field Manager 1.2.1 Name Must be a Canadian resident and responsible for the trial site location.	
1.1.2 Address		1.2.2 Address	
1.1.3 Telephone	1.1.4 Facsimile	1.2.3 Telephone	1.2.4 Facsimile
1.3 Canadian Agent 1.3.1 Name To be completed if the applicant is not a Canadian resident.			
1.3.2 Address		1.3.3 Telephone	1.3.4 Facsimile

Additional Information

1.4. Health Canada, Feeds Section-CFIA Indicate whether Health Canada and/or the Feeds Section, CFIA, should be informed of the application for preliminary safety determinations of the PNT as a novel food or novel feed.		1.5 Unregistered Pesticide Use Indicate whether the trial site location will be subject to unregistered pesticide use.		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Health Canada	Yes <input type="checkbox"/>	No <input type="checkbox"/>	1.6 Import Permit No. If the PNT is imported, provide the import permit number issued under the <i>Plant Protection Act</i> .		
Feeds Section, CFIA	Yes <input type="checkbox"/>	No <input type="checkbox"/>			

2. Trial Specifics

(Note: If the space provided is not sufficient, attach pages describing trials.)

2.1 Purpose Fully describe the purpose of the field trial, including the nature and type of data to be collected.			
2.2 Location Town and Province	2.3 Dates Planting	2.4 Harvest (anticipated)	2.5 Size Trial size in hectares
2.6 History If previously tested in Canada, please provide PBO trial number, date and location.			2.7 Submission Type New <input type="checkbox"/> Renewal <input type="checkbox"/> Perennial renewal <input type="checkbox"/>

**3. Description of the Unmodified Plant Species
(if not already covered by a PBO Biology Document)**

Name	
3.1 Latin Name(s)	3.2 Common Name(s)
Fertility	
Yes	3.3 Describe mechanisms and frequency of intra- and inter-specific outcrossing
<input type="checkbox"/>	
No	3.4 Describe the mechanism of infertility
<input type="checkbox"/>	
Habitat	
3.5 Managed habitats in Canada	3.6 Un-managed habitats in Canada
3.7 List any locations in Canada or elsewhere where the plants is a known pest	
Other Phenotypic Characteristics	
3.8 Tendency to weediness	Provide information on plant mechanisms responsible for:
 	3.9 Allelopathy
3.10 Dormancy	3.11 Pollen dispersal
3.12 Seed dispersal	3.13 Vegetative dispersal
Toxins	
3.14 List any known toxins for this species, including natural defence compounds	
3.15 Indicate the levels at which these compounds induce toxicity	
3.16 Indicate the species affected by these toxins	

4. Description of the Plant with Novel Trait (PNT)

4.1 Name or Designation of PNT		
<p>Novel Trait</p> <p>4.2 Describe each specific novel trait associated with this PNT</p>		
<p>Trait Introduction and/or Selection Method</p> <p>4.3 Mutagenesis</p> <p>4.3.1 Induction Method</p>		<p>4.4 Other</p> <p>Please provide details for modification by any means other than mutagenesis or transformation</p>
<p>4.3.2 Selection Method</p>		
<p>4.5 Plant Transformation (i.e. rDNA techniques)</p> <p>4.5.1 Transformation Method</p>		
4.6 For transformation plasmids, please provide the following information: (below)		
4.6.1 Name of plasmid	4.6.2 Naturally Pathogenic	4.6.3 Disarmed Vector?
	Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4.6.4 Genetic map provided?	4.6.5 Construct previously tested in Canada	If yes, then how?
Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	<p>PBO Trial No. (below)</p>
<p>4.6.6 For each gene construct, describe all genes, regulatory elements, gene products, non-translated DNA sequences and, where applicable, affected metabolic pathways.</p>		

5. Characteristics of the Novel Trait(s)

5.1 Spatial and Temporal Trait Expression							
Trait	Expression						
	Constitutive (Yes/No)	If not constitutive, indicate specific tissue					Developmental stage of trait expression
		Leaf	Seed	Pollen	Roots	Other	
5.2 Altered Plant Characteristics							
5.2.1 Please indicate any changes with respect to the following:							
5.2.1.1 Weediness		5.2.1.2 Allelopathy			5.2.1.3 Dormancy		
5.2.1.4 Pollen dispersal		5.2.1.5 Seed dispersal			5.2.1.6 Vegetative dispersal		
5.2.2 Please detail any toxins produced by the PNT that were not produced by the unmodified plant							
5.3 Stability of the Novel Trait(s)							
Please detail how you have determined the stability of the novel trait(s).							

6. Trial Site Location

Habitat		
6.1 Describe the biological diversity of the trial site(s), including potential impacts resulting from the field test.	6.2 Is the trial site, or sites, part of a managed ecosystem?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	6.3 If the site is managed, how close is the nearest natural ecosystem?	
	6.4 How close is the site from an area of special ecological interest, including protected areas and sanctuaries?	
Indigenous Species		
6.5 Specify the related wild and cultivated plant species present at the trial site and how close they are to the novel plant material under test.		
6.6 Are there any endangered species on or near the site? If yes, please list.	Yes <input type="checkbox"/> No <input type="checkbox"/>	6.7 What mechanisms are in place to prevent the local fauna from removing novel plant material from the site?
Contact the Canadian Wildlife Service, RENEW Secretariat, 351 Blvd. St-Joseph, Hull, P.Q. K1A 0H3. Telephone (819) 953-4389		
6.8 To what extent are novel gene products toxic when ingested by native faunal populations, including mammals, birds, reptiles, and insects? How has this been determined?		
6.9 Map location of trial site has been provided		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	A map must be received by the PBO within 7 days following planting.

7. Trial Protocol

Reproductive Isolation

7.1 State the reproductive isolation measures being implemented for this trial and give details.

Seeding

7.2 Material will be planted by:

Hand

Mechanically

7.3 Will any unmodified plants of the same or a related species be planted?

Yes

No

If so, why?

7.4 Is dissemination of the seed from the trial site a possibility?

Yes

No

7.5 Describe your management plan to avoid the dissemination of seed from trial site.

7.6 Describe your plan for recording the quantities of seed planted and any excess. Also, describe the disposition plan for any excess, or non-planted, seed.

Spraying *

7.7 Name of pesticide

Please complete this section if the trial site is subject to the use of an unregistered product, or a registered product used for a non-registered purpose.

7.8 Total area sprayed (hectares)

7.9 Active ingredient

* Required by PMRA to determine compliance with the Pest Control Products Act

Harvesting 7.10 Will plants be allowed to set seed?		7.11 If so, will the seed or other material be harvested by hand or machine?
Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.12 Describe your plan to avoid dissemination of seed from the trial site during harvesting.		
7.13 Describe your disposition plan for non-propagatable plant material.		
7.14 Describe your disposition plan for all propagatable plant material, including how and where harvested material may be stored. Provide name, address and phone number of contact person responsible for disposition records.		
Post-Trial Land Use		
7.15 Name and address of the person(s) having control over the site, including isolation distance, during the post-harvest land use period.		7.16 What is the anticipated post-trial land use? *
		* Please note applicants are required to inform the PBO of the types of cover crops used on a trial site during each year post harvest restrictions are in effect.
		7.17 Describe how the site boundaries will be marked to facilitate subsequent inspection.

Contingency Plans

7.18 Describe your contingency plan in the case of accidental release of seed or plant material, or the breakdown of isolation

7.19 Describe your contingency plan in case of unexpected spread of the novel plant material.

Monitoring the Trial Site

7.20 Describe the extent and frequency of trial site monitoring during the course of the field trial.

7.21 Describe the extent and frequency of trial site monitoring during the post-trial period.

7.22 Describe what monitoring results will be recorded, how they will be recorded, who is responsible for them and where the results will be located.

7.23 If any controlled monitoring procedures are proposed for this trial (e.g. plantings of unmodified plants of a related species to determine possibility and frequency of gene flow), detail these.

Public Notice

7.24 Describe your plan for providing public notification of your proposed field trial.