

PROCEDURES FOR THE REGISTRATION OF CROP VARIETIES IN CANADA

Consultations on the new variety registration regulatory proposal issued October, 2000 are to be completed by the end of March 2001. Proposed changes will then require amendments to the Seeds Regulations with implementation anticipated by Summer 2002. Details of the Regulatory Proposal are available on the CFIA web site at: www.cfia-acia.agr.ca/english/plaveg/variety/vartoce.shtml.

*In the interim, this updated document will provide information on recent policy and procedural changes that have been implemented by the Variety Registration Office since the last revision to the Procedures document published **March 24, 2000**.*

As this is an interpretive document to the Seeds Regulations Part III, the wording in this document may not be identical to the wording of the Regulations. Please refer to the Seeds Regulations Part III if you require information on the actual wording.

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THIS DOCUMENT REPLACES THE ONE PUBLISHED ON **MARCH 24, 2000**

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PART I

GENERAL INFORMATION

I. 1. Legislation:

The *Seeds Act and Regulations* is the federal legislation governing the testing, inspection, quality and sale of seeds in Canada.

Section 3(1)(b) of the *Seeds Act* states that no person shall:

sell or advertise for sale in Canada or import into Canada seed of a variety that is not registered in the prescribed manner.

This document clarifies and explains the legislation specified in Part III of the *Seeds Regulations* (sections 63 to 77) concerning the application process and the variety registration system. Companion documents include the *Variety Registration Application Form*, and the appropriate objective description form for most crop kinds.

Copies of the *Seeds Act and Regulations* and accompanying Schedules, Procedures, etc. are available on the CFIA web site at www.cfia-acia.agr.ca. For information on obtaining hard copies of the *Seeds Act and Regulations*, please see Appendix VIII.

I. 2. False or Misleading Statements:

It is an offence under the *Seeds Act* to make a false or misleading statement either verbally or in writing to an official engaged in carrying out his duties under this Act. **In addition, such statements could result in the refusal or suspension of a registration.**

I. 3. Registration:

a) In Canada, varieties are currently registered on the basis of merit. (see Glossary II.7)

The variety registration system has three mandates:

- to ensure that agronomically inferior or unadapted varieties are excluded from the Canadian marketplace,
- to ensure that new varieties meet current requirements for resistance to economically important diseases and
- to ensure high quality products for processors and for consumers.

b) Unless otherwise specified in the certificate of registration, the registration is valid for all provinces and territories of Canada, until such time as the registration is cancelled or suspended, and without any restrictions on the production of seed or commodity.

Regional tests normally provide the basis for national registration. A variety is to be entered into official tests in the area(s) of anticipated adaptation. If it is supported by a recommending committee (see I. 9) and granted a registration, it may be imported or sold in all of Canada, except where regional restrictions apply.

c) When a variety is registered, the Registrar issues a certificate of registration to the applicant. Only one certificate is granted per variety.

- d) The *List of Varieties which are Registered in Canada* is updated and published quarterly. The list includes varieties that have been granted national, interim, regional, and contract registrations. It is available from the Canadian Food Inspection Agency's web site at: www.cfia-acia.agr.ca/english/plaveg/variet/vartoce.shtml.
- e) Where a registration is granted that is limited in duration or geographic scope, or is made subject to a documented quality system (see section I. 4.3), the registrant will receive a notice from the Registrar by registered mail, giving the reasons for the restriction(s) to the registration.

I. 4. Restricted Registrations:

4.1 Interim Registration:

- a) An interim registration is normally granted for either of two reasons:
 - production of grain or other commodity for market acceptability tests; or
 - emergency/crisis reasons (e.g. - disease).
- b) An interim registration gives all the rights/privileges of full registration, but for a specified period of time only.
- c) An interim registration may be granted initially for a period of up to three years, if requested by the recommending committee, provided the appropriate fees are submitted. Otherwise, a variety will be granted a one year registration.
- d) An interim registration may be renewed for additional periods, to a maximum total life of five years.
- e) An interim registration may be granted on a regional basis, or where the registration restricts the manner in which seed or commodity crop is produced (contract registration).
- f) There is no provision for an interim registration to be granted for undefined periods of time such as from planting date to harvest date. In the case of a winter wheat variety, if the applicant wishes to have the issuance of the registration deferred until fall, this must be indicated on the application. This would prevent the registrant from selling any seed of the variety until the variety is registered.
- g) A minimum of one year of evaluation in variety registration trials is required for an interim registration.

4.2 Regional Registration:

- a) In certain cases, some varieties may be desirable in one region, but could cause serious problems in other regions. Regional registration may be granted for crop varieties in those instances where the variety poses a potential threat to agriculture in specific regions for reasons such as seed/grain distinguishability, quality, disease or where the variety or its progeny may be detrimental to human or animal health and safety, or the environment.
- b) For regional variety registration purposes, "harm" is defined as harm to the industry (eg. feed wheat in milling wheat). Characteristics related to regional adaptation such as lack of winter hardiness does not constitute harm. It does not include when a variety has not received all of its approvals in potential foreign markets.

4.3 Contract Registration:

- a) This category is used for those varieties where delivery of the resulting commodity into traditional commodity channels would cause harm to those channels. Thus, a variety must demonstrate the possibility of harm if granted an unrestricted registration in order to qualify for this type of registration. Examples of this include

high erucic acid rapeseed, or crops modified to produce cosmetic, pharmaceutical or industrial substances. **In addition, the quality control system must address any regulatory concerns under the Canada Grain Act and the Canadian Wheat Board Act.**

- b) The applicant must make available to the Registrar a quality control system that describes fully how any and all potentially adverse effects of the variety will be managed. Appendix VI provides further information. **In the case of wheat and barley, the Variety Registration Office will share the quality control system with the Canadian Grain Commission and the Canadian Wheat Board to determine its acceptability. It would be prudent for applicants to consult with these parties on the quality control system, as part of the manual development, before the variety is presented to the registration recommending committee.**
- c) The applicant must agree in writing to provide information on the distribution, use and disposition of any seed of the variety or any progeny thereof to the Registrar, upon request. This declaration can be found in the application form.
- d) In some circumstances, the production of crops from the variety will be required to be conducted using sufficient isolation distances for the species. This will be required in cases where cross pollination to grain of a traditional commodity type would have a negative effect on the latter crop.

I. 5. Refusal to Register:

The Registrar will refuse to register a variety if:

- a) its name could deceive or mislead the purchaser with respect to the composition, genetic origin or utility of the variety;
- b) its name is likely to be confused with a variety that is already registered;
- c) the application fails to establish that the variety has merit for the purposes claimed;
- d) the variety does not meet the standards for varietal purity established by the Canadian Seed Growers' Association (CSGA) or the *Seed Regulations* for a variety of that species or crop kind;
- e) the variety or its progeny may be detrimental to human or animal health and safety, or the environment when grown and used as intended;
- f) false statements, or falsified documents have been submitted as part of the application;
- g) the information is not sufficiently complete to allow it to be evaluated;
- h) the variety is of a species or crop kind not required to be registered by the *Seed Regulations*;
- i) misleading or incorrect information was submitted;
- j) the variety cannot be distinguished from a variety already registered or known to exist;
- k) the variety name is likely to offend the public;
- l) the representative reference sample contains off-types in excess of the CSGAs' standards for varietal purity; or
- m) the variety name is a registered trademark **for seed**.

Where the registration of a variety has been refused, the Registrar will send the applicant a notice by registered mail, stating that the registration has been refused and the reasons for the refusal.

I. 6. ***Suspension and Cancellation (Deregistration) of Registration:***

The registration of a variety may be suspended or cancelled if requested by the registrant. **Prior to requesting the cancellation of a registration, the registrant is required to check the variety's pedigreed seed availability, or develop a disposal plan acceptable to seed growers in possession of pedigreed seed of the variety.** The Variety Registration Office will publish a list of varieties whose registrations are proposed for cancellation. If our office is notified in writing that pedigreed seed of a specific variety is still available, and there is still commercial interest in the variety, the cancellation of registration will be deferred pending resolution among the interested parties.

Where the registration of a variety has been suspended or cancelled, the Registrar will send the registrant a notice by registered mail stating that the registration has been suspended or cancelled and the reason(s) for the action.

6.1 *Suspension*

The Registrar will suspend the registration of a variety for up to two years where:

- a) the variety has an adverse effect on Canadian agriculture and the food system due to disease susceptibility or inferior quality;
- b) seed of the variety has demonstrated significant levels of contamination such that the genetic purity of the variety has been jeopardized;
- c) the variety has been altered in such a manner that it differs from the representative reference sample;
- d) the variety or its progeny may be detrimental to human or animal health and safety, or the environment;
- e) false or misleading information was submitted as part of the application;
- f) the variety name was trademarked after registration.

6.2 *Cancellation*

The Registrar will cancel the registration of a variety where the variety:

- a) has been altered in such a manner as to convert it to a variety that is registered under a different name;
- b) has been found to be indistinguishable from another variety already registered or known to exist;
- c) is of a crop kind or species no longer subject to the variety registration requirements.

The Registrar may also cancel the registration of any variety whose registration has been suspended for two years and where the reasons for the suspension are still valid.

I. 7. Reinstatement of Registration:

The Registrar may, upon written request, and the submission of appropriate fees, reinstate the registration of a variety without a requirement for a new application. However, there must be just cause for any reinstatement. In the case of reinstatement of permanent registrations cancelled at the request of the registrant, where a considerable period of time has elapsed since the cancellation, the Variety Registration Office may require the involvement of a recommending committee(s) to determine if the variety in question still has merit. **In the case of reinstatement of interim registrations, a recommendation for registration from a recognized committee must accompany the request.**

Where more than one year has elapsed since the cancellation, a new legal sample will be required to be submitted.

I. 8. Review of Registration Decisions:

8.1 *Process*

Where the Registrar refuses to register a variety, or grants the variety a registration that is restricted regionally or in duration, or where the registration restricts the manner in which seed or commodity crop is produced (contract registration), the applicant may request that the Registrar review the decision. Similar procedures may be used for the review of the suspension or cancellation of registration.

If there is a valid objection to a registration decision, the Registrar may consult with an expert or group of experts knowledgeable in the area of concern who have no interest in the outcome of the review.

The selected expert(s) will recommend a course of action to the Registrar. The recommendations are not binding on the Registrar.

8.2 *Procedures for Application for Appeal of a Registration Decision*

- a) The appellant must make a written request to the Registrar within 30 days of receipt of notice that the decision was made.
- b) The appellant must include the reasons for requesting the review along with substantiating information or documentation.

I. 9. Recommending Committees:

All committees that recommend varieties for registration must be officially recognized by the Minister of Agriculture and Agri-Food Canada for this purpose. Appendix VII lists the currently recognized committees.

The recommending committees are responsible for:

- formulating testing procedures that are appropriate for their crop(s) including a mechanism for verification of trials/validation of data;
- regularly reviewing the testing procedures to ensure that they reflect acceptable scientific practices; and
- ensuring that reference varieties are current and fairly represent the requirements of Canadian agriculture.

I. 10. Descriptions of Varieties:

As of April 1, 1994, the Variety Registration Office ceased producing descriptions of registered varieties. Requests for information on specific varieties are referred to the Canadian representative/distributor or breeder.

Information describing the variety is still required as part of the application for crop inspection and variety verification purposes.

The Canadian Seed Growers' Association has recently undertaken a project to post variety descriptions on their web site. These descriptions are based on the information provided to them by CFIA for crop certification purposes. For descriptions of variety provided to the Variety Registration Office after January 31, 2000, the applicant is asked to clearly indicate any information used for crop or seed inspection purposes that should be considered confidential and not posted on the CSGA web site. This could include information on the breeder of the variety and information on quality parameters. Pedigree/breeding information and experimental data provided by the recommending committees are not forwarded to the CSGA.

Information on variants/offtypes, on variety name synonyms, or name changes is considered to be public information and will not be considered Confidential Business Information.

I. 11. Confidential Business Information (CBI):

Although pedigree information is required as part of the registration review process, it is not released for hybrid crops as it is considered confidential business information (CBI). Other legitimate forms of CBI may be withheld upon written request of the registrant, and consent of the Registrar. The dissemination of potential CBI is subject to the Access to Information and Privacy (ATIP) legislation. The withholding of information from dissemination (other than pedigrees of hybrid crops) will require review by ATIP officials. The registrant may be required to show just cause under ATIP legislation as to how dissemination would breach confidentiality.

I. 12. Advertising a Variety Prior to Registration and while under Suspension:

- a) **Prior to Registration:** A company may advertise a variety prior to registration provided all of the following conditions are met:
- the variety has been supported for registration by a recognized recommending committee;
 - an application for registration with the appropriate fee has been received by the Variety Registration Office; and
 - the variety advertisement clearly states "registration pending".

Sales may not occur until registration is granted.

- b) **While under Suspension:** A variety whose registration is suspended may not be advertised while under suspension.

PART II

APPLICATION PROCEDURES

II. 1. General:

- a) Applications and supporting documents submitted must be in one of Canada's official languages (English or French). Translations must accompany all documents that are in a language other than English or French.
- b) Appendix I lists the crops for which variety registration applies.
- c) All required fees must accompany applications.

II. 2. How to Apply:

- a) Applications for the registration of crop varieties should be submitted on the *Variety Registration Application Form* available from the Canadian Food Inspection Agency's web site at www.cfia-acia.agr.ca/english/plaveg/variety/vartocce.shtml or from the Variety Registration Office. The most recent version of the application form includes a Fee Submission form which should accompany fees. **If the applicant chooses to not use the most recent form, the applicant must submit a clear indication of fee submission with the application.** These, along with other required supporting documentation and reference samples, must be sent to:

Variety Registration Office
Plant Health and Production Division
Canadian Food Inspection Agency
59 Camelot Drive
Nepean, Ontario
K1A 0Y9

Tel : (613) 225-2342
Facs: (613) 228-6629

- b) Applications for variety registration **must be submitted separately** from applications for Plant Breeders' Rights.
- c) Applications are processed on a first come, first served basis.
- d) In the event two applications are received by the Variety Registration Office that, based on all available information, appear to be identical varieties, preference will be given to registering the variety with the first complete application, and having an acceptable reference seed sample submitted. (see also II. 5.1 Definition of Variety)

Where the two applications are submitted by the same applicant, the applicant will be given the option to select one variety for registration. The registration of the second variety will be held pending resolution of the varietal distinguishability issue.

In the event that two applications are received for two different varieties of the same crop kind with the identical or very similar proposed variety name, preference will be given to the variety with the first complete application (including fees and legal reference sample).

- e) In order to facilitate the evaluation process, applications should be submitted as far as possible in advance of the desired period of sale or importation for sale. The time required to process applications varies depending on the extent of review required, how complete the applications are and the number of applications pending at any one time. Please allow **two weeks** for the completion of the preliminary review, when a check is done on the acceptability of the seed sample and required documentation. (A more rapid response may be possible if a facsimile number is provided). Allow up to an additional **four weeks** for the detailed review of applications. After receipt of all required information, a registration decision can normally be made and registration documentation completed within **two weeks**.

For soybean and field pea varieties, a laboratory analysis for genetic purity is conducted prior to registration. This analysis takes four weeks to complete. For plants with novel traits, additional reviews by the Pest Management Regulatory Agency to substantiate claims made with respect to pesticidal tolerances or properties may be required. Such reviews may require up to **120 days**.

II. 3. **Incomplete Applications:**

If an application for registration is incomplete with respect to the submission of fees, the application will not be returned. However, the application will not be considered accepted until fees are submitted and **no review will be initiated**. If the application is not considered to be received due to lack of fee submission, no advertising of the variety may be undertaken. The order of the review of applications will take into account the day the fees are submitted.

If an application for registration is incomplete with respect to other requirements such as a description of variety, recommendation for registration from a recommending committee, acceptable legal reference sample or photographic slides, the application for registration will be retained pending this information.

II. 4. **Recognized Applicants:**

Applications for registration shall be made by a permanent resident of Canada to whom any notice or correspondence under the *Seeds Act and Regulations* may be sent. This may be a Canadian representative, or in the case of varieties developed in Canada, by the breeder.

Upon registration, the applicant automatically becomes the registrant, unless otherwise specified in the application. For restricted registrations, the registrant must ensure that the terms and conditions of the restrictions are met. As such, the registrant need not be the breeder or owner of the variety.

II. 5. **Required Information:**

A complete application package, **which must be supplied by the applicant**, contains the following information:

- a) a proposed variety name (see II. 5.2). As of January 1, 1996, a Canadian trademark search is not required to be submitted as part of the application for registration. Applicants are required to sign a declaration that they have not applied for or trademarked the name of that variety. The declaration is found in the Variety Registration Application Form (page 1). However, the Trademarks Office of Industry Canada strongly suggests that applicants have a trademark search conducted in order to identify potential trademark infringements.
- b) the scientific and/or common names of the species.
- c) a description of pedigree, origin, history and methods of development of the variety including the experimental test number(s) and the name and location of the breeding organization. (See II.5.3)

- d) a detailed description of the variety respecting morphological, pathologic, agronomic, physiologic, and biochemical characteristics (where applicable). For triticale and wheat varieties, a kernel description developed by the Canadian Grain Commission must be submitted in order for the Variety Registration Office to accurately determine the geographic scope/appropriate restriction for variety registration (see II. 5.4).
- e) results of valid experimental trials comparing the agronomic and quality characteristics of the variety to the performance of the appropriate reference varieties designated by the recommending committees.
- f) a valid recommendation for registration from a recognized recommending committee. For all crops except forages, the recommendation can not be more than two years old. For forages, the recommendation can not be more than four years old. Where support for registration is conditional upon submission of additional information, please ensure that the latter information is supplied.
- g) a statement as to whether the variety is sold in other countries and if so, by what name(s).
- h) particulars of the provisions for the maintenance of seed stocks. Authorization is required from the breeder of a foreign variety for the Canadian representative to maintain breeder seed in Canada. If there is intent to maintain breeder seed in Canada, this must be done under the supervision of a plant breeder recognized by the C.S.G.A.
- i) the name and address of the Canadian representative and/or distributor as well as the name and address of the breeder/owner, if different from the Canadian representative. Telephone and facsimile numbers facilitate rapid communication, **as do electronic mail addresses**. Unless otherwise indicated by the applicant, all correspondence with respect to the registration or cancellation of a variety will be addressed to the Canadian representative listed on the application form.
- j) where the applicant is a person, company or organization other than the breeder or owner of the variety, the application must be accompanied by a signed statement from the breeder or owner of the variety indicating that the applicant has been authorized to apply for registration in Canada. If, at any time, there is a change in the Canadian representative of a variety, it is the responsibility of the breeder or owner to inform the Variety Registration Office of the change.
- k) for all species except potatoes, a representative reference sample of seed (see Appendix II) must be submitted. Unacceptable samples will only be returned upon submission of an acceptable legal reference sample or upon withdrawal of the application.
- l) for registration of potato varieties, a set of photographic slides detailing plant morphology (see II. 5.10). It is recommended that molecular data, identifying the variety, be included with the registration package.
- m) the Registrar may require that the applicant supply further information that will allow him to determine the merit and identity of the variety. (see II. 5.1 Definition of Variety)
- n) the applicant will be asked if the variety is to be added to the Organisation for Economic Co-operation and Development (OECD) List of Cultivars Eligible for Certification. This information is not required for variety registration, nor is there any obligation to add a variety to the list. **In most cases, CFIA will not add to the list varieties for which breeder seed is maintained outside of Canada. These varieties should be added by the National Designated Authority of the country in which breeder seed is maintained. Exceptions may be made for varieties from countries not participating in the OECD Seed Schemes.** Note that "composite" canola varieties will not be added to the OECD list of cultivars. Transgenic varieties may be added to the list, but must meet the regulatory requirements of each importing country. Varieties with interim registrations are eligible for addition to the OECD List of Cultivars. If the variety being added to the OECD list is a hybrid, the applicant **must** supply descriptions of each inbred parent as well as the hybrid variety.
- o) the appropriate fees must be submitted along with a "Fee Submission Form" (page 6 of application form). Review of an application package will not be initiated until appropriate fees have been received.

5.1 *Definition of a Variety:*

A variety is considered to be a cultivar, and denotes an assemblage of cultivated plants, including hybrids constituted by controlled cross-pollination, that:

- are distinguished by common morphological, physiological, cytological, chemical or other characteristics; and
- retain their distinguishing characteristics when reproduced.

Where a variety has a similar genetic background to a previously registered variety, it may be eligible for registration provided it has merit and is distinguishable from the previously registered variety. The Registrar must be assured that he is not registering a previously registered variety under another name. There is also an obligation on the part of the Variety Registration Office to ensure that the registration of a variety will not compromise the varietal identity principles upon which seed and crop certification is based. The onus is on the applicant to show distinguishability for non-hybrid crops and for hybrid crops where the two varieties in question are developed by the same breeding organization. In determining the distinguishability of two varieties, the applicant should consider the magnitude and consistency of the differences as well as the heritability of the traits involved.

Currently, varieties will not be registered if distinguished **solely** on DNA analysis.

5.2 *Variety Name Guidelines:*

- a) The proposed variety name indicated on the *Variety Registration Application Form* will be the designation that is used for all official records including the certificate of registration. This includes spaces, hyphens and capitalization. References in any other correspondence will not affect the official designation of the variety. Any proposed changes to variety names prior to registration must be communicated in writing.
- b) A variety shall be known by one name only in Canada. If a commercialized variety from another country is proposed for registration in Canada, the established name may be accepted even though it may not comply completely with Canadian guidelines. If the variety name used in the country of origin is not acceptable to the Registrar, the Registrar will request that a synonym be used in Canada under the conditions set out in c).
- c) A variety may not bear the identical name to a **different** variety of the same crop kind marketed outside Canada.
- d) In the case of a variety bred outside of Canada, an applicant may choose a synonym under the following conditions:
 - only one name will be used for the variety in Canada
 - the owner of the variety agrees to the use of the synonym
 - all known names and synonyms are indicated on the application form
 - all synonyms are public information, and
 - it is understood that the use of a synonym may make the variety name unacceptable for Plant Breeders' Rights in Canada.
- e) A variety name is a generic term and shall not be trademarked for use on seed of the variety. A trademarked company "house" name or brand name may be used as part of the variety name, providing the company notifies the Variety Registration Office in writing that it does not object to the use of its trademark as part of the variety name.

Once a variety is registered, trademarking the variety name will result in the suspension or cancellation of registration.

- f) A variety name shall not be the same as, or very similar to, the name of another variety of the same or closely related crop, or of a variety of a different crop that may, by Regulation, be used with it in mixtures or in the same grade table.
- g) Wherever possible, the variety name should be unique.
- h) The name of a variety that has been deregistered may not be reused in either its original form or translated form, for another variety of the same or similar crop kind.
- i) Species names, common crop names or names of botanical types should not be used as variety names.
- j) Variety names, varied only by the addition of number(s), letter(s) or word(s), are acceptable providing their pedigree indicates the direct descendance from the variety to which the suffix is added.

The name of the new variety should not be misleading in terms of the pedigree of the variety. The proportion of germplasm contributed by an existing variety to a new variety should be taken into account when giving the new variety a name that is very similar to that of the existing variety. For example, Jones Plus should have at least 50% of the parental germplasm contributed by the variety Jones.

When a suffix is used, please give attention to the form in which it is to be used, e.g. "George III", and "George 3" or "Jane Plus" and "Jane +".

- k) Any explicit or implicit claims incorporated as part of a variety name, may only be used if they are accurate and verifiable.
- l) A variety name shall not be such as to be considered offensive.
- m) A variety name that is acceptable for variety registration may not be acceptable for Plant Breeders' Rights purposes due to differences in naming guidelines. Applicants for Plant Breeders' Rights should ensure the acceptability of the proposed variety name under PBR independently from the variety registration evaluation.
- n) The name under which a variety is registered must be identical to the name under which a variety is granted Plant Breeders' Rights. Plant Breeders' Rights legislation is restrictive as to the conditions under which a variety name may be changed.
- o) When selecting a variety name, consideration should be given to the limitations of seed tags and the equipment used to generate them. Long variety names may not fit on the seed tag and the printing equipment may be unable to print special characters or fonts, or may be limited in generating both upper and lower case letters. Please pay close attention to use of hyphens, spaces and the case of the letters to be used. Seed tags must bear the variety name exactly as registered.
- p) The Variety Registration Office will not approve variety names prior to the receipt of an application for registration, or an application for variety name amendment.
- q) A variety name that differs from the name of another variety of the same or closely related crop kind used in another country by the addition of a prefix or suffix will be accepted in Canada. The onus is on the applicant to ensure that if he intends to market the variety outside Canada, the variety name complies with the regulations of the country in which he intends to market.

- r) In order to avoid disappointments on variety name acceptability, applicants may wish to review the OECD list of cultivars at www.oecd.org/agr/code for the same and closely related species. Other sources include the Crop Science and Plant Variety Protection registration at www.ars-grin.gov/npgs/searchgrin.html. While these sources will not provide a definitive answer on variety name acceptability, they are a good source of information to determine if the proposed name is already in use.

5.3 *Description of Pedigree/Breeding:*

- a) The origin of the variety should include the name and location of the institution(s) involved in the variety's development, the pedigree of the variety, breeding methodology and history, including dates, selection criteria and experimental designations. The derivation and maintenance of breeder seed stocks should be fully described.
- b) In the case of hybrid or composite varieties, an uncoded pedigree and derivation of the inbred (parental) lines must be submitted. This information is considered confidential and will be treated as such.
- c) Where the parentage of a variety includes experimental lines, please give the genetic background of these lines. This information is valuable in distinguishing variants and offtypes found in seed fields subsequent to variety registration as well as determining the uniqueness of the variety.
- d) Varieties will only be considered for registration if:
- developed or maintained by a plant breeder recognized by the Canadian Seed Growers' Association, or
 - the seed of the variety has been accepted for certification in the country of origin by an official seed certification agency.
- e) In the case of varieties resulting from recombinant gene technology, information on the gene(s) inserted, its source and gene products must be provided. Exact DNA sequence information must be provided to facilitate the generation of gene probes for variety verification purposes.

If the applicant has previously supplied this information as part of an application for environmental release through the Plant Biosafety Office, this information will be accessed directly and supplied to Variety Verification unit staff at the time of registration.

If the applicant is using constructs for which another organization has been granted environmental release, the applicant must submit a letter of permission from this organization to allow access to the DNA sequence information (Confidential Business Information).

5.4 *Varietal Characteristics:*

- a) The description should include as much relevant morphological information as possible to ensure that seed and crop inspection as well as variety verification, can be properly conducted. For certain crops (alfalfa, wheat, barley, oats, fescue, red clover, mustard, flax, lentils, peas, timothy, field beans, soybeans, canola/rape, brome grass and orchard grass), objective description forms have been developed and are available from the Variety Registration Office. These forms list the traits that must be provided for variety registration as well as supplemental traits. For other crops, standard forms are not available but information on relevant characteristics may be obtained from the Variety Registration Office. **Where a variety description is supplied in two formats, e.g. on an ODF, and as a summary page, the onus is on the applicant to ensure that the two descriptions are consistent.**
- b) Where the description of variety is developed outside of Canada, the onus is on the applicant to ensure that the description is representative of the variety under Canadian growing conditions.

- c) For triticale and wheat varieties, a copy of the kernel description developed by the Canadian Grain Commission (CGC) must be included. Kernel descriptions from the CGC are no longer required for barley varieties.
- d) If there is known variability in the variety, details of this must be provided. If information is available on possible off-types that should be rogued, this should be included, as well as those variants that are considered acceptable and the maximum acceptable frequency of occurrence in each class of pedigreed seed. In cases where doubt exists, the applicant may also be asked to provide genetic information on the origin of these variants.
- e) Disease reaction information should include resistance and susceptibility to the diseases that are economically important to the specific crop in Canada. Disease information should be supplied directly by the recommending committee where possible. Data should be submitted to substantiate all claims of insect or disease resistance.

As of July 1, 1990, alfalfa varieties must be resistant to bacterial wilt (*Corynebacterium insidiosum*) in order to qualify for registration.

In order to receive registration in eastern Canada, a wheat variety must have a minimum level of resistance to fusarium head blight. Provincial guidelines within eastern Canada vary as to the exact requirements.

- f) Claims that are made by the applicant, such as quality, insect tolerance, herbicide tolerance, maturity, seedling vigour, etc., of a variety should be substantiated by Canadian **scientific** data. It may be appropriate, in certain cases, to include U.S. data.
- g) If a variety possesses characteristics that would indicate it has a particular use or market, the variety description should include a statement as to its potential utilization. Claims of specific strengths e.g. tolerance to herbicides, must be supported by valid scientific data. This information may also be required by Industry Canada under the authority of the Competition Act. All claims to be used in advertising must be submitted at the time of application for registration.
- h) For potato varieties, the Potato Section of the Canadian Food Inspection Agency has expressed concerns about accepting potato varieties for certification in cases where the variety description is not submitted in a format acceptable to them. UPOV forms that describe traits solely with a numerical descriptor code that must be cross referenced to other documents is not a preferable format for potato descriptions. The Potato Section prefers that the information be provided in a format in which the trait is described qualitatively.
- i) Photocopies of objective description forms completed for the variety for Plant Breeders' Rights purposes may be submitted if:
 - it is clearly marked on the photocopy that the submission is for Variety Registration Office use, and
 - information has been provided for the traits required for variety registration purposes.

The submission of information for "non-mandatory" traits is useful to the VRO in determining rapidly if the variety can be distinguished from a previously registered variety or if a subsequent candidate variety is distinguishable.

- j) If an application is made for both Plant Breeders' Rights and variety registration, the onus is on the applicant to ensure that descriptive information submitted for variety registration purposes does not contradict descriptive information submitted for Plant Breeders' Rights purposes. The applicant must also ensure that both offices are individually informed of changes to the applications or to descriptions of variety.

5.5 *Experimental Data:*

- a) The applicant **must** submit the experimental data used by the recommending committee in supporting the variety for registration directly to the Variety Registration Office.
- b) Unless recommending committee protocols indicate otherwise, only data considered by the recommending committee in supporting the variety for registration should be included in the application. The complete package of information (data, notes, etc.) that the committee used to make the recommendation decision should be submitted to the Variety Registration Office. This would include decisions to object to, or to not support the registration of a variety. Other data to support claims of variety performance (see II.5.4(e), (f) and (g)) should also be submitted.
- c) Data used by a recognized recommending committee in making a registration decision, when quoted to support a variety for registration must be used in its entirety without "selection" and are subject to approval by the appropriate recommending committee.
- d) **Actual experimental data including a summary of the agronomic performance must be included. Summarized merit scores are not acceptable in lieu of actual data.**

5.6 *Notarized Affidavits for Plants with Novel Traits and Varieties derived from PNT's:*

For plants with novel traits developed by genetic engineering or by traditional plant breeding using transgenic parents, the applicant must

- a) submit a notarized affidavit with the application (one affidavit per variety), indicating that molecular tests conducted on seed of the variety entered in variety registration trials and of the legal reference sample, confirming that the variety contains the correct genetic makeup, and
- b) provide the detailed laboratory protocols used to conduct the molecular tests. If the protocols have been previously submitted, it is acceptable to indicate that the samples were analysed using the specific protocol. The protocol reference number (including version number) must be cited in the affidavit.

In the case of potatoes, the affidavit should indicate that tests were conducted on seed entering the variety registration trials and the seed certification system.

5.7 *Support for Registration:*

To speed the processing of all registration applications, a copy of a letter or motion of support from the registration recommending committee must be submitted directly by the applicant. The recommendation may not be more than two years old, or in the case of a forage variety, not more than four years old.

5.8 *Fees:*

As of December 1, 1997, fees came into effect for the evaluation of variety registration applications, and related services. Please ensure that a separate Fee Submission Form is included in each application package along with the appropriate fee (See Appendix IX). **Once an application review has been initiated, no refund will be issued.**

5.9 Reference Samples:

- a) The reference samples are legal samples for use in monitoring varietal purity of seedlots offered for sale in Canada and may be used as evidence in a court of law. The submission of an improper or non-representative sample for a variety could result in a variety not being registered, seed lots being rejected for pedigreed status and/or the suspension of a registration.
- b) With the exception of hybrid or “composite” varieties, the sample should be of breeder status (see I)). Where breeder seed is not available, foundation seed may be acceptable provided that:
 - it is tagged with an official tag issued by a seed certification agency, and
 - it is accompanied by a letter explaining why breeder seed is not provided.
- c) Seed samples of all hybrid varieties or "composite" varieties of *Brassica spp.*, shall be of the first generation of pedigreed seed to be offered for sale. Such samples must be tagged with tags issued by an official seed certification authority. If such seed is not available, hand-pollinated seed or seed produced in isolation cages under the breeder’s supervision may be submitted as a legal reference sample provided the following conditions are met:
 - the seed is produced under the direct supervision of a plant breeder recognized by the CSGA;
 - the sample is accompanied by a declaration signed by the breeder indicating the manner in which the seed was produced and indicating that the seed is representative of the variety;
 - the seed is properly sealed and tagged with the variety name/experimental number, lot number/crop certificate number and signature of the plant breeder;
 - the breeder commits in writing to provide a certified seed sample within one year of registration.

Seed produced by hand pollination or in isolation cages is not eligible for sale by variety name.

- d) Where seed samples are submitted with tags from a European seed certification agency, information must be provided on:
 - the generation of the seed expressed as the number of generations prior to certified seed, and
 - the number of generations from breeder seed that are allowed in total.
- e) All reference samples originating from outside of Canada must be sent via the Canadian representative.
- f) Sample sizes must conform to the requirements listed in Appendix II.
- g) The seed sample should not be treated with any pesticide, as seed treatments may cause problems with certain types of laboratory analysis. In addition, some delivery agents will not transport seed treated with pesticides unless specially packaged.
- h) Samples **and tags must** either be sewn or tied and fastened with a tamper-proof seal. When samples are submitted in seed envelopes, they should be well taped shut **and the tag well taped to the outside**. The container should be of one of the following types of material:
 - Cotton or polyjute bags (most desirable)
 - Manilla seed envelopes
 - Heavy paper bags (double bagged)

Samples submitted in sealed plastic bags will not be accepted as this packaging effects the longevity of the seed. **Seed must be submitted in new containers and must be shipped in a manner to ensure the intact arrival.**

- i) Sample bags shall bear an outer tag. For non-hybrid seed **produced in Canada**, the tag **must** be a C.S.G.A. breeder seed tag **and must include the following**:
- variety name (experimental number is acceptable if the name is not finalized);
 - crop kind;
 - lot number (if applicable);
 - crop certificate number;
 - pedigreed status;
 - signature of the plant breeder

Although the C.S.G.A. breeder tag indicates it may be signed by a Canadian agent, this is not acceptable for variety registration purposes.

- j) Seed of varieties **produced in foreign countries** (other than the U.S.) should be fastened with a breeder seed label issued by an official pedigreeing agency. Breeder seed from the U.S. will be accepted if tagged with the **equivalent** information required for a C.S.G.A. breeder seed tag (see i) above). These samples must provide information on the year the seed was produced.
- k) Seed samples submitted from a crop harvested more than one year prior to application must be accompanied by a germination analysis **conducted by a recognized laboratory** within six months of sample submission.
- o) Reference samples must be at least Foundation No. 1 grade for purity and minimum Foundation No. 2 for germination.
- p) Unacceptable seed samples will be returned to the applicant upon registration of the variety or upon withdrawal of the application.

5.10 Colour Slides for Potatoes:

In lieu of the requirement for reference samples, applications for permanent registration of potatoes must include a set of colour slides of the following characteristics of the candidate variety:

- a) a typical tuber;
- b) the apical end of the tuber;
- c) a tuber cut lengthwise;
- d) a typical sprout;
- e) a typical flower;
- f) a typical flowering plant
- g) a typical compound leaf

A complete set of slides is required for permanent and new interim registrations.

The photographs must be taken in such a manner that the subject makes up at least 60% of the photograph.

5.11 Interim Registration Renewals/Reinstatements**:**

The registrant must submit:

- a) a letter requesting the renewal/**reinstatement** of registration
- b) a recommendation from a recommending committee supporting renewal/**reinstatement** for the variety
- c) the appropriate fees along with the fee submission form (Appendix IX)

The onus is on the registrant to ensure interim registrations are not allowed to expire. **If the interim registration of a variety has been allowed to lapse for a period greater than one year, for crops other than potatoes, a new legal reference sample must be submitted.**

If an application for renewal (with applicable fees) is received prior to the expiry date, the application will be considered to be a renewal. If the application is received after the expiry date, the application will be considered to be a reinstatement and appropriate fees will apply.

5.12 *Extension of Regions of Registration:*

The registrant must submit:

- a) a letter requesting the extension of regions of registration
- b) a letter from the appropriate registration recommending committee indicating they do not object to the registration of the variety in the region of their jurisdiction.

5.13 *Changing a Variety Name After Registration:*

A variety name may be changed following registration with receipt of the following:

- a) a written request by the Canadian representative indicating an acceptable alternative name;
- b) written permission by the breeder or owner of the variety (where applicable);
- c) a signed declaration that a Canadian trademark has not been applied for or received for use of the specific name on seed;
- d) the applicable fee along with a Fee Submission form; and
- e) the original certificate of registration, so that an amended certificate can be issued.

The name under which a variety is granted Plant Breeders' Rights must be identical to that under which the variety is registered. A separate application and appropriate fees must be submitted to the Plant Breeders' Rights Office. Under Plant Breeders' Rights legislation, there are limited circumstances under which a name change may be accepted.

II. 6. *Obligations of the Registrant Following Registration:*

- a) Publicly generated co-operative tests or other data quoted in advertising a registered variety for sale must be used in its entirety and are subject to approval by the appropriate recommending committee.
- b) The Variety Registration Office must be notified of any proposed changes to the descriptive information of a variety including the designation of variants and off-types, as well as changes of Canadian representative. This information must be provided separately from information submitted to the Plant Breeders' Rights Office. Any changes to descriptions of variety submitted to the Variety Registration Office will only be made after consultation with area CFIA inspection staff, variety verification personnel and other affected parties has been completed. Changes to official descriptions will not be made during the growing season.
- c) For those varieties added to OECD seed scheme certification lists by the Canadian breeder or representative, description of variety and legal reference samples must be provided to OECD seed certification authorities by the Canadian breeder/variety maintainer upon request.
- d) The registrant must not trademark the variety name following registration.
- e) Registrants are responsible for ensuring that all terms and conditions of restricted registration are complied with.

- f) Registrants are responsible for submitting legal reference samples **that are properly tagged and sealed**, to the Variety Verification Unit, upon request.
- g) The Variety Registration Office must be notified if a variety registered for sale in Canada is granted a synonym in another country after its Canadian registration is granted.
- h) For varieties with novel traits, registrants are responsible for providing updated molecular testing protocols for the detection of transgenes when updated by the laboratory conducting the analysis.
- i) For varieties with contract registration, registrants are responsible for providing updated quality control system manuals.
- j) For hybrid canola varieties, registrants are responsible for providing updates to hybridity testing protocols.

II. 7. Glossary:

“Composite” Variety: The variety created by the controlled blending of select seed of two specific lines. In the case of *Brassica napus*, the progeny of this blending must be constituted of at least 70% seed created by intercrossing of the lines and the remainder by self/sib pollination. For *Brassica rapa*, the progeny of the blending must represent 50% seed created by intercrossing of the two parental lines and the remainder by self/sib pollination.

Forage type oats, triticale and peas: varieties that are sold as being for herbage or whole plant harvest for livestock feed. Does not include varieties marketed for production of grain for livestock feed.

Commodity type field peas: includes green, yellow or Austrian winter peas, but does not include pigeon pea, marrowfat peas or maple type peas.

Home garden potato variety: A potato variety that is not being sold for the table stock or processing market; seed acreage is restricted to a maximum of one (1) hectare.

Merit: Equal or superior to appropriate reference varieties with regard to characteristics that render the variety beneficial for a particular use in a specific area of Canada.

Plants with Novel Traits (PNTs): A plant with a gene or trait that is novel to the species in Canada. Such a gene may be derived through recombinant DNA technology or through traditional plant breeding techniques.

Plants derived from PNTs: A variety that results from traditional plant breeding using a PNT as a parental line.

Offtype: Plant in a seed field which deviates in one or more characteristics from the official description of the variety.

Variant: Any seed or plant which

- a) is distinct within the variety but occurs naturally within the variety,
- b) is stable and predictable with a degree of reliability compared to other varieties of the same kind, within known tolerances, and
- c) was originally part of the variety as released. It is not an offtype.

Registrant: The party who receives the certificate of registration and to whom correspondence is directed on any legal action taken with respect to the variety.

APPENDIX I

Crops Required to be Registered

Alfalfa (forage type)	<i>Medicago sativa</i> L. (including
Barley - two row	<i>M. sativa</i> L. spp. <i>falcata</i> (L.) Arcangeli)
- six row	<i>Hordeum vulgare</i> L. convar. <i>distichon</i> Alef.
Bean, field	<i>Hordeum vulgare</i> L. convar. <i>hexastichon</i> Alef.
Bird's foot trefoil	<i>Phaseolus vulgaris</i> L.
Bromegrass, meadow	<i>Lotus corniculatus</i> L.
Bromegrass, smooth	<i>Bromus riparius</i> Rehm.
Buckwheat	<i>Bromus inermis</i> Leysser
Canola, oilseed rape	<i>Fagopyrum esculentum</i> Moench
Canarygrass, annual	<i>Brassica napus</i> L., <i>Brassica rapa</i> L. (= <i>B. campestris</i>)
Canarygrass, reed	<i>Phalaris canariensis</i> L.
Clover, alsike	<i>Phalaris arundinacea</i> L.
Clover, red	<i>Trifolium hybridum</i> L.
Clover, sweet (white blossom)	<i>Trifolium pratense</i> L.
Clover, sweet (yellow blossom)	<i>Melilotus alba</i> Medikus,
Clover, white	<i>Melilotus officinalis</i> (L.) Pallas
Fababean (small seeded)	<i>Trifolium repens</i> L.
Fescue, meadow (forage type)	<i>Vicia faba minor</i> L.
Fescue, red (forage type)	<i>Festuca pratensis</i> Hudson
Fescue, tall (forage type)	<i>Festuca rubra</i> L. var. <i>rubra</i>
Flax (oilseed)	<i>Festuca arundinacea</i> Schreber
Lentil (grain type)	<i>Linum usitatissimum</i> L.
Lupin (grain and forage types)	<i>Lens culinaris</i> Medikus
Mustard	<i>Lupinus</i> spp.
Oat (grain type)	<i>Brassica juncea</i> (L.) Czern. & Coss.
Orchardgrass	<i>Sinapis alba</i> (L.) (= <i>B. hirta</i> Moench)
Pea, field (commodity type)	<i>Avena sativa</i> L., <i>Avena nuda</i> L.
Potato (commercial production)	<i>Dactylis glomerata</i> L.
Rye (grain type)	<i>Pisum sativum</i> L.
Ryegrass, annual (forage type)	<i>Solanum tuberosum</i> L.
Ryegrass, perennial (forage type)	<i>Secale cereale</i> L.
Safflower	<i>Lolium multiflorum</i> Lam.
Soybean (oilseed)	<i>Lolium perenne</i> L.
Sunflower	<i>Carthamus tinctorius</i>
Timothy (forage type)	<i>Glycine max</i> (L.) Merrill
Tobacco (flue-cured)	<i>Helianthus annuus</i> L.
Triticale (grain type)	<i>Phleum pratense</i> L.
Wheat, common	<i>Nicotiana tabacum</i> L.
Wheat, durum	<i>X Triticosecale</i> Wittmack
Wheat, spelt	<i>Triticum aestivum</i> L. emend. Fiori & Paol.
Wheatgrass, beardless	<i>Triticum durum</i>
Wheatgrass, crested	<i>Triticum spelta</i>
Wheatgrass, intermediate	<i>Agropyron spicatum</i> (Pursh) Scribn. & J.G.
Wheatgrass, northern	Smith f. <i>inermis</i> Scribn. J.G. Smith) Beetle
Wheatgrass, pubescent	<i>Agropyron cristatum</i> (L.) Gaertner,
Wheatgrass, Siberian	<i>Agropyron desertorum</i> (Fischer ex Link) Schult.
Wheatgrass, slender	<i>Agropyron intermedium</i> (Host) Beauv.
Wheatgrass, streambank	<i>Agropyron dasystachyum</i> (Hook) Scribn.
Wheatgrass, tall	<i>Agropyron trichophorum</i> (Link) Richter
Wheatgrass, western	<i>Agropyron sibiricum</i> (Willd.) Beauv.
Wildrye, Altai	<i>Agropyron trachycaulum</i> (Link) Malte ex H.F. Lewis
Wildrye, Dahurian	<i>Agropyron riparium</i> Scribn. & Smith
Wildrye, Russian	<i>Agropyron elongatum</i> (Host) Beauv.
	<i>Agropyron smithii</i> Rydb.
	<i>Elymus angustus</i> Trin.
	<i>Elymus dahuricus</i> Turcz ex Griseb.
	<i>Elymus junceus</i> Fischer

Please note that varieties of all crops in this Appendix are registered on the basis of merit.

APPENDIX II

Reference Sample Size Requirements

2 kilograms

Barley
Fababean
Field Bean
Oat
Pea
Rye
Soybean
Triticale
Wheat

500 grams

Alfalfa	Lupin
Bird's-foot trefoil	Mustard
Bromegrass	Orchardgrass
Buckwheat	Rapeseed
Canarygrass	Ryegrass
Canola	Safflower
Clover	Sunflower
Fescues	Timothy
Flax	Wheatgrass
Lentil	Wild Rye

5 grams

Flue cured tobacco
Parental lines of hybrid and composite canola

Germplasm Preservation

In order to prevent loss of valuable germplasm and to ensure genetic preservation of Canadian varieties, the Canadian Seed Growers' Association (CGA) requires that a representative sample of Breeder Seed of each crop variety developed in Canada (past and present), with the exception of hybrid varieties, be deposited in the central genebank, as part of the permanent national germplasm collection. A representative sample of the variety (minimum 12,000 seeds) should be sent at the time of applying for registration to:

**Dr. Ken Richards
Plant Gene Resources of Canada
Agriculture and Agri-Food Canada
Saskatoon Research Centre
107 Science Place
Saskatoon, Saskatchewan S7N 0X2**

(See "Regulations & Procedures for Production of Breeder Seed", CGA 1989)

The genebank sample (different from the mandatory legal reference sample required for variety registration) will be available to the scientific community for research and breeding purposes only.

APPENDIX III

Registration Policy for Canola/Rapeseed Varieties

- 1) A canola/rapeseed variety is to be entered into official tests in the area(s) of anticipated adaptation. If a variety is intended to be sold in Ontario or other provinces in eastern Canada, as a minimum, it must be entered into trials conducted by the Ontario Oil and Protein Seed Crops Committee (OOPSCC). If a variety is intended for sale in western Canada, it must be entered into trials sponsored or conducted under the auspices of the Western Canada Canola/Rapeseed Recommending Committee (WCC/RRC).
- 2) If a canola/rapeseed variety is tested and supported in both eastern and western Canada, then it will automatically be granted a national registration. In view of the major difference in acreage of canola between eastern and western Canada, it is not acceptable to test a spring variety and receive support from the east, then request a national registration for it. If a spring canola/rapeseed variety is tested and supported in eastern Canada but is not considered and/or supported by the WCC/RRC, then it will be granted a regional registration for eastern Canada only.
- 3) If a spring canola variety of *Brassica napus* is supported for registration in western Canada, the Variety Registration Office will contact the Ontario committee to determine if they object to the variety being granted a national registration. There may be objection to the registration in Ontario due to excessive levels of free fatty acids.
- 4) Maximum allowable levels of erucic acid allowed in foundation seed of canola must be submitted with the application. For hybrid canola varieties, these levels **must** be provided for certified seed. For composite canola varieties, these levels **must** be provided for select seed. Standards for maximum levels of erucic acid should be set at levels consistent with the new definition of canola to be implemented August 1, 2001. For further information please contact the Canola Council of Canada at (204)982-2100.
- 5) Composite and Hybrid Varieties:

It is a requirement for the registration of hybrid canola varieties, that the methods and procedures used to test the hybridity of the variety must be submitted with the variety registration application package. These must be sufficiently detailed to allow the replication of testing by Canadian Food Inspection Agency staff.

Once a variety is registered, no changes may be made to the source of male sterility used for the inbred lines or to the seed production methodology. Such changes may result in agronomic changes to the variety and/or may change the variety such that it becomes identical to a variety registered under another name. Changes to sterility source and seed production methodology may also alter the variety so that it no longer conforms to the legal reference sample of the variety.

The progeny of the "composite" method may differ from the progeny of identical parents produced using the traditional hybrid method. The progeny of one composite variety could differ from the progeny of another composite variety using the identical parents if the proportions of parents used to produce composite select seed differ. The applicant will be required, where appropriate, to demonstrate the differences between the varieties for seed and crop inspection purposes.

In describing varieties developed using "composite" canola production practices, the applicant must state the proportion of each component within the progeny, each component must be described, and a testing methodology that can be used to verify the identity and purity of the variety must be submitted. The exact proportion of each component must be stated along with suggested appropriate tolerance levels for inherent biological variation.

At this time, composite varieties developed using more than two parental lines will not be considered for variety registration. Also, composite varieties are not being entered onto the OECD Seed Scheme List of Cultivars. For hybrid canola varieties to be added to the OECD list, the applicant **must** supply descriptions of each inbred parent as well as the hybrid variety.

APPENDIX IV

Registration Policy For Varieties With Novel Traits

1) Varieties with Novel Traits Requiring Unconfined Release

Under Part V of the *Seeds Regulations*, varieties with novel traits must receive authorization for unconfined release from the Plant Biosafety Office prior to variety registration.

Similarly, livestock feed safety authorizations by Feed Section, CFIA (where appropriate) must be completed prior to variety registration.

2) Health Considerations

Where a variety has a novel trait that may result in a new use (e.g. new edible oil) or that may have a new impact on human/animal health, (eg. allergenicity) prior to registration, an assessment of the safety of the trait is required to ensure the acceptability for human/animal consumption. Such evaluations are conducted by the Office of Food Biotechnology, Health Canada and must be completed prior to being registered by the CFIA.

For varieties producing products that do not conform to the legal definition of the traditional product, assessment may be required by Health Canada prior to the sale of the product in Canada, for example, high oleic acid sunflower oil varieties.

3) Pesticide Tolerance

Where a candidate variety is claimed to be tolerant to a pesticide and the tolerance to the pesticide is both new to the species and is the primary merit of the variety, the registration of the variety will be deferred pending a decision on the registration of the pesticide for that particular use by the Pest Management Regulatory Agency (PMRA) of Health Canada. Claims of pesticide tolerance must be supported by valid scientific data.

Exemptions from this policy may be given for varieties tolerant to persistent herbicides where there is no intent to register the herbicide for application to the variety in question.

Tolerance to a single pesticide should not be considered to provide tolerance to a class of pesticides.

Data on pesticide tolerance of a plant variety may be sufficient for the purposes of variety registration but may be insufficient for the review of pesticidal tolerance by PMRA officials. Please contact the PMRA for data requirements under the *Pest Control Products Regulations*.

4) Crop Plants with Novel Pesticidal Properties:

They are regulated under the *Seeds Act and Regulations*, and not the *Pest Control Products Act* since the primary use of the plant is to produce a crop. Non-crop plants used primarily for pest repellent or pesticidal purposes are subject to the *Pest Control Products Act and Regulations*.

The PMRA will act as advisors to the Variety Registration Office on issues of efficacy, and the Variety Registration Office will act as liaison between applicants and the PMRA. Reviews by the PMRA may take up to 120 days.

The applicant must provide information on the nature, source and characteristics of the genes and proteins that have been introduced. The information would include tissue sites and expression levels of the pesticidal protein. This information is required to assess efficacy as well as varietal characterization.

Data will be required from a minimum of three statistically valid efficacy trials with replicates and appropriate controls. Trials must be conducted in a manner consistent with the proposed use of the variety parameters to be measured and would potentially include insect mortality, foliage protection and crop yield as compared to the controls. Appropriate experimental design and statistical analysis are required.

APPENDIX V

Action by Variety Registration Office on Recommendations from Cereal Crop Committees in Eastern Canada

In February 1993, representatives of the three eastern cereal variety recommending committees met to define harm as it relates to regional registration. There was a consensus that harm could be caused under the following circumstances:

1. kernel visual distinguishability, (for **soft white winter wheat**)
2. high susceptibility of diseases that cause the production of mycotoxins in the marketed product.

The Variety Registration Office has adopted this definition of harm for the purposes of regional registration.

General comments:

1. Once a variety has been supported by any one recommending committee, it would receive national registration, unless one of the **two** circumstances stated above apply.
2. If a wheat or triticale variety is supported for a regional registration, this recommendation should be made based on a Canadian Grain Commission kernel description indicating the variety could present problems if granted a national registration. Otherwise, the variety should be supported for a national registration.

APPENDIX VI

Quality Control System Requirements for Varieties Subject to Contract Registration

Background

These requirements apply to varieties where the "biochemical or biophysical characteristics of a variety distinguish it from the majority of registered varieties of the same kind or species and the variety may have an adverse effect on the identity of those registered varieties". Because these varieties have the potential to cause harm if they enter the traditional commodity channel, there must be assurance of appropriate means of control, via "quality control systems" (Q.C.S.). There must be assurance that the systems are in place and that they are effective.

The quality control system was designed to be consistent with other quality management systems designed for seed industry programs. The principles of these quality management systems are:

- show what you propose to do
- do it
- prove it was done

Requirements

As part of the application for restricted (contract) registration of varieties that could otherwise cause harm, the applicant must submit a proposed Q.C.S. to manage potentially adverse effects that could be caused by the variety. The proposed Q.C.S. should be submitted in the form of a **quality manual** to be used by the relevant parties for the handling of the variety. Components of the Q.C.S. include, but are not limited to, the following:

- a) management responsibility
- b) training of personnel
- c) contract review
- d) product identification and traceability
- e) inspection and testing
- f) methods for control of non-conforming product
- g) procedures for corrective action
- h) control of records.

A) Management Responsibility:

1. Define the organization's quality policy. This is a written statement of potential adverse effects that could result if the variety were to enter the traditional commodity channels.

An example of the quality policy is as follows: The entrance of a high erucic acid rapeseed into traditional canola channels must be prevented as it has the potential to cause harm:

- if insufficient isolation distances are observed from the production of commodity canola;
- if high erucic acid rapeseed is crushed and the oil is marketed as canola oil:
 - the oil would be in violation of labelling laws as it would not be canola oil
 - the oil would be in violation of food regulations with respect to compositional standards for canola oil and could pose a human health risk due to the presence of elevated levels of erucic acid;
- the sale of non-conforming product could have a negative impact on domestic and international markets of Canadian canola seed and canola oil.

2. Indicate who is responsible for ensuring the quality policy is followed and the variety is handled appropriately. The responsibility, authority and interrelation of all personnel who manage, perform and verify work affecting quality systems shall be identified. The interrelation of personnel should be identified through the use of an organization chart. The applicant should appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the Q.C.S. is implemented and maintained. Ensure that the person responsible for the disposal of non-conforming product is specifically identified.
3. Provide commitment that the quality policy for the variety is understood, implemented and maintained at all levels of the organization.
4. Submit procedures for the Q.C.S. procedures, internal quality audits, and their documentation. The Q.C.S. should be reviewed at appropriate intervals by the designated management representative to ensure its continuing suitability and effectiveness. Records of such reviews shall be maintained.

B) Training of Personnel and Communication:

1. Submit and maintain documented procedures for identifying and addressing Q.C.S. training needs on a routine basis. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required.
2. Provide appropriate training of all personnel involved in the Q.C.S. Appropriate records of training shall be maintained and be available upon request.
3. Indicate the level of availability of Q.C.S. procedures documents to personnel, the frequency of review of Q.C.S. documents and the means of ensuring that obsolete documents are removed from all points of issue or use.
4. Indicate how the results of internal quality audits of product and quality management systems will be communicated to personnel having responsibility in the area audited.

C) Contract Review:

1. The management representative shall describe and maintain the procedures in place for reviewing contracts to ensure compliance of the quality policy.
2. Each contract should be reviewed by the management representative to ensure that:
 - a) the quality policy is adequately addressed;
 - b) all parties involved have the capacity to meet contractual requirements.

Records of such contract reviews should be maintained.

D) Product Identification and Traceability:

The management representative shall establish and maintain documented procedures and records for identifying the variety during all stages of seed and crop production, handling, processing, storage, delivery and use. This will include procedures for monitoring of growers' fields, identifying harvested product, processed product, etc. to ensure that the quality policy has been addressed by contract adherence.

Where isolation distances are required, documentation of actual isolation distances used must be maintained. Any non-conforming procedures or product must be identified, including deficiencies in documentation.

E) Inspection and Testing

The management representative shall establish and maintain documented procedures for inspection and testing to ensure the specific product quality requirements are met including the testing of harvested products.

F) Control of Non-Conforming Product or Process:

1. The management representative shall establish and maintain procedures to ensure that any seed or harvested product that does not conform to the specified standards is prevented from entering traditional commodity markets or being used as seed for further planting. (This could include ensuring non-conforming product is rendered unviable for seed purposes.) This procedure must ensure that non-conforming materials are identified, documented and segregated. Where the non-conformity relates to a requirement under the *Seeds Regulations*, the procedures must stipulate that the Director of Plant Health and Production Division is contacted.
2. The management representative shall maintain records detailing the nature of non-conformities and the disposition of any non-conforming product or process. This should include contract review, documentation or record control procedures that do not conform to the prescribed process.
3. Where isolation distances are required from surrounding traditional commodity crops, and where these distances were not maintained, details must be provided on the disposal of seed or grain produced within the required isolation zone.

G) Corrective and Preventive Action:

1. The management representative shall document and maintain procedures for:
 - a) investigating causes of non-conformities
 - b) immediately notifying those individuals/growers/organizations concerned
 - c) developing and implementing a corrective action plan to prevent recurrence
 - d) analysing all processes, work operations, quality records and service reports to detect, identify and eliminate potential causes of non-conforming product
 - e) initiating preventive actions to address potential non-compliance;
 - by monitoring and following up on corrective action implementation and its effectiveness
 - by implementing and recording changes to documented procedures resulting from corrective action.
2. The management representative shall document the corrective actions taken to address specific non-compliances.

H) Control of Records:

1. Records shall be maintained by all parties involved to demonstrate achievement of the required quality policy and the effective operation of the Q.C.S. Pertinent sub-contractor, grower and processor quality records are elements of this system.
2. The management representative shall maintain procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records including:
 - a) product identification and traceability
 - b) monitoring, audit, inspection and testing results
 - c) records of nonconformance
 - d) disposal/action records
 - e) reviews of Q.C.S.
 - f) training of personnel on the Q.C.S.
 - g) contract reviews
 - h) record retention times.
3. Records must be clear, legible, readily retrievable and accessible.

General Information

The Q.C.S. manual should be submitted as part of the application for registration. The manual should be written so that:

- a) all required activities are described
- b) all *Seeds Regulations* requirements are comprehensively covered
- c) the language can be easily understood by the individuals who have to read it, follow it and implement it
- d) it is free of ambiguity and conflicting statements
- e) it clearly specifies individual responsibilities
- f) all required documents and records are identified and their use explained
- g) there is a mechanism for ensuring that documentation is kept up to date and properly supported.
- h) **In the case of wheat and barley suitable for the Canadian Wheat Board Area, the Variety Registration Office will share the quality control system with, and obtain agreement from, the Canadian Grain Commission and the Canadian Wheat Board to ensure that regulatory concerns under their legislative mandates are met. These organizations are currently developing criteria for acceptance of quality systems.**

It would be prudent for applicants to consult with these organizations on the quality control system during its development and before the variety is presented to the registration recommending committee.

APPENDIX VII

Contact Persons for Committees Recommending Varieties for Registration

FORAGES

B.C. Cultivar Evaluation Committee on Forage Crops:	Dr. Brian Holl B.C. Cultivar Evaluation Committee on Forage Crops Department of Plant Science University of British Columbia 344 - 2357 Main Mall Vancouver, B.C. V6T 1Z4
Alberta Forage Variety Committee:	Mr. Arvid Aasen, Secretary Alberta Forage Variety Committee Alberta Agriculture, Lacombe Research Centre 6000 C & E Trail Lacombe, Alberta T4L 1W1
Saskatchewan Advisory Committee on Forage Crops:	Dr. Bruce Coulman Saskatchewan Advisory Committee on Forage Crops Agriculture and Agri-Food Canada Research Station 107 Science Place Saskatoon, Saskatchewan S7N 0X2
Manitoba Forage Crops Committee:	Ms. Amy Hawkins Manitoba Forage Crops Committee Box 2000 Arborg, Manitoba R0C 0A0
Ontario Forage Crops Committee:	Mr. J.E. Johnston, Secretary Ontario Forage Crops Committee Ontario Ministry of Agriculture, Food and Rural Affairs P.O. Box "G", Hwy 11b New Liskeard, Ontario P0J 1P0
Comité des plantes fourragères du Conseil des productions végétales du Québec:	D ^r . Réal Michaud Comité des plantes fourragères du C.P.V.Q. Agriculture et Agro-alimentaire Canada Station de recherche 2560, boul. Hochelaga Sainte-Foy (Québec) G1V 2J3
Atlantic Field Crops Committee Forage Crops Task Group	Mr. Bill Thomas Atlantic Advisory Committee on Forage Crops N.S. Dept. of Agriculture and Marketing P.O. Box 550 Truro, N.S. B2N 5E3

CEREALS AND OILSEEDS

Prairie Registration Recommending Committee on
Grain, Subcommittee on Wheat, Rye and Triticale:

Dr. Stephen Fox, Secretary
PRRCG Subcommittee on Wheat, Rye
and Triticale
Crop Development Centre
University of Saskatchewan
51 Campus Drive
Saskatoon, Saskatchewan S7N 5A8

Prairie Registration Recommending Committee on
Grain, Subcommittee on Oilseeds:

Dr. Scott Duguid, Secretary
PRRCG, Subcommittee on Oilseeds
Agriculture & Agri-Food Canada
Morden Research Centre
Unit 100-101 Route 100
Morden, Manitoba R6M 1Y5

Prairie Registration Recommending Committee on
Grain, Subcommittee on Barley and Oats:

Dr. John Noll,
PRRCG, Subcommittee on Barley and Oats
Agriculture and Agri-Food Canada
Cereal Research Centre
195 Dafoe Road
Winnipeg, Manitoba R3T 2M9

Western Canada Canola/Rapeseed
Recommending Committee:

Raymond Gadoua, Coordinator
Western Canada Canola/Rapeseed
Recommending Committee
107 - 105 North Road
Saskatoon, Saskatchewan S7N 4L5

Ontario Cereal Crops Committee:

Dr. A. Smid, Secretary-Treasurer
Ontario Cereal Crops Committee
Ridgetown College
University of Guelph
Ridgetown, Ontario N0P 2C0

Comité des oléoprotéagineux du Conseil
des productions végétales du Québec :

Caroline-Joan Boucher
Secrétaire du C.P.V.Q. Inc.
225, Grande-Allé Est, 4e étage
Québec (Québec) G1R 2H8

Comité des céréales du Conseil des productions
végétales du Québec :

Yves Dion
Ministère de l'Agriculture, des Pêcheries
et de l'Alimentation
Service de phytotechnie de Saint-Hyacinthe
Station de Saint-Bruno
335, chemin des Vingt-Cinq Est
Saint-Bruno-de-Montarville (Québec) J3V 4P6

Atlantic Field Crops Committee
Cereal Crops Task Group:

Dr. Hans Nass
Atlantic Advisory Committee on Cereal and
Protein Crops
Agriculture and Agri-Food Canada
Cereal and Livestock Research Centre
P.O. Box 1210
Charlottetown, P.E.I. C1A 7M8

Ontario Oil and Protein Seed Crops Committee:

Dr. Elroy Cober, Secretary
Ontario Oil and Protein Seed
Crops Committee
Agriculture and Agri-Food Canada
Eastern Cereal & Oilseed Research Centre
960 Carling Avenue, C.E.F.
Ottawa, Ontario K1A 0C6

Manitoba Sunflower Committee:

Mr. Lloyd Thiesen, Secretary
Manitoba Sunflower Committee
Box 1236
Winkler, Manitoba R6W 4B3

BEAN AND SPECIAL CROPS

Ontario Pulse Crop Committee:

Mr. Chris Gillard, Secretary
Ontario Pulse Crop Committee
Ridgetown College, University of Guelph
Ridgetown, Ontario
N0P 2C0

Prairie Registration Recommending Committee on
Grain, Subcommittee on Specialty Crops:

Robyn Russell
PRRCG, Subcommittee on Specialty Crops
Agricore Cooperative Ltd.
Research & Development
11111 Barlow Trail S.E.
Calgary, Alberta T2C 4M5

Ontario Tobacco Evaluation Committee:

Dr. Hassien Haji
Ontario Tobacco Evaluation Committee
Agriculture and Agri-Food Canada
Research Station
P.O. Box 186
Delhi, Ontario
N4B 2W9

POTATOES

Western Potato Council:

Dr. Dermot Lynch, Secretary
Breeding and Selection Committee
Prairie Potato Council
Agriculture and Agri-Food Canada
Research Station
P.O. Box 3000, Main
Lethbridge, Alberta T1J 4B1

Ontario Regional Potato Committee:

Sam Squire
Ontario Regional Potato Committee
109 Hutchison Dr.
Alliston, Ontario L9R 1M4

Comité de la pomme de terre du Conseil des
productions végétales du Québec

D^r. Pierre Turcotte
Comité de la pomme de terre du C.P.V.Q.
Station de recherches de St-Bruno
CEROM
335 Chemin des vingt Cinq Est
St Bruno de Montarville, Quebec J3V 4P6

Atlantic Regional Potato Evaluation Committee:

Dr. Walter Arsenault, Trial Coordinator
Atlantic Regional Potato Evaluation Committee
Agriculture and Agri-Food Canada
Research Station
P.O. Box 20280
Fredericton, N.B. E3B 4Z7

APPENDIX VIII

Obtaining Copies of the Seeds Act and Regulations

The *Seeds Act and Regulations* can be accessed on the Canadian Food Inspection Agency web site at www.cfia-acia.agr.ca.

If hard copies of the *Seeds Act and Regulations* are required, fees are charged for material as follows:

1. Seeds Act	\$3.00
2. Seeds Regulations and Seeds Fees Order	\$5.00
3. Schedule I (Grade Tables) and Weed Seeds Order	\$6.00
4. Schedule II	\$2.00
5. Schedule III	\$2.00
6. Weed Seeds Order	\$2.00
7. Complete set of Act, Regulations, Schedules and Orders	\$12.00

A shipping and handling charge of \$5.00 (\$8.00 outside Canada) applies to each request. Canadian residents should include 7 percent GST.

Payment should be by cheque or money order only, in advance in Canadian funds drawn from a Canadian bank and made payable to the Receiver General for Canada.

Please address requests for these publications to:

Seed Section
Plant Health and Production Division
Canadian Food Inspection Agency
59 Camelot Drive
Nepean, Ontario K1A 0Y9

For additional information, please contact the Seed Section at:

Telephone: (613) 225-2342
Facsimile: (613) 228-6629

APPENDIX IX

Submission of Fees

As of December 1, 1997, fees are charged for the evaluation of variety registration applications, and related services:

Application for permanent registrations (national, regional or contract)	\$875.00
Application for interim registrations	\$200.00
Annual Renewal of interim registrations	\$100.00
Reinstatement of a suspended or cancelled registration	\$200.00
Amending a variety name	\$200.00

All payments must be made in Canadian funds. No Goods and Services Tax apply.

1. Cheques or money orders must be made payable to the Receiver General for Canada. Please ensure that all cheques can be drawn from a Canadian bank

Cheques/money orders submitted in foreign funds will be returned and the application review will not be initiated.

2. To pay by Credit Card:

Submit the following information:

- a) type of credit card (only Visa or Mastercard accepted)
- b) card holder name
- c) company name
- d) telephone number
- e) credit card number
- f) expiry date

Applicants are responsible to clearly communicate the service requested (as per above) along with the appropriate fee.

Where a variety has been previously granted an interim registration and where the variety is currently being considered for permanent registration, the fee for permanent registration applies.

Interim Registration Fees

Upon receipt of the \$200.00 application fee, a variety will be granted an interim registration for one year. If the variety has interim registration support for two or three years, the applicant has two options:

- i) if the annual renewal fees are paid at the time of the initial registration, the registration will automatically be granted for the full duration. (e.g. for a three year interim registration, the fee would be \$400.00).
- ii) if the applicant chooses to only pay for an initial interim registration, then the interim registration will only be granted for one year. If the registrant wishes to have the interim registration renewed, then an application for renewal, a copy of the original letter of support and the renewal fee(s) will be required.

- NOTE:**
- 1) **Once review of an application has been initiated, no refund will be issued.**
 - 2) **A fee submission form which is part of the application form is attached and should be used and submitted with each application package.**

Fee Submission for Variety Registration

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

To be completed by Applicant

Variety: _____

Crop Kind: _____

		Cost	Project code
Application for permanent registration (national, regional, contract)	\$875		3792
Application for interim registration	\$200		3794
Annual renewal of interim registration	\$100		3800
Reinstatement of suspended or canceled registration	\$200		3796
Amending a variety name	\$200		3798

By Cheque or Money Order

Cheque Money Order

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

By Credit Card

Visa Card Holder's Name: _____
Please print

Master Card Company Name: _____ Telephone #: () _____

OTHER CREDIT CARDS NOT ACCEPTED Card Number: _____ / _____
Expiry date

Signature: _____

NOTE: Once review of an application has been initiated, no refund will be issued.

Areas in grey are for office use only

Applicant: _____	Reference #: _____

Date fee received: _____	VARIETY REGISTRATION OFFICE