

# Canadian Food Inspection Agency

## **DRAFT** Model Operating Procedures

Guidance for Variety Registration Recommending Committees

October 1, 2014

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## Overview

This document provides guidance to the variety registration recommending committees (RCs) in the development of their crop-specific operating procedures. Each RC (also referred to as “committee” in this document) must put in place procedures and processes to ensure **fair, transparent, and consistent** determination of merit for Schedule III, Part I crop kinds and designs of test protocols for Parts I and II crop kinds as set out in the [Seeds Regulations](#). It is expected that each committee will incorporate the principles and objectives described in this document into their operating procedures (see page X).

### Roles of the Recommending Committees in Variety Registration in Canada

The RCs are volunteer, crop-specific committees of experts whose role is to define merit for Part I crops, design the test protocols for Part I and II crops, and make a recommendation to the Registrar, Variety Registration Office, Canadian Food Inspection Agency (CFIA) for registration of varieties of Part I and Part II crop kinds. The definition of merit for a given crop kind is determined in terms of the key attributes that provide commercial value in the marketplace. The members of the committees are to apply their expertise in their specific crop sector to determine what the merit should be for their crop and how to best determine if a candidate variety has merit. In determining the best test protocols to assess merit, the committee also weighs the commercial impact of the test protocols, balancing the need for adequate data against the burden of delayed time to commercialization of these varieties. The process should be as rapid as possible while meeting the minimum requirements to assess merit with an acceptable level of risk. The committee consists of value chain stakeholders (individuals or representatives of an organization) who are experts on a particular crop, and the membership should reflect the interests of the full value chain stakeholder group for that crop kind. **Above all, variety recommendation is a crop value chain stakeholder driven process.** The committees’ recommendations to the Registrar carry significant weight and are a requirement for eligibility for registration under the *Seeds Regulations* (Schedule III, Parts I and II crop kinds); however, the final decision to register new varieties rests with the Registrar, Variety Registration.

This document was generated to ensure that the following criteria for the RCs are met in accordance with the spirit and the letter of subsections **65.1** (1) to (3) of the *Seed Regulations*:

#### Representative Recommending Committee Membership

- The committee is composed of proportional representation reflecting the full value chain of stakeholders for that crop sector (broad categories being: producers, developers, end users), such that the committee’s decisions represent a consensus in that crop sector with respect to current and future variety development and future crop sector value generation.
- Membership in the committee is open to all crop sector experts (producer, developer, and end user) upon expression of interest. The process for becoming a voting or non-voting member is open, unbiased and predictable.

#### Transparency and Predictability

- Consistency and predictability are exhibited in the evaluation and determination of merit across committees in Canada for the same crop kind.
- Committee governance structure is clear and efficient.

- A clear set of merit criteria must be established based on the discrete values of check varieties or the mean of check varieties. Varieties that demonstrate relatively equal or better values to the checks or check mean are eligible for recommendations. All eligible varieties should be voted on for recommendation in a block rather than as an individual variety.
- There are clear options for varieties failing to meet one or more of the merit criteria. In cases where there are deficiencies in one or more merit criteria, but where the proponents wish to make their case on the overall attributes of the variety, they may elect to request a review by the committee: a set aside of the rules by simple majority (50% +1) vote. The set aside vote is a procedural vote, made *en masse* for a group consisting of all varieties fitting the scenario. All the merit criteria test results for subsequently registered varieties shall be published.
- A summary sheet of the benchmark merit criteria for all the check varieties shall be published annually to ensure developers understand their breeding targets within these criteria (e.g. publishing the performance of the checks for all required merit criteria).
- A formal appeals process is included in the committee procedures to allow for variety developers to challenge a negative decision from the committee on the basis of procedural errors. Any complaint in this regard shall be heard by an independent third-party tribunal with representation from across the value chain (producers, developers and end users).

#### **Facilitating Innovation in the Industry (time to market vs. regulatory burden)**

- All committee decisions must be based on efficiency, supporting innovation, and minimizing regulatory burden while minimizing risk and providing value to the appropriate crop sector. The balance between having adequate scientific data to fully assess merit versus the impact of delayed time to market and other innovation-related considerations should be clearly understood and taken into account for the full crop sector when developing test requirements.
- Although committees meet annually, at a minimum, they can meet more frequently (by electronic meetings and/or face-to-face meetings) at any time throughout the year, in accordance with their operating procedures.
- There should be flexibility in the decision-making/recommendation process so that innovative products falling short of the merit criteria are given due consideration for a possible path to market using Interim and/or Contract registration when deemed appropriate by the committee.
- For crop kinds with multiple market (quality) classes, a candidate failing to make a particular market class should still be eligible for consideration for any of the other classes for which it may be qualified. The committee would need to be notified of this change, in advance, and prior to the annual meeting at which varieties are recommended for registration.
- There should be a process for up to 100% privately generated data to be submitted in support of a variety registration recommendation. This data must meet the committee's test protocol requirements as published in their procedures document. The acceptable data sets for merit consideration and registration recommendation may be all private, all public or any combination of the two. In setting out its yearly testing plans, committees

should give equal consideration to all requests for testing. The committee must ensure that resources are allocated equally to all candidate varieties received (entries).

- Foreign data, representative of Canadian crop production areas (suitability to be determined by the committee), in whole or in part, subject to meeting the committee test protocols, is considered in part or in its entirety as meeting the data set requirement for merit assessment and variety registration recommendation.
- **Restricted Registrations** – by default, committee registration recommendations are National. However, there are forms of restricted registration such as Interim registration and Contract registration. The committee should consider Interim in situations where a variety is deficient in one or more characteristics but still has merit (one of the regulatory requirements for consideration for Interim registration); or Contract where the variety has merit but may cause harm to mainstream commodity production of that crop kind. These restricted forms of registration should also be considered by the committee where appropriate.
- The committee’s deliberation and decision-making processes should be streamlined, efficient and timely. With the current trend towards “automated” voting procedures, it is anticipated that the requirement for formal ballot votes will continue to decrease.
- Clear and consistent committee conflict of interest guidelines for recommendation voting should be in place, as well as a procedure for dealing with appeals based on conflict of interest (p. 13).

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# The Guidance Document

## Introduction

This document outlines the pre-registration testing system protocol and evaluation process for a variety registration recommending committee. The recommending committee (also referred to as “committee” in this document) evaluates candidate varieties of designated crop kinds for merit as a part of pre-registration requirements and makes a recommendation for registration, for their region of Canada, to the Canadian Food Inspection Agency (CFIA), Variety Registration Office (VRO). The procedures for entering a variety for testing are documented and reviewed annually by the committee, and are available to the public upon request to the Chair of the committee.

As required by the *Seeds Regulations* paragraph **65.1** (1) (e), each recommending committee shall function transparently and deal with varieties in a fair and consistent manner.

## Legislation and Authority

The *Seeds Act* is the legislative authority for the *Seeds Regulations*. In section **65.1** of the *Seeds Regulations* (appendix I) there is a provision for the Minister of Agriculture and Agri-Food to approve crop-specific variety registration recommending committees. The purpose of each committee is to establish and administer protocols for testing varieties of crop kinds listed in Parts I and II of Schedule III of the *Seeds Regulations* to determine the merit of varieties and, subsequently, to make registration recommendations to the Registrar, VRO. In practice, the Minister’s authority to approve this committee is delegated to the Registrar (currently the National Manager, Seed Section, CFIA).

These committees are integral to the variety registration system and serve to provide expertise and guidance to the Registrar.

(Reference Appendix I)

## Role of the Variety Registration Office (VRO)

The VRO reviews and approves each committee’s operating procedures document annually. Any changes to this document require approval by the committee members and subsequent approval by the VRO. The VRO issues an annual approval letter on behalf of the Minister, signed by the Registrar, to each variety recommending committee in Canada.

Please note that if a recommending committee does not support or test any variety during a three year period, their recognition will not be renewed in the subsequent fourth year. The renewal can be resumed upon receipt of a recommendation in respect of a variety.

The VRO provides guidance on the requirements of *Seeds Act* and *Seeds Regulations* to all the recommending committees as required. It also ensures that the committees are functioning transparently and that varieties are dealt with in a fair and consistent manner, in accordance with

the approved operating procedures. The committees must provide their expertise and advice to the VRO, and this is considered by the Registrar in rendering a decision on variety registrations.

The list of all approved recommending committees can be found on the following CFIA website at:

<http://www.inspection.gc.ca/plants/variety-registration/registration-procedures/recommending-committees/eng/1359958262947/1359958370983>

## The Committee's Core Mandate and Objectives

### The committee's core mandate is:

- To determine merit<sup>1</sup> criteria to be used in evaluating candidate varieties (as defined in the *Seeds Regulations*), to establish practical and science-based test protocols, to develop a written procedures manual, and to evaluate trial data to determine the merit of potential varieties of crop kinds for which they are recognized. The committee has no registration recommending authority outside of the region of Canada for which they are recognized.

### The committee's objectives are:

- To recommend for registration to the VRO, candidate varieties based on merit and in accordance with the approved committee operating procedures.
- To determine the eligibility requirements for registration of varieties of a crop kind listed in Part I and II of Schedule III, of the *Seeds Regulations* paragraphs 67.1 (1)(a to m) (appendix II). This includes a committee recommendation for registration. Part I crop kinds require assessment of merit by the committee, whereas Part II crop kinds do not.

### The Committee's name

The recommending committee's identification (Title) should be clear and based on the region they represent, the crop kind(s) and classes (where applicable). For example: the Prairie Wheat, Rye, and Triticale Recommending Committee or the Ontario Cereal Crops Recommending Committee. Each committee's procedures document should be made available to the public, either online or upon request to the secretary or chair of the recommending committee.

## The Committee's Roles and Responsibilities

As noted in the overview, each RC must put in place procedures and processes to ensure **fair**, **transparent**, and **consistent** determination of merit for varieties of Schedule III, Part I crop kinds and design of test protocols for Parts I and II listed crop kinds as set out in the [Seeds Regulations](#). It is expected that each committee will incorporate the principles and objectives described in this document into its operating procedures.

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<sup>1</sup> "merit" means, with respect to a variety, that the variety is equal or superior to appropriate reference varieties with regard to any single characteristic or combination of characteristics that renders the variety beneficial for a particular use in a specific area of Canada; (*valeur*)

In addition, the committee's role in determining merit of a candidate variety is to foster innovation in the crop while mitigating risk and providing increased value to their specific crop sector.

The committee should attempt to balance the value of: accelerated time to market, encouraging crop innovation, and the rapid improvement of the crop versus the value of ensuring varieties with clear benefit (based on precision of prediction) are recommended for registration.

The overall effect of the committee's requirements and processes on Canada's international competitiveness in that crop also needs to be considered. A balance should be struck between fostering innovation, determining the merit of a variety (for Part I), and keeping the market risk acceptable. The categories and number of merit criteria should be reviewed on a regular basis with these considerations in mind.

### **Historical background of the committee** (Optional)

(Appendix: History and Background of the RC)

This section can include previous names of the committee and any other previous changes.

### **Membership**

The officially recognized recommending committee consists solely of members who vote to make recommendations to the VRO regarding variety registration. In accordance with paragraphs 65.1 (1) (a) and (b) of the *Seeds Regulations*, the committee must have the knowledge and expertise required to establish and administer testing protocols and to determine the merit of varieties of that species, kind or type of crop for the specific region(s). The recommending committee members are often selected from a larger crop expert advisory group who constitute a pool of expertise for the recommending committee to draw on, as required.

The committee shall reflect the full value chain of crop-specific stakeholders: individuals actively engaged in the development, production, processing, marketing, and/or evaluation of varieties in Canada. The committee should include equal representation from the three broad-based value chain stakeholder groups (keeping in mind that a smaller committee is favoured over a larger one in order to optimize efficiency):

- **Variety/Trait Developers and Assessors** representation (breeders, agronomists, pathologists, entomologists, molecular geneticists, business leaders with expertise in one or more aspects of the specific crop),
- **Producer** representation (crop specific producer organizations)
- **End User** representation (e.g. millers, grain traders representing domestic and export markets for the specific crop, food processors).

Representation is by broad-based grouping, and may be designated by stakeholder value chain organizations within those groups as opposed to individuals (e.g. the Variety/Trait Developers

group may, if determined by the committee, have designated organizations to be represented on the committee such as a breeder from the CSTA Breeders' committee or domestic millers chosen by the Canadian Millers Assn., etc.). **In this circumstance it is these organizations that may nominate their own representatives for this designated position on the committee.** In addition to these voting members, the Canadian Seed Growers' Association (CSGA), the Canadian Seed Trade Association (CSTA), and the VRO will all have an *ex officio* (non-voting) seat on the committee available to them. As an example, a committee might have 21 members, of which 18 are voting (6 each from the three broad based groups) and 3 non-voting. The committee may elect to have subject matter experts present by request (from outside the committee), as required, to provide detailed expert input related to the merit assessment of varieties being considered.

The identification, affiliation and area of expertise of the committee members must be provided in advance to the VRO and to the committee membership: the name of the person, title on the committee, expertise criteria (e.g. agronomy, pathology, quality, milling, processing, exporting/marketing etc.) , title in his/her organization, their organization, their address, their phone number and e-mail address.

It is expected that the committee members will discuss changes to the operating procedures, including governance and the setting of future goals for merit in the crop, with the entire crop expert advisory group present at the meeting to obtain consensus. Committee members will then vote on any subsequent changes.

Committee members can only serve on the committee for a maximum term of three years; however, they can let their name stand to be voted in for subsequent terms. This must be clearly stated in the procedures document. The existing committee votes on the upcoming changes to its members via a simple majority (if representation by organization is part of the committee structure then this is simply a procedural function to ratify already appointed new members).

### **Committee structure**

Each recommending committee will have a Chair and a Secretary, which shall be approved by a simple majority vote (50% + 1) of the voting members. If the Chair is unavailable to act in his/her position, the Secretary will assume that role and, as the elected or acting Chair, must appoint a temporary Secretary from among the voting membership.

### **Crop expert advisory group and visitors**

Crop expert advisory groups may also be associated with the committees. There should be no restrictions on the number of these advisors. Crop-specific experts/stakeholders should be eligible to attend general meetings in a non-voting capacity. They must provide advanced written notification to the committee with a brief explanation of their credentials. This process should be clearly explained in the procedures document. A code of conduct and terms of reference should be provided to all members of the committee.

There should also be a provision for other visitors with an interest in the crop sector to attend the meetings (e.g. students, educators and researchers, members of the press). This is subject to the

logistics of the venue chosen, and provided the visitors self-identify (including affiliation), and notify the committee secretary, in advance, of their intention to attend.

Crop expert advisory group members should have an opportunity to be recognized by the Chair to provide expert input to the voting committee. Ad hoc working sub-committees made up of either committee members or crop expert advisory group members or a combination of both, may be established by the committee to constitute a more robust expert group as necessary.

### **Process for becoming a member of the VR recommending committee**

The variety registration recommending committee is comprised solely of those members authorized to vote on the recommendation of a candidate variety. The RC may or may not be a subgroup of a larger crop expert advisory group. Members, authorized to vote on VR recommendations may be selected from a larger group. Where this is the case, the process must be clearly explained in the procedures document. Anyone wishing to be considered for RC appointment can apply directly with the committee during the membership business section of a meeting. Member-stakeholder organizations holding a voting position on the committee can also replace their member prior to expiry of their current term.

### **Voting Procedure**

Voting for changes to the committee operating procedures and for variety registration recommendation are by a simple majority vote: 50 per cent plus one person (provided there is a quorum). The Chair and Secretary vote as part of the committee.

For all varieties meeting all the criteria for merit (e.g. protein = check mean), a single vote should be conducted to recommend them for registration as a block or group. Varieties not meeting the merit criteria, but for which the proponent wants their strengths to be taken into account may be brought before the committee with a request to “set aside the rules” and have their merits re-examined.

### **Set aside rule**

As noted above, the applicant can request that the committee set aside the rules to consider the merit of a variety that otherwise has failed to meet the standard in one or more required characteristics. For this to proceed, a single simple majority vote must be held to set aside the rules. The committee would then hear the applicant’s recommendation request (a presentation of the attributes of the variety and why it should be considered) followed by a registration recommendation vote based on a simple majority. For example, a new and valuable technology has been introduced in an otherwise partially deficient variety and the committee is being asked to make a decision on the new, valuable attributes not yet captured in the definition of merit for that crop kind. In this example, the proponent may be requesting interim registration or a full registration. As another example, if the minimum data set or minimum merit performance are lacking due to extenuating circumstances, the committee may choose to take this into account.

There are only three possible voting options:

1) To **support** (the motion),

- 2) To **object** to (the motion) or, rarely,
- 3) To **abstain** from voting.

Abstaining is only appropriate if there is a real or perceived conflict of interest (see below). A lack of suitable data is not a valid reason for abstaining from voting on variety recommendations.

**Conflict of interest** (with respect to voting on the committee)

In general, a conflict of interest may arise if the impartiality of a member could be undermined due to a conflict between their self or professional interest and the public interest.

Conflict of interest is minimized by instituting automated procedures for variety evaluation (a pre-set, clearly written set of specific merit criteria that, if met in its entirety will result in the variety being added to a list of similarly qualified varieties to be recommended automatically by a single procedural vote of the committee.

There is the potential for a conflict of interest to occur within the committees if a voting member derives direct benefit from the outcome of the vote and determines that he or she is in a position of undue influence with regard to the variety. The choice of abstaining from the vote is left up to the individual voting member and in accordance with the code of ethics of the committee. It is recognized that a voting member may derive benefit from the outcome of a vote but that he or she is capable of acting impartially and professionally on behalf of their constituency when it comes to voting. It is also recognized that having a committee of crop-sector experts voting on variety recommendations means that voting members will occasionally have a vested interest in one or more of the varieties coming up for the vote. This is a feature of all variety registration recommending committees in Canada where voting on an individual variety occurs.

If a variety proponent believes that a conflict of interest is responsible for their variety not being recommended by the committee, they can file an appeal with the committee and present their case.

## **Committee Meetings Requirements**

The current committee membership should meet in person at least once a year for registration recommendation voting and for general committee business, including annual review and revision (if necessary) of the procedures document. In order to be efficient and responsive to variety developers, the committee may have additional meetings (virtual or in person) to conduct their business, which may include registration recommendation votes. These meetings will be in accordance with the governance requirements outlined in the procedures document.

## **Trial Procedures**

### **Site information**

Information about the site crop rotation (history on the land use), soil condition, seeding rate, fertilizer application, disease control, pesticide application, and harvesting date should be provided to all members and variety proponents.

## **Location**

For public co-operative trials, a list of crop production regions should be outlined in the procedures document. Locations for trials should be chosen on the basis of being representative of the crop production region where the variety is intended to be grown after commercialization. The trial coordinator(s) should select trial sites each year and present their choices to the committee for approval prior to testing entries in the next crop year.

An appendix to the procedures document must be included, consisting of a list of locations, name of the trial coordinator(s), and contact information. This is to be made available to the public.

## **Data set requirement: station-years**

The minimum required number of station-years of field trialing (sum total of the number of trials conducted across years and locations) should be included in the procedures document. This is one of the data set requirements for merit assessment by the committee.

## **Check varieties**

The choice of check varieties should be reviewed annually by the RC. Changes to check varieties are by majority vote of the committee. As a general principle, any candidate variety entering into the test system should be judged for merit against the same set of check varieties being used at the time of entry into the system.

A list of check varieties and their appropriate application (e.g., pathology checks, quality checks, agronomy checks) must be included. Generally, check varieties shouldn't change for at least three years, but it is at the discretion of the committee to make these decisions based on their crop sector's needs. Check varieties are typically commercially grown varieties whose attributes are such that they provide a stable measurement of one or more merit criteria at a desirable level and can act as an appropriate minimum standard for that trait or set of traits.

## **Merit Assessment Criteria**

The attributes or traits that constitute merit for a given crop kind are to be clearly defined by the committee, made publicly available and may be published by the VRO. Under the *Seeds Regulations*, merit can be one or more characteristics of a variety that provides value in any one region of Canada.

All merit assessment is based on the principle of being equal or superior to the appropriate check or checks within the same experimental trial. By default, unless otherwise specified, the standard for merit (for those traits that the committee defines as part of merit) is equal to checks. Equal means arithmetically equal to the appropriate check(s) based on valid trial data (i.e. trials meeting the minimum statistical and agronomic requirements). Alternatively, the merit minimum standard may, as designated by the committee, be a number relative to the designated check(s) (e.g., check mean plus 1%). In either case the check variety is the baseline for the merit standard.

## **Agronomic characteristics where a component of merit**

A list of all required agronomic traits and their number of trials requirement (station-years, number of years) with a unit of measurement must be provided. The unit of measurement should be consistent with the objective description form designed by the VRO (e.g., relative maturity

units for soybean). It is recommended that this information also be summarized in a tabular format and added as an appendix. As with all merit criteria, the merit level performance for required traits is equal to the designated check or checks mean for that trait and from that same trial, same location.

The mathematical calculation procedure used for determining merit (e.g., rounding off procedure, significant figures) and method of measurement (e.g., any official test protocol(s)) must be provided in the procedures document.

### **Pathology characteristics where a component of merit**

A list of all required pathology traits and their number of trials requirement (station-years, number of years) with a unit of measurement must be provided. The unit of measurement should be consistent with the objective description form from the VRO. It is recommended that this information is also summarized in a tabular format and added as an appendix. Disease rating systems should be clearly referenced and the method of calculation clearly identified. The rating system used must be recorded in the RC procedures document (e.g., S, MS, R, MR or scales 0-9). The designated check varieties for each disease assessment must be clearly identified ahead of time. Pathology (tolerance) tests used should have their protocols clearly explained in the procedures document and the protocol must be highly reproducible and follow scientifically valid experimental designs. As a minimum, tests should utilize a susceptible and a disease-tolerant check variety (control) and be of a scientific replicated test design.

### **Quality where a component of merit**

A list of all required quality traits and their number of trials requirement (minimum station-years and minimum number of years tested) with a unit of measurement must be provided. The unit of measurement should be consistent with the objective description form designed by the VRO. Each quality criteria should have a set value relative to the designated check or checks mean that is acceptable and must meet in order to exhibit merit (e.g., a discrete number or equal to the mean of the appropriate checks of the trial). It is recommended that this information is also summarized in a tabular format and added as an appendix.

The mathematical calculation used for determining merit (e.g., rounding off procedure) and method of measurement (e.g., any official test protocol(s)) must be provided.

### **Experimental Design**

A clear description of the scientific experimental designs (e.g., RCBD, split plot, square and rectangular lattice designs) must be provided, and these designs should provide valid statistical analysis (F-statistic, error term and ANOVA). Trial design and size limitations are determined by the committee.

### **Site Examinations**

The committee must establish a procedure and set a standard for the field trial inspection and reporting process to ensure that its requirements are met. This would apply equally to both privately conducted and/or public/co-operative type trials accepted by the RC. Criteria for trial

inspection must be included in the procedures document. Trial sites should be designated acceptable or not acceptable by the trial coordinator by harvest time. In summary, all trials (private and public) should be inspected and held to a standard determined by the committee, and must be monitored by the trial coordinator.

## **Analysis and Data Summary**

The data set for a trial will be deemed acceptable after harvest and analysis for yield and determination of coefficient of variation (CV) for yield for that trial. The acceptable level of CV will be determined by the committee and stated in the procedures document (it varies by crop kind but is always less than 20%).

Requirements for data handling, data validation, and data analysis processes must be accurately described and must be followed (e.g., rounding off numbers, format of calculation of check means, handling of missing data). The full data set for all traits measured must be available to all trial entry proponents.

## **Private Trial Consideration**

The committee must have a provision to accept privately generated trial data in part or in whole to provide a complete data set as required for merit assessment. The data must be conducted using the same testing protocols (e.g., test design, check varieties) as co-operative (public) trials, follow the same test protocol guidelines, and all valid data generated must be submitted. All trials should also use the same source seed check variety for all the designated checks. Data generated from privately run trials meeting the committee's requirements are treated the same as public or co-operatively generated trial data.

The following guidelines have been established:

The committee must be informed that a private company wishes to conduct recognized trial so that:

- a) The appropriate seed lots of the check variety(s) can be sent to the variety developer for testing, or appropriate arrangements can be made with the private company to locate seed of the check variety that has been adequately tested for quality.
- b) The trial can be visited for evaluation by the committee.
- c) The evaluation committee (part of the recommending committee) will know prior to the annual meeting that private data is forthcoming on certain entries. Data will be submitted to and in a format specified by the recommending committee.
- d) Companies are expected to submit results of private tests to the appropriate coordinator at least fourteen days prior to the annual meeting of the committee.

## **Designated Trial Co-ordinators**

Trial coordinators are appointed by the committee. Coordinators can be from public or private organizations and will possess the necessary technical skill and expertise in running agronomic assessment field trials for crop kinds. Responsibilities of the trial coordinators include:

- Coordinating and organizing regional screening (e.g., disease) and registration recommendation tests.
- Working with the committee in determining appropriate number of sites, their location and co-operators.
- Supplying seed for planting to co-operators with adequate instructions for packaging and seeding. This usually includes a planting plan and list of data to be collected.
- Ensuring that data are collected, summarized, and made available for distribution to developers and committee members in accordance with deadlines for entry decisions and variety registration.
- In accordance with the committee procedures, ensuring that suitable check varieties (including agronomic and disease check as recommended by experts) are included in the test.
- Ensuring that all the replicated data for all traits measured are available to the committee upon request.

## **Eligibility for Trial Entry**

Varieties with potential for merit are eligible for entry into the co-operative public trials. The entries should meet minimum performance level criteria. . There may be situations where eligible entries cannot enter the public trial due to resource constraints, in which case the trial coordinator should provide to the proponent a list of eligibility criteria for private trialing (either contracted, in-house, private co-operative trials, or a combination of these). These criteria will not exceed the merit criteria for that crop kind.

## **Basic Testing Requirements**

### **Eligibility**

The deadline for submission of seed and for fee payment for testing must be stated, if applicable. Eligibility for entry into public (co-operative) trials may require preliminary (private) data to support the potential merit of the variety prior to entering public registration trials. Any such requirements should be clearly identified in the procedures document as well as the method of selecting entries for incorporation into the public trials.

### **Fees**

Fees for public trial testing as well as for inspection of private trials (if applicable) must be specified.

### **Seed**

It is the responsibility of the variety developer to submit a distinguishable, uniform and stable variety into the test system. The varietal purity of the sample should be the same as the Certified class seed of that crop kind. Varieties clearly not meeting this standard may be withdrawn from the test by the committee.

## **Variety descriptions**

### **Trial data**

All raw and summary trial data must be submitted to the committee in a timely manner and in the format specified by the committee.

## **Special Requirements**

### **Phytosanitary**

The committee may impose additional requirements as necessary, for example, seed-borne disease testing prior to entering the public trial as a phytosanitary measure to protect a given geographical area, a province, or Canada as a whole.

### **Plant with novel trait(s) (PNTs)**

Proponents must inform the committee where a variety is derived from a PNT. The proponent should confirm that food, feed and environmental safety approvals are in place and that the PNT has “unconfined release status” or the equivalent (e.g., an exemption letter from the CFIA Plant Biosafety Office). The committee cannot refuse entries into the system for which the necessary sign-offs are in place (e.g., they cannot refuse entry on the basis of a lack of major foreign market approvals).

### **Security of entries**

All persons and institutions involved in conducting trials on behalf of the committee agree to abide by a written “Code of Ethics” (include Code of Ethics for Plants Breeders and Co-operators Conducting Variety Evaluation Trials in Canada, including trial inspectors).

The seed of candidate entries are proprietary property and should be handled with this in mind. Under no circumstances will seed submitted for these trials be redistributed in any manner other than for the purpose of conducting the registration trials, both public and private.

### **Withdrawal of Entries**

A procedure shall be in place to accommodate a request for the withdrawal of entries either from trials or from recommending committee assessment process. Typically such requests are made to the trial coordinator who passes it along to the Chair of the committee. Under this circumstance, data summaries and performance information are not included in any formal documents generated after the request.

## **Registration Recommendation**

The committee has three primary registration options to consider when recommending a variety:

- (1) National registration
- (2) Interim registration
- (3) Contract registration

Based on the result of the trials, the committee will provide recommendations to the CFIA as follows:

- To ‘support’ or ‘do not support’ candidate varieties for registration
- To ‘object’ or ‘do not object’: Some varieties may be desirable in one region but could cause problems in other regions. In this case, the VRO would consult recommending committees other than the committee that supported the variety to see if they object or do not object to this variety being recommended. An objection by the committee can only be based on the candidate variety being assessed as a potential harm to a given crop sector in a given region of Canada (e.g., due to disease susceptibility or to inferior quality characteristics). As a result, a Restricted registration may be imposed by VRO.

### **National registration**

Candidate varieties which have merit, as determined by the committee, will be recommended for registration. By default, all varieties receive National registration by receiving support from any recommending committee.. After the committee’s recommendation and during the registration process, other regional committees that exist for that same crop kind may be contacted to see if they have any objection to the National registration of that variety. Subject to providing a rationale, they may object on the basis of disease or quality aspects that may threaten crop production in their region, in which case the Registrar may apply a regional restriction on this National registration, omitting that committee’s region of Canada.

### **Interim registration**

The committee may consider a recommendation for Interim registration in situations where, after a minimum of one year of testing, the data indicates that a candidate may be eligible for registration. This provision is intended to be used in situations such as:

- (a) where a variety proponent brings forward an innovative variety with a valuable characteristic(s) not necessarily captured in the merit assessment, viewed as being of benefit to the crop sector and worth bringing to the market quickly. It may be slightly deficient in one or more merit characteristics but its attributes outweigh its deficits. Normally such a variety would be considered for registration and concurrent (continued) testing,
- (b) where a variety demonstrates outstanding merit after the one year of testing the committee has the option, if they deem it appropriate, of considering it for interim registration and further, concurrent testing.
- (c) where a variety is brought forward that is deficient in one or more merit criteria, but the proponent has evidence (presented to the committee) of commercial interest in an identity preserved (IP) production program between the developer and an end user (this can be a tool to allow a variety to establish a niche market)

Interim registrations are typically recommended for three years initially and would normally involve new data being brought back to the committee and a request made for National registration with a full set of data to the committee. The registrant has the option of making a request to the committee for an extension of Interim registration for a total of no more than five years, by submitting the full data package with subsequent data collected since registration. Interim registrations expire after their designated term.

Reference: **68.** (2) (a), *Seed Regulations*

(2) The Registrar shall make the registration of a variety subject to the following terms and conditions, where applicable:

(a) in the case of a variety of a species, kind or type of crop that is listed in Part I or II of Schedule III, if a minimum of one year of testing demonstrates that the variety may be eligible for registration but that further testing is required before a final decision can be rendered, the registration shall be limited to an initial period of not more than three years that shall be extended on written request by the applicant if eligibility for registration continues to be demonstrated, but under no circumstances shall the total duration of the registration exceed five years;

### **Contract registration**

Contract registration is available for candidate varieties where biochemical or biophysical characteristics distinguish them from the majority of registered varieties of the same kind or species. Further, it must be shown that these characteristics may cause **harm toward varieties registered for traditional commodity markets**. To qualify for Contract registration, the owner/sponsor of the variety must demonstrate the possibility of industry harm if granted an unrestricted registration. Contract registration is only a possibility for varieties that may cause harm based on scientific assessment of agronomic performance, disease reaction or end-use quality, not based on socio-economic factors. The determination of whether a variety has the potential to cause harm is a scientific process where it is determined whether the variety has the potential to have an adverse effect on the identity of other registered varieties of that crop kind or if the variety or progeny thereof may be detrimental to human or animal health and safety of the environment. As a general rule, Contract registration is not to be used as a substitute for traditional forms of registration (National or Interim) in situations where the committee has objected to the registration of the candidate variety based on deficiency in merit. However, the committee may suggest that the candidate be considered for Contract registration where there is rationale to do so.

Reference: **68.** (2) (c) (i to iv) of the *Seed Regulations*

(c) where the biochemical or biophysical characteristics of a variety distinguish it from the majority of registered varieties of the same kind or species and it may have an adverse effect on the identity of those registered varieties, the registrant shall

- (i) establish and maintain a quality control system for the management of potentially adverse effects of the variety, including management responsibility, contract review, product identification and traceability, inspection, testing, control of nonconforming product, corrective and preventive actions, records and training of personnel,
- (ii) describe the quality control system in a document and submit the document and any subsequent amendments to that document to the Registrar for review and approval,
- (iii) implement the quality control system, and
- (iv) agree in writing, for the purpose of verifying compliance with subparagraph (iii), to provide the Registrar with information relating to the distribution, use and disposition of any seed of the variety or any progeny thereof.

### **Appeals**

Candidate variety proponents are eligible to object to the committee's decision on the basis of procedural errors by the committee (including conflict of interest) and/or on the basis of erroneous data having been used by the committee.

The committee must have a written appeals procedure. The variety proponent should notify the committee quickly with its intent to appeal, and the appeals procedure should be handled in a timely manner so that registration could occur before the next crop season. The result of the appeal along with the rationale should be conveyed in writing to the variety sponsor.

DRAFT

## **Appendix I: Authority provided under section 65.1 in the *Seeds Regulations***

(to be included in all operating procedures documents)

### **RECOMMENDING COMMITTEES**

**65.1** (1) The Minister shall approve, for Canada or a region of Canada, a committee to establish and administer protocols for testing the varieties of a species, kind or type of crop listed in Part I of Schedule III, to determine the merit of the varieties and to make recommendations respecting their registration if

- (a) the members of the committee have the knowledge and expertise required to establish and administer testing protocols for varieties of that species, kind or type of crop;
- (b) the members of the committee have the knowledge and expertise required to determine the merit of the varieties of that species, kind or type of crop;
- (c) the testing protocols established by the committee are appropriate for that species, kind or type of crop, are practical and are based on scientific principles;
- (d) the procedures established by the committee for determining the merit of varieties of that species, kind or type of crop are appropriate for that purpose and are based on scientific principles;
- (e) the operating procedures established by the committee will ensure that its functioning is transparent and that varieties are dealt with in a fair and consistent manner; and
- (f) no other committee is approved as a recommending committee for that species, kind or type of crop for Canada or the region.

(2) The Minister shall approve, for Canada or a region of Canada, a committee to establish and administer protocols for testing the varieties of a species, kind or type of crop listed in Part II of Schedule III and to make recommendations respecting their registration if

- (a) the members of the committee have the knowledge and expertise required to establish and administer testing protocols for varieties of that species, kind or type of crop;
- (b) the testing protocols established by the committee are appropriate for that species, kind or type of crop, are practical and are based on scientific principles;
- (c) the operating procedures established by the committee will ensure that its functioning is transparent and that varieties are dealt with in a fair and consistent manner; and
- (d) no other committee is approved as a recommending committee for that species, kind or type of crop for Canada or the region.

(3) In carrying out its functions, a recommending committee must apply the testing protocols it has established, act in accordance with its operating procedures and, in the case of a committee approved under subsection (1), apply the procedures it has established to determine the merit of varieties.

(4) For the purposes of subsections 67(1) and 67.1(1), the recommendation of a recommending committee must be based on the following:

- (a) in the case of a species, kind or type of crop that is listed in Part I of Schedule III, the results of testing the variety in accordance with the relevant testing protocols and a determination of whether the variety has merit; and
- (b) in the case of a species, kind or type of crop that is listed in Part II of Schedule III, the results of testing the variety in accordance with the relevant testing protocols.

## **Appendix II: Eligibility Requirements for Variety Registration**

(to be included in all operating procedures documents)

**67.1** (1) A variety of a species, kind or type of crop that is listed in Part I of Schedule III is eligible for registration if

- (a) the variety has merit;
- (b) the variety has been tested in accordance with the testing protocols of a recommending committee;
- (c) the recommending committee has made a recommendation respecting registration of the variety;
- (d) the variety or its progeny is not detrimental to human or animal health and safety or the environment when grown and used as intended;
- (e) the representative reference sample of the variety does not contain off-types or impurities in excess of the Association's standards for varietal purity;
- (f) the variety meets the standards for varietal purity established by the Association or these Regulations for a variety of that species, kind or type;
- (g) the variety is distinguishable from all other varieties that were or currently are registered in Canada;
- (h) the variety name is not a registered trademark in respect of the variety;
- (i) the variety name is not likely to mislead a purchaser with respect to the composition, genetic origin or utility of the variety;
- (j) the variety name is not likely to be confused with the name of a variety that was or currently is registered;
- (k) the variety name is not likely to offend the public;
- (l) no false statement or falsified document and no misleading or incorrect information have been submitted in support of the application for registration; and
- (m) the information provided to the Registrar is sufficient to enable the variety to be evaluated.

(2) A variety of a species, kind or type of crop that is listed in Part II of Schedule III is eligible for registration if the requirements for eligibility set out in paragraphs (1) (b) to (m) are met.

(3) A variety of a species, kind or type of crop that is listed in Part III of Schedule III is eligible for registration if the requirements for eligibility set out in paragraphs (1) (d) to (m) are met.

## Other appendices:

### Such as

- **History and Background** of the committee (optional)
  - Date of the creation
  - Committee name changed over the period
  - Change in the administrative process, membership etc.
  - Major change in the procedures document
  
- **Code of Conduct**
- **Terms of Reference**
- **Membership** of <name of the committee>
- **List of trial locations**
- **List of check varieties**
- **Application form for entry**
- **Assessment criteria, including official test methods, where applicable**
- **Formula for data analysis**
- **Glossaries**
  - Registration
  - Variety
  - Variety registration
  - Merit
  - Proponent/ applicant
  - Coordinator