



Crop Variety Registration in Canada ISSUES AND OPTIONS













Crop Variety Registration in Canada: Issues and Options

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PURPOSE

The Government of Canada has committed to a transformational shift in Canadian agricultural policy, with a renewed emphasis on research and innovation, competitiveness and market development. We continue to make efforts to reduce unnecessary regulatory burden as part of our commitment to a science-based regulatory framework that promotes research and innovation and allows for an efficient, transparent and predictable interaction between government and industry.

To this end, Agriculture and Agri-Food Canada (AAFC), the Canadian Food Inspection Agency (CFIA) and the Canadian Grain Commission (CGC) have collaborated on an Options Paper that describes the current crop variety registration (VR) system in Canada and outlines some potential options for modernizing and streamlining the system.

A responsive and efficient seed and grain regulatory system is needed to maximize Canadian farmers' ability to compete on a global stage. The crop sector is currently undergoing a positive transformation, including changes to the marketing and end uses of crops, shifts in research investment priorities and funding, and streamlining regulations.

Four potential options are presented in this Options paper, with varying levels of direct involvement and oversight by crop value chains and the federal government.

These options should be considered in a medium term context and complementary to the Minister of Agriculture and Agri-Food's February 2013 letter. In that letter, the Minister requested that crop variety Recommending Committees (RC) review their operating procedures to identify and potentially implement measures, as appropriate and applicable, to streamline the way they operate. Changes to RC operating procedures are expected to be implemented by early 2014.

To provide feedback on these options, we encourage you to complete the <u>Crop Variety Registration</u> in Canada Questionnaire. The online form will be available until November 30, 2013.

I - SETTING THE CONTEXT

It is an opportune time to examine Canada's current crop variety registration (VR) system, given that:

- There is heightened emphasis on innovation, competitiveness and increased market access as key issues for the Canadian agriculture and agri-food sector. This is evident in the new Growing Forward 2 policy framework.
- The role of the federal government is also changing. Under Growing Forward 2, AAFC-led research, development and transfer activities will be increasingly focused on enabling a strong scientific foundation (e.g., through development of germplasm, mechanisms for resistance to disease and insects, etc.) while providing programming to enable greater industry leadership to drive research priorities, including variety development and finishing.

- The Government of Canada is committed to regulatory modernization that keeps food safe and protects the animal and plant resource base, while aiming to provide the appropriate level of government oversight. The Government of Canada is also committed to reducing red tape and unnecessary duplication and paperwork through its Red Tape Reduction Action Plan.
- The Government of Canada has also initiated several changes to the regulation of the grain sector in Western Canada including, most notably, the removal of the Canadian Wheat Board (CWB) single desk for wheat and barley marketing. Prior to August 2012, the CWB played a strong role in the VR system by bringing customer needs into the consideration of the regional recommending committees for Western Canadian wheat and barley. This role has now changed with the CWB being one of many grain marketers being represented on the recommending committees.
- The VR system is currently the underlying foundation of the quality assurance system for cereals, canola, flax and other field crops that focuses on delivering the end-use qualities desired by domestic and international buyers.

II - VARIETY REGISTRATION IN CANADA - THE PAST AND THE PRESENT

1. History of and rationale for variety registration

The original *Seeds Act*, promulgated in 1905 as the *Seed Control Act*, was amended in 1923 to require varieties be licensed by the Minister prior to sale in Canada. A licensing system was established in Canada due to the fact that seed sellers in the United States were promoting a wheat variety in Canada which they falsely claimed would yield 100 bushels per acre (which was untrue). When the legislation took effect in 1923, all new varieties were required to be tested either at an experimental farm or privately, and were approved for registration by a Committee of Plant Breeders of the Canadian Seed Growers' Association.

An amendment to the *Act* in 1937 exempted all vegetable varieties from registration with the exception of potatoes. Fruits have never been included in the variety registration system though information on particular varieties is listed in international databases to facilitate export. The list of crops currently subject to variety registration can be found on the CFIA's web site at: http://www.inspection.gc.ca/english/plaveg/variet/proced/regproappe.shtml#aa

Annex A provides a detailed description of the variety development and registration process. Although this annex and many of the examples provided in this paper pertain to Western wheat and other cereal crops, as an illustration of how the process works, the intent of this emphasis is not meant to draw attention away from other crops subject to VR.

The current *Seeds Act* is the enabling legislation governing the regulation of the seed industry in Canada. It encompasses the testing, inspection, quality and sale of seeds in Canada. The *Canadian Food Inspection Agency Act*, identifies the CFIA as being responsible for the administration and enforcement of the *Seeds Act*.

The purpose of variety registration is to provide government oversight to ensure that health and safety requirements are met and that information related to the identity of the variety is available to regulators to prevent fraud. It also facilitates seed certification, the international trade of seed and the tracking and tracing of varieties in commercial channels.

More specifically, variety registration is designed to:

- Have an oversight role for maintaining and improving quality standards for grains in Canada;
- Facilitate and support seed certification and the international trade of seed by:
 - o Verifying a variety meets the internationally recognized definition of a variety: a distinguishable, uniform, and stable population of plants;
 - o Establishing a repository for the official variety description and reference seed sample which are used to verify varieties throughout their commercial lifespan; and
 - o Ensuring varietal identity and varietal purity of seed lots as they are multiplied through a limited number of generations to produce seed for Canadian farmers and export markets.
- Verify claims made which contributes to a fair and accurate representation of varieties in the
 marketplace (i.e., by verifying variety descriptions, reference variety seed samples that define
 the variety in the market); and
- Facilitate varietal identity, trait identity and traceability in the marketplace to ensure standards are met and to support trade.

2. Key Components of the current Canadian Variety Registration System

i. Tiered Variety Registration

In July 2009, the Government of Canada introduced a flexible variety registration system with the potential to reduce regulatory burden while continuing to maintain the core benefits of the VR system to the sector outlined above. Previous to the 2009 changes, all crop types requiring VR were subject to pre-registration testing and merit assessment.

Extensive public and industry consultations were carried out by the CFIA, leading to the 2009 changes. Through these consultations, the Agency determined that stakeholders considered the variety registration system important and that the merit-based approach was appropriate for some crops, but that it was too rigid for others.

The VR system was also an area considered by other multi-stakeholder groups, like the National Forum on Seed.

The Seeds Regulations ("the Regulations") now divide Schedule III, which lists the crop types requiring variety registration into three Parts. For registration under any Part, a basic registration package is required to be submitted by applicants. The package includes a completed application form, a reference seed sample, a description of the variety, details of the pedigree and history of development of the variety, and an application fee.

There are three regulatory options with varying registration requirements. Crops listed in Parts I and II require the involvement of a recognized committee of industry experts, a "Recommending Committee" (RC). These RCs perform the critical role in shaping the types of varieties available to producers in Canada.

In all cases, the CFIA's Variety Registration Office (VRO) verifies that:

- the variety is distinguishable from all other varieties that were or currently are registered in Canada;
- the variety name is not likely to be confused with the name of a variety that was or currently is registered;
- the variety meets or exceeds the standards for varietal purity established by regulations or by the Canadian Seed Growers' Association for a variety of that species, kind or type; and
- where the variety or its progeny is a Plant With Novel Trait (PNT), verification that the genetics have been approved for unconfined release in Canada and have food, feed, and environmental release approval¹.

As Schedule III is included as part of the Regulations, for a specific crop kind to move from one Part of Schedule III to another, a regulatory amendment is required. Crop placement amendments can be considered based on two components:

- 1) a crop specific rationale for change; and
- 2) crop specific stakeholder consensus for change.

The required regulatory amendment typically takes up to two years to complete due to the consultations required to achieve consensus, drafting the amendment, publication in the *Canada Gazette*, etc.

The defining characteristics of each tier are as follows:

Part I crops (majority of crops including wheat, barley, pulses and canola)

The unconfined release authorization of PNTs in Canada (food, feed and environment) is provided by both Health Canada (food) and CFIA's Animal Health Directorate (animal feed) and Plant Bio-safety Office (environment). The science-based assessment for unconfined release assesses the risk of novel traits in plants and ensures that any novel plant trait poses no more risk to humans, animals or the environment than the conventional counterparts. This safety assessment and authorization is separate from, and required prior to, any varieties with a novel trait being registered.

Requires a RC to set conditions and testing procedures for crop performance trials. The
RC must assess merit based on the performance trial data and recommend the variety
for registration to the CFIA's VRO. This merit assessment is made by comparing the
performance test results from field trials to the attributes of reference varieties (also known as
"check" varieties). For more information, go to Annex A.

Part II crops (currently only safflower)

 Requires a RC to set conditions and testing procedures for trials that generate performance data. However, RCs for Part II crops do not assess the data generated in these trials to determine if the new variety performs as well or better than reference varieties (i.e., the variety has "merit"). A Part II registration still requires a RC recommendation (i.e., verification that the test requirement has been successfully met) to the CFIA's VRO.

For Part I and II crops, once a RC has recommended a variety for registration, the CFIA's VRO accepts the recommendation and, after reviewing and validating the information package that must accompany the application for registration, registers the new variety.

Part III crops (currently only potatoes and sunflowers. Oilseed soybean and forage crops are expected to move to this Part by the end of 2013)

- Applicants must supply registration information package to the CFIA's VRO for review and validation
- Does not require a RC as there are no merit assessment or pre-registration performance trial requirements

ii. Recommending Committees

Variety registration for Part I and Part II crops is based on a recommendation from a RC. The Regulations require that to maintain their approval, each RC provides a written set of procedures or protocol document to the CFIA's VRO, describing how the RC operates. The Minister of Agriculture and Agri-Food annually approves their procedures, thus requiring RCs to submit them for scrutiny each year. The Regulations require that the RCs operate in a transparent, fair and predictable manner.

Seventeen regional RCs exist for Part I and Part II crops. A list of the Committees can be found on the CFIA's web site at http://www.inspection.gc.ca/plants/variety-registration/registration-procedures/recommending-committees/eng/1359958262947/1359958370983

RCs are made up of crop specific stakeholders who are experts engaged in the development, production, processing, marketing, and/or evaluation of each crop kind. The RCs set the test standards and protocols for Part I and Part II crops in Canada. For Part I crops, they also set the minimum standards or criteria for the "merit" requirements used to evaluate candidate variety and decide on whether the candidates meet the definition of having merit. If a candidate is deemed to have merit, the RC will make a recommendation for registration to the CFIA's VRO.

The following provides an illustration related to Western wheat, but note that a set of reforms are pending that would modernize and streamline many of the currently noted procedures for registration recommendation.

For Western Canadian wheat varieties, the designated RC is the Prairie Recommending Committee for Wheat, Rye and Triticale (PRCWRT).

The PRCWRT has two types of membership: full (voting) and associate (non-voting). New PRCWRT members are nominated by a current full member and are approved by a simple majority vote of the Committee. Membership lists are updated annually and provided to the CFIA's VRO for each of the three Evaluation Teams (one each for agronomy, disease, and quality evaluation), indicating the elected Chairs and secretaries, and for the associate members.

Individuals who do not qualify for full or associate membership but are interested or otherwise involved with the process may register for the meetings as guests. Guests have a voice in discussions and may provide input at the Evaluation Team and Committee levels, but do not have a vote.

Voting members of the three Evaluation Teams fall into one of four industry groups:

- 1. Individuals engaged in variety development or evaluation;
- 2. Cereal pathologists;
- 3. Cereal quality specialists; and
- 4. Representatives of industry with expertise in the grain industry such as producers, processors, seed growers, provincial specialists and the like.

Voting members of the three Evaluation Teams must represent a sector of the cereal value chain. New members are considered based on their ability to contribute to the recommendation process rather than the organization they represent.

Full members who fail to attend the PRCWRT Annual Meeting for two consecutive years will be moved to Associate Member status unless an acceptable excuse is provided to the Committee Chair.

Associate members are individuals with a legitimate interest in Committee activities. Examples of associate members include, but are not restricted to Canadian Food Inspection Agency officials, provincial government specialists, and administrators or business managers whose organizations are active in variety production, development or evaluation. Associate Members do not have voting privileges, but are allowed a voice during Committee and Evaluation Team meetings and will receive all information packages and access to proprietary data posted on the Committee web page.

iii. The concept of "merit"

In the Regulations, "merit" means requiring new varieties be equal or superior to reference or "check" varieties with regard to specific characteristics which render the new variety beneficial

for a particular purpose and in a particular region of Canada. The Regulations do not prescribe what these characteristics should be, how to assess for them, or what the reference should be for the assessment - this is the role of the expert RCs.

The RC operating procedures recognize that in practice, few candidates meet or exceed the mean of the checks in all of the important characteristics under consideration. Typically, many will show a collection of strengths and weaknesses in relation to the various checks, and judgements are made by considering the entirety of traits which may include, depending on the crop type, yield, agronomic characteristics, disease tolerance, and end-use quality characteristics. The number of merit criteria Part I crops must meet varies depending on the specific crop.

For example, Western Canadian wheat varieties, because there are nine market classes and a multitude of uses/customer requirements, have 33 to 49 specific characteristics assessed for merit, depending on *Canada Grain Act* class (e.g., six diseases, 32 quality parameters, nine agronomic traits for the Canada Western Red Spring class). The weighting of parameters varies with each class of wheat – a candidate does not have to display superiority in every parameter measured, but rather it must display performance either similar to or greater than the check varieties.

After the flexible variety registration system came into effect in 2009, the Western Canada Canola/Rapeseed RC took advantage of the flexibilities inherent in the new system and changed the definition of merit. It went from a complex series of "must have" and "should have" requirements coupled with a multi-criteria index calculation, to a combination of minimum oil and protein level assessments. Canola varieties must also meet the minimum definition of canola (i.e., low erucic acid in the oil, low total glucosinolates in the seed and minimum total saturated fats level in oil).

While the canola RC chose to continue to require testing of this Part I crop for quality and end use characteristics as well as disease resistance and yield, members felt market forces would take care of ensuring these were met or exceeded. A new "Interim Canola Registration" policy was introduced in 2010 by the CFIA's VRO whereby all private data sets based on a single year of testing can be used for registration purposes (protocols determined by and subject to recommendation by the RC).

iv. Testing

Registration testing is designed and implemented to provide credible, science-based performance data on new varieties. As noted previously, there is a regulatory requirement for the RCs of Part I and Part II crops to establish and apply testing protocols as part of their assessment process.

To be eligible to enter into the RC assessment testing, variety developers must first present evidence of the merit (if applicable) of the entry to the testing coordinator. This evidence is typically one or two years of field trial results from multiple locations compared to known reference varieties for agronomic, disease, and quality trait performance.

Since the data is generated to support the registration requirements for the crop type is considered proprietary, it does not have to be made publicly available. However, the majority of RCs currently make this data available.

As noted, for Part I crops where merit is assessed, a candidate variety is expected to meet or exceed the performance (based on data generated from the testing) of a reference (or "check") variety prior to being considered suitable for registration.

For example, the Western Canada Canola/Rapeseed RC coordinates the second year of testing (often referred to as "co-op" testing). This second year of public testing (field and quality) is combined with first year private data to develop a score sheet of quality parameters prescribed in the canola/rapeseed RC procedures document (oil, protein, saturates, erucic acid, glucosinolates). This score sheet is used as the basis for canola variety registration recommendation. As well, developers have the option to pursue interim recommendation based on one year of private data only.

For Part II crops, RCs determine whether or not to recommend registration of a new variety based on the variety having met the field test requirements according to the RC operating procedures. There is no merit assessment involved.

v. Crop types not covered by the VR system

Though most major crops grown in Canada are subject to variety registration, there are exceptions. While there is no process specified in the Seeds Act or the Regulations to formally exempt crops from registration, in actual practice, an exemption has been conferred for certain crops, based on the realities of growing and marketing those particular crops, and a consensus decision among members of the crop value chain. Operating outside the formal variety registration system, some of these crop value chains have created systems to recognize and document varieties for certification and international trade purposes, for example. Any request for an exemption from VR would require an amendment to the Regulations. Value chains for crops that fall outside the variety registration system (e.g., corn, food-grade soybeans, chickpeas, fruits and vegetables, ornamental plants, turf grasses, etc.) may pursue objectives similar to those conferred by the VR system through other means.

For example, in 1996, at the request of the corn industry, corn was exempted from VR. The request for exemption came from growers demanding to be on an equal footing with American growers and to have access to the newest hybrids at the same time as U.S. growers. Industry stakeholders felt that the variety registration requirements in place at the time put Canada two or three years behind the U.S. and a lack of synchronization negatively affected product supply planning. At the time, there was no flexibility in the registration system to register varieties without the requirement for a merit assessment.

Currently, the corn industry (through the Canadian Seed Trade Association) developed and maintains a database of corn hybrids that are commercially available in Canada.

For a crop type currently not covered by the VR system (e.g., emerging bio-industrial crops like camelina and brassica carinata), the requirements are essentially similar to those currently

in place for a crop desiring to move from one Part to another. That is, there must be a strong rationale put forward for the crop type and evidence of value chain stakeholder consensus. A regulatory change is necessary to make the crop type subject to variety registration.

vi. Linkage between crop variety registration and the grain quality assurance system

The VR system is the underlying foundation of the Canadian grain quality assurance system (GQAS) for cereals, canola, and flax. The system focuses on delivering the end-use qualities demanded by domestic and international grain buyers. The GQAS is designed to provide customers with the quality of grain they require, consistently, year after year. The GQAS also provides the ability to segregate grain according to class, type and grade, thus enabling end-users to purchase shipments of grain with predictable processing qualities. In addition, it is important to understand that a key strength of the GQAS is not only to facilitate trade, but also help to ensure that regulatory grain safety and cleanliness requirements are met.

As Canada's grain quality assurance agency, the CGC links its "Variety Designation Lists" (lists of varieties approved as eligible for a particular grain class) to the merit based registration process for Part I crops in support of its quality assurance mandate. Under the authority of the *Canada Grain Act*, a grain variety must be registered to be eligible for delivery into a prescribed market class (e.g. Canada Western Red Spring) and to receive the associated payment. As such, varieties are submitted into merit trials specific to a particular market class. Recommending Committees then evaluate all new varieties against "class-specific" benchmark varieties for a number of "class-specific" end-use, disease resistance, and agronomic performance criteria; varieties that are successful in meeting the merit criteria for a specific grain class are recommended for registration.

The CGC's Variety Designation Lists are then used by producers and grain handlers to identify which varieties are eligible for delivery into a particular class and the relevant payment amounts. Handlers also use the lists as a tool to help keep ineligible varieties from undermining the quality of grain shipments and potentially causing problems for end users. When the CFIA cancels a variety registration on request of the owner, the variety is subsequently removed from a CGC Variety Designation List and is no longer eligible for a top grade.

The integration of the GQAS and VR requirements is continually evolving with changes in the agricultural sector in order to ensure continued improvement of Canadian products and, ultimately, facilitate market access. For example, the creation of the creation of the General Purpose class in 2008 and the classification of certain Western wheat varieties recently changed in response to market demands and producer needs. By ensuring consistent enduse attributes and functional uniformity, shipments are more consistent in processing quality, cargo to cargo and year to year. This is particularly important for a diverse-use commodity like wheat, as large quantities are produced each year spanning a wide range of growing environments in Western Canada.

Currently, the Western Canadian wheat classification system spans the breadth of protein content, from low to high protein wheat varieties. However, it is important to note that high protein alone does not automatically impart high quality to a given variety. Once the protein level is above 11.5 to 12 per cent, it is the functionality of the wheat, not just the quality that comes into play.

vii. Linkage between crop variety registration and seed certification

After a crop variety has been recommended for registration by a RC, the final step is an application to the CFIA's VRO. Registrants are required to supply information including the variety description (phenotypic description), the breeding history, identification of the breeder, the Canadian representative/applicant, the varietal type, the species, the crop kind, the Association of Official Seed Certifying Agencies (AOSCA) listing and OECD Seed Schemes listing (if requested), and a reference seed sample. Some additional information may be required, depending on the crop kind. For example, for PNT varieties, a test protocol to allow detection of the novel trait must be submitted, reviewed and approved by the CFIA prior to registration of the variety.

The CFIA also grows out each new reference seed sample the next field season after the sample is received. Results are examined for varietal purity according to the variety description submitted by the applicant. In a few cases, where warranted, supplemental DNA analysis is used for identification purposes.

The CFIA's VRO verifies all the aforementioned information, as well as any PNT traits (i.e., that they are approved traits for unconfined release in Canada) and for listing in a CFIA-maintained database for official reference and traceability purposes.

For crops not subject to variety registration (e.g., corn, food-grade soybeans), the Canadian Seed Growers' Association (CSGA) requires very similar information for its "Form 300" certification process prior to seed of a new variety being certified by the CFIA. The "Form 300" process bears some similarity to Part III registration in that it captures much of the same information, but this information is not verified by the CFIA or captured in its database. With regard to OECD Seed Schemes listing, the CFIA is Canada's designated authority and listing of varieties must occur through the VRO.

Both OECD and AOSCA are bodies dedicated to standardization/harmonization of international seed certification standards as a means to facilitate trade between and among countries. Since 1958, the OECD Seed Schemes have been open to OECD member countries as well as other United Nations members. Currently, 58 countries, including Canada, participate. The Schemes ensure the varietal identity and purity of seed through appropriate requirements and controls throughout the cropping, seed processing and labelling operations.

The forerunner to AOSCA was the International Crop Improvement Association, founded in 1919 by Canada and 12 U.S states. It has since grown to include more than 50 agencies in the U.S., Canada, New Zealand, Australia, Chile, Argentina and South Africa, both governmental and non-governmental, responsible for official seed certification. Both the CFIA and the CSGA are members of AOSCA.

The pedigreeing of seed and seed crops maintains varietal purity through the seed multiplication process. This is especially important to maintain yield, quality, disease resistance and the other distinguishing characteristics of a variety, which emerge through the variety development and registration process.

Pedigreeing or pedigreed seed multiplication refers to a generation by generation, controlled seed multiplication process with unique purity standards at each stage of seed multiplication. The process is strictly defined by the CSGA and involves standards for field planting considerations and inspections.

The CSGA is recognized by the *Seeds Act* and the Regulations as the official Canadian pedigreeing agency responsible for prescribing varietal purity standards and certifying seed crops of all agricultural crops, with the exception of potatoes, which are handled by the CFIA because of some unique considerations (e.g., method of propagation, disease control).

viii. Ministerial letter to Recommending Committees

In February 2013, the Minister of Agriculture and Agri-Food wrote to each RC requesting support for the Government's efforts to enhance innovation by undertaking a review of their respective committee structures and operations with a view to removing potential barriers that unnecessarily encumber innovation in the crop sector. The Minister asked RCs to consider how best they could help ensure that Canada has an approach to variety registration going forward that encourages innovation in variety development and balances the interests of producers and the other members of the crop value chain. RCs were specifically asked to consider all aspects of the workings of their committee including:

- Utilizing the flexibilities available under the current system for streamlining the procedures of the committee;
- Reassessing and if possible reducing: data requirements, number of years of pre-registration field trials and acceptability of foreign data, if applicable;
- Adjusting committee structure and membership in order to ensure full and balanced valuechain representativeness; and
- Seeking opportunities to streamline merit assessment, where appropriate and applicable.

To date, a number of RCs have responded to the Minister's letter outlining their intentions to review their current structure and operation and/or providing specific proposals for change.

III – OTHER COUNTRIES' APPROACHES TO VARIETY REGISTRATION

Generally speaking, the process of developing a new variety and bringing it to market is a lengthy one, no matter the type of crop or where it is developed. However, not all countries have legislated variety registration systems like Canada's. In the United States, there is no requirement for a mandatory variety registration process with federal government oversight. However, plant breeders may undertake two to three years of performance trials prior to commercialization. These trials are used to provide reliable performance data to growers and functional property data on the grain to end users. Australia also does not have a mandatory variety registration system. However, for new wheat varieties to obtain a classification necessary for entry into the Australian wheat export system, variety developers must obtain performance data over a certain number of years of field trials.

European Union (EU) countries all have mandatory variety registration/seed certification requirements for marketing major agricultural crop kinds. When it comes to EU-wide directives specific to variety registration, the possible yield, resistance against damaging organisms, environmental behaviour and quality shall be assessed, but the directive is silent on specific guidelines (e.g., for number of locations or duration of tests). Consequently, testing requirements and regimes are quite different in the member states. In 2012, the EU began a review of its legislation related to variety registration and seed certification. In recognition of greater financial pressures on its member states and the need to reduce the administrative burden on users of the variety registration/seed certification system, the review put forward several scenarios for public consultation. The results of the review were released in May 2013, and can be found at: http://ec.europa.eu/food/plant/plant_propagation_material/review_eu_rules/index_en.htm. The new proposal attempts to balance the strength of the current system with the desire of stakeholders to reduce cost and complexity and increase efficiency. Adoption across the EU is expected to take a further 2-3 years.

In Brazil, the Ministry of Agriculture oversees a crop registration system. Each crop value chain is responsible for specifying requirements for registration of a crop (e.g., number of years and locations of pre-registration field trials, which criteria must be met, etc.). The federal government confers the final variety registration based on the recommendation of a value chain.

IV - VARIETY REGISTRATION - OPTIONS FOR THE FUTURE

Recently, there has been significant discussion on the role of variety registration in Canada, particularly for wheat in Western Canada. Some stakeholders suggest that the registration of crop varieties in Canada is the cornerstone of the seed and grain quality assurance system and sets Canada apart from many of Canada's competitors. This consistency of quality is a key part of the Canada brand. In addition, there is a sense that the RCs have sufficient flexibility to adjust their operating procedures to suit the needs of each crop kind's value chain requirements.

Other stakeholders, however, have indicated that the VR system is overly focused on quality attributes for some wheat classes, for example. The narrow focus on specific attributes can limit innovation as some varieties which meet market demands, other than these attributes, may not be recommended by RCs and cannot be grown in Canada. Under the Regulations, RCs are required to operate in a fair, open and transparent manner. Despite this, concerns have been expressed that the subjectivity of decision-making through the voting process of RCs contributes to uncertainty and is not consistent with the science-based approach involved in developing new varieties.

Still other stakeholders have indicated that the current VR system could use some "tweaks" to increase its speed and the number of new varieties recommended for registration, but, in general, the current system is flexible, functions appropriately and Canada should not "throw the baby out with the bathwater".

Given the various views, this engagement process will solicit input, for the federal government's consideration, on four potential options. This review and the potential implementation of any option should be considered in a medium term context (2-3 years). It is also complementary to the more immediate changes that may be undertaken by RCs in terms of opportunities to streamline their current processes in response to the Minister's February 2013 letter.

Also, it is important to note that the options outlined below do not provide specific implementation details or in-depth analysis of the effects on systems for which VR is interrelated such as the grain quality assurance and seed certification systems. Following the engagement process, the Government of Canada will need to assess implementation issues such as the appropriate delivery agent(s) and ensuring all applicable health, safety and other considerations are taken into account.

OPTION 1

Allow the flexibility inherent in the current VR system to emerge

As significant changes to the registration system have been made relatively recently (i.e. in 2009), and the process of developing new varieties is a lengthy one (no matter the crop kind or country), it could be argued that the current system has not yet been in place long enough to demonstrate all of its inherent flexibility. For example, movement of crop kinds into new tiers of the three-part registration system has not yet occurred, though movement of some crops is pending. As noted, there are flexibilities within the Recommending Committees to modify operating procedures (e.g. merit requirements). Some RCs have taken advantage of these flexibilities, some have not. The decision to remove kernel visual distinguishability (KVD) for wheat in 2008 was broadly supported by stakeholders as there was concern KVD was presenting an impediment to improving yield. Finally, the General Purpose class in the wheat classification system has only been available since 2008.

One option, therefore, would be to allow the impacts of recent changes to the system to become more fully evident and then re-assess within the next five years if the system requires more change.

Awareness-building efforts regarding the flexibilities of the current system, in particular communication of how it is structured, how the RCs operate, what the federal government role is in VR, and the flexibility in how crop variety developers can work with the RCs to produce the data required, could help ensure variety registration is better understood and used to maximize intended benefits throughout crop value chains.

OPTION 2

Streamline Regulatory Process by requiring all crops meet minimum registration requirement with the option for some crops to have merit assessment through an independent assessment process

Under this option, the federal government would signal its intent to move all crop kinds currently in Parts I and II to a basic registration requirement, currently known as Part III.

When the redesigned VR system was put into place in 2009, the default for most crop kinds was placement in Part I, with the expectation that migration to Parts II and III would follow quickly for those crops that wished to be subject to fewer requirements. Some stakeholders have expressed concerns about the length of time this has taken to occur.

Under Option 2, the default would be movement to Part III, which features the minimum registration requirement (see first paragraph of Section 1, vii of this paper) and federal government oversight. However, those crop kinds whose value chains agree they benefit from a RC and an independent merit assessment requirement could signal their intent to stay within Parts I or II, as applicable. The

requirement for a strong rationale and crop value chain consensus under the current VR system would still be necessary for crop kinds to remain in Parts I or II. This would allow value chains for which members collectively agree more oversight is required to still maintain this level (i.e., no movement would occur). Consideration could be given, for example, for some (but not necessarily all) wheat classes remaining in Part I, but others moving to Parts II or III.

OPTION 3

Streamline regulatory process by maintaining a minimum level of federal government oversight (similar to the current Part III), and eliminate any merit assessment or performance data under the VR system

This option includes many of the same elements as Option 2 above. However, there would be no possibility of crop kinds remaining in Parts I or II as these tiers, and the need for RCs and merit assessment, would be eliminated entirely.

This option represents a further reduction in the level of federal government oversight over the VR system. For example, without RCs, there would be no requirement for them to submit their operating procedures for approval by the CFIA's VRO each year, as is currently the case.

However, as with current Part III crops, the VRO would still maintain an important oversight role through its verification of the information included in applications for registration, holding reference seed samples, etc. The variety registration requirements within Part III would continue to enable competition on a level playing field where fraudulent practices are prevented via regulatory oversight of the characterization and identification of varieties. Seed certification would also continue to be supported by variety registration under this option.

In the consultations leading up the 2009 implementation of the tiered VR system, the concept of crop specific consultative groups that could take the place of RCs as a forum for value chain discussions, once crops moved into Part III was put forward. This concept recognized there is value in bringing crop-specific stakeholders together for coordinated discussion and decision-making. This currently occurs when RCs meet annually to approve changes to their operating procedures. The crop specific consultation group would be outside the VR system and would be industry-led.

Under this option, crop value chains would be free to design and implement systems that generate and disseminate independent performance and other data/information that is currently a function of the RCs under the existing co-operative trial process under Parts I and II. This would be similar to what currently exists in the corn sector in Canada. It is important to note that the CFIA has no authority under the *Seeds Act* or the Regulations to collect or publish post-registration test data as a requirement of variety registration.

OPTION 4

Withdrawal of federal government oversight role in VR, allowing industry or third parties to assume these functions

This option would involve eliminating the direct federal government oversight role in the VR system. CFIA and Health Canada would continue to ensure the safety of PNTs for food, feed

and environmental release as would a mechanism to ensure traceability. International obligations requiring the federal government to act as the national focal point would also continue to be met.

In essence, this option would be equivalent to exempting all crops from variety registration - as currently is the case for corn, food-grade soybeans and certain other crops. Variety registration functions performed by the CFIA's VRO (such as accepting and verifying the crop registration information package from each applicant, collecting and holding representative seed samples and conducting variety verification tests) could be transferred to crop-specific organizations or the seed industry to manage.

The Canadian Seed Growers' Association, or other third party, could assume functions currently performed by the CFIA's VRO(e.g., storage of reference samples, the "grow out" of new varieties, , monitoring and resolution of disputes over variety claims, etc.).

ANNEX A - The Variety Development and Registration Process in Canada for Cereals

Variety development, from initial breeding through to the marketing of seed for planting by a farmer involves several years of breeding line evaluations, trait selection and testing followed by field trials, and then finally registration followed by seed multiplication. Depending on the crop type, the breeder, and the complexity of the selection criteria, this process can take upwards of 12 years to reach readiness for commercial sale.

Cereal crop breeding typically involves a minimum of 6 to 7 years (and often more) of plant breeding and selection work, followed by a year or two of early testing to identify superior lines in the breeding program. Breeders need to know their breeding targets many years in advance in order to ensure their success in the marketplace.

The next step is the entry of qualified candidates into the official variety registration recommendation trials. There is an official trial coordinator who reports to the Recommending Committee (RC) and operates under their documented operating procedures. The costs for entering the trials are borne by the variety developer.

Most trials under the auspices of a RC are inspected by a representative of and are approved by the RC.

Again, taking Western wheat as an example, the trial the variety enters is determined by its intended end use (i.e., which wheat class it is intended for) and may also include the targeted zone of adaptation. Each trial type has its own unique set of check varieties against which the candidate will be compared. This comparison is against a specific set of criteria used in determining overall merit. A candidate has merit if it is equal to or better than the appropriate check varieties for the wheat class for which it is being assessed (e.g., Canada Western Red Spring, Canada Prairie Spring, Canada Western Amber Durum, etc.). In these field trials anywhere from 5 to 7 agronomic traits are assessed that determine suitability for commercial production. Disease susceptibility is assessed for prevalent cereal diseases that cause significant economic losses. Quality assessments focus on four areas: Physical Grain Quality; Milling Quality; Rheological Quality, and End-Use Quality. One notable exception is the General Purpose class where there is no quality test requirement. Expert evaluation teams within the RC, one each for breeding and agronomy, disease, and quality assessments, deliberate separately and vote to arrive at their final assessment.

Next, the three Evaluation Teams meet and report their results to the main PRCWRT and, after hearing all the results and recommendations based on agronomy, disease, and quality, the voting members of the PRCWRT then vote on whether or not the variety has overall merit and can be recommended for variety registration.

Candidate varieties require 24 station-years of data collected over three calendar years. It was also necessary to test in pre-registration trials prior to entry into a registration trial, but this requirement is proposed to be eliminated to shorten the testing duration by one year. The choice of test trials the variety developer enters into is normally match the intended region where production will take place.

If the variety is recommended by the PRCWRT (typically in February of each year), the next step is to file a variety registration application with the VRO. The VRO has a performance standard of 8 weeks of processing time for a complete and accurate application package.

In general, if a variety obtains recommendation in the winter (February) of a given year and if the application is sent to the VRO by March of that year, then the variety will be registered in time for planting that crop year. Typically with cereals, the first year of registration is one of very limited commercial sales and instead is focussed on pedigreed seed production. The seed multiplication ratio determines how quickly a variety developer can scale up to commercial quantities of seed. It is simply the amount of seed one can harvest from one seed planted. It depends on the biology of the crop kind. Crops such as canola and corn have high seed multiplication ratios (~1,000) whereas cereal grains are an order of magnitude less (~100). The lower seed multiplication ratios in cereals necessitate more cycles of pedigreed seed production and a longer time to market. There are, however, provisions in the Regulations and the seed certification system to allow variety developers to enter into seed multiplication prior to variety registration, helping to alleviate this limitation.

Variety developers are required to submit a variety registration application package to the CFIA's VRO. The VRO requirements for registration for cereals are:

- i. The fee (\$875 for new national registration);
- ii. a completed application form which includes a trade mark declaration, a plant with novel trait (PNT) declaration (if applicable), a molecular PNT trait test protocol (if applicable) and in the case of AAFC varieties, sign off from the AAFC Office of Intellectual Property;
- iii. a letter of recommendation from the RC (Part I and Part II crops);
- iv. a copy of the data package used by the RC to reach its recommendation;
- v. a description of the variety (an objective description form or ODF);
- vi. the breeding history and pedigree information for the variety;
- vii. a 500g breeder seed reference seed sample; and
- viii. the written designation of the Canadian representative, the breeder, the owner, the variety maintainer, and the Canadian distributor for the variety.

Of the 340 wheat varieties currently registered in Canada, 56 are of U.S. origin and 26 are of European Union (EU) origin. Barley averages around 11 varieties registered per year, but in the past few years, it has dropped off to fewer than 10. In the past five years, seven U.S.-developed varieties have been registered in Canada.

In comparison, there has been an average of 24 varieties of canola, another Part I crop, registered each year over the past six. Of the 404 varieties recommended for registration to date, only 145 were eventually registered.

Number of new varieties registered in Canada, selected crops, by year

	2007	2008	2009	2010	2011	2012
Wheat	14	17	22	25	19	21
Barley	13	13	13	10	7	6
Canola	26	17	30	31	25	16

Source: CFIA Variety Registration Office