



PRELIMINARY PROPOSAL

SEED REGULATORY FRAMEWORK MODERNIZATION INCLUDING ADJUSTMENTS TO THE VARIETY REGISTRATION SYSTEM

February 20, 2006

Canadian Food Inspection Agency

The CFIA expects to complete consultations on this preliminary proposal by March 2006 and subject to the required approvals being received commence consultations on a final proposal in April 2006.

Canada

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1. INTRODUCTION

This proposal outlines initial measures designed to facilitate modernization of the seed regulatory framework as it relates to the introduction of new varieties, the importation of seed, the sale and advertising of seed for sale in Canada and the management of associated risks in the face of existing and emerging challenges. At the heart of this proposal is the perceived need for structures and supporting processes that will allow policy and regulatory change to occur in a timely manner and on an ongoing basis, albeit at different rates according to the specific conditions that prevail in various commodity sectors and regions of Canada.

The Canadian Food Inspection Agency (CFIA) has been working with stakeholder organizations, provincial governments and other federal government departments to develop a new seed sector consultative framework. It is anticipated that this new framework will support the enhanced analytical and consensus building capacity required to allow the seed regulatory system to respond more effectively to evolving sector needs. The formation of the National Forum on Seed (NFS), a broad based stakeholder initiative supported by government and designed to increase stakeholder participation and leadership in the regulatory change process, represents an important first step in the development of a new and stronger consultative framework.

Initial joint work by the CFIA and the NFS has focused on the development of a permanent consultative framework and on addressing issues related to the design and operation of the variety registration system, an important component of Canada's seed regulatory framework. The current proposal responds to and builds on this recent work by advocating the creation of a new seed program advisory and consultative framework as well as changes to the variety registration system. It is anticipated that if adopted, this proposal will strengthen the variety registration system and facilitate discussion, analysis and consensus building activities on options for addressing a range of important seed regulatory issues, including but not limited to variety registration.

1.1 Consultation Overview

Over the next 12 months the CFIA expects to:

- 1) confirm support for strengthening the consultative framework and establish any required new structures and processes;
- 2) confirm support for proposed adjustments to the variety registration system and make any required changes; and
- 3) identify additional priority areas for improvement of the seed regulatory framework and initiate discussion on and development of options.

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2. PROPOSAL ELEMENTS

2.1 Overview

There are three elements to this proposal: the Consultative Framework; a Tiered Variety Registration System and; Contract Registration. Within each element there are four components that respectively:

- 1) identify and assess problems and related issues;
- 2) summarize consultation feedback with respect to the identified problems and related issues;
- 3) assess options for addressing identified problems based on an evaluation of costs, benefits and general considerations for each option; and
- 4) further assess and confirm the best alternative.

2.2 Questions

To facilitate further refinement of this proposal it is requested that at a minimum you respond to each of the following questions for each of the three proposal elements: the Consultative Framework, a Tiered Variety Registration System, and Contract Registration.

- 1) Do you support or oppose this proposal, or parts thereof?
- 2) Where you disagree with this proposal, what is the nature and extent of your disagreement and do you have any suggested alternatives?
- 3) Are there any benefits or costs associated with the options being considered in this proposal that you believe have not been correctly identified?

Any other comments of a general or specific nature are welcome and encouraged.

Please refer to Appendix I for definitions of terms used throughout this discussion paper.

Please communicate your questions and responses to Sherrilee Bushell-Viau, Project Manger, Seed Regulatory Modernization Initiative (bushellviaus@inspection.gc.ca) or by facsimile at (613) 228-4552.

3. PROPOSAL ELEMENT #1 – CONSULTATIVE FRAMEWORK

3.1. Problem Identification & Analysis

The seed regulatory policy change framework does not have sufficient consultative capacity to allow policy, regulatory and program adjustments to take place in a timely and predictable manner. The absence of adequate consultative capacity: restricts the potential for differentiated regulatory approaches to crop kind specific issues; for raising awareness among regional, issue and crop specific stakeholder communities of the broader context in which seed regulatory policy is developed; and for facilitating the ongoing exchange of views and ideas required to ensure seed regulatory policy remains supportive of broader policy priorities and strategic direction.

3.2. Consultation Feedback

Feedback from consultations to date indicates support for an analysis based and consensus-driven permanent consultative process and supporting structures that facilitate more responsive and targeted crop kind specific management of the seed regulatory system. However, it is clear from the same feedback that the level of predictability, transparency and inclusiveness of any new consultation model is of critical importance to stakeholders.

Stakeholders have consistently expressed frustration with the length of regulatory and policy change processes and confirmed the need for a consultative and consensus building model that supports a more timely and responsive regulatory change process. Feedback has also highlighted the need for new consultative options for facilitating crop specific policy and regulatory solutions to problems where appropriate as well as for ensuring that crop specific policy development is not conducted in a vacuum.

Strong support has been expressed for the development of inclusive crop based consultative processes that encompass the complete crop kind value chain and that have the necessary expertise to objectively assess and build consensus on change options where required. While there is support for maintaining a national focus on issues, it is recognized that regional differences exist and may require the development of regionally based consultative processes and approaches in some instances.

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3.3. Analysis of Options

Two options are considered: the status quo and a new consultative model.

Option #1: The Status Quo

Currently the CFIA has an official Advisory Committee on Variety Registration (ACVR) that assesses options and provides recommendations on variety registration policy and related issues. This committee consists of eight members who represent the seed trade, seed growers, five recommending committees for major crops, and the Canadian Grain Commission. The CFIA also has 21 Recommending Committees that are officially recognized for the purpose of testing and assessing the merit of new varieties and recommending varieties that meet or exceed the minimum merit requirements. The membership and structure of these committees varies among the different crop kinds and regions.

There are currently no official advisory and consultative mechanisms in place to support general seed program management or the development of regulatory policy options to address ongoing and emerging issues outside the area of variety registration, despite the fact that the scope of seed regulatory activity of the CFIA extends well beyond questions of variety registration. To date, when it has been necessary to consult on issues, targeted ad hoc processes have been employed.

Benefits	For whom?
Issue specific and targeted ad hoc approach to consultation can, depending on the circumstances, be relatively quick and low cost.	All

Costs	For whom?
Issue specific and targeted ad hoc approach to consultation can, depending on the circumstances, be time consuming and expensive.	All
Issue specific and targeted ad hoc approach to consultation limits scope for amortizing investment in ad hoc consultative infrastructure across a wider range of often interrelated issues – opportunity cost.	All
Issue specific and targeted ad hoc approach to consultation limits opportunity for coordinated crop specific and general seed regulatory policy development – opportunity cost.	All
Issue specific and targeted ad hoc approach to consultation limits Seed Program capacity to develop regulatory responses to emerging challenges/risks - opportunity cost.	All

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Option #2: Strengthened Consultative Framework

A new, strengthened consultative framework would be established to facilitate analysis and consensus building on all aspects of the seed program and to support the development of regulatory and non-regulatory options to address seed sector issues. The new consultative framework would have three components: the National Forum on Seed (NFS); a new Seed Program Advisory Committee (SPAC); and Crop Specific Consultative Groups (CSCG's) designed to work together in a coordinated manner. The current Advisory Committee on Variety Registration (ACVR) and Recommending Committees would continue to support the Variety Registration Office.

The NFS's current role as a focal point for stakeholder to stakeholder discussion on seed sector issues and the identification of seed regulatory policy development priorities would be explicitly recognized. The SPAC would be established as an expert advisory body to support the ongoing operation of CFIA's Seed Program. CSCGs would be established to facilitate timely and responsive regulatory policy change at a crop specific level. The CFIA would officially recognize stakeholder led Crop Specific Consultative Groups that would include representation from the complete value chain for given crop kinds.

Benefits	For whom?
Improved seed program management based on strengthened advisory capacity.	All
Increased timeliness of regulatory policy change in response to strengthened consultative and related consensus building capacity	All
Increased transparency and predictability of the regulatory policy change process due to inclusiveness and openness of consultative framework.	All
Increased stakeholder awareness of seed regulatory policy issues and involvement in the identification of options for addressing them.	All
Increased capacity to identify issues and tailor regulatory responses on a crop / region specific basis.	All
Increased involvement of other government departments and other levels of government in seed regulatory policy development.	All
Increased capacity of the seed program and regulatory policy framework to respond to existing / emerging risk.	All
Fewer ad hoc consultative initiatives and their associated costs.	All
Costs	For whom?
Start-up costs to establish the SPAC and CSCGs.	All
Operational costs for the NFS, the SPAC and CSCGs.	All

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3.4. Implementing the Best Alternative (Proposal)

Based on an assessment of the options and consultation feedback, option #2 is the best alternative. This option addresses the issues identified in Section 3.1 by providing a permanent, inclusive mechanism for consultation on current and future crop specific issues as well as general seed regulatory policy issues. The highlights of Option #2 are summarized as follows:

A new, strengthened consultative framework would be established to facilitate analysis and consensus building on all aspects of the seed program and to support the development of regulatory and non-regulatory options to address seed sector issues.

The new consultative framework would have three components: the National Forum on Seed (NFS); a new Seed Program Advisory Committee (SPAC); and Crop Specific Consultative Groups (CSCGs) designed to work together in a coordinated manner.

The current Advisory Committee on Variety Registration (ACVR) and Recommending Committees would continue to support the Variety Registration Office.

Seed Program Advisory Committee

Mandate

The Seed Program Advisory Committee (SPAC) would provide ongoing expert advice to CFIA on the operation and development of the Seed Program. The SPAC's focus on operational performance would complement the role of the NFS as the focal point for the identification of seed regulatory policy and development priorities and the role of the CSCGs as the focal point for crop kind specific issues.

Composition

The membership of the SPAC would be drawn from the regulated parties, the scientific community, other federal government departments, provincial government departments, other regulatory agencies, the general stakeholder community and elsewhere as required by CFIA to ensure that the seed program has access to the type of expertise that it requires to operate effectively.

Crop Specific Consultative Groups

Mandate

Crop Specific Consultative Groups (CSCGs) would be officially recognized by the CFIA. Their primary function would be to provide advice on crop kind specific

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aspects of seed regulatory policy and would work with the CFIA, other Federal Government Departments, Provincial Governments and the National Forum on Seed to identify and develop seed regulatory policy priorities and to ensure a coherent national seed regulatory policy framework.

It is intended that CSCGs play a lead role in facilitating change through the analysis of issues and the development of regulatory policy options and recommendations to address crop kind specific circumstances and needs. It is anticipated that CSCGs would both initiate seed regulatory policy proposals for consideration of the CFIA, NFS and/or other authorities and respond to proposals submitted for their consideration and input. An illustrative list of the types of issues that CSCGs might choose or be asked to address is contained in Appendix IV.

Inclusiveness

CSCGs membership would be broad based and include, at a minimum, the components of each crop value chain as outlined below:

- primary producers
- developers
- seed growers
- seed trade
- federal/provincial policy, research and regulatory bodies
- marketers & handlers
- processors & end users

CSCGs would also provide opportunity for broader public participation where issues warrant it. Where possible CSCGs would draw on existing crop kind based committees and organizations either in whole or in part. CSCGs would have regionally balanced representation according to the location of crop development, production, processing and handling activities.

Meeting and Reporting

To ensure inclusiveness and transparency, CSCG meetings would be conducted in an open forum that would allow for participation of non-member interested parties.

CSCGs would facilitate the development of recommendations regarding regulatory policy development options for communication to the CFIA, other government departments and agencies or the National Forum on Seed (NFS), as appropriate.

Once established CSCGs would meet regularly and on an as needed basis.

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Establishment and Recognition Process

The CFIA would work with the NFS and crop specific stakeholder communities of interest to facilitate the establishment of CSCGs. The NFS would assist the CFIA in the initial development of governance procedures, terms of reference, membership criteria and operational guideline for CSCGs and thereafter on refinements as required.

Once in operation, a CSCG would receive guidance from and be monitored by the CFIA in consultation with other authorities and the NFS as required, to ensure adherence to operational guidelines and optimal information exchange on issues of potential interest.

The CFIA would recognize each CSCG as the official consultative mechanism for its respective crop specific seed regulatory and policy issues. Recommendations to the CFIA from the CSCGs would form the basis for either crop specific or general seed regulatory policy development initiatives as appropriate.

Operational Guidelines

CSCG activities would be guided by the following guiding principles of effective consultations:

- inclusiveness
- transparency
- accountability
- openness
- honesty and forthrightness

4. PROPOSAL ELEMENT #2 - TIERED VARIETY REGISTRATION SYSTEM

4.1. Problem Identification & Analysis

There have been concerns expressed that the current variety registration system lacks the flexibility to address the specific needs of individual crop kinds and to allow timely registration of new varieties. There have also been concerns expressed regarding the timeliness of amendments to rules, procedures, and regulations that are required for the variety registration system to be responsive to change. Regulators have expressed concern that the information currently being collected on varieties of certain crop types is insufficient to sustain the effective operation of, and maintain confidence in, the seed certification and regulatory system for certain crop types in the longer term.

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4.2. Consultation Feedback

The variety registration system has been under review since 1998. General consensus on the direction of required change has been achieved in a number of important areas and is reflected in the CFIA's September 5, 2002 proposal (<http://www.inspection.gc.ca/english/plaveg/variet/revetu/revisdprope.shtml>) as well as in the reports of three subsequent NFS sponsored workshops (www.nationalforumonseed.com).

While stakeholder views differed with respect to the degree and, in some instances, the nature of change outlined in the 2002 proposals, there appears to be general support for the concept of a tiered variety registration system that is sufficiently flexible to address the individual needs of crop kinds in a timely and predictable manner.

Where there is support for the reduction or elimination of merit requirements as a component of the variety registration system for certain crop types, it is often qualified by an expression of the need to maintain prior assessment requirements for the provision of varietal performance information as part of the registration process, so that growers are able to make informed decisions.

Feedback from consultations to date has indicated a general frustration with the lack of flexibility within the current variety registration system to accommodate crop specific needs in the face of continually evolving sector needs. The procedural and related administrative burden associated with the current variety registration system is in turn perceived as an impediment to innovation. At the same time, regulatory authorities have raised concerns regarding the certification of seed of varieties of crops exempt from registration.

Consultations identified support for a two tiered approach to variety registration, with one tier requiring the collection of performance data prior to registration which may or may not be used to assess the merit of new varieties and another tier which would not require any performance testing prior to registration. The consultations also suggested that health and safety requirements should more clearly apply to all crops regardless of their placement within a tiered system.

Consultations recommended that the crop placement change process should include a grace period for crops moving from exemption to registration to allow sufficient time to register previously exempted varieties prior to taking any regulatory compliance action. It was also suggested that, at least for the initial phase of implementation of a revised registration system, registration should not be required for use of official CFIA tags for currently exempt crops as long as an acceptable alternative was in place.

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4.3. Analysis of Options

Three options are considered: the status quo, a new tiered variety registration system, and no registration system.

Option #1: The Status Quo (Merit based registration)

All varieties of crops currently subject to registration would continue to require a mandatory assessment of merit prior to recommendation for registration from a recognized recommending committee. For a list of crops currently subject to registration please refer to Appendix II. In addition to, the merit assessment, an assessment for distinctness, uniformity and stability (DUS) is completed at the time of registration. Recommending committees would continue to be recognized to formulate procedures, oversee testing, and recommend varieties for registration. Crops currently exempt from registration would remain exempt.

Benefits	For whom?
Prohibits commercialization of inferior varieties with respect to agronomic, quality and/or disease characteristics for the majority of agricultural crops	Producers, Seed Growers, Processors, End-users, Handlers, Government
Facilitates and encourages the breeding and commercialization of superior varieties in some instances for crops subject to registration	All
Maintains recommending committees to facilitate information exchange among crop stakeholder groups for crops subject to registration	Developers, Trade, Seed Growers, Governments, Processors, End-users
Ensures availability of objective information regarding performance to facilitate informed variety purchasing decisions for crops subject to registration	Producers, Seed Growers, Processors, End-users
Satisfies international requirements (OECD Seed Schemes) for crops subject to registration and facilitates international trade	Trade, Seed Growers
Supports regulatory oversight of plants with novel traits (PNTs) for crops that are subject to variety registration	All
Provides sufficient regulatory oversight to quickly respond to domestic or international market issues for crops subject to registration	All

Costs	For whom?
Lacks flexibility within the registration system to address specific needs of crop sectors	All
Regulatory burden due to merit basis of registration for some crops	Developers, Trade

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Loss of market opportunities to introduce innovative new varieties due to merit requirements of crops subject to registration	All
Costs and fees for registration trials including collection and evaluation of data for crops subject to registration	Developers, Trade, Governments
Time and travel required to participate in recommending committee meetings	Developers, Trade, Seed Growers, Producers, Processors, End-users, Governments
Registration fees for crops subject to registration	Developers, Trade
Delay in the time required for new varieties to reach the Canadian marketplace due to time required to complete variety registration trials and apply for registration for crops subject to registration	All
Reduced ability to provide regulatory response to domestic or international market issues in crops exempt from registration	All

Option #2: Tiered variety registration system

Amend the variety registration system to include two tiers of registration. Tier I would require a DUS assessment at the time of registration as well as a mandatory prior assessment of crop varieties which may or may not include merit. Sub-categories within Tier I would include requirements ranging from full mandatory prior assessment including merit evaluation of agronomic, disease and quality traits to prior assessment of only one of agronomic, disease, and/or quality traits without merit requirements. Tier II would list crop varieties without requirement for any prior assessment. Crops not subject to either tier of registration would be exempt from registration but would continue to be subject to all other Seed Regulatory requirements as is currently the case.

Proposals for changes in crop placement between or within tiers would be considered by CFIA once a case for change was made and the requisite level of consensus achieved on a crop specific basis through Crop Specific Consultative Groups. In the absence of a case for change and the requisite level of consensus, the current registration requirements for a crop kind would remain the same. (Refer to Appendix II for a list of crops currently subject to merit based registration).

Recommending committees would continue to be recognized for assessing and recommending varieties for Tier I crops and could potentially continue in some form for crops in Tier II on a case by case basis.

Benefits	For whom?
Provides flexibility to address current and future needs of individual agricultural crops	All

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Reduces regulatory compliance burden for some crops by introducing options for reducing or eliminating merit requirements	Developers, Trade
Continues to provide a minimum level of protection from inferior varieties for Tier I crops by either preventing their commercialization or ensuring availability of objective information regarding their performance characteristics Continues to encourage the breeding and commercialization of superior varieties in some instances for Tier I crops	Producers, Seed Growers, Processors, End-users, Handlers All
Provides more options for registration while still maintaining the benefits of the registration system, such as sufficient regulatory oversight to respond to market issues	All
Continues to ensure compliance with health and safety requirements for Tier I and II crops	All
Continues to provide options to require a minimum level of testing and merit assessment for some crops	Producers, Seed Growers, Processors, End-users, Handlers
Provides flexibility to reduce impediments to commercialization of new innovative varieties for some crops	All
Satisfies international requirements (OECD Seed Schemes) for Tier I and II crops	Trade, Seed Growers
Reduces delay in new varieties reaching the market due to flexibility to reduce merit assessment requirements	All
Does not impose any new costs since the default placement of crops is the current level of regulatory oversight	All
Continues to include potential to restrict registration to specific regions of Canada to mitigate possible adverse effects in other regions for crops in both Tiers of registration	All

Costs	For whom?
Continued costs associated with maintaining recommending committees for Tier I crops with respect to time and travel costs for meetings	Developers, Trade, Seed Growers, Producers, Processors, End-users, Governments
Costs and fees would remain for registration trials including maintenance and collection and evaluation of data for Tier I crops (however provides flexibility to reduce testing requirements)	Developers, Trade, Governments
Maintains delay in the time required for new varieties to reach the Canadian marketplace for Tier I crops	All

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Registration fees would continue to be required for Tier I and II crops	Developers, Trade
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Option #3: No registration system

Complete de-regulation of the registration system and the complete removal of merit and DUS assessment requirements prior to sale, advertisement or import into Canada. All crops by definition would become exempt from variety registration as it currently exists. Recommending committees would no longer be officially recognized.

Benefits	For whom?
Reduced costs due to dissolution of the Variety Registration Office and its committee support structure.	Government, General Public
Elimination of fees and costs associated with testing new varieties for merit and registration	Developers, Trade, Government
Reduced regulatory burden and potential increase in the number and type of new varieties available in the marketplace with attendant downstream impacts.	All

Costs	For whom?
Would require changes to the current grain marketing system for crop types where Kernel Visual Distinguishable (KVD) is a core component.	All
Would result in reduced availability of independently generated performance information on new varieties and resultant risk transfer to seed growers and purchasers.	Producers, Seed Growers, Processors, End-users, Handlers
Would require development of an alternative mechanism to satisfy OECD Seed Schemes based CFIA certification for varietal Distinctness, Uniformity and Stability (DUS) to avoid seed trade disruption. Potential loss of consumer acceptance of and confidence in seed certification system stemming from reduced public oversight and government enforcement and compliance capacity.	Trade, Seed Growers, Developers All
Would require development of alternative regulatory compliance mechanisms to support regulation of Plants with Novel Traits (PNTs).	All
Potential increase in enforcement, compliance, and monitoring activities in support of seed regulatory framework.	Government, General Public
Loss of regulatory capacity to monitor, trace and remove from the marketplace seed of a variety with potential long term negative impacts on foreign market access.	All

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4.4. Implementing the Best Alternative (Proposal)

Based on the analysis of options and feedback from previous consultations, option #2, the tiered registration system, best addresses the issues identified in Section 4.1. The tiered system may provide more flexibility to address current and future needs of some crop types and at the same time would reduce administrative and regulatory burden that may pose an impediment to innovation in some crop types. Both tiers in this option would satisfy Canada's international obligations, and would ensure sufficient regulatory oversight to facilitate the operation of and maintain confidence in the seed certification system, without introducing any significant new costs to the registration system and potentially reducing some. The highlights of Option #2 are summarized as follows:

Amend the variety registration system to include two tiers of registration: mandatory assessment and listing. The proposed tiers including the type of assessment and application requirements for each tier are described below.

Maintain the current level of registration (Tier I with merit or exempt status) for each crop kind until the case for change has been established and the requisite consensus has been achieved within the appropriate stakeholder community of interest. Further description of the crop placement change process is provided below.

Provide for a period of grace to apply before new regulatory compliance requirements take effect, when a change in crop placement results in a move to a higher level of registration (i.e. from Exempt to Tier II, Tier II to Tier I, or within Tier I). Further description of the grace period process and procedure is provided below.

TIER I: Mandatory Assessment

Mandatory prior assessment of crop varieties would be required for crop kinds in Tier I. The assessment may or may not include merit requirements. In addition, at the time of registration, crop varieties in this Tier would be assessed for distinctness, uniformity and stability (DUS) as well as eligibility for seed certification through the provision of a complete application, description and reference sample.

This tier may be further divided into subcategories to specify the type of assessment (agronomic, disease and/or quality) required for each crop and whether merit is required. Please refer to Appendix III for a complete list of all 26 possible sub-categories that may be included in Tier I.

Recommending committees would continue to be officially recognized for crops in this Tier to recommend varieties that have met the applicable requirements. The

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committees would also be responsible for ensuring the availability of information generated on the performance of varieties.

Interim registration is designed to provide flexibility within the merit component of registration to provide temporary registration for emergency situations or marketing evaluations while the mandatory assessment for registration is being completed. As such, interim registrations would only be applicable to this Tier of registration.

TIER II: Listing

Crop varieties in this tier would be assessed for distinctness, uniformity and stability (DUS) as well as eligibility for seed certification through the provision of a complete application, description and reference sample at the time of registration. Some form of crop specific committee structure may be retained for this tier in some instances.

Application Requirements:

The proposed minimum application requirements for registration of varieties of crop kinds in Tier I are as follows:

- A valid recommendation from a recognized registration committee
(Note: when merit is not required, the committee is simply recommending a variety for registration because minimum assessment requirements have been completed)
- Data from registration trials to demonstrate merit (if applicable)
- Data to supplement additional claims of variety performance (if applicable)
- Plus requirements for Tier II listing (see below)

The proposed minimum application requirements for registration of varieties of crop kinds in Tier II are as follows:

- Acceptable variety name and list of synonyms in other countries
- Scientific and common name of the crop kind
- Statement of whether applied or granted Plant Breeders' Rights
- Pedigree, origin and breeding history of the variety
- Statement of whether the variety contains novel traits
- Detailed description of the variety
- Acceptable legal reference sample
- Name and address of the Canadian representative, breeder and distributor
- Letter of authorization from the breeder to apply for registration and/or maintain seed stocks (if applicable)

Additional Application Requirements:

Additional health and safety requirements, such as a maximum total glycoalkaloid (TGA) level in potatoes, will continue to apply to crop species subject to registration regardless of crop tier placement. Any new health and safety requirements for

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variety registration will be established in consultation with other government departments and stakeholders as required.

For plants with novel traits (PNTs), affidavits indicating which specific events the variety contains, detection methods and data to support specific trait claims (i.e. herbicide tolerance) will continue to be required regardless of crop tier placement. If a detection method has previously been submitted to the Variety Registration Office or Plant Biosafety Office, a reference number may be sufficient,

For hybrid and composite varieties, a hybridity testing method, and a description and sample of each of the parental lines will continue to be required for varieties entering the Canadian seed certification system depending on the crop kind.

Process for Crop Tier Placement Changes

The current level of registration (Tier I with merit or exemption) would be the default or starting placement for crops within a new tiered registration system. Once a revised registration framework is in place, changes to crop placement would be considered on a crop specific basis. To consider changes to the tier placement of a crop a case for change must be established and the requisite degree of consensus achieved within the complete crop value-chain through a Crop Specific Consultative Group.

In order to provide sufficient time for new administrative procedures to be completed, changes in crop placement within a tiered registration system would normally occur no sooner than one year after a crop placement amendment.

Grace Period

When there is the requisite consensus to change to a higher tier of registration, for example, from exemption to listing registration (Tier II) or from listing (Tier II) to mandatory assessment registration (Tier I) or within Tier I, an agreed upon grace period will be applied. The duration of the grace period will be recommended by the appropriate Crop Specific Consultative Process and should provide sufficient time for applicants to apply for registration at the new tier prior to any new regulatory compliance requirements taking effect.

For crops moving from exempt to listing registration, the grace period should provide sufficient time to apply for/confirm the listing status of any previously unregistered varieties. For crops moving from listing to mandatory assessment registration or within Tier I, the grace period should provide sufficient time to enter new varieties into the appropriate trials.

5. PROPOSAL ELEMENT #3 - CONTRACT REGISTRATION

5.1. Problem Identification & Analysis

The current contract registration system restricts eligibility to a limited category of low volume high risk varieties that have the potential to cause adverse market impacts if not segregated from other registered varieties in the market place, but that otherwise have significant market potential. There is increasing pressure to accommodate within the variety registration system higher volume lower risk innovative and value added varieties that do not meet current merit requirements for registration, but that also have significant market potential. This would require either a relaxation or elimination of current merit requirements for entire crop kinds or a new, more robust contract registration model geared to high volume production. Any new model would need to be based on an audited third party oversight model that included a risk based assessment and approval process and increased CFIA regulatory capacity to take corrective or preventative actions for non-compliance with the terms and conditions of a contract registration.

5.2. Consultation Feedback

There has been strong support for changes to the variety registration system that would allow for increased flexibility to accommodate higher volume lower risk innovative and value added varieties that do not meet current merit requirements for registration, but that have significant market potential. There has been support for the contract registration program to include a risk-based approach for determining the eligibility of varieties for contract registration, for mitigating potential adverse effects, and for establishing the degree of monitoring necessary.

Feedback from consultations has demonstrated general support for including provision for terms and conditions of contract registration to be set on a case-by-case basis according to the level of risk and support for increased authority for taking corrective actions on noncompliant contract registration. There is also consensus that any additional costs due to the introduction of more flexibility for monitoring the contract registration program should be the responsibility of the registrant.

5.3. Analysis of Options

Two options are considered: the status quo and a risk-based contract registration system.

Option #1: The Status Quo

Currently only niche market varieties that pose significant risks if commingled with traditional varieties are eligible for contract registration. Other potentially lower risk and value added varieties are currently ineligible for contract registration.

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Regulations stipulate the terms and conditions that may be applied to contract registration are required isolation distances in field production. There is minimal authority to enforce regulatory corrective and preventative actions to resolve or mitigate potential risks to traditional varieties.

Benefits	For whom?
Government would continue to assume primary role and costs in compliance monitoring of contract registered varieties	Trade, Developers, End Users
Introduction of some added valued varieties that can be controlled through existing risk management framework.	Developers, Trade, Seed Growers, Producers, Processors, End-users

Costs	For whom?
Potential loss of markets for innovative and value-added varieties that may pose adverse effects if commingled with traditional varieties – opportunity cost.	All
Monitoring compliance with terms and conditions of contract registered varieties	Government
Potential cost due to leakage of contract registered varieties into traditional commodity due to limited CFIA compliance and enforcement capabilities.	All

Option #2: Risk-based Contract Registration System

Amend the contract registration program to increase CFIA’s flexibility to set terms and conditions of contract registration on a case-by-case basis. This would allow increased flexibility for contract registration to be applied to lower risk innovative or value added varieties that may have an adverse effect if commingled with traditional varieties.

CFIA regulatory authority would be strengthened to provide for corrective and preventative actions to be taken to resolve or mitigate potential risks of leakage from contract registration based segregation systems. This would include provision for the refusal of applications for and suspension or cancellation of contract registration when unacceptable risks or problems are identified. Additional authorities would be provided to CFIA to provide for more comprehensive ongoing review and oversight of quality management systems.

Based more solidly on the “beneficiary pays” principle, registrants of contract registered varieties in a new contract registration system would be required to undergo regular third party audits of their quality management system. The nature and the extent of audit requirements would vary with the degree of assessed risk associated with the contract variety.

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Benefits	For whom?
Increased market access for innovative and value-added varieties	All
Increased compliance tools to resolve potential issues and mitigate risks	All

Costs	For whom?
Increased costs to registrants for regular third party audits of their closed-loop quality management system	Developer, Trade
Continued potential costs due to leakage of contract registered varieties	All

5.4. Implementing the Best Alternative (Proposal)

Based on the feedback from preliminary consultations and an analysis of options, option #2, to introduce increased flexibility and improved enforcement in the contract registration program is the best alternative. This option addresses the identified issues by providing increased flexibility in the registration system to accommodate varieties that would not otherwise be eligible for registration without the government assuming significant additional monitoring costs, and strengthens the regulatory enforcement and compliance measures for corrective or preventative actions for contract registered varieties. The highlights of Option #2 are summarized as follows:

Amend the contract registration system to allow the terms and conditions of contract registration to be set on a case-by-case basis according to potential for adverse effects. Amend the *Seed Regulations* to include increased provisions for refusal, suspension, cancellation and review of contract registrations. Require contract registrants to undergo regular third party audits of their quality management systems. Further description of the proposed amendments is provided below.

Terms & Conditions

The terms and conditions of contract registration including reproductive isolation requirements, isolation distances and post-harvest land-use restrictions would be stipulated on a case-by-case basis for each variety according to guiding principles applied on the basis of the risks involved. Risk-based principles for determining terms and conditions of contract registration would be developed through consultation with appropriate experts on a general and crop specific basis.

The terms and conditions of contract registration, including audit requirements, would be stipulated for each variety by CFIA in consultation with other authorities as required. As in the current contract registration system, a mechanism for appealing the decision of the Registrar with respect to stipulated terms and conditions of registration would be available.

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Increased Compliance & Enforcement

The *Seeds Regulations* would be amended to include:

- Provision to suspend or cancel registration when the quality management systems (QMS) and/or the terms and conditions of the contract registration are not maintained.
- Provision to refuse applications for contract registration from applicants with a history of non-compliance.
- Provision to review the QMS of a contract registered variety if the registrant or distributor changes.

Regular Audits

The contract registration program would require the registrant to include as part of their QMS regular audits by a third party to monitor compliance with the terms and conditions of registration. Third party audits would be conducted by an accredited conformity verification body. The degree of detail and frequency of the audit would be dependant upon the level of risk associated with the variety and past history of compliance. The results of audits would be required to be retained and reported to the CFIA.

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Appendix I: Definitions

Crop - a species expressly cultivated for use. For variety registration purposes, crop species are limited to agricultural crops.

Conformity Verification Body - a third party impartial body having the organization, staffing, competence and integrity to perform conformity verification services to specified criteria. Verification services are understood to include such functions as assessing, evaluating, recommending for acceptance and subsequent audit of seed establishments. A conformity verification body may perform one or more of these tasks.

DUS - refers to the distinctness, uniformity and stability of a variety which is assessed for variety registration. DUS is also required for Plant Breeders' Rights assessments however for variety registration purposes the assessment process of DUS is different. For example, for variety registration distinctness is assessed based on a comparison of the pedigree of a candidate variety with all previously registered varieties (for varieties with similar pedigrees, the descriptions are compared) while PBR assesses distinctness through side by side comparison trials of characteristics. Distinctness for variety registration is assessed to establish that the variety has not been previously registered under another name.

Merit - equal to or superior to reference check varieties for agronomic, disease and/or quality characteristics.

Plants with Novel Traits (PNT) - a plant variety possessing a characteristic that is intentionally selected or created through a specific genetic change and is either not previously associated with a distinct and stable population of the plant species in Canada or expressed outside the normal range of a similar existing characteristic in the plant species.

Requisite consensus - the level of consensus required for specific regulatory and/or policy changes to move forward is dependent upon the type of change, degree of need for change, and its relative impact. For example, health and safety related regulation or policy changes may require less consensus because of the need to protect Canadians.

Variety - a variety is considered to be a cultivar, and denotes an assemblage of cultivated plants, including hybrids constituted by controlled cross-pollination, that are distinguished by common morphological, physiological, cytological, chemical or other characteristics; and retain their distinguishing characteristics when reproduced.

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Appendix II: Crops Currently Subject to Merit Based Registration

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

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Appendix III: Chart of All Possible Sub-categories for Assessment in Tier I

Possible Sub-categories	Agronomic Assessment		Disease Assessment		Quality Assessment	
	Merit	No Merit	Merit	No Merit	Merit	No Merit
1	✓		✓		✓	
2	✓		✓			✓
3	✓		✓			
4	✓			✓	✓	
5	✓			✓		✓
6	✓			✓		
7	✓				✓	
8	✓					✓
9	✓					
10		✓	✓		✓	
11		✓	✓			✓
12		✓	✓			
13		✓		✓	✓	
14		✓		✓		✓
15		✓		✓		
16		✓			✓	
17		✓				✓
18		✓				
19			✓		✓	
20			✓			✓
21			✓			
22				✓	✓	
23				✓		✓
24				✓		
25					✓	
26						✓

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Appendix IV: Illustrative List of Issues for Crop Specific Consultative Group consideration

Changes to crop tier placement

Grading standards (examples: addition of crop kinds to Schedule I, changes to germination and/or purity standards)

Seed testing requirements

Plants with novel traits

Labelling requirements (examples: truth in labelling vs. grade name)

Contract registration (examples: risk management requirements)

Seed certification requirements

Market impact of novel products

Importation for own use

Variety names on all seed sold

Varietal mixtures

Specialty seed labelling