



**VARIETY REGISTRATION PRE-PROPOSAL
Discussion Paper**

October 25, 2005

Table of Contents

1. Introduction	1
1.1. Consultation Overview	1
2. Proposal Elements	2
2.1. Overview	2
2.2. Questions	2
3. Tiered Registration System	2
3.1. Problem Identification & Analysis	2
3.2. Consultation Feedback	3
3.3. Analysis of Options	3
3.4. Implementing the Best Alternative	7
4. Consultative Process for Crop Movement	9
4.1. Problem Identification & Analysis	9
4.2. Consultation Feedback	9
4.3. Analysis of Options	9
4.4. Implementing the Best Alternative	12
5. Contract Registration	13
5.1. Problem Identification & Analysis	13
5.2. Consultation Feedback	14
5.3. Analysis of Options	14
5.4. Implementing the Best Alternative	15
Appendix: Chart of All Possible Sub-Categories for Assessment in Tier 1 ..	17

Variety Registration Pre-Proposal Discussion Paper

1. **INTRODUCTION**

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 Canadian Food Inspection Agency's (CFIA) September 5, 2002 proposals (<http://www.inspection.gc.ca/english/plaveg/variet/revisdprope.shtml>) as well as the outcomes of three subsequent National Forum on Seed sponsored workshops.

However, stakeholder views continue to differ with respect to the degree and in some instances the nature of change outlined in these proposals. As a result, CFIA is currently developing a proposal that will allow regulatory reform to occur on an ongoing basis, albeit at different rates according to the specific conditions that prevail in various commodity sectors. This will require a modified regulatory and policy change framework that can be adjusted in a more timely, transparent and predictable manner than is presently the case.

Over the past three years, the CFIA has been working with a number of stakeholder groups to develop consultative options to facilitate the operation of such a framework, while at the same time attempting to resolve differences on substantive issues stemming from the September 5, 2002 Variety Registration Review proposal. Once in place, the new framework should allow timely implementation of the proposed changes to the Variety Registration system. Specific proposals for change will be developed and implemented where required at different rates according to the conditions prevailing in the respective commodity sectors.

There is currently a high degree of consensus around the need for change, including an increased flexibility to manage the Variety Registration System. Modernization of the Variety Registration Policy, Regulations, and Procedures remains the first priority. Once the proposed framework is in place for the system as a whole, crop kind specific changes will be considered when the case for change has been established and the requisite degree of consensus is achieved.

1.1 **Consultation Overview**

During the next 12 months the CFIA will be consulting widely and engaging stakeholders on the substance of the proposed changes outlined in this Discussion Paper. The intent of these consultations is to:

- 1) Strengthen the consultative framework by March 2006.
- 2) Introduce and implement proposed changes to the Variety Registration system will take place on or before March 2007.
- 3) Review and identify additional priority areas for improvement within the seed regulatory system on an ongoing basis.

The CFIA is committed to concluding the pre-consultations on proposed changes to the Variety Registration System on or before March 2006.

Variety Registration Pre-Proposal Discussion Paper

2. PROPOSAL ELEMENTS

2.1 Overview

There are three proposal elements: Tiered Registration System, Consultative Process for Crop Movement, and Contract Registration. For each element there are four components that respectively:

- 1) Identify and describe current system issues,
- 2) Summarize the consultation feedback to date with respect to the element and related issues,
- 3) Assess options based on benefit cost criteria that focus on impacts on the general public, producers, developers, seed growers, seed trade, marketers, handlers, processors, end users, regulators and more general considerations for each option, and
- 4) Identify a 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: Tiered Registration System, Consultative Process for Crop Movement and Contract Registration. Other comments of a more general or specific nature are welcome and encouraged.

- 1) Please confirm your support or opposition to the proposal, or parts thereof.
- 2) Where you disagree with the proposed option, please identify the nature and extent of disagreement and any suggested alternatives.
- 3) Please identify any general or specific benefits or costs associated with the listed options that have not been documented to date.

3. PROPOSAL ELEMENT #1 - TIERED REGISTRATION SYSTEM

3.1. Problem Identification & Analysis

There are concerns in some quarters that the current variety registration system lacks the flexibility to address the specific needs of individual crop kinds and to allow timely amendments to rules, procedures, and regulations that are required for the system to be sufficiently responsive to changing market conditions, changes within crop value chains, and changes within the seed sector generally. There are also concerns as to whether sufficient information is being collected on varieties of

Variety Registration Pre-Proposal Discussion Paper

some crop types to facilitate the operation of and maintain confidence in the seed certification and regulatory system in light of the challenges it may face.

3.2. Consultation Feedback

Consultations have demonstrated general support for the concept of a tiered registration system that is sufficiently flexible to address the individual needs of crop kinds. Feedback has also highlighted the need for timely changes within the variety registration system. Many participants cautioned that with the removal of merit requirements, there is still a need to ensure availability of basic objective information regarding the performance of varieties at the time of registration to allow growers to make informed decisions. Consultation participants have indicated that changes to the registration system should take into consideration the future needs of crops as well as current needs.

Feedback from consultations to date has indicated a general frustration with the ability of the registration system to address current and future general and crop specific needs for timely and responsive adjustment in the face of changing circumstances. Consultations have also identified concerns with the impact of the current system on innovation as a result of administrative and/or regulatory burden. Regulators have raised some concerns with the ability of the current system to generate all the information necessary for regulatory purposes, particularly for crops exempt from registration

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

3.3. Analysis of Options

A description and analysis of a series of options to address the problems identified in Section 3.1 are listed below. These options include maintaining the status quo of a merit based registration system, a tiered registration system, and the complete removal of the variety registration system.

Option #1: Merit based registration

This option would result in no changes to the current system. All varieties of crops currently subject to registration would continue to require a mandatory prior merit assessment and recommendation for registration from a recognized recommending committee. Recommending committees would continue to be recognized to formulate procedures, oversee testing, and recommend varieties for registration. Those crops which are currently exempt would remain exempt.

Benefits	For whom?
-----------------	------------------

Variety Registration Pre-Proposal Discussion Paper

Prohibits commercialization of inferior varieties with respect to agronomic, quality and/or disease characteristics for the majority of agricultural crops	Producers, Growers, Processors, End-users, Handlers
Encourages the breeding and commercialization of superior varieties for crops subject to registration	All
Maintains recommending committees to facilitate information exchange among stakeholders for crops subject to registration	Developers, Trade, Growers, Governments, Processors, End-users
Ensures availability of objective information regarding performance to facilitate informed variety 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, Growers
Supports regulatory oversight of 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 of merit basis of registration for some crops	Developers, Trade
Loss of market opportunities due to impediment to introduction of innovative new varieties	All
Fees and costs for maintaining and evaluating variety registration trials	Developers, Trade, Governments
Time and travel required to participate in recommending committee meetings	Developers, Trade, 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	All
Reduced ability to provide regulatory response to domestic or international market issues in crops exempt from registration	All

Option #2: Tiered registration system

This option would result in an amendment of the registration system to include two tiers of registration. Tier 1 would require mandatory prior assessment

Variety Registration Pre-Proposal Discussion Paper

which may or may not include merit requirements. Sub-categories within Tier 1 would include requirements ranging from full mandatory prior assessment including merit evaluation of agronomic, disease and quality traits to prior assessment of agronomic, disease, and/or quality traits without merit requirements. Tier 2 would list crop varieties without any prior assessment.

Proposals for the movement of crop types into any tiers or within would move forward only after the case for change was made and the requisite level of consensus achieved on a crop specific basis. In the absence of consensus, the merit requirements for a crop kind would not change.

Recommending committees would continue to be recognized for assessing and recommending varieties for Tier 1 crops and may continue in some form for Tier 2.

Benefits	For whom?
Provides flexibility to address current and future needs of individual agricultural crops	All
Reduces regulatory compliance burden for some crops including reduced merit requirements	Developers, Trade
Provides a minimum level of protection from inferior varieties for Tier 1 crops by either preventing their commercialization or ensuring availability of objective information regarding their performance characteristics	Producers, Growers, Processors, End-users, Handlers
Encourages the breeding and commercialization of superior varieties for crops subject to registration for some Tier 1 crops	All
Provides lighter options for registration while still maintaining the benefits of the registration system, such as sufficient regulatory oversight to respond to market issues	All
Ensures compliance with health and safety requirements for Tier 1 and 2 crops	All
Reduces impediments to commercialization of new innovative varieties for some crops	All
Satisfies international requirements (OECD Seed Schemes) for Tier 1 and 2 crops	Trade, Growers
Reduces delay in new varieties reaching the market due to reduced merit assessment requirements for some crops	All

Costs	For whom?
Costs associated with maintaining recommending committees for Tier 1 crops with respect to time and travel costs for meetings, and fees for maintenance and evaluation of registration trials (however this should be reduced depending on the sub -category within Tier 1)	Developers, Trade, Growers, Producers, Processors, End-users, Governments
Delay in the time required for new varieties to reach the Canadian marketplace for Tier 1 crops	All
Registration fees for Tier 1 and 2 crops	Developers, Trade

Variety Registration Pre-Proposal Discussion Paper

Option #3: No registration system

This option would result in a complete de-regulation of the registration system and the complete removal of merit and distinctness, uniformity and stability (DUS) assessment requirements prior to sale, advertisement or import into Canada. All crops by definition would become exempt from variety registration as we know it. Recommending committees would no longer be officially recognized.

Benefits	For whom?
Reduced costs due to dissolution of the Variety Registration Office	Government, General Public
Removal of fees and costs associated with testing new varieties for merit, and registering varieties	Developers, Trade, Government
Reduced regulatory burden for stakeholders resulting in reduced impediments to innovative new varieties due to less time required for new varieties to reach the marketplace	All

Costs	For whom?
Potential disruption in the grain marketing system in particular where KVD is an important system component	All
Potential reduced availability of objective information with respect to agronomic, disease, and/or quality characteristics	Producers, Growers, Processors, End-users, Handlers
Costs due to lack of protection from misrepresentation of varieties	Producers, End-Users, Processors
Potential disruption in international trade due to inability to satisfy international requirements under the OECD Seed Schemes	Trade, Growers
Costs associated with the creation of alternative systems to variety registration to facilitate certification and international trade	Trade, Growers, Developers
Potential loss of markets due to inferior varieties that do not meet quality standards	All
Potential loss of consumer acceptance and confidence of seed sector due to lack of government oversight to ensure compliance with health and safety standards	All
Potential negative impact on environment, feed and food system due to lack of mechanism to support regulatory oversight of PNTs	All
Increased costs in enforcement, compliance, and monitoring to maintain credible seed certification system	Government, General Public
Reduced regulatory control in dealing with domestic and international market disruptions	All

Variety Registration Pre-Proposal Discussion Paper

3.4. Implementing the Best Alternative (Proposal)

Based on the information in the analysis of options and feedback from previous consultations, option #2, the tiered registration system, is the option that best addresses the problems identified in Section 3.1. 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. The tiered option would satisfy Canada's international obligations if consistently applied, 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 possibly reducing some.

As such, the CFIA proposes to amend the registration system to include two Tiers of registration: Mandatory Assessment and Listing. The CFIA proposes to maintain the current level of registration (Tier 1 with merit) for all crops unless the case for change has been established and sufficient consensus has been achieved within the complete value-chain of a specific crop. The following describes the proposed Tiers including the type of assessment and application requirements for each tier.

TIER 1: Mandatory Assessment

Mandatory prior assessment of crop varieties will be required for crop kinds in Tier 1. The assessment may or may not include merit requirements. In addition, at the time of registration, crop varieties in this tier will be assessed for uniqueness, uniformity and stability 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 the Appendix for a complete list of possible Sub-categories that may be included in Tier 1.

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

Variety Registration Pre-Proposal Discussion Paper

situations while the assessment is being completed, As such, interim registrations will only be applicable to this Tier of registration.

TIER 2: Listing

Crop varieties in this tier will be assessed for unique ness , uniformity and stability 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.

Application Requirements:

The proposed minimum requirements for registration of varieties of crop kinds in Tier 1 are as follows:

- A valid recommendation from a recognized Registration Committee (Note: when merit is not required, the committee is simply recommending 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 2 listing (see below)

The minimum requirements for registration of varieties of crop kinds in Tier 2 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 Breeder's 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 Requirements:

Additional Health and Safety requirements, such as a maximum Total Glycoalkaloid (TGA) level in potatoes, will apply to crop species regardless of crop Tier placement. The CFIA will establish Health and Safety requirements in consultation with other government departments and stakeholders as required.

For plants with novel traits (PNTs), affidavits indicating that the variety contains the correct genetic makeup, detection methods and data to support novel claims (i.e. herbicide tolerance) will be required regardless of crop Tier placement.

Variety Registration Pre-Proposal Discussion Paper

For hybrid and composite varieties, a hybridity testing method, and a description and sample of each of the parental lines is required for varieties entering the Canadian seed certification system.

4. PROPOSAL ELEMENT #2 - CONSULTATIVE PROCESS FOR CROP MOVEMENT

4.1. Problem Identification & Analysis

As crop kinds change and evolve, the policy and regulatory framework needs to keep pace in order to support innovation and competitiveness in the sector, or at the very least to ensure there is not undue regulatory and administrative burden. Introducing a greater degree of flexibility, transparency and inclusiveness into the system would help to respond to these changing needs. This is required to ensure timely, predictable changes based on the needs of individual crop kinds with respect to the degree of regulatory oversight.

4.2. Consultation Feedback

Feedback from consultations indicated that there is general support for an appropriate consensus-driven consultative process that provides flexibility within the system. Desire for greater flexibility is balanced against concerns regarding the level of predictability, transparency and inclusiveness of the current consultation process.

Consultations to date have demonstrated a general frustration with the duration of the process of regulatory and/or policy change. Consultations have illustrated the need for a timely responsive regulatory change process. These discussions have also highlighted the need for flexibility for individual crops to move forward with change at their own pace.

Feedback has indicated support for inclusive crop based consultative groups that encompass the complete crop value chain and have the necessary expertise to build consensus on key issues for crops. It was highlighted that the groups should aim to have national focus, but recognized regional differences exist for some crops while at the same time cautioning against additional layers of bureaucracy.

Recent consultations recommended that the crop movement process should include a grace period for crops moving from exemption to registration to allow sufficient time to register previously exempted varieties. The consultations also suggested that 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.

4.3. Analysis of Options

To address the identified issues, three options are described and analyzed. Options include maintaining the current consultative process for crop changes, utilizing existing committees or organizations, and utilizing possible new Crop

Variety Registration Pre-Proposal Discussion Paper

Specific Consultative Groups to facilitate, but not replace, broader CFIA led consultation.

Option #1: Current process for crop changes

This option would result in no changes to the current consultative process for implementing changes to the level of regulatory oversight of crops. Stakeholders would continue to individually request a change to the CFIA, either directly or through organizations and associations. The CFIA would then consult with individual committees (including appropriate Recommending committees and the Advisory Committee on Variety Registration), organizations and associations regarding the request. The CFIA would review comments from the individual groups and determine appropriate measure to be taken. If necessary, the CFIA would then consult on the proposed solution with concerned individuals and groups and repeat the cycle until there is a sufficient case to move forward with change which usually requires substantial consensus on a proposal. Once achieved, the CFIA would begin the formal process of regulatory or policy change as required.

Benefits	For whom?
Allows direct communication between individual stakeholders and the CFIA	All

Costs	For whom?
Lacks stakeholder to stakeholder discussion between the committees and organizations for each crop to encourage consensus building throughout complete crop value chain	All
Time and travel costs to individually consult, assess comments, develop proposed solution and individually consult again	Government, General Public
Time consuming process that is unable to be responsive to changes in crop sectors	All
Lack of predictability and transparency in the process	All

Option #2: Existing committees or organizations

This option would formalize a process utilizing only existing committees (i.e. Recommending committees, Advisory Committee on Variety Registration, etc.) or related organizations to propose or consult on changes with respect to regulatory oversight for individual crops. Existing committees would individually discuss the need for change and propose a change in the regulatory oversight of a crop to the CFIA when sufficient consensus has been achieved within their respective committee or organization. The CFIA would then consult individually with any other stakeholder in the value chain as well as other parties and individuals with more general interest that may be impacted by or concerned with a proposal. The CFIA would review feedback and determine appropriate measures to be taken. If necessary, the CFIA would then consult on options with stakeholders and interested

Variety Registration Pre-Proposal Discussion Paper

parties and repeat the process until there is a sufficient case to move forward with change. Once achieved, the CFIA would begin the formal process of regulatory or policy change as required.

Benefits	For whom?
More formalized process for change that utilizes existing committees and organizations	All
Potentially increased focus on consensus building within existing committees	All

Costs	For whom?
Lacks stakeholder to stakeholder discussion between the committees and organizations for each crop to encourage consensus building throughout complete crop value chain	All
Time and travel costs to individually consult, assess comments, develop proposed solution and individually consult again	Government, General Public
Time consuming process that is unable to be responsive to changes in crop sectors	All
Lack of predictability and transparency in the process	All

Option #3: Crop Specific Consultative Process

In this option, new crop specific consultative process that encompass stakeholders which represent the complete value chain for a crop species or related group of crop species would be established to facilitate CFIA led consultation relating to crop specific movement issues. Existing committees and organizations would be drawn upon as much as possible for these consultative processes. These consultative processes would be organized by crop type on a National or Regional basis as appropriate for that crop (for example, wheat may need Eastern and Western consultative processes).

These crop specific consultative processes would include a more formal component designed to determine whether there was a sufficient case to move forward with change or a particular issue on which to develop consensus on various options at the crop specific level. Once a sufficient case for change is established and the requisite level of consensus is achieved, the CFIA would then begin the formal process of regulatory or policy change as required.

Benefits	For whom?
Stakeholder to stakeholder discussion encourages consensus building	All
Less resource intensive, more efficient process	All
Permits timely, responsive change for crop specific issues	All
Formalized inclusive process including stakeholders from entire value chain that provides increased transparency and predictability in the change process	All

Variety Registration Pre-Proposal Discussion Paper

Capitalizes on existing committee and organization structures	All
---	-----

Costs	For whom?
Initial costs to establish crop specific groups	All
Time and expenses to participate in meetings	All

4.4. Implementing the Best Alternative (Proposal)

Based on an assessment of the options and consultation feedback, the creation of Crop Specific Consultation Processes in option #3 is the best alternative. This option addresses the problems identified in Section 4.1 in that it provides a potential permanent, inclusive mechanism for consultation on current and future crop specific issues, that would include but not be limited to variety registration issues. The crop specific consultation groups would play an important role in ensuring a process for change that is predictable, transparent and efficient that will in turn facilitate responsive regulatory and policy change in support of CFIA led consultation.

As such, the CFIA proposes the development of a formal crop specific mechanism for consultation on regulatory oversight issues, supported by Crop Specific Consultative Groups (CSCGs) as required. The CFIA proposes that CSCGs include representatives for the complete crop value chain and be open to other interested parties and where possible build on existing committees, organizations, and processes. The proposed mandate, role, membership and reporting structure of CSCGs is described below.

The CFIA further proposes that when a crop changes to a level of increased regulatory oversight (i.e. from exempt to Tier 2, or Tier 2 to Tier 1, within Tier 1) an agreed upon grace period would be applied before implementation of changes and regulatory compliance actions taken. Further description of the grace period process and procedure is provided below.

Crop Specific Consultative Groups

Mandate & Role

The primary function of the CSCGs would be to facilitate broad-based consultation across crop specific value chains and interested parties to provide consensus-based advice to governments on crop specific regulatory and policy issues. The CSCGs would, in the case of Variety Registration, facilitate the provision of advice to the CFIA on the need for change in the level of regulatory oversight for crops including crop movement within Tier 1 and between Tier 1, Tier 2 and exemption and would support broader CFIA or other government departments consultation initiatives when requested. CSCGs may also provide advice as required to the CFIA or other governments on any crop specific issues such as

Variety Registration Pre-Proposal Discussion Paper

grading standards, oversight of plants with novel traits, labelling requirements, tags, etc.

Membership

CSCGs membership must be sufficiently broad to include the entire crop value chain. Where possible the membership should be based on existing committees and organizations. Membership should reflect the national focus. Membership within each CSCG should be such that, as a minimum, the interests of the following groups are accommodated:

- producers
- developers
- seed growers
- seed trade
- federal/provincial regulatory bodies
- marketers & handlers
- processors & end users

Reporting Structure

Crop Specific Consultative Groups should be able to facilitate the development of recommendations to the CFIA and to other government departments and parties. While essentially autonomous, the CSCGs would develop, communicate and report recommendations to the CFIA, AAFC, NFS and other organizations as appropriate.

Grace period

When there is a sufficient consensus to change to a higher tier of registration, for example, from exemption to Listing registration (Tier 2) or from Listing (Tier 2) to Mandatory Assessment registration (Tier 1), an agreed upon grace period will be applied. The duration of the grace period will be recommended by the appropriate CSCG and should provide sufficient time for applicants to apply for registration at the new Tier prior to taking any regulatory compliance actions. For crops moving from exempt to Listing registration, the grace period will provide sufficient time to apply for listing status of any unregistered varieties. For crops moving from Listing to Mandatory Assessment registration, the grace period will provide sufficient time to enter new varieties into the appropriate trials.

5. PROPOSAL ELEMENT #3 - CONTRACT REGISTRATION

5.1. Problem Identification & Analysis

Questions have been raised with respect to the existing flexibilities within the Contract Registration System. Stakeholders find the current Contract Registration System too rigid, and have acknowledged the need to provide an appropriate level of regulatory oversight to address the needs of potentially large acreage varieties

Variety Registration Pre-Proposal Discussion Paper

where a risk of adverse effects exists. There is also concern regarding the availability of the necessary enforcement and compliance measures to take corrective or preventative actions for non-compliance with the Terms and Conditions of Contract Registration and the costs associated with of monitoring compliance of quality management systems.

5.2. Consultation Feedback

There is general support from consultations that the registration system needs to be sufficiently flexible to provide for registration of new innovative and value-added varieties. There has been some 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 and support for increased authority for taking corrective actions on noncompliant contract registration. It has also been made clear 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

To address the issues identified in Section 5.1, an option which introduces increased flexibility in setting Terms and Conditions, increased compliance and enforcement tools and Registrant monitoring requirements for Contract Registration is assessed in addition to the current contract registration system.

Option #1: Current contract registration system

This option would result in no changes to the current Contract Registration system. Eligibility for contract registration would continue to be assessed on a case by case basis for niche market varieties that pose potential significant adverse effects if commingled with traditional varieties. Regulations would continue to stipulate the only Terms and Conditions that may be applied to Contract Registration including required isolation distances. There would also continue to be minimal authority to take regulatory corrective and preventative actions to resolve or mitigate potential risks to traditional varieties.

Benefits	For whom?
Government would continue to assume primary role in compliance monitoring of contract registered varieties	Trade, Developers

Costs	For whom?
Potential loss of markets for innovative and value-added varieties of potentially larger acreage, that may pose adverse effect if commingled with traditional varieties.	All

Variety Registration Pre-Proposal Discussion Paper

Potential cost due to loss of markets for traditional varieties resulting from lack of regulatory authority to resolve issues and mitigate risks of adverse effects of contract registered varieties.	All
---	-----

Option #2: Increased flexibility and enforcement

In this option, the Contract Registration program would be amended to increase the flexibility to set Terms and Conditions of Contract Registration on a case by case risk management 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.

This option would also increase the authority to regulate corrective and preventative actions to resolve or mitigate potential risks to traditional varieties by including the provision for refusal of applications for and suspension or cancellation of Contract Registration when potential risks or problems are identified. In addition, authority would be provided for additional review of quality management systems when significant changes are made.

Based more solidly on the “beneficiary pays” principle, this option will also require registrants of Contract Registration to be responsible for regular third party audits of their quality management system. The extent of the audit will be dependant on the degree of associated risk with the variety.

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

5.4. Implementing the Best Alternative (Proposal)

Based on the feedback from consultations and an analysis of options, option #2, to introduce increased flexibility and 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 regulators having to assume significant additional monitoring costs, and provides increased regulatory enforcement and compliance measures for corrective or preventative actions for contract registered varieties.

<p>As such, the CFIA proposes to amend the Contract Registration system to allow the terms and conditions of Contract Registration to be set on a case</p>

Variety Registration Pre-Proposal Discussion Paper

by case basis, according to potential for adverse effects. The CFIA proposes to amend the *Seed Regulations* to include increased provisions for refusal, suspension, cancellation and review of Contract Registrations. The CFIA further proposes that the registrant be held responsible for regular third party audits of contract registered varieties. 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 will be established on a case by case basis for each variety. The Terms and Conditions will be prescribed by CFIA based on recommendations from appropriate experts to ensure adequate measures are in place to mitigate the potential for adverse effects.

Increased Compliance & Enforcement

Part III of the *Seeds Regulations* will 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 for a two-year period from applicants with a history of non-compliance.
- Provision to review the QMS of a contract registered variety if the registrant or distributor changes.

Third Party Audits

The Contract Registration program will require the registrant to include a part of their quality management system regular audits by a third party to monitor compliance with the terms and conditions of registration. Third party audits would be conducted by a Conformity Verification body. The degree of detail of the audit will be dependant upon the level of risk associated with the variety and past history of compliance. The results of audits will also be required to be retained and reported to the CFIA.

Variety Registration Pre-Proposal Discussion Paper

Appendix: Chart of All Possible Sub-categories for Assessment in Tier 1

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						✓