

# **REGULATORY PROPOSAL**

## **ELIMINATION OF MANDATORY PRIOR MERIT ASSESSMENT FOR VARIETY REGISTRATION**

**October 23, 2000**

Comments are requested by March 30, 2001 and are to be accompanied by detailed rationale/justification as to the submitted position.

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## Preface

On December 20, 1999, the Variety Registration Office (VRO) published on the Canadian Food Inspection Agency (CFIA) website a regulatory proposal suggesting that the mandatory assessment of merit only be retained for variety registration of agricultural crop species in which disease resistance or commodity quality is important. For other crops currently subject to variety registration, the requirement for mandatory assessment of merit would be abolished. This position was consistent with the industry's view as established through the FAAR consultation held between October 1998 - March 1999. This proposal was circulated widely for consultation with the consultation period ending in late March, 2000. Based on the responses received by that time, there was general consensus supporting the principle of a two tiered registration system. At that time, it appeared there was consensus for the majority of the crops over which ones should require mandatory merit testing.

In mid-April, the VRO received multistakeholder input from key organizations in the soybean sector in Ontario and Quebec with a position regarding soybeans that was different than earlier in the year. The processors and growers indicated they no longer required a mandatory assessment of merit for soybeans. They further suggested that registration be voluntary for the majority of varieties. As this initiative pertained to a high value (\$862 million in 1998-1999\* for all of Canada), widely grown crop such as soybeans in which quality and agronomic performance traditionally have been important as a screening tool, the CFIA reconsidered whether there is a role for prior assessment of merit in variety registration for any crop species.

Under this scenario, the future role of variety registration for most crops could be solely to recognize varieties from a varietal identity and purity, human/animal/environmental health and safety and fraud protection standpoint. The actual variety performance (agronomic, quality and disease) would be commodity driven, similar to what exists in the United States.

The reconsideration of the 1999 regulatory proposal has resulted, not only in changes needed to Part III of the *Seeds Regulations*, but also in new proposals for consequential amendments to

Part I. These new proposals require stakeholder input.

With the foregoing in mind, the implementation of a revised variety registration system will be delayed pending further consultation with all crop sectors/organizations on a revised regulatory proposal. It is currently anticipated that regulatory changes may not be in place until summer 2002, instead of summer 2001.

\* p. 366. Soya and Oilseed Handbook 2000 (P. Golbitz, ed., Soyatech Inc. Bar Harbor, Maine)

## INTRODUCTION

In developing this proposal, the VRO has attempted to address emerging trends in variety registration. The goal is to develop a system that will be practical and relevant for a minimum five year period following implementation. This approach is due to the time involved in developing and implementing regulatory change (1 - 2 years).

This current proposal results from a series of events. In mid-April 2000, the VRO received multistakeholder input from the soybean industry in Ontario and Quebec that differed from the position they articulated earlier in the year. The April position stated that the industry no longer required a mandatory assessment of merit for soybeans prior to variety registration. This position caused the VRO to question whether:

- other sectors would reconsider their positions in the immediate future and
- mandatory assessment of merit prior to variety registration was required for **any** crop species.

The VRO considered the role that variety registration plays in areas other than prior merit assessment including seed/crop certification, seed advertising and labelling, health and safety, fraud protection and our obligations under international agreements with respect to seed. The VRO also considered proposed requirements for non-health and safety related disease data and grain grading information based on feedback from stakeholders. The reconsideration of the regulatory proposal started with the premise that no varieties of any species should require prior assessment of merit and the proposal was built upward from this consideration.

The current regulatory proposal results from this reconsideration as well as a July 5 preconsultation meeting of the Advisory Committee on Variety Registration (ACVR) to which a number of sectoral representatives were invited. At this meeting, a number of challenges to the consultation process were elucidated. It was clear that there are differing opinions as to:

- who is the client of variety registration. The seed sector views the commodity producer as the client while other sectoral groups view the final purchaser of the commodity as being the client
- which multistakeholder group best represents the views for any specific commodity in a specific region.
- how to address the producers' need for performance information and whether the variety registration system should play a role in obtaining data in fulfillment of a provincial responsibility.

## REGULATORY PROPOSAL

With the publication of this regulatory proposal, the Variety Registration Office is requesting comments with particular emphasis on:

- 1) **the crop kinds/species for which mandatory prior merit assessment can be eliminated**
- 2) **the crop kinds/species for which some form of mandatory prior assessment of merit should be retained**

Based on the ACVR preconsultation meeting, as a minimum, it appears the following crops should be subject to some form of mandatory prior merit assessment:

alfalfa  
canola/oilseed rape, including *Brassica juncea*  
flax  
mustard  
tobacco (flue cured)  
wheat (durum, winter, spring) for the Canadian Wheat Board Area  
soft white winter wheat for eastern Canada

The proposed type of merit assessment for these crops is expanded upon later in this proposal and will form part of the discussion in the consultation.

- 3) **the crops to which prior assessment of merit should continue to apply and the type of merit assessment they should be subject to**  
(e.g.): i) agronomic performance + disease + quality  
OR  
ii) disease + quality  
OR  
iii) only quality  
OR  
iv) only disease
- 4) **which crops require supplementary data to address human/animal health and safety and/or environmental safety concerns and/or grain grading issues**
- 5) **consequential amendments proposed to Part I of the *Seeds Regulations*.**

**Comments are requested by March 30, 2001 and are to be accompanied by detailed rationale/justification as to the submitted position. Preferential consideration will be given to responses containing detailed rationale, and to responses from defined client groups, e.g. producers and processors/end users, as well as from organizations where changes to the variety registration system could impact other legislation.**

Although comments are requested on the proposal, the following components of the proposal are not considered to be subject to consultation:

- specific data will be required for health and safety issues
- varieties of all agricultural plant varieties with novel traits (PNTs) will be subject to mandatory registration
- the generation of performance information historically conducted by provincial agriculture departments is not sufficient justification to retain merit assessment for variety registration under the *Seeds Act*.
- varieties will be required to have some form of registration in order to be eligible for certification for sale in Canada
- Canadian Grain Commission grading issues as additional crop specific requirements

As a result of the consultation, changes will be required to Parts I and III of the *Seeds Regulations*. Procedural changes will be included in the “Procedures for the Registration of Crop Varieties in Canada”.

## **BACKGROUND**

The initial role of variety registration when it was established in 1923 was to validate the identity of a new variety and determine its suitability for seed certification. The exclusion of inferior varieties from the marketplace based on poor agronomic performance was not introduced until 1928 in the case of cereals, and until 1937 for other crops. As recently as 1992, the role of variety registration was viewed as providing assurance that new varieties met current requirements for resistance to economically important diseases and for high quality products for processors and consumers.

The 1998-1999 Variety Registration Review (FAAR Report) suggested that a merit based system continues to retain its utility for some crops. However, there is diversity of opinion as to which crop kinds should be subject to the prior assessment of merit from within each sector. There is further diversity of opinion as to who is the client of variety registration and which organization best represents the views of each sector.

It is proposed that the mandatory prior merit assessment be abolished as a criterion of variety registration for most crops currently subject to variety registration. Variety registration would include new crops such as industrial hemp, agricultural PNTs not currently subject to variety registration, and (with the exception of non-PNT hybrid field corn) to any variety of any crop where the use of variety names are restricted to pedigreed seed under Section 10 (3) of the *Seeds Regulations* (Schedule II). Any variety that is to be certified in Canada or that bears a CFIA tag would be subject to variety registration, except if produced under the OECD or AOSCA pedigreed seed schemes. For these crop kinds, CFIA will be in a position to safeguard the “one variety, one name” principle. Non-PNT hybrid field corn varieties would only require registration if pedigreed seed is being produced in Canada. However, registration would not be required for hybrid corn varieties being sold in Canada for which certified seed is produced elsewhere.

Where human and/or animal health and safety, environmental safety or grain grading issues exist that may be addressed at the point of variety registration, data to address these issues will be required. This would include home garden potato varieties, previously exempted from the variety registration requirements. Although data will be required to address health and safety issues resulting from glycoalkaloids, there is no proposal to subject commercial or home garden potato varieties to the requirement for prior merit assessment. Data requirements for human, animal and environmental safety and grain grading will be elaborated further in this paper.

The removal of mandatory assessment of merit for most species may allow inferior or unadapted varieties into the Canadian marketplace. As a result, the onus will be on seed growers, producers and processors to become better informed before making their seed and commodity purchases.

Although the exclusion of inferior varieties from the market of certain crops would no longer be regulated by the *Seeds Act and Regulations*, there is a need for the CFIA to be accountable for the varietal integrity of seed sold domestically and internationally. The CFIA is Canada's official seed certifying agency and, as such, is responsible for the varietal integrity of seed certified in Canada. The CFIA is a member of the Association of Official Seed Certification Agencies (AOSCA) and is the National Designated Authority (NDA) under the Organization for Economic Co-operation and Development (OECD) Seed Schemes.

## **PROPOSED REQUIREMENTS FOR VARIETY REGISTRATION**

All varieties subject to registration will require the submission of the following:

- acceptable variety name
- synonyms (if any) used for the variety in other countries
- permission to grant a synonym in Canada (where applicable)
- pedigree, origin and breeding history
- description of variety showing how the variety is distinguishable
- organization responsible for breeder seed maintenance (for crops other than potatoes)
- name of the Canadian representative/distributor
- legal reference sample of any pedigreed status or, in the case of potatoes, photographic slides (Pedigreed seed would not be required for registration of crops not listed in Schedule II of the Seeds Regulations)
- appropriate fees
- for PNTs, notarized affidavits pertaining to the genetic identity of the legal reference sample and molecular protocols as well as evidence of prior food/feed/environmental safety authorizations, as required
- quality control system for varieties under contract registration
- inbred line descriptions for those hybrids being entered onto the OECD list
- varietal/hybridity testing methods for hybrid and composite canola varieties.

Much of this information may have been previously submitted to crop certification officials (Canadian Seed Growers' Association) or to the CFIA's Plant Breeders' Rights Office. Where a determination of eligibility for crop certification or a grant of Plant Breeders' Rights has already been made, the Variety Registration Office requirements may be partially fulfilled by the applicant providing information such as the CSGA Form 300, information from foreign certification authorities, or Plant Breeders' Rights forms. Evaluation fees may be reduced if this type of information is provided as part of the application.

The proposed registration requirements are consistent with those of the United States for eligibility for certification under Section 68 of the Federal Seed Act Part 201.

## **ADDITIONAL CROP SPECIFIC REQUIREMENTS**

### **A) Merit Considerations:**

As a result of the July 5, 2000 ACVR preconsultation meeting, it was decided that prior assessment of merit should be required in circumstances where:

- there is a complex set of varietal traits involved in the seed purchasing decision
- there is clear differentiation among varieties for resistance to significant diseases
- there are market demands for specific quality characteristics e.g. oil quality and content.

For the crop kinds subject to prior merit assessment, the following will be required:

- a valid recommendation for registration from a recognized committee
- results of experimental trials used by the recommending committee upon which the recommendation is based.

Based on the ACVR preconsultation meeting, as a minimum, the following crops are proposed to be subject to some form of mandatory prior assessment of merit:

<b>CROP</b>	<b>TYPE OF ASSESSMENT</b>
alfalfa (forage type)	bacterial wilt resistance
canola, oilseed rape	blackleg/white rust resistance, quality
flax (oilseed)	disease resistance, quality
mustard	quality
tobacco (flue cured)	disease resistance, quality
wheat (durum, winter, spring) for the Canadian Wheat Board Area	disease resistance, quality
soft white winter wheat for eastern Canada	disease resistance, quality

These crops were selected based not only on their meeting the three criteria listed above, but also on the current practice of excluding varieties of these crops from the market place when the varieties do not meet the parameter(s). While it is clear that disease and quality are important in other crops such as oats and barley, currently high yielding varieties exhibiting inferior disease and quality characteristics are recommended for registration, leaving these latter traits to be market driven.

The registration recommending committees will also address health/safety issues for canola (erucic acid and glucosinolate content) and wheat (*Fusarium*/mycotoxins) as well as grading issues for wheat, flax and *Brassica juncea*.

Following the consultation, additional crops may be added to this list based upon clear articulation of the specific criteria that must be considered as part of the merit assessment. It is requested that both the specific criteria and the minimum standards that must be met be delineated in the submitted justification. While there is no doubt that yield continues to be an important component of the producers' decision to purchase a specific variety and in the overall benefit of a variety, unless there is strong justification to retain it, yield performance will become a commodity driven issue as it is in the United States.

It is anticipated that the shift in emphasis from agronomic performance to disease and quality traits as criteria for variety registration will result in compositional changes in the structure of the remaining registration recommending committees. Under the revised system, key stakeholders may be granted veto power over the support for registration granted by recommending committees e.g. the Canadian Grain Commission for wheats registered in the Canadian Wheat Board Area with respect to their quality and grain inspection issues (KVD). The key stakeholders should be defined based on commodity issues.

**B) Health and Safety Concerns:**

For certain crops, data will be required to satisfy health and safety considerations.

<b>Crop Kind</b>	<b>Toxicant</b>	<b>Standard</b>	<b>Accepted Test</b>
industrial hemp	delta-9-tetrahydrocannabinol	0.3%	licensed laboratory
lupin	alkaloid	0.03%	U of PEI/gas chromatograph
potato (commercial and home garden)	total glycoalkaloid	20 mg/100 g fresh weight unpeeled	HPLC (Carman et al 1986)
reed canarygrass	tryptamine carboline gramine	zero zero equal to or less than the levels of Palaton or Venture	Any lab with gas chromatograph and appropriate standards
wheat (for types not subject to merit requirement)	<i>Fusarium</i> /mycotoxin	minimum moderately susceptible	varies among regions



It should be clarified that spelt and triticale are not proposed to be subject to requirements for Fusarium data prior to variety registration. For these crops, food and feed safety issues will be addressed on a lot by lot basis at the commodity level. Future modifications to this list could be made should the need arise, e.g. Fusarium mycotoxin in barley and oats.

Although ergot and fescue endophytes are considered health and safety issues, preliminary consultation has suggested that variety registration is not an effective mechanism to address these concerns.

### C) Grading Considerations

There is a legal requirement under the *Canada Grain Act*, for varieties to be registered under the *Seeds Act* in order to be eligible for grades higher than the lowest grade. As grading is linked to both quality and kernel visual distinguishability (KVD), in the absence of a prior merit assessment, variety registration must take into account the needs of the grading system:

Crop Kind	Requirement
triticale	CGC description showing the variety is distinguishable from wheat and rye
wheat (for types not subject to merit requirement)	CGC description showing the kernel characteristics along with an indication as to whether the variety registration should be made subject to a restriction

The submission of this information for some varieties will facilitate a timely decision of regional registration in the absence of a merit based system.

### D) Supplementary Data

Data would continue to be required to substantiate:

- implicit or explicit claims incorporated into variety names
- voluntary claims made as part of a description of variety that pertain to disease/pest resistance, quality, pesticide tolerance etc.
- the uniqueness of the variety where this is not clear based on the pedigree and variety description.

## **CROPS SUBJECT TO FUTURE VARIETY REGISTRATION SYSTEM**

- all crops that are currently subject to variety registration
- all agricultural crop PNT varieties that are sold or imported into Canada, in order to provide a mechanism for the genetic identity, tracking and recall of these varieties (as recommended in the 1998-99 Variety Registration Review (FAAR Report)).
- seed of all agricultural crops produced in Canada where the crop kind is listed in Schedule II of the *Seeds Regulations* and the use of variety names is restricted under Section 10(3) to pedigreed seed, or where an official government tag is to be affixed. (This would include those species not currently required to be registered, e.g. specialty type soybeans)
- industrial hemp (See Appendix)

Varieties multiplied solely for export under the OECD and AOSCA seed certification schemes would continue to be exempt from the variety registration requirement, as they are registered in the country of origin. This is consistent with the European system of national lists.

Voluntary registration would be available for any other agricultural crop exempt from variety name restrictions, (e.g. Kentucky bluegrass, millet varieties), or for any varieties exempt from mandatory variety registration (e.g. non-PNT hybrid corn varieties certified in the U.S.).

Inbred lines of canola used solely for the production of hybrid or composite varieties will remain exempt from variety registration.

### **CONSEQUENTIAL AMENDMENTS:**

In addition to the changes required to Part III of the *Seeds Regulations*, it is proposed that mung beans and coloured types of field beans be deleted from Schedule II of the *Seeds Regulations*. As such, registration of varieties of these types would only be required if the varieties are produced in Canada other than under the OECD or AOSCA seed schemes.

The sale of unregistered varieties as common seed is presently prohibited in Canada. Under Part I of the *Seeds Regulations*, the importation of common seed of alfalfa, canola/oilseed rape, flax, hemp, lupin, mustard, reed canarygrass, tobacco, triticale and wheat within the Canadian Wheat Board area would be prohibited.

It is anticipated that a reduction in application evaluation activities resulting from the removal of merit assessment would result in a review of the evaluation fees.

## **TYPES OF VARIETY REGISTRATION**

Under the new proposal, interim registration would be abolished for crops not requiring prior mandatory assessment of merit i.e. varieties would not be granted interim registration upon request of the applicant. Interim registration would only be granted upon the recommendation of a recommending committee for those species requiring prior merit assessment.

Regional registration would continue to be used to address issues of harm such as free fatty acids in canola oil in eastern Canada, kernel visual distinguishability in wheat, Fusarium mycotoxins in wheat and in the case of PNTs where unconfined environmental release may be restricted to certain provinces. The VRO would continue to consult with provincial and regional contacts regarding issues pertaining to regional registration. Regional registration would not be granted upon request of the applicant, or in cases where, based upon the available data, there is no evidence of harm.

Contract registration would continue to be used where the biophysical and biochemical properties of a variety would cause harm if it were to be mixed with traditional commodity channels and the registrant of the variety will continue to be responsible to ensure that the variety does not contaminate the traditional commodity. The VRO would require applicants to consult with relevant organizations including provincial and regional contacts to obtain a determination of potential harm in those cases where varieties have properties that differ from the norm of the species. The determination of merit generally will be considered separately from the determination of harm.

## **REFUSAL, SUSPENSION AND CANCELLATION OF REGISTRATION**

Variety registration would continue to provide a mechanism for recall and disposal of seed of varieties along with provision for refusal, suspension and cancellation of registrations.

## **ALTERNATIVE REGULATORY STRATEGIES**

The devolution of the federal variety registration system away from a merit based system could result in provincial governments extending their existing performance testing and recommendation systems.

Marketing agencies may select only certain varieties for marketing. Crop insurance agencies could choose to restrict the varieties to which crop insurance will apply. In addition, the Canadian Grain Commission and the Canadian Wheat Board could redesign their systems to restrict the grades for which certain varieties may qualify.

Commodity industry recommendation lists may also be used to provide independent information to producers or to promote the use of certain varieties of specified quality required by the industry (e.g. malting barley lists). The removal of a requirement for a mandatory merit assessment may increase the importance of these lists.

## CURRENT ENVIRONMENTAL FACTORS

There are several factors that can be considered when evaluating the revised proposal:

- increasing level of private sector involvement in variety development and less publicly funded research with resultant increasing demands from farmers for accurate third party information on varietal performance
- increasing level of education and sophistication of producers, especially evident in the corn and oilseed sector
- increasing globalization of the seed market
- major recent downsizing in several provinces may impact the ability to produce the data currently required for variety registration
- some seed industry representatives promoted the adoption of registration recommendation based on as little as one year of data, but subsequently argued the use of minimal standards renders the merit process meaningless
- consensus that one year of disease data is not enough to prove moderate resistance, however, for some crops, quality and disease data can be based on as little as one year of data
- increasing concern regarding the use of CFIA tags on pedigreed seed entered into Canadian certification system without a verification of pedigree uniqueness, varietal distinguishability and purity, and acceptability of the variety name
- although the need for resistance to economically important diseases has not diminished, the ability to test and evaluate new cereal varieties in eastern Canada has diminished due to a reduction in plant pathology resources. The same holds true in western Canada for crop species other than cereals and canola.
- increasingly difficult to justify a merit based variety registration system because, for most crop species, farmers may import seed of unregistered varieties for their own use.
- increasing importance that commodity customers are placing on end-use quality and uniformity for some crops.

## **POSSIBLE IMPACTS OF THE REVISED PROPOSAL**

The registration of all agricultural crop varieties for sale in Canada, including those produced in Canada for export, will allow Canadian regulatory authorities to have timely access to legal reference samples for post control testing required under OECD certification scheme rules.

Developmental costs may be reduced as mandatory prior assessment of merit is no longer required for most crops. However, the cost of generating performance data may increase due to the absence of a merit based variety registration system for many crops. Market opportunities may arise for private agricultural consultants to produce independent data on varietal performance.

The initial implementation of the revised variety registration system will create an initially large volume of applications that need to be evaluated.

Varieties may enter the marketplace more rapidly, provided pedigreed seed is available.

It would become legal to sell seed of coloured bean and mung bean varieties by variety name without the seed being pedigreed.

Seed of heritage varieties may be eligible for sale by variety name provided the varieties meet the registration requirements and the seed is pedigreed (for applicable crops species).

Unregistered varieties of crops other than alfalfa, canola/oilseed rape, flax, hemp, lupin, mustard, reed canarygrass, tobacco, triticale and wheat within the Canadian Wheat Board Area, could be sold as common seed (with no reference to variety name).

The future involvement of variety registration recommending committees will change. In some cases such as soybeans, there will be no involvement on the part of these committees. In other cases, the involvement will shift from a holistic view of merit (performance, disease, quality and special attributes) to a specific view of merit e.g. only quality.

## APPENDIX

### A. ALL VARIETIES OF THE FOLLOWING CROPS WILL BE SUBJECT TO SOME FORM OF VARIETY REGISTRATION

**Note:** Prior Assessment of Merit will only be required for the species listed in the section titled “Merit Considerations”

alfalfa (forage and reclamation)	peanut
alkaligrass, weeping	potatoes (commercial and home garden)
barley (grain and forage types)	rapeseed (forage type)
bean, field (navy type)	redtop
bean, faba (large and small seeded)	rye (grain and forage types)
bromegrass (meadow, smooth, sweet)	ryegrass (forage and turf types)
buckwheat (common and Tartarian)	sainfoin
canarygrass (annual, reed)	sorghum
canola, oilseed rape	soybean (all types)
chickpea	sudangrass
clover (alsike, red, sweet, white, annual species)	sunflower (oilseed and non-oilseed)
cowpea	timothy (common and dwarf)
fescue (all types)	tobacco (flue-cured and burley types)
flax (oilseed and fibre)	trefoil, bird's-foot
foxtail (creeping, meadow)	triticale (grain and forage types)
hemp (industrial)	vetch (crown, cicer milk)
kale (forage type)	wheat (spring, durum, winter, spelt)
lentil (grain and plowdown)	wheatgrass (beardless, crested, intermediate, northern, pubescent, Siberian, slender, streambank, tall, western)
lupin (non-ornamental)	wildrye ( Altai, Dahurian, Russian)
medick, black	<b>varieties of plants with novel traits of all agricultural species</b>
mustard (black, yellow, oriental, Indian)	
oat (grain and forage types)	
oatgrass, tall	
orchardgrass	
pea, field (all types)	

### B. VARIETIES OF THE FOLLOWING ARE REQUIRED TO BE REGISTERED WHEN SEED MULTIPLICATION IS BEING CONDUCTED IN CANADA

corn, field, hybrid  
any other species exempt from the variety name restriction not being produced in Canada under the OECD or AOSCA seed certification schemes. This would include interspecific hybrids of species listed in Appendix A (above).

**Note:** Inbred lines of crops listed above that are used solely for seed production of hybrid or composite varieties continue to be exempt from the variety registration requirements.