



– Variety Registration Working Group II –

Summary Report of June 20 & 21, 2005 Meeting Results

Held Monday and Tuesday, June 20th and 21st, 2005

– Best Western O'Connor, Ottawa –

I. BACKGROUND TO CONSULTATION

This was the first regulatory working group meeting convened since the first National Forum on Seed meeting in April 2005. The fundamental premise for this process is the perception that there is a need for a flexible, timely regulatory process, connected to primary and downstream customers. The intent is to continue the consultative process that created a National Forum, by considering proposals for regulatory change to develop consensus and to provide well-reasoned information to government for development of a full proposal on variety registration. A summary of the consensus recommendations from Variety Registration Working Group I meeting is available in Appendix I.

There were three targeted goals

1. To undertake substantive discussion on questions arising from the January Variety Registration group meeting
2. To identify the consultative process that will achieve consensus at the crop kind/regional level
3. To give effective policy advice to CFIA, as they continue the process of regulatory change

This is not the final report on Variety Registration from the National Forum on Seed. The Secretariat synthesized the consultation taking place at the second working group into an interim report for the participants. The National Forum on Seed (NFS) will review the report at their meeting in July. Discussion will continue at the NFS and the report will serve as the basis for information that the NFS will then submit to the CFIA.

A. CFIA Perspective

CFIA plans to have a regulatory change proposal ready in the fall of 2005 for one final round of consultation prior to regulatory writing during the winter of 2005-2006, with publication in Canada Gazette Part I in early 2006. CFIA is supportive and encouraged by the development of this variety registration working group and by the National Forum on Seed. CFIA looks forward to good quality material from the National Forum on Seed that will serve as policy advice to CFIA that they can incorporate into the regulatory proposal. The

CFIA requires substantive consensus on the recommendations of the Working Group and the National Forum on Seed that must include the complete value chain. If consensus is lacking, any proposal is less likely to be successful.

B. State of the Consultation Debate

Dale Adolphe, CSGA, led a presentation and discussion summarizing the work of the previous Variety Registration Working Group (VRWG). He indicated that the overriding objective of this meeting was to move forward the work of the January Working Group on consensus points from page 13 of the Report from VRWG I, and areas for further work and consultation from page 14 of the Report (Appendix I). The fallback position is to facilitate progress on CFIA's development of an initial proposal for variety registration for discussion and consultation at a 3rd Working Group meeting – likely in the fall of 2005.

II. DISCUSSION AND CONSENSUS

There is still some skepticism about the process and CFIA's openness to accepting the recommendations. However, the consultation provided the following recommendations:

A. Schedules

It was proposed that crop specific working groups (CSWG) would have the expertise to determine the placement of each crop in the appropriate schedule.

1. Schedule A – A functional crop committee needs to assess new varieties as they come through the system. The Variety Registration Office (VRO) must work with them. Some difficulties remain across regions of Canada – Recommending Committee system is not viable in certain areas.

2. Schedule B - Reports favoured retention of Schedule B for the time being, giving preference to having it and not needing it, rather than not having it and needing it. If the industry does not actually use it, CFIA can delete it in the future.

3. Schedule C - The minimum information required for registration of a variety would be analogous to what is currently required for entry into seed certification as is currently reflected in the CSGA's Form 300. CSGA currently

relies on registration to provide certification eligibility information for crop kinds subject to registration. For certification, varieties are required to be distinct, uniform and stable.

Many agreed it was important that Schedule C have minimum criteria – one variety, one name. Variety PNT status should be reviewed.

4. Health and Safety Assessment

Health and safety issues take priority over schedule placement and could apply to species that could be in any schedule including species, such as herbs, that are currently exempt.

Screening for Health and Safety issues is needed and requirements would be determined by CFIA or Health Canada.

5. Exempt – Participants could see possibilities for some crops to be exempt, but expressed concern about lack of oversight under the *Seeds Act* for Exempt crop kinds.

6. Proposed Schedule Re-organization:

a. Proposed Schedule I (A/B): The group also proposed that Schedule A and B could be merged into a common group requiring collection of data. This means that Schedule A/B would include crop kinds requiring the collection of pre-registration performance information (whether or not that information is used for merit assessment and whether or not the information is collected on one or more of the elements related to agronomics, disease, or quality).

Requirement for data collection would be according to a specified performance protocol. The wording should include: “Requirement for performance data using an approved protocol.” However, it would require a “recommending committee”. The cost involved may create challenges for the system, but benefit would accrue when more information becomes available to end users and consumers. Closing comments on Schedule I suggested that it might have less flexibility, could increase time required, and may have negative impact on innovation.

b. Proposed Schedule 2 (C): This schedule would contain crop kinds for which no data collection would be required and is equivalent to the current Schedule C.

B. Minimum Requirements for the Use of the Official CFIA Certified Tag

Initially, the group was satisfied that the requirements for Schedule C listing would be sufficient to meet the requirements for the use of official CFIA tags. After subsequent discussion of the implications, consensus changed in favour of a modified approach.

There are two scenarios to consider:

Part I of the current regulations provides for multiplication of pedigreed seed of a crop that is subject to registration as an unregistered variety for export.

Schedule II provides for the importation, or Canadian production, of certified seed of varieties that may or may not require Registration of the crop kind for sale in Canada. If certified seed can not be produced in Canada using the CFIA labels, certified seed may still be imported and sold in Canada using interagency labels.

I. Options:

There was some support for a proposal that Schedule C listing would be required for the use of CFIA tags for crops currently included in the *Seeds Regulations* Schedule III (crop kinds currently subject to registration). There was some support that for the initial phase of the review, Schedule C listing would not be necessary for those crops on the current Schedule II (crop kinds requiring certification to be sold by variety name), which are not included in Schedule III. This would mean that varieties currently exempt from registration would not require registration for the use of CFIA official tags during the initial implementation of the revised registration system.

Another variation on this theme for which there was some support, is the requirement for Schedule C listing for the use of the CFIA tag, but to only require registration of specific varieties for which the variety proponent desires certification and not require Schedule C listing for the crop kind in general. For example, if a company wanted to have their variety certified and use a CFIA tag, then Schedule C listing of that variety would be required, however, Schedule C listing would not be required for all varieties of that crop kind.

2. Further Considerations

- CSGA’s Variety Certification Eligibility Application (Form 300) requirements should be applied for the use of a CFIA certified tag, since it is presently required.
- Form 300 could apply to all crop kinds exempt from registration.

- Should Form 300 be synonymous with the new Schedule C?
- There is a connection between the registration system and certification system, as registration provide basic information for entry into certification.
- Schedule C could provide this information
- Form 300 may have to be revised to gather more information that CFIA may require for certification.
- There may be an implication that crops that are exempt would not be able to produce pedigreed seed in Canada and use CFIA labels for sale of seed in Canada.

C. Performance Information

The Working Group recognized the difficulties inherent in separating the discussion regarding the data collected for variety registration (pre-registration testing or variety characterization) and performance testing (adaptive testing information collected post-registration). Post Registration adaptive testing was largely considered to be beyond the purview of this Variety Registration Working Group and is the responsibility of the marketplace with stakeholder involvement. Despite the fact that post registration performance testing was not part of the responsibilities of this group, there was considerable emphasis on the need for stable funding for post-registration performance testing.

For crop kinds that require evidence of data collection of performance information, some participants felt that there should be a protocol established, including provision for some oversight. Data must be evaluated to assure that it is scientifically valid. In addition, it was noted that the CFIA has a regulatory role in assuring that data, or claims made in the marketplace, are truthful.

D. Crop Specific Working Groups

I. Purpose and Function

The primary function of Crop Specific Working Groups (CSWG) is to function as a consensus builder on key issues for each crop kind. CSWGs may have expertise and discretion to determine whether data must be collected, or evidence of collection provided for each crop kind with respect to disease

data, quality data, and agronomic data and whether merit evaluation of this data is required.

In the proposed Schedule I context, there would be information generation potentially with respect to quality, disease or agronomic data that could be used by the CSWG for merit assessment, or simply for provision of that information without it being considered merit assessment.

2. Operation of the Crop Specific Working Groups

The aim is to create national groups with as broad a scope as possible, with recognition of regional differences within these groups. There may be a need to create specific regional groups for some crop kinds (e.g., separate wheat or cereal CSWGs for East and West). The guidelines for Variety Recommending Committee Procedures could also be used as a guideline for inclusiveness requirements for the CSWGs. After the initial projects, CSWGs would only be required to meet on an ad hoc, as needed basis to respond to specific issues.

With the proviso that there is no intention to create a new layer of bureaucracy, there was a bias in favour of an unfettered discretion on the part of the CSWGs that would allow for making recommendations and also, over time, developing a flexible environment for deciding that certain information may no longer be required because it is no longer being used for decision making purposes.

The possibility was raised that CSWGs could play a role in establishing protocols for collection of data that may or may not be used on a regional basis for registration decisions. Some felt that data should only be required from the regions where the variety is adapted and intended to be sold. For some varieties – it is important that information be collected, but not prevent a variety from being registered (e.g., wheat in Ontario – no KVD).

Some felt that the Working Group could establish a template under which the same data would be collected from Coast to Coast. Some differences exist across the country under the current system, which some consider to be a problem.

3. Further Considerations:

- There is some concern that the system allows potential for competing regional vs. national recommending committees
- There is a need to clarify the governance and accountability of CSWGs.

4. Principles & Process for Managing Change to Schedule Placement

General Principles suggested for the process of managing change are as follows:

- A predictable, transparent process is required
- Process options may involve Crop-Specific Working Groups (CSWGs)
- There was some discussion on moving a crop from Exempt status and that a grace period would be required

F. Contract Registration

Brian Marchylo, Canadian Grain Commission, presented the risk analysis model developed by the CGC Contract Registration Technical Committee. This was generally well received.

Key elements included:

- Need for a risk assessment, based on a function of Hazard X Exposure
- Technical Committee is establishing a matrix of hazards and exposure to assess the level of risk associated with a candidate variety for contract registration

There was no clear consensus developed on Contract Registration, although thinking around the concept was further clarified.

The Registration system is seen as a *gate-keeper* that ensures that varieties with the potential to cause harm don't become mixed with the commodity crop. The importation of unregistered US varieties also has the potential to cause significant risk. The monitoring component is seen to be the

main difference between unrestricted registration and contract registration.

Some considerations relating to the Contract Registration discussion are:

- Concern that low value, large acreage varieties may increase the probability of misrepresentation of the nature of the variety
- Encourage committees to recommend registration of specialty varieties (i.e. voluntary IP) in the larger context of promoting the development of value-added varieties
- Size of production may influence the value and risk of contract registration of a variety
- Use of Contract Registration may increase in response to new approaches to variety development, such as Plant Molecular Farming and the production of more traditional crops for industrial purposes
- The cost of monitoring and who pays for it is an issue and a limiting factor
- If a company is paying a premium for a variety, delivery verification is not of such concern, since the contracting party will want to know they are receiving what they are paying for. This will be a greater issue where there is low value and high volume production

III Next Steps:

This report will be tabled at the next meeting of the National Forum on Seed for further discussion. Decisions on further action will be taken at that meeting, and then communicated to the industry. Another meeting of the Working Group in October could be contemplated.

Appendix I Consensus from VRWG I

Consultation General Consensus Points from VRWG I:

- need for made in Canada system
- same standards for imported seed as domestic seed
- need for third party oversight
- move forward quickly
- system variation by crop kind
- recognize regional and species diversity
- variety characterization for Schedules A, B and C
- committee recommendations not needed in Schedules B and C

Partial Consensus Points and Areas for Further Work and Consultation:

- some support for Schedule C default (i.e. minimum requirement to use CFIA certification tags)
- collection of performance information might not be mandatory
- need for public funding to support performance testing
- data is required for registration and certification
- processes for moving crop kinds between Schedules
- determining whether Schedule B is needed
- financial responsibility for collecting data
- specifying requirements to prove distinctness
- is distinctness needed for Schedule C
- scope of contract registration (IP production)
- needs of heritage variety seed industry

IV – Reconfirmation of Consensus Points

The reconfirmation was carried out to ensure participants at this VRWG meeting were in agreement with the points on which consensus was achieved in January 2005

1 - Need for Made in Canada system

2 – Same standards for imported seed as for domestic seed

3 – Need for third party oversight.

- *agreed that unless answers are available concerning what type of oversight and by whom, consensus would not be possible*

4 – Move forward quickly with Variety Registration changes to provide certainty

5 – System requires variation by crop kind

- Need to recognize regional and species diversity
 - *Reality check – discussion took place and final agreement was that extent of regional and species diversity that can be provided is directly related to who pays and whether the resources available to do this kind of work exist.*

6 - Variety characterization for Schedules A, B and C

- Committee recommendations not needed in Schedule B and C –
 - *Committee recommendations, it was agreed, were relative to whether the seed should be registered or not, but not related to other factors.*