



CSTA Comments on the Regulatory Proposal for Variety Registration

Bill Leask Executive Vice-President, February 2000

On behalf of the CSTA Board of Directors, I am pleased to comment on the above "Regulatory Proposal" document amended on December 20, 1999. CSTA has been an active participant in all aspects of Variety Registration ranging from serving as voting representatives on numerous recognized committees to participating at a policy level on the Advisory Committee.

The documents contain a considerable number of bullet points under the sections "Regulatory Requirements for Listing" and "Regulatory Requirements for Registration with Merit" and I assume that this detail was included to help us understand the difference between the proposed categories of registration. However our comments at this juncture are only at the conceptual or policy level to the extent necessary to proceed with amendments to Part III of the Seed Regulations or Schedule III. I wish to be clear that our support for the concepts contained in the Regulatory Proposal doesn't include an endorsement of all the details which will be reviewed at another time as an amended "Procedures" document.

Comments are requested on three critical areas namely:

1. The division of registration into two categories
2. The crop kinds in each category
3. "Non merit" data requirements for species in the "Listing" category

It was also clearly stated that other recommended changes to operational requirements including harm and market acceptance will be considered as separate initiatives. I concur with this approach because we need to have a clear understanding of the legislated mandate of Variety Registration before attempting to answer the operational details.

It is the consensus of the CSTA Board that there is strong support for the concept of dividing registration into two categories.

We offer the following comments:

1. "Merit" is not the appropriate word to distinguish the categories and should not be used in category names.

Use of this word creates unnecessary confusion and it raises many questions. What is merit? Who decides merit? What is non-merit? etc. The distinction between the two categories is the requirement for a "committee recommendation" with the application.

Crop kinds in the "Listing" category would not require a decision of a "recommendation committee" for each variety and the applicant will deal directly with the Variety Registration Office (VRO). Species in the traditional "Registration" category require deliberation on the criteria considered to be a legislated requirement under the Seeds Regulations and the application would require the support of a "recommendation committee" including the relevant data supporting the decision. If the legislated criteria are complex and require the deliberations of a multi stakeholder "recommendation committee" then the crop species is in the category "Registration with Committee Recommendation". If there is no legislated requirement for the species, the "Listing" category applies and a "recommending committee" decision is not required and the applicant deals directly with the VRO.

The reference to non-merit in the "Listing" category suggests that varietal testing does not take place for these species and this is not the case. Crop testing committees will continue to organize extensive programs for varietal testing for a provincial/regional recommendation as part of a third party evaluation used in a seed-buying decision. Western forage testing and the work of the Ontario Corn Committee are good examples of ongoing extensive varietal testing to fulfil a market driven need rather than a legislated requirement.

We suggest that the categories be described as: "Registration with Committee Recommendation" and "Registration Listing" and eliminate references to merit.

2. By eliminating the reference to non-merit data in your third question, we get a clearer understanding of your intent for potatoes, hemp and alfalfa.

The health/safety/disease concerns of these crops can be important and would be included in my evaluation of overall merit. It seems that what you are proposing is that the bacterial wilt of alfalfa, THC content of hemp and bacterial ring rot and TGA of potatoes should meet a legislated standard. The decision procedure is not complex for these criteria and does not require the deliberation of a recognized recommendation committee. As such, this species can remain in the "Listing" category and the applicant will submit the application directly to the VRO including test results as evidence that the legislated standards are met.

With this clarification, **the concept seems reasonable that crops may remain in the "Listing" category if the health / safety / disease concern is relatively simple to determine.** There would be no need to convene a meeting of a recommendation crop committee to review individual variety applications if the determination is simple and straightforward. The application would go directly to the VRO. However, the committee may wish to review the requirements and, from time to time, recommend changes to the VRO.

The CSTA strongly endorses that alfalfa remain in the "Listing" category and, if in fact a legislated standard applies for bacterial wilt, then the above proposal would be appropriate and still allow the crop species to remain in the "Listing" category.

The CSTA has endorsed moving soybeans to the "Listing" category similar to alfalfa. Discussions are ongoing with other soybean stakeholder groups.

The CSTA has considered why triticale should remain in the category "Registration with Committee Recommendation" support given the low level of activity with this crop.

P.S. I note that triticale is not on the December 20 document list and I suspect that it was inadvertently deleted when I see "tobacco (grain type)".

3. The suggestion that the "Registration" category will continue to operate in the status quo should not imply that the operations of a recommending committee are to remain as in the year 2000.

In the letter dated Jan. 17, 2000, it is clear that recommending committees retain the responsibility to determine the criteria and traits to be evaluated and the relative contribution to the final determination. Committees will be challenged with many new

and specialty traits and will require considerable flexibility to be accommodated..

4. On the conceptual or policy level, the CSTA Board urges that the "Current Mandate" of the Variety Registration system be revisited.

Our intent is to add clarity to the legislated requirements under the Seeds Regulations and to distinguish the mandatory requirements and role of the VRO from other work done by varietal testing committees. Testing committees need to evaluate the legislated criteria and, in that capacity, are accredited as a 'recommending committee' by the VRO. The point is, the work done by the testing committee for purposes of meeting the VRO requirements can be a small subset of the total work done. The extensive testing of overall agronomic performance for purposes of a provincial / regional recommendation is an example of work done which is not a legislated requirement of the VRO. There is a need to differentiate work done for VRO requirements from the evaluations useful for buyers of seed. Arguably, the data to be submitted by the "recommending committee" need only be that required to meet the legislated needs of the VRO.

It is not clear which sections of the Seeds Act and Regulations are the reference source for the "Current Mandate". Part III, Section 63 defines 'merit' with respect to a variety as " that variety is equal or superior to appropriate reference varieties with regard to characteristics that render the variety beneficial for a particular use in a specific area of Canada". This definition remains valid and need not be amended. It is sufficiently broad to allow varieties with unique traits to be considered to have merit and not be excluded from the marketplace because of a narrow definition of merit. From a conceptual level, the mandate helps to define the kind of criteria that are to be controlled by legislation under the Seeds Act and Regulations. We must assume that the "Current Mandate" is the interpretation drawn from the Act and Regulations and I would like to know the specific regulatory wording that leads to the part of mandate "to ensure that agronomically inferior or unadapted varieties are excluded from the Canadian marketplace".

Attempts to fulfill this part of the mandate have been a source of confusion for many committees. How much varietal test data is required to meet the mandate of the VRO? It cannot be equivalent to the data required for a provincial / regional recommendation as this takes years of ongoing testing and is clearly not the VRO mandate.

The CFIA Registration Review recommended that this part of the mandate be deleted and CSTA supports that recommendation.

Further, we question why the CFIA would choose to be encumbered by accepting a legislated responsibility for this part of the mandate statement when, at the farm level,

any farmer has ready access to a large number of unadapted varieties and it would be futile for CFIA to ensure compliance or attempt enforcement. The answer to this point is an internal matter for CFIA to decide.

With the deletion of this part of the mandate statement, it becomes clearer that the amount of agronomic data required for VRO purposes is only that which is sufficient to do the determination of the legislated aspects of quality or disease. In the absence of a clear reference in the Regulations leading to this mandate statement, it would seem that there is no regulatory amendment required to change the mandate.

5. CSTA supports the concept of a "Listing" category.

When we proceed to developing the procedures documents we need to clarify the intended purpose of the information which will determine the data requirements. For example, the variety description and reference sample may be used as one means for entry to the seed certification program including OECD certification. However, many varieties are entered into Canadian production and certification using descriptions from other Certification agencies or the CSGA Form 300. Will the variety description from these sources be accepted for the "Listing" requirement? This and other questions should be reviewed as a procedures document at another time.

6. CSTA supports a Plant with Novel Trait (PNT) listing for the varieties / hybrids containing the novel trait.

The CSTA Biotech Committee called for a novel trait listing several years ago. We support your comments regarding the need for information for seed monitoring, seed recall and information on pedigreed seed exports. This listing would only apply to the hybrids / varieties that are a PNT. We suggest that you consider the needs of such a "Listing" as contributing to the larger CFIA Mission Statement of assuring market access. While the legal authority for mandatory participation in the "Listing" may reside with "Variety Registration" regulations, the operational details might be better managed by the Plant Biotechnology Office.

Consider the following;

The document specifically refers to a "Listing" for agricultural crops with PNTs. There is a long list of horticulture and ornamental species with PNTs currently under international confined testing. During a recent industry meeting, President Ron Doering highlighted the challenge for CFIA to implement regulations for a long list of horticulture crops.

Shouldn't these crops be accommodated?

Our domestic "Listing" initiatives should be compatible with other international initiatives. The OECD has started a similar database and the UNEP under the Biosafety Protocol has proposed that all domestic approvals of PNTs be posted on their "Clearing House" database as notification to other nations of our approvals. Clearly there is a need to structure the database and data requirements to be compatible with other international initiatives. This should be done in consultation with industry and other government participants.

7. The VRO should reinstate an industry workgroup to handle procedural details

As a concluding point, we would strongly urge reactivating the Variety Registration Advisory Committee. There are numerous procedural and operational details which would flow out of a renewed mandate. It would be far more efficient for an Advisory Committee workgroup to propose the changes to procedures documents. We would be willing to participate in such a group.