

Seed Regulatory Modernization Variety Registration Task Team Final Report

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Acknowledgment

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It is with our thanks that we acknowledge and recognize the dedication of all the individuals who participated, led and supported the Variety Registration Task Team.

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*see **Appendix 1** for list of task team members, their organizations and their stakeholder categorization for this process. The committee has 25 members total of which 21 were stakeholder-members (the rest CFIA and the facilitator) and 20* were voting members (the Chair only votes if there is a tie). The stakeholder grouping breakdown is: Seed Industry (6),

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Producer Groups (5), Commodity or Value Chain Associations (5), other non-government (2), Government, grain sector (1), and Government, variety developer (1).

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Subject Expert(s):

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Executive Summary

The CFIA is committed to a full-scale review of the following parts of the *Seeds Regulations*: Part I-Seeds other than Seed Potatoes, Part II-Seed Potatoes, Part III-Variety Registration, and Part IV-Registration of Establishments that Prepare Seed and Licensing of Operators of the *Seeds Regulations*. The objective of the Variety Registration Task Team was to provide recommendations in a report to the Seed Regulatory Modernization Working Group on opportunities for improvement with respect to how the *Seeds Regulations* govern variety registrations in Canada.

The *Seeds Act* and *Seeds Regulations* have undergone periodic amendments and modernizations since the first laws were established in 1905. During this current initiative, the CFIA is looking to update the *Seeds Regulations* to:

- improve responsiveness and consistency
- reduce complexity
- become adaptable and flexible to address future technological advances and scientific innovation
- protect producers and consumers by strengthening existing requirements

Canada's variety registration system is internationally recognized and respected for ensuring varietal identity and varietal purity while providing the tools for seed certification of those varieties and ensuring Canadian varieties are internationally recognized as plant varieties. In Canada, to qualify for variety registration the following must be met:

- meet the regulatory definition of variety (varietal eligibility):

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variety has the meaning assigned to **cultivar** by the International Union of Biological Sciences' Commission for the Nomenclature of Cultivated Plants and denotes an assemblage of cultivated plants, including hybrids constituted by controlled cross-pollination, that

(a) are distinguished by common morphological, physiological, cytological, chemical or other characteristics, and

(b) retain their distinguishing characteristics when reproduced; (*variété*)

- It must then meet the eligibility requirements for variety registration listed in the *Seeds Regulations* section **67.1 (1) or (2) or (3)**:

67.1 (1) A variety of a species, kind or type of crop that is listed in Part I of Schedule III is eligible for registration if

(a) the variety has merit;

(b) the variety has been tested in accordance with the testing protocols of a recommending committee;

(c) the recommending committee has made a recommendation respecting registration of the variety;

(d) the variety or its progeny is not detrimental to human or animal health and safety or the environment when grown and used as intended;

(e) the representative reference sample of the variety does not contain off-types or impurities in excess of the Association's standards for varietal purity (the Canadian Seed Growers Association "Circular 6");

(f) the variety meets the standards for varietal purity established by the Association or these Regulations for a variety of that species, kind or type;

(g) the variety is distinguishable from all other varieties that were or currently are registered in Canada;

(h) the variety name is not a registered trademark in respect of the variety;

(i) the variety name is not likely to mislead a purchaser with respect to the composition, genetic origin or utility of the variety;

(j) the variety name is not likely to be confused with the name of a variety that was or currently is registered;

(k) the variety name is not likely to offend the public;

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(l) no false statement or falsified document and no misleading or incorrect information have been submitted in support of the application for registration; and

(m) the information provided to the Registrar is sufficient to enable the variety to be evaluated.

(2) A variety of a species, kind or type of crop that is listed in Part II of Schedule III is eligible for registration if the requirements for eligibility set out in paragraphs (1) (b) to (m) are met.

(3) A variety of a species, kind, or type of crop that is listed in Part III of Schedule III is eligible for registration if the requirements for eligibility set out in paragraphs (1) (d) to (m) are met.

SOR/2009-186, s. 4.

- Since 2009, crops subject to registration can move to one of three levels of registration requirements (Part I, Part II, or Part III requirements) and placement in a registration level is a value-chain stakeholder-driven process that CFIA facilitates via a regulatory amendment process. Part I registration crops are “merit-based”; they must demonstrate merit (defined in the regulations - they must be equal to or superior to designated varieties used as “checks” in the registration test system for that crop kind. It can be as little as one trait in one region of Canada). The test protocols for merit determination and in many cases the actual testing for merit as well as the evaluation of merit are conducted by CFIA-recognized crop-specific regional variety registration recommending committees in Canada (there are 10 at present). These recommending committees are comprised of a balanced group of value-chain crop experts (as laid out in the *Seeds Regulations*) and are subject to oversight by CFIA. By regulation, they are expected to behave in a fair, predictable, and transparent manner.
- In practical terms, a registration package will require: 1) paying a fee (< \$1,000), 2) providing an official reference seed sample (Breeder seed) that meets the pedigreed seed standard for purity and is representative of the variety, 3) providing a standardized variety description suitable for distinguishing the variety from other varieties registered in Canada (it is used for crop inspection and seed certification), 4) undergoing a name check (suitability assessment), 5) providing scientific data to back up claims made in the variety description (e.g. disease tolerance, herbicide tolerance, end-use characteristics, etc.), and providing all the information required on the registration application form (trademark declaration for the variety name, pedigree, breeding history, plant with novel trait(s) or PNT trait declaration with proof of genetics/proof of trait and signing to attest to the accuracy of the information provided on the form). CFIA has a performance standard of 8 weeks of processing time to complete a submitted and

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complete registration package. Once registered, a registration number is assigned, a registration certificate is sent to the Registrant, and the variety can then be imported and/or sold in Canada.

- Variety Registration is the entry point into the seed market for the 53 crop kinds currently subject to registration in Canada and listed in Schedule III, *Seeds Regulations*. It ensures that data for determining varietal identity and also varietal purity are in place and that the name (denomination) is acceptable in Canada.

Critics of the registration system focus primarily on merit-based variety assessments which, depending on the crop, can take anywhere from one to three summers of field testing and analysis (e.g. cereal crops, depending on the grain class they are bred for). Time to market is an issue for variety developers (time is money). Other stakeholders point to a less than desired way of treating innovative varieties which can block or slow down market entry. Still, others reference other geographies where there are no registration systems and point out that they believe Canada can operate without a variety registration system. Starting with the initial topics suggested by the Seed Regulatory Modernization Working Group (available upon request : Appendix 2, Document 4) and adding a few of their own, the Variety Registration Task Team presented a work plan for the analysis and discussion of the following thirteen topics:

- THE BIG PICTURE QUESTION: Should Canada have a National variety registration system?
Follow-up question: If yes, who should be running it?
- Varietal eligibility (meeting the definition of variety)
- Crop Placement in the Variety Registration System
- Varietal Purity in the registration system
- One Variety, One Name Policy in Variety Registration
- Cancellation of Variety Registration
- Parsing Subsets of Species in Schedule III, *Seeds Regulations*
- Regional Restrictions on National Registrations
- The Use(s) of Incorporation by Reference (IbR) for Variety Registration
 - Who should administer the IbR document?
- Heritage, Heirloom, Heterogeneous Varieties, and Alternatively Bred Varieties
- Regionalized Crop Placements in Schedule III, *Seeds Regulations* (crop placements within regions of Canada is not currently done)
- Phenotype, Genotype, and the Variety Registration System (looking to the future)
- Recognition of and acceptance of foreign equivalent to variety registration for the Canadian variety registration process, Part 3 crops only (currently this comprises of 23 forage species, oilseed soy, non-ornamental sunflower, and potatoes)

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In addition, the following overarching topics, provided by the Seed-RM WG, were to be considered during the discussion of specific topics:

- Future Trends
- Government versus Industry Role
- Linkages and unintended consequences (e.g. variety cancellation & common seed)
- Incorporation by Reference – opportunities for use thereof
- International obligations (e.g. OECD and AOSCA seed schemes)
- Alternative service delivery including licensing and accreditation

The Task Team focused on four major opportunities for improvement:

1. Ability to adapt the requirements to changes occurring within the seed sector (*modernize; facilitate growth*).
2. Simplifying or eliminating the registration requirements, where possible (*streamlining regulations*).
3. Strengthening existing requirements, if needed (*addressing shortcomings*).
4. Creating a commercial path for innovative products not currently addressed in the regulations (building more flexibility into the system).

For each of the topics addressed the Variety Registration Task Team developed multiple options (ideally 3 or more), each with a rationale along with pros/benefits and cons/risks of each possible option prior to providing recommendations on each Topic. Each of the Task Team Topic reports, 1-13, submitted to the Seed Regulatory Modernization (Seed-RM) Working Group (WG) is available in this final report. The task team held 27 meetings from April 29, 2021 through to August 5, 2022. A total of 42 options across the 13 topics were proposed, discussed, and rationale developed. Pros and cons were identified for each option. The variety registration Task Team generated 42 recommendations for presentation to the Seed-RM WG.

In expressing the final recommendation results, the concept of a qualified consensus represents the threshold for agreement by the group. Here is the definition of qualified consensus used by CFIA throughout the whole co-development process:

Definition of qualified consensus:

*CFIA indicated that the Working Group will be made aware whether there is **qualified consensus** or not. What we mean is that we record whether or not the majority of each of the

stakeholder groups agree on an option/recommendation. If even one stakeholder group did not have a majority support, then we could not proceed to make a recommendation on a given topic. This would hold true even if the rest of the stakeholder groups clearly favoured a particular option.

Topic 1: Should There Be a Variety Registration System in Canada?

Reference: Topic Report 1; Appendix 2, Documents 1, 2, and 3.

Two options were developed: Yes or No and if yes, then a second question was to be answered (who should run the variety registration system).

Final Recommendation: A majority, 16/20 favored YES to Option 1. This was not a qualified consensus, however, because a majority of the Seed Industry stakeholders indicated they can do without a VR system. The seed associations, our National field crop certification organization, along with producers favored having a registration system. This raised the second item, given a majority supported having a registration system, we had a qualified consensus (unanimity) on the task team for the position that government should run the National Variety Registration System.

Topic 2: Varietal Eligibility

Reference: Topic Report 2; Appendix 2, Document 1

This addresses the current system of varietal eligibility determination as part of variety registration. CFIA conducts an assessment (paper based at the point of registration application) of whether or not a variety meets the definition of variety in Canada (from the Seeds Regulations). Unlike the EU, we do not apply a DUS (distinct, uniform, stable) requirement for registration. In Canada we look for distinguishable (from other varieties within Canada) and stable; uniform is not one of our requirements.

Two options were developed: Keep the current definition or move to the DUS standard

Final Recommendation: there was qualified consensus (unanimous) for keeping Canada's varietal eligibility requirement (distinguishability and stability) vs. EU's DUS; we have flexibility with our system, for more heterogeneous varieties. This goes to meeting the International definition of "variety". Note: this was helpful in dealing with Topic 10 (Heritage/Heirloom, Heterogeneous Materials, and Alternatively Bred Cultivars).

Topic 3: Crop Placement in the Variety Registration System

Reference: Topic Report 3; Appendix 2, Document 1

This refers to the current stakeholder-driven process of moving crop kinds from one Part of Schedule III to another part (there are three parts/three registration streams from highest (1) to lowest (3) regulatory requirements). Crop sectors can “move” a crop kind from one level of requirement to another following a process involving the submission of a rationale and evidence of the level value across the value-chain for that crop.

Four questions were raised and two options for each were developed.

Final Recommendations: 1) A qualified consensus supported removal of Part 2 Registration from Schedule III, otherwise no other changes, 2) A qualified consensus (unanimous) supported crop placements needing to be a stakeholder-driven process, 3) A qualified consensus (unanimous) supported a process to be developed by CFIA for both adding new crops into Schedule III (making them subject to registration) and finally, 4) A qualified consensus (unanimous) also supported CFIA developing a process for removing a crop from Schedule III (removing a crop from variety registration).

Topic 4: Varietal Purity (Variety Registration)

Reference: Topic Report 4; Appendix 2, Document 1

This refers to a specific situation with oilseed soybean varieties in Canada (some but not all) that CFIA presented to the team. A lot of time and effort (a disproportional amount relative to the crop and its acreage vs. the other 52 crop kinds under variety registration. CFIA spends a lot of time dealing with variants vs. off-types due to the high number and frequency of seed hilum colour variants, in particular. One suggestion was to lower the variety purity requirement (field visually based) from 99.7%, dropping it a few percentage points and then removing any allowance for variants and simply including them in the other category (with off-types and everything else). This would solve the variant issue in soy and CFIA would not consume time/effort in discussions with breeders nor would they have to resort to the level of DNA fingerprinting they do to sort out what is of the variety and what is not of the variety.

There was only one option developed from discussions.

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Final Recommendations/comments: It was noted that this is not regulatory amendment material and that CSGA is the one with the authority to set field crop purity standards within the seed certification system, including variety purity. Further, Canada is a member of AOSCA and any proposed change to varietal purity in soy would have to go through AOSCA as well. The task team developed qualified consensus (unanimous) recommending that CSGA work with AOSCA to review varietal purity standards not only for oilseed soy but also for other crops.

Topic 5: One Variety, One Name Policy in Variety Registration

Reference: Topic Report 5; Appendix 2, Document 1

CFIA, Variety Registration Office has always operated under the policy of one variety/one name. This is to avoid confusion in the seed market and addresses the principle of fair and accurate representation of a variety in the marketplace (part of the regulations). The seed trade would like more flexibility in variety naming and the question of multiple names for the same variety (to support flexible licencing arrangements by seed companies) was raised.

Two options were developed: keep the policy as-is or remove the policy

Final Recommendations/comments: The task team developed a qualified consensus (unanimous) to maintain the current policy of “one variety.one name” for variety registration in Canada.

Topic 6: Variety Cancellation

Reference: Topic Report 6; Appendix 2, Document 1

Three options were developed: 1) Keep the current system whereby the Registrant can cancel their registration by request, 2) Change the system to allow for parties other than the Registrant to influence cancellation, 3) to allow cancellation only when the variety is deemed to cause harm (cancellation for cause by the Registrar). Also, when the topic of “unintended consequences” came up, the impact of variety cancellation on off-patent and off-plant breeders’ rights varieties was raised. The impact on the common seed market was also raised and the task team unanimously chose to share this report with the Common Seed Task Team and ask for their input on the common seed angle. The common seed task team came up with five options on this topic: 1) status quo, 2) make all registrations for life, 3) allow for an

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interested party to become the variety maintainer, prior to cancellation, 4) have an application process for canceling a variety with an appeal period for cancellation (to be made to the Registrar) and 5) that seed harvested from a certified hybrid (e.g. hybrid canola, hybrid corn, hybrid cereals, etc.) should not be sold as common seed in Canada.

Final recommendations/comments: The task team did not reach a qualified consensus on any of the three options that were developed. Option 1 (keep the current system) had the majority support but did not reach the threshold for consensus by the task team. The input received from the Common Seed task team did not change the recommendations in this report, after a re-vote. Producer stakeholders on the VR task team chose Option 2 (bring other stakeholder (producer) parties into the cancellation process). There is no single option to recommend to the Seed Regulatory Modernization Working Group, therefore, the two options (1 and 2) with the most support, along with an explanation of level of support, was forwarded to the working group.

Topic 7: Parsing Subsets of Species in Schedule III, *Seeds Regulations*

Reference: Topic 7 Report; Appendix 2, Document 1

This refers to the numerous crop kinds in Schedule III of the *Seeds Regulations* which are parsed or have qualifying text, in brackets, associated with them (e.g. flax (*oilseed type*) or triticale (*grain type*)) which can be problematic for the regulator as it often requires interpretation. Two options were developed: 1) parsing is permitted for subsets of species which allows them to be treated differently (the current situation for a number of species) and 2) no parsing would be permitted and all subsets of species would be treated the same. In addition, there was an amendment to Option 2 made whereby all crops would be moved to Part 3 registration.

Final recommendations/comments: The team developed a qualified consensus for Option 1 (keep the current parsing of crop kinds in Schedule III) with a note that this will be easier to implement once Incorporation by Reference (for Schedule III) happens (they are assuming). Of note: the majority of Seed Industry stakeholders support Option 2 (no parsing and move all to Part 3 registration).

Topic 8: Regional Restrictions on Registrations

Reference: Topic 8 Report; Appendix 2, Document 1

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Currently some crops (notably wheat) when recommended by a regional committee (e.g. the PRCWRT or Prairie Recommending Committee for wheat, rye, and triticale) have CFIA contacting other recommending committees in Canada for the same crop and asking the question: do you have any objection to the National registration of this variety? There are only two grounds for this: disease issues or seed/grain quality issues such that it might provide confusion in the market. If they do object, a regional restriction for the sale of seed for that variety is put on the registration. This is time consuming (slows down the final registration) and problematic for CFIA. The task team developed three options: 1) to continue to allow regional restrictions on variety registrations, 2) to make all registrations National and not allow regional restrictions, and 3) To allow regional restrictions on National registrations in select species and develop a process to ascertain the status of each of the species subject to registration.

Final recommendations/comments: There was a qualified consensus for Option 3: To allow regional restrictions and develop a process to ascertain how it is applied and to what species in Schedule III it should apply to. This would provide clarity to CFIA (and the recommending committees, variety developers) that is currently lacking. Further, there was also a qualified consensus for the following statement: CFIA is encouraged to have recommending bodies in Eastern Canada (Ontario, Québec, Atlantic Region) be consolidated to one recommending body for the Eastern Canada Region.

Topic 9: The Use of Incorporation by Reference (IbR) in Variety Registration

Reference: Topic 9 Report; Appendix 2, Document 1, 5, 6

The Variety Registration section of the *Seeds Regulations* (Part 3, *Seeds Regulations*) was examined to take advantage of the use of incorporation by reference to remove parts of the regulations and move them to an administrative document that can be altered without the need for the lengthy regulatory amendment process. The only part of the regulations related to variety registration that would make sense for this tool is Schedule III at the back of the regulations. It is the table that defines the 53 crop kinds subject to registration in Canada and defines which type of registration (Part I, II, or III) the crop kind is subject to. Using IbR on this document would allow for timely entry, exit and changes within the registration system for any given crop kind. Two options were developed: 1) No changes to the current system, and 2) Use incorporation by reference to incorporate Schedule III of the Seeds Regulations and remove it from the regulations, make it an administrative document.

Final recommendations/comments: A qualified consensus of task team members recommended CFIA use incorporation by reference to remove Schedule III from the *Seeds Regulations* and reference it in the regulations. There was also qualified consensus that CFIA should hold the pen on this document. This will facilitate much more rapid stakeholder driven additions of new crops, removal of crops, parsing of crop kinds and crop placements in the flexible variety registration system. It removes the need for a regulatory amendment to make changes in this area. We could not find any other items in Section 3 of the *Seeds Regulations* (Variety Registration section) that could be incorporated by reference.

Topic 10: Heritage, Heirloom, Heterogeneous and Alternatively Bred Varieties

Reference:: Topic 10 Report; Appendix 2, Document 1

A sub-committee with Dr. Jennifer Mitchell Fetch as Chair and an outside expert (Mr. Aabir Dey from the Bauta Family Initiative on Canadian Seed Security) was struck and developed the material to take back to the main committee to discuss, set options and try to make a recommendation. The goal was to establish a regulatory path, if needed for the commercialization of heritage and heirloom varieties as well as farmer-bred (one form of alternatively-bred) varieties. The issue of heterogeneous varieties was discussed as well and there was consensus within the group that no change was necessary for heterogeneous varieties as our system is not DUS based like the EU, meaning we allow for much more diversity in our varieties than other geographies. With regard to heritage and heirloom varieties, the task team/sub-group started with establishing a definition for heritage and heirloom:

- A **heritage variety**: is a cancelled or "to-be-cancelled" variety of a crop kind subject to registration (Schedule III) which is 50 yrs. or older.
- An **heirloom variety** is a non-hybrid variety of a crop kind subject to variety registration (Schedule III) that was never registered but grown in Canada prior to 1970.

Final recommendations/comments: 1) there was qualified consensus on the issue of heterogeneous materials and populations: that Canada's system of registration based on distinguishability and stability but not uniformity (as in the EU) can accommodate these heterogeneous materials, 2) There was qualified consensus that Canada's current variety registration system can accommodate alternatively bred (e.g. organic, low carbon, farmer-selected material, etc.) varieties and that no change to the regulations is required. Further, CFIA is recommended to work with AAFC and create a guide for farmers/new breeders on how to navigate the VR system with these types of materials, 3) the task team could not reach

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qualified consensus regarding heritage and heirloom varieties. Four options were considered to commercially enable these types of varieties and in the end two options were almost equally supported: 1) heritage and heirloom varieties could be managed in the current system as a Part 2 registration crop in Schedule III* (so no regulatory changes) AND 2) there should be a regulatory exemption from Schedule III for heritage/heirloom varieties (this would require a regulatory amendment). The two equally supported options for heritage and heirloom varieties had enough support to move them both forward as options for the Working Group to consider.

* *this option is at odds with our Topic 3 Report recommendation to remove Part II registration from the system.*

Topic 11: Regionalized Crop Placements in Schedule III, Seeds Regulations (unique crop placements within different regions of Canada)

Reference: Topic 11 Report; Appendix 2, Document 1

Three options were considered: 1) To allow crop placements within regions of Canada such that, by region, a crop kind could be either a Part 1 or a Part 3 registration crop, 2) To allow regional placement¹ of Part 1 crops into Part 1 or Part 3 of Schedule III², 3) No Change to the current system but initiate change at the Recommending Committee level* to encourage an expedited pathway to market even though it is a Part 1 crop (e.g. pulses – create a special provision for colored beans whereby the committee trialing system is by-passed in favor of a developer/end-user documented agreement to work with the variety in the market)

Final recommendations/comments: We have no qualified consensus for any of the three options we developed. We cannot forward a specific recommendation. There are two options forwarded onto the Seed-RM WG for consideration from the Variety Registration task team: 1) To allow regional crop placement such that, by region, a crop kind can be either Part 1 or Part 3 registration AND 2) No change to the system as it is felt that it meets the needs of the stakeholders.

Topic 12: Phenotype, Genotype, and the Variety Registration System

Reference: Topic 12 Report (includes a primer on the topic); Appendix 2, Document 7 (a primer on the topic), Document 8 (a copy of the presentation on markers by Dr. Curtis Pozniak, CDC/U of Saskatchewan)

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Three options were developed: 1) no change to the current system, 2) Encourage CFIA to pursue a vision of increasing use of BMTs (bio-molecular techniques) on the variety registration program and to change the *Seeds Regulations* to incorporate molecular characterization as a recognized tool for existing work; to make a clear vision of increasing use of BMT based assessment of varietal identity and varietal purity, recognizing that industry is out in front of this technology and has been using BMT extensively for a long time. 3) Transition to an all-genotype based system for variety registration (exclusive use of BMTs).

Final recommendations/comments: The task team developed a qualified consensus for Option 2 (for CFIA to change the regulations to empower the use of BMTs or biomolecular tools for variety identification and purity determinations in the variety registration space). Specifically, it is recommended that CFIA change the following part of the *Seeds Regulations* as follows: **Part 3: Variety Registration, 67 Applications for Registration (1)** (iv)...to include a reference to "bio-molecular techniques (BMTs)".

Topic 13: CFIA Recognition of Foreign Variety Registrations and their Equivalent (Harmonization on registration requirements)

Reference: Topic 13 Report

Three options were developed: 1) no change, 2) modify the list of registration requirements in Part 3, Seeds Regulations (Variety Registration section), for Part III Registration crops (as listed in Part III, Schedule III) to allow for recognition of foreign registration equivalence such that foreign data packages could be used by CFIA to meet Canada's registration requirements. Canada would still perform their own variety eligibility determination (distinguishability and stability) based on this data, 3) Complete acceptance of foreign registration packages or their equivalent in lieu of Canadian Part III registration (acceptance as equivalent). Acceptance as equivalent would be on the basis of meeting the core information requirements: varietal eligibility determination, data to support claims in variety description, seed sample, variety description, "tombstone information" on the principals involved in the registration (Breeder, Canadian Representative/Registrant, Variety Maintainer, Owner, etc.). A streamlined Part 3 registration process would be put in place (shorter processing time – less than 8 weeks).

Final recommendations/comments: After a re-vote on June 29, 2022 where we had 12 voting members present (vs. 8 on the original vote), there was a qualified consensus (unanimous) for Option 2: to have CFIA modify the *Seeds Regulations* Part 3 (the list of registration requirements) to allow for the acceptance of foreign registration data (or its equivalent) to

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allow those same data packages to be submitted for Canadian Part 3 registrations. Canada would still perform their assessment of varietal eligibility but on the foreign data.

Topic 1 Report (rdims# 15168518 v5)

SEED REGULATORY MODERNIZATION

VARIETY REGISTRATION TASK TEAM

Topic #1: Should there be a Variety Registration System in Canada?

OPTIONS AND RECOMMENDATIONS REPORT

July 21, 2021

Topic #1: Should there be a Variety Registration System in Canada?

Currently, Canada has a tiered variety registration system. This system covers 53 crop kinds with three different tiers of registrations, with each tier having different requirements.

The question posed to the task team was: Should there be a Variety Registration System in Canada? If there should be a variety registration system, should it be run by the government?

ANALYSIS OF OPTIONS:

OPTION 1: Yes, we want a variety registration system.

Rationale: The current variety registration system has worked well in Canada. It provides assurance to producers that registered varieties meet the unique identity requirements of a variety, for distinguishability and stability that provides the eligibility verification required for officially recognized seed certification. The Canadian system is known and respected internationally. Since its review in 2014 and subsequent modification, it is flexible, transparent, and not overly bureaucratic.

For those crops where merit is a requirement, it provides assurance that minimum standards of agronomic performance, disease and pest resistance, and end-use quality are met. Harm due to disease susceptibility or lack of suitability for end-use markets is avoided. Value chain members set the standards therefore there is confidence in the product and rapid uptake of new varieties by growers and end-users. Since check varieties are regularly updated continued improvements result. Proponents maintain that the variety registration system is not a deterrent to investment in plant breeding in Canada. Alleged deterrents to this investment include the Canadian approval process for PNTs and the challenge of value capture in many cereal markets in Canada.

This option would maintain but modernize the current system, where the CFIA is providing the service of variety registration with the responsibility to ensure compliance with varietal identity

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standards. This option includes using Incorporation by Reference (IbR) to CFIA operating procedures (e.g. Schedule III of the Seeds Regulations) to provide a more flexible system that is still under the auspices of the Canadian government. This would retain support in both domestic and international markets for the reputation and credibility of Canadian seed identity and quality assurance.

Pros/Benefits:

- Variety registration ensures varietal identity standards are being met (distinguishable, stable)
 - There is a direct linkage between VR and Seed certification.
 - Removal of the VR system would require changes to the seed certification system.
- Variety Registration protects the quality and prevents harm to the industry (breeders through to farmers).
 - cv. **CDC Triffid** oilseed flax is cited as an example of government supporting industry.
 - Protects growers from crop failures due to varieties not adapted to the Canadian environment.
 - Protects the integrity and competitiveness Canadian-produced seed products.
 - Protects the wider plant health system.
- Merit criteria provide value to the crop sector, the grain sector, and end-users.
 - The export industry is based on the known variety merit characteristics that provide an assurance of quality.
 - Merit is the way to keep plant breeders responsible for their varieties.
 - Merit gives a basic set of performance criteria specific to Canada.
 - Merit provides quality classifications that reflect end-use processing quality (wheat).
 - For wheat, *Fusarium* resistance has been improved because of VR.
 - For cereals quality classification/evaluation in VR speeds up value chain acceptance and adoption of varieties in the market.
 - There is greater value (greater uptake) of any associated royalties to the variety developer in the first few years of seed sales
 - In cases where we are seeing some traits eroding, merit characteristics can be adjusted to compensate (peas losing protein content, and subsequently having protein content added as merit criteria).
 - Merit testing provides an opportunity for the industry to raise the standards for registration and in so doing, pushes it towards constant improvement.
- VR is a system that is known and can continuously be improved.
 - Recommending Committee protocols are transparent science-based. They operate in the interest of all involved.
 - VR allows RC procedures to change as required. They can be reviewed carefully and transparently maintained. From the standpoint of predictability, it's all there.

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- Once a variety is recommended, the breeder seed goes to the select growers within months and the varieties reach commercialization very quickly.

Cons/Risks:

- For Part 1 registration crop kinds, it adds a regulatory burden to variety developers (time/money).
 - Taking time to go through the VR system may slow down variety development and innovation.
 - Recommending committee processes are onerous and time consuming.
 - Adds regulatory burden to the seed developers.
- Merit may not always be the best way to evaluate a variety
 - With only looking at certain merit criteria, it could lead to only a few varieties being seeded which could adversely affect the climate.
 - The current system may be too lenient in allowing varieties to be registered that are not meeting 'the bar' set.
 - Quality can be determined in other ways besides VR. Data may not be needed for VR.
- Increase in disease resistance is not declining due to the VR process, it's because companies are competitive and feel the need to push to continue improving their crops.
- There are product lines that are identical in USA and Canada, so what are we doing differently if the product line is the same in both.
- It is be perceived as a form of non-tariff barrier.

OPTION 2: No, we do not want any type of variety registration system.

Rationale: There is no need for a variety registration system in Canada. The USA does not have such a national variety registration system and has a thriving agricultural sector. Crop improvements occur in response to grower and end-user demand. Post release mechanisms can be developed, with input from the value chain, to ensure quality requirements are met. Without the merit testing requirements of variety registration, variety developers would have less red tape to navigate to market their varieties. This should lead to more predictable planning and should result in greater investment by more companies breeding varieties for the Canadian market. Market forces would then need to drive varietal attributes and decide which varieties succeed.

Varietal identity verification required for crop certification would be managed by the seed certification agency as in the USA.

This option would remove the current variety registration system. This would leave room for a private system to be developed if there was sufficient interest and financial support. This would

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mimic the seed system in the United States, where there are much lower levels of officially recognized seed certification and no national system for the registration of varieties.

Pros/Benefits:

- Reduces resource requirement for variety development/commercialization
- New technologies and materials may be more easily accessible
 - Crops not subject to VR allow growers to access new technology and materials earlier than if they were within the VR system.
 - This could encourage new technologies to be developed.
 - Corn and IP soybean example
- Smaller variety developers have more ability to come to market (less barriers to entry).
 - This would be true even if only merit was eliminated.
 - This could help to equalize ability to come to market.
- Crops that have moved away from VR have seen positive results in the value chain.
 - Part 3 takes away merit and quality requirements, but we have seen significant genetic gain in those crops (soybean).
 - Corn has reacted positively to being outside of VR.
 - There would be a faster entry to market.
- Allows for an increase in industry/market driven development
 - The market and growers will pay for what they want.
 - Industry strives for steps that the registration system does not. The more straightforward it is to commercialize, the more investment we will see.
 - Many decisions on a variety are made based on the need and the climate, even before it hits the committees' review of the merit criteria.
 - Resources previously spent on VR trials could be put towards enhanced provincial/performance testing, which would be of more use to growers.

Cons/Risks:

- Without merit criteria...
 - Market forces would end up driving market attributes; there is no way to force an increase in certain areas
 - We could disadvantage our exports.
 - We could see varieties enter Canada that may not have the winter hardiness that is necessary.
 - There may be some transfer of risk to an early adopter of a variety
- Examples where problems occurred:
 - Soybeans moved into SASK and did poorly, costing many growers. There is no market now due to low protein. If there had been merit criteria for this area and protein content, this might have gone better, or not have happened.

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- Bean varieties that are not registered are being grown, but because they are not adapted to our conditions, they are leading to crop failures.
- American wheat that was indistinguishable from CWRS did not meet the quality requirements, and cost an organization a lot of money.
- Without D & S (distinguishable, stable) from VR, the certification system would be in trouble.
- It is much more difficult to do the technical evaluation of varietal eligibility for crops that are in VR, compared with a crop like corn.
- Breeders in small programs (or working with small acreage crops) would not be able to mimic the VR system to provide the required data for a specific cultivar.
- A new system would need to be developed for some crops (wheat) to determine if the variety meets end-use quality guidelines.
 - This is already being done in Malt Barley in Canada and Wheat Councils in Kansas and Australia.

DISCUSSION:

There was not a qualified consensus on whether or not the system itself should still exist. Although a majority of the members: 16 of the 20 voting members, spoke in favour of having a variety registration system, a majority of Seed Industry stakeholders felt that elimination of the VR system would be in the best interest of the entire value chain. The seed crop certifying association explained that officially recognized verification of variety certification eligibility provided by the VR system, is necessary to maintain the seed certification system.

There was consensus from all sectors that, should there be a variety registration system, then the government should continue to be the manager/risk-holder, as the government is seen as a neutral party that doesn't have self-interest as a private industry entity might. The government is also seen as a more trustworthy body from an international perspective.

After reviewing the results of the voting, as grouped by sector of the seed value chain, Option 1 was favored over Option 2 by the majority of task team members. However, the qualified consensus was not achieved.

The process of recommending an option forward to the Seed Regulatory Modernization Working Group requires qualified consensus. This means that the producer and the seed industry sector groups must both support (in the majority) an option for it to be recommended forward. In this case, the majority of the Seed Industry sector favored Option 2 over Option 1, leading to no qualified consensus.

Thus, no option is put forward for a recommendation from the Variety Registration Task Team on this topic.

RECOMMENDATIONS:

Neither formal Option discussed was put forward for recommendation by the Task Team.

1. Primary discussion suggested that, in the event that there is a formal variety registration system, the government should continue to be the manager. [note: Alternative Delivery system (ASD) of the variety registration system is a topic on the work plan]

Topic 1 Report Addendum: Written Submissions Members of the VR task team on Canada's National Variety Registration System

#1 Alanna Gray, Keystone Agricultural Producers (KAP) (Producer Group)

From: Alanna Gray

Sent: 2021-06-09 5:27 PM

To: Mark Forhan <mark.forhan@inspection.gc.ca>

Subject: RE: second e-mail for VR Task Team Mtg #4; Needs Assessment Survey Results from CFIA (to help inform the VR Task Team)

Hi Mark,

Here are some thoughts/comments re: variety registration.
I can put this in a word document and format it, if required.

Thank you and talk soon.

Alanna

Q: Do we need Variety Registration?

A: We need a system that ensures farmers have access to new varieties that are accepted by end-users and that can withstand the changing climate. The current system ensures that new varieties maintain the quality and characteristics that many end users expect when they buy Canadian grain.

KAP supports a well-funded system of plant breeding in Canada that ensures the continued development of crop varieties that adapt to a changing environment and international marketplace. The regulatory system for the commercialization of new varieties must protect producer interests and include government oversight and a periodic system review.

Variety registration pros:

- A clear understanding of what varieties are and are not acceptable for buyers
- Merit testing
- Government oversight

Variety registration cons:

- Administrative burdens
- Inflexibility
- A system that is not based on market demand

Q: If yes, who should run it? Government or another entity?

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

A: If non-government entities control the variety registration system they may be self-interested actors and unable to remain objective in their decision making.

Government provides clear guidelines of what breeding technology and traits are acceptable. They also ensure that varieties with traits that aren't acceptable by the market (like round up ready wheat) do not enter the supply chain.

#2 Laurie Friesen, Seed Program Manager, Saskatchewan Pulse Growers (Producer Group)

From: Laurie Friesen

Sent: 2021-06-07 12:23 PM

To: Mark Forhan <mark.forhan@inspection.gc.ca>

Subject: RE: second e-mail for VR Task Team Mtg #4; Needs Assessment Survey Results from CFIA (to help inform the VR Task Team)

Hi Mark,

. Please see the attached.

Have a great day,

Laurie

Laurie Friesen

Seed Program Manager

Saskatchewan Pulse Growers

***and here is the attachment:**

Variety Registration (VR) - Big picture (do we need a VR system and who should run it)

1. Do we need variety registration?

We need a variety registration system in Canada. The main advantages of a VR system are twofold:

- Protect the interest of growers in Canada
- Protect the integrity and competitiveness of Canadian produced grain

Growers need to know that the varieties they are investing in have been assessed in a transparent and unbiased system. Variety registration provides assurance that the varieties they grow will meet the purported attributes. This is particularly true where merit for key traits is a requirement for registration. Variety registration requirements such as performance testing provides unbiased, comparative data of new varieties against current top-performing varieties that allows growers to make informed decisions.

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Variety registration also protects valuable export markets which growers rely on to market their grain and ensure competitive pricing. Merit requirements such as protein in peas ensures end-users of the quality of the Canadian product. Global trade is competitive and we need a system which provides assurance of quality and maintains the Canadian advantage.

Variety registration ensures varieties are adapted to the region in which they to be grown. This is particularly true in Saskatchewan which has a short growing season. As an example, varieties of dry beans not registered or tested in Canada have been brought in from the US resulting in crop failure in Saskatchewan due to lack of adaptability.

I believe the pros of variety registration far out-weigh the cons however I respect the concerns of the industry with regard to the length of time required to achieve registration.

2. Who should run the VR system in Canada?

The Canadian government should continue to administer variety registration.

Pros:

- Ensures an unbiased approach and transparency
- Avoids conflict of interest
- Provides testing for minor diseases that may not be available or economical for private labs
- Maintains consistency in testing and assessment
 - Standardized lab testing (e.g., disease)
 - Consistent field assessment of variety traits
- Maintains consistent and affordable costs to the variety developer
- Private industry may not be willing to provide all of the requirement of the VR system or may significantly inflate costs.

Cons:

- Resource strain on government
- Barrier to private industry to add variety registration activities to their business portfolio

#3 Dr. Curtis Rempel, VP Crop Production & Innovation, Canola Council of Canada (Commodity Group)

From: Curtis Rempel

Sent: 2021-06-07 2:45 PM

To: Mark Forhan <mark.forhan@inspection.gc.ca>

Cc: Seed Regulation Modernization <cfia.seedregmod-modregsem.acia@inspection.gc.ca>

Subject: Canola Value Chain Assessment

Hi Mark

These 2 questions are fundamental questions for the membership of the Canola Council of Canada and the wcc/rrc. I know that some individual companies have already responded, but I have not been able to engage our entire value chain for a broader discussion. Our CCC board meeting is June 15, 16 and I will be raising this for board discussion.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

As you know, wcc/rrc is currently undergoing a review of procedures to further remove cost and time for variety evaluation process and we are tracking our internal timelines for this review, and this will be in place for presentation and decision at the December 2021 meeting.

The variety registration process has provided a robust and orderly framework to bring innovation into the marketplace while ensuring that all varieties meet canola standards to facilitate functional domestic and international trade. The entire canola value chain needs to have the discussion regarding the future of variety registration – whether it is needed or not – and the role of the government if a recommending committee and system remains in place. Our 2015 review affirmed the need for variety registration and provided clarity on the important role the GOC plays and that was an entire value chain discussion which we initiated. I am hoping to do the same in this review, but will need some time to undertake this.

Regards

Curtis

Curtis B Rempel MBA PhD PAg
Vice President, Crop Production and Innovation
Canola Council of Canada
Adjunct Professor
Dept of Food and Human Nutritional Sciences
Faculty of Agriculture and Food Sciences
University of Manitoba

#4 Bill Gehl,

From: Bill Gehl
Sent: 2021-06-05 9:21 AM
To: Mark Forhan <mark.forhan@canada.ca>
Subject: Bill Gehl comments on Gov't Role

Good morning Mark. I'm having difficulties with my skill level on the computer so ended up just taking a screen shot.

Note from Mark Forhan, CFIA: the document he sent starts on the next page (single snapshot file – acts as a picture and takes up a full page so there were a few formatting issues on cut and paste)

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I don't have any "cons" to existing system save it may be too lenient in allowing varieties to be registered that are not meeting "the bar" set.

Pros- Canadian system is rather unique in world and as it is one of the few places that produce high quality wheat for export. It's important that we understand why our system developed like this

-Wheat is produced in many countries in the world yet Canadian wheat continues to be sought after and this is not by chance.

-Our fore fathers realized that Western Canada was able to produce top quality wheat's that would draw demand from markets as medium quality wheat's were produced in many more areas outside of the "Northern Great Plains" of North America.

-We have built this reputation over the last 100 years and it starts with our plant breeding programs continues with varietal registration, production, transportation/storage, quality assurance via CGC and sales.

-Worlds exporting grain markets are still dominated by 4 companies and even though these same companies are operating in most grain producing countries, many of their sales that originate in places such as Russia will have a significant portion of Western Canadian *produced wheat included in the sale, proving that a high quality wheat is still in demand* from customers in this Global Market Place.

-As a farmer on the production side, our wheat classification system has proven to supply varieties that perform well in various regions across Western Canada from the Red River to Peace River.

-Our plant breeders have managed to combat many pest and diseases over the decades whilst making sure our customers are receiving a product that works for their market place and simply put "MERIT" is the reason for this.

- Being a member of the Prairie Grains Recommending Committee (PGRC) for Wheat, Rye and Triticale, I personally have seen the amount of flexibility that is being offered to breeders to bring their varieties forward for recommendation even though those varieties many have fallen short in some areas. They were thought by the majority of members to be an acceptable variety that could garner some interest and market share.

-So my point is- the system has been developed to suit our producers and customers but yet is not rigid and is flexible enough to allow varieties that may not have made it entirely on "MERIT" alone.

-As a farmer, there are already almost too many varieties to choose from. Having "Me Too" varieties available adds nothing to production levels in fact may slow the uptake of actual improved varieties.

In closing "YES" we need the Government involved as I view that as "their job"!!

And "YES" we need a robust variety registration system

Bill Gehl

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

#5 Dale Burns, Canola Breeder, Bayer Crop Science (Seed Industry)

From: Dale Burns

Sent: 2021-06-04 5:51 PM

To: Mark Forhan <mark.forhan@inspection.gc.ca>

Subject: RE: second e-mail for VR Task Team Mtg #4; Needs Assessment Survey Results from CFIA (to help inform the VR Task Team)

Hi Mark. This turned out to be tougher than I thought! Here are my comments.

Do we need a variety registration system' (Y/N)

After a lot of thought, no, at least not in its current form. There is a need for a system to identify and manage unique products, each meeting unique customer needs that they, the customer, define. Whether this is best accomplished by registration or a catalogue approach could be debated, yet overall registration itself does not truly guarantee performance. There are so many major and minor crops, it is difficult to conceive a system which is flexible enough to work for all.

Without registration, data would still be generated due to competition for customers. Eliminating yield and blackleg from canola recommendation trials has not slowed genetic gain for either trait. Similarly, it is likely that end users would entice demand for e.g. higher oil by adopting a component pricing system in the absence of quality-based recommendation leading to registration.

If individual developers are not connected to potential customers, there is likely another option where each crop group within the industry could establish a list of needs to signal breeding direction and data needs.

Processes in place during seed multiplication to deliver consistent high performance would remain with or without registration. This is just good business.

In many crops, it appears that registration and recommendation are treated as equals. A system without registration could still maintain recommendation and/or supplemental data collection if enough support existed within the crop.

Best regards,

Dale R. Burns

Product Development Scientist – Canola Breeding



He/him

Bayer Canada – Crop Science Division

#6 Dr. Lauren Comin, Alberta Wheat & Barley Commission (Commodity Association)

From: Lauren Comin

Sent: 2021-06-04 3:24 PM

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

To: Mark Forhan <mark.forhan@inspection.gc.ca>

Subject: RE: second e-mail for VR Task Team Mtg #4; Needs Assessment Survey Results from CFIA (to help inform the VR Task Team)

Hi Mark,

I failed to jot down the action item from last meeting so thank you for the reminder to send you our thoughts.

I am speaking from the western barley and wheat perspective- I don't know a great deal about varieties that are registered outside of PGDC in the west.

We absolutely need a variety registration system and I believe that the government is the currently the correct body to control it.

The variety registration system has several important benefits. The first is the assurance that varieties that are released for commercial use won't exacerbate existing pest issues, can be managed agronomically and have the genetic potential for a quality profile that will be marketable. This not only protects the producer, but also our plant health system. A second is it reassures customers that varieties that are grown and sold from Canada will be of a certain minimum standard in terms of quality and consistency.

The government has no ulterior motives to undermine the system (one would hope!) and is not vulnerable to changes in membership affecting direction etc. It is potentially a more trustworthy body for international customers, as well.

Cheers,

Lauren Comin, PhD

Director of Research Alberta Wheat and Barley

#7 Steve Denys, Maizex Seeds (Seed Industry)

From: sdenys

Sent: 2021-06-07 6:53 AM

To: Mark Forhan <mark.forhan@inspection.gc.ca>

Subject: Supporting Points for the Option to Eliminate Variety Registration

Mark,

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

Sorry for the delay. See attached supporting points for the Option to Eliminate Variety Registration. If any questions, let me know.

Stephen Denys
Brand Director
Maizex Seeds

MS Word attachment from Steve Denys:

June 6th, 2021

To: Variety Registration Task Team
From: Stephen Denys

Points of Reference for Option of Eliminating Variety Registration

The following is a summary of points supporting the Option of Eliminating Variety Registration in Canada:

- Accelerate the access to new genetics for farmers and end-user of the seed.
 - The example to this is the experience in corn and IP soybeans where the elimination of variety registration by merit has accelerated improvement in performance driven by grower or end user demand in a more-free market environment.
 - The result as evidenced to the positive in crops like corn and soybeans would be a 2–3-year faster entry to the Canadian market, on part with the introduction of varieties in the United States or other countries around the world, putting Canadian farmers on an equal footing.
 - Quality parameters would not disappear as demonstrated in corn or IP soybeans as market driven parameters, some the same, some different, used by seed companies and growers as measurements for performance. The removal of merit (e.g., yield/disease) in canola has not led to quality depreciation and field experience has proven that where criteria for registration was removed, the quality of those criteria in varieties introduced to the market has not suffered.
 - The result will be increased choice for farmers.
- Create the opportunity for niche markets within the broader acreage of crops
 - The elimination of variety registration would open up more opportunities for niche markets and provide opportunities for varieties that do not fit into the current system such as forage wheat (and forage soybeans if not for the movement either to Part 3 or exempt as for IP soybeans) where there is a market demand and evidence of success in other countries where variety registration is not a parameter for commercialization.
 - Variety registration acts as a barrier to entry for varieties that would meet government mandates including clean fuel standards by slowing down the process that could lead to investment and the introduction of varieties to reach these opportunities.

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- Eliminate barriers to entry for private investment
 - This is a key point. Despite calls from government, farmers and industry for increased investment in crops like wheat, the reality is the variety registration system is a barrier to entry for private investment and protects primarily the public breeding institution. True investment will only be achieved through a level playing field stimulated by the elimination of variety registration.
 - As evidenced in other crops not tied to variety registration investment will be made by companies small to large and from around the world. Currently the Canadian market is seen as a closed shop from an investment perspective in many crops.
- Create the opportunity for genetics development in Canada for export to other countries
 - Investment will also lead to an enhanced opportunity to increase the export and value returned from developing genetics in Canada that can be used elsewhere in the world.
- Increase industry communication and collaboration
 - Removing variety registration would result in increased collaboration between variety developers and end users.
 - The current system acts as a barrier or shield that creates distance between developers and end users of the crop produced.

Misnomers Around the Elimination of Variety Registration.

The following are issues discussed during the first Task Team meetings tied to variety registration and the points to address the perceived negative outcomes from eliminating variety registration.

- Product Performance will Deteriorate and performance information will not be transparent:
 - This is false. In this day and age, developers cannot afford to invest in genetics that will not be supported by sales in the market. Internal testing supported by industry or provincial trials in conjunction with grower groups is already used to benchmark performance and aid in variety screening in many crops.
 - Performance in crops not governed by variety registration has accelerated not declined.
 - Once commercialized communication systems today and instant performance measurement through yield monitors screen performance on modern farms. Growers instantly know what works and what does not in their decision making for subsequent years and this information is readily shared via social media, grower clubs, the coffee shop and in provincial publications.
 - The Ontario soybean and corn trials are examples of initiatives that make data available to the public.
- Seed Certification is not possible without variety registration:
 - This is false. In crops like corn and IP soybeans, seed certification occurs without variety registration and to the same standards as crops under variety registration using the same systems.
 - The concept of seed certification without a VR system is practiced in major seed producing markets such as the US and Australia with great success.
 - The high use of common seed in cereal crops provides a strong indication that seed certification is not viewed as a service of high importance particularly for producers in the West with or without variety registration.
- Investment in crops like wheat will decline:

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- As previously pointed out, investment will actually increase given the perception of Canada as a market open to investment putting developers on a level playing field.
- Grain classification cannot occur without variety registration:
 - This in fact is false as grain classification is mandated through the Grains Act and in the absence of variety registration, developers would simply need to classify their variety in compliance with the Grains Act. End user demand by variety class would not disappear. The grain system already segregates on this basis.
 - In crops like IP soybeans where segregation is stringently enforced by the market, the elimination of variety registration has allowed the industry to flourish.
- The Canada brand will be diminished:
 - This is false. As evidenced in other crops, the Canada brand is protected in crops like wheat through the quality standards including those for example governed through the Grains Act. In the absence of variety registration, developers will declare their varieties and test them accordingly or varieties will be developed that meet exact needs dictated by the market and without government intervention.
 - The Canada brand will not diminish but has the opportunity to be enhanced. Canadian IP soybeans are recognized globally for meeting exacting end use standards and for having world best quality specifics. This is supported by farmers and a grain system that uses transparency systems from the seed at planting to the delivered product overseas to meet customer driven standards.
 - For crops including wheat, systems that facilitate the extensive testing of variety specific samples across the growing regions are in place. Multiple labs testing and using the same methods can protect the “Canadian brand” even more than the present system based on variety registration.
- Farmers will no longer be better protected from inferior products:
 - This is false. As discussed previously, the large level of investment tied to variety development, developer integrity, non-variety registration tied trials together with performance transparency through farmer experience creates a far different market than the market of 100 years ago when variety registration initiated.
 - In fact, a market driven system actually further protects farmers from inferior performance versus what is experienced through variety registration today.
 - It should be pointed out that variety registration has not protected the market from varieties that once commercialized did not provide yield or benefits as expected.
 - It was pointed out in a task team meeting that varieties from other countries like the U.S. are being sold in Canada to the detriment of growers. Variety registration has not closed the border in these instances. In fact, using seed certification systems is the better way to prevent this from occurring. This has been done successfully in crops like corn where there is no variety registration.
- Only large companies will benefit from the elimination of variety registration:
 - This is false. As experienced in other crops including corn and soybeans, companies both large and small will develop varieties with the opportunity to be successful in the Canadian market.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- In fact, it can be argued that the only way smaller companies can be successful is to have a level playing field with both larger companies and public breeding institutions. This is best achieved in the absence of variety registration.
- It will be difficult to impossible to replace variety registration mandated trials:
 - As discussed, there are already provincial and industry trials in place that provide farmers and industry with performance benchmarks.
 - For export driven markets, developers will work more closely with end users to ensure products are commercialized that meet end use needs. This is already being experienced in crops outside of variety registration.

Topic 2 Report (rdims# 15280278 v2)

**SEED REGULATORY MODERNIZATION
VARIETY REGISTRATION TASK TEAM
Topic #2: Varietal Eligibility
OPTIONS AND RECOMMENDATIONS REPORT
July 21 2021**

Topic #2: Varietal Eligibility?

Currently, the variety registration process requires each application for the registration of a varieties to prove that they meet the definition of a variety. In Canada, this means proving that the variety is 'distinguishable' and 'stable'. This process requires providing: a description of the variety, detailed pedigree information, generation the Breeder declared Breeder Seed at, and a breeding history. This is required information for a preliminary determination of varietal eligibility with the final step being the field grow-out of the reference seed sample and comparison to the Breeder's description (verification).

Questions discussed:

- Should uniformity be added as a criterion for varietal eligibility?
- Should CSGA's Form 300 certification process be harmonized with CFIA's Part III registration process for varietal eligibility?

ANALYSIS OF OPTIONS (Should uniformity be added as a criteria for varietal eligibility?):

Option 1: The criteria for varietal eligibility should not be changed; 'uniformity' should not be added.

Rationale:

The current variety registration system requires proof of distinguishability and stability. This system has served Canada well in the past, providing both flexibility and structure to the determination of varietal eligibility. We are currently aligned internationally with our definition of a variety.

This option would maintain the current status and definition of varietal eligibility, without the addition of the 'uniformity' criterial.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

There was unanimous support for the current approach to variety eligibility for registration. Variability in a variety provides for greater buffering capacity. This allows a breeder to incorporate different adaptations to environment and reactions to disease or other pests giving the variety a potentially wider range of adaptation. At the same time, it is possible to build in uniformity for characteristics where that is important, such as end-use quality traits. This approach allows a breeder to build in as much variability and uniformity as is desired. It also eliminates the onerous and unproductive task of meeting rigid uniformity requirements for the sake of uniformity.

Pros/Benefits:

- Without uniformity, you can put together a set of lines that carry differences so that you build in buffering.
 - Harrington barley had several different subtypes which allow the variety broad adaptability.
- A variety had up to 40% variability, but no grower complained because it produced well.
- By not changing, we maintain alignment with international standards on the definition of a variety (referring only to phenotype).

Cons/Risks:

- The system would become more rigid, with less flexibility allowed for development of novel varieties.

Option 2: The criteria for varietal eligibility should be changed to include 'uniformity'.

Rationale:

This option would add the criteria 'uniformity' to the definition of varietal eligibility.

There was no support amongst the task team members for this option. The argument in favor would be harmonization with jurisdictions which currently use this approach. Uniformity has some appeal visually and would make the task of roguing during seed production somewhat easier.

Breeders familiar with the European situation where this is a requirement argue that it adds unnecessary and unproductive work to the development of varieties.

Pros/Benefits:

- Creates a much more rigid system (similar to that of the EU), meaning it is more predictable.

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- Ever plant would have to be identical in both phenotype and genotype. If you demand complete uniformity, all plants would need to carry all genes.
- This would allow for minute tweaks to already prosperous varieties, solely by adding a gene.
- Harmonizes with PBR/UPOV

Cons/Risks:

- This could create a barrier to entry (financially) if genetic testing is required on every new variety coming to market.
- Monocultures are more susceptible to problems (disease etc.).
- You risk declining fields that might differ solely based on environmental variability.
- This could be a major setback to varietal development.
- The internationally recognized term 'variety' has a specific description that involves the phenotype of a variety, not the genotype that would have to be considered if uniformity were added.
 - This could affect our international markets if we become stricter on our definition of a variety.

DISCUSSION:

There was consensus from all seed sectors that varietal eligibility was an important discussion, and that there was no appetite for changing the definition of a 'variety', as that could have significant impacts to both the domestic and international sectors. Additionally, there was agreement that the 'uniformity' criteria used in the EU would add unnecessary burden to the variety developers and limit the flexibility of the variety registration system.

RECOMMENDATION:

The task team developed qualified consensus (unanimous) on July 21 to recommend Option 1 (keep Canada's current requirements for what is a variety) forward to the Seed Regulatory Modernization Working Group.

ADDITIONAL RECOMMENDATION (Should CSGA's Form 300 certification process be harmonized with CFIA's Part III registration process for varietal eligibility?):

CFIA and CSGA should harmonize the varietal eligibility determinations of Part III Variety Registration and Form 300, respectively.

DISCUSSION:

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When discussion moved to the determination of varietal eligibility between varieties registered with the CFIA and varieties eligible for certification through the CSGA's Form 300 process, it was identified that there were significant gaps between the requirements, despite both parties conducting different forms of varietal eligibility assessment. CSGA adheres to AOSCA's version of varietal eligibility which is not as in depth as CFIA's assessment. This difference in requirements was shown to be an administrative problem, as opposed to a regulatory burden needing to be adjusted.

RECCOMENDATION:

The task team also developed qualified consensus on the following recommendation: that due to this being a process based change as opposed to a regulatory one, they would choose to instead recommend that CFIA and CSGA work together administratively to bring these two similar processes into alignment (registration and CSGA's Form 300 certification only processes).

Topic 3 Report (rdims# 15370705 v3B)

**SEED REGULATORY MODERNIZATION
VARIETY REGISTRATION TASK TEAM
Topic #3: Crop placement in the Variety Registration System
OPTIONS AND RECOMMENDATIONS REPORT
July 21 2021**

Topic #3: Crop placement in the Variety Registration System

Currently, crops that are subject to variety registration are listed in Schedule 3 of the Seeds Regulations. This Schedule is divided into three parts, each having different requirements in order for a variety of that crop to be registered. Crops that are listed in Part 1 of Schedule 3 have the most requirements in order to be registered. These crops have merit criteria, and require a recommending committee to review trial data to ensure that these merit criteria are met. The committee then recommends the variety for registration by the CFIA. Crops that are listed in Part 2 of Schedule 3 have no merit criteria, but still require a recommending committee to look over trial data and provide a recommendation to the CFIA. Crops that are listed in Part 3 of Schedule 3 have no merit criteria and no recommending committee requirements.

There is a process in place to allow crops to move from one Part of Schedule 3 to another. The value chain stakeholders (of that crop) are required to meet to determine if there is agreement across the entire value chain that this move should happen, and then a proposal is put forward to CFIA. There needs to be both consensus from the value chain and a rationale to explain why the move is needed.

In the current system, there is no process for adding a new crop kind to Schedule 3. There is also no process for removing a crop from Schedule 3, though this has been done on an ad hoc basis in the past.

Questions discussed:

- Should Part 2 of Schedule 3 be kept or removed?
- Who should be able to determine where in Schedule 3 a crop is placed?
- Should different regions be allowed to place crops differently in Schedule 3?
- Should there be a process to add crop kinds to Schedule 3?

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- Should there be a process to remove crop kinds from Schedule 3?
- Could IbR be used to improve the process for making changes to Schedule 3?

ANALYSIS OF OPTIONS

Question 1: Should Part 2 of Schedule 3 be kept or removed?

Option 1: Part 2 of Schedule 3 should be removed.

Rationale:

This Part 2 is not used and causes confusion for users. Part 2 registration also requires additional work for the CFIA staff. Crops that fit into part 2 could be accommodated in either Part 1 or Part 3. Removal would simplify the system and still accomplish the purpose of the categorization. This option would simplify Schedule 3, leading to only two Parts.

Pros/Benefits:

- This Part has never been used to its full potential.
- This would streamline Schedule 3.
- This was an identified Ministerial recommendation from the 2014-2015 VR review.
- There is only one crop in Part 2 (safflower), which simplifies removal.

Cons/Risks:

- A legal review would be required by the CFIA to ensure that this is legally possible.
- This would remove the 'full range' of flexibility of the VR system.

Option 2: Part 2 of Schedule 3 should be maintained.

Rationale:

This option would maintain the status quo of the variety registration system. This would avoid any potential legal problems with its removal. While Part 2 is poorly understood and little used its retention would not cause serious problems.

Pros/Benefits:

- System can still be called 'flexible'
- This option allows for a review of trials to be completed by a competent body, without the additional burden of merit criteria.

Cons/Risks:

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- This category is not being used.

DISCUSSION:

In general, there seemed to be consensus that Part 2 was not a useful inclusion to Schedule 3 at this time. The majority of concerns discussed were around whether the CFIA would legally be able to have a 'two part' flexible variety registration system. The other topic of discussion was centered on what assurances a Part 2 registration provides and whether the crop in Part 2 would be better to move to Part 1 or Part 3. This would likely have to be up to the value chain of that crop.

After reviewing the results of the voting, there was qualified consensus from the members present, that "Option 1: Part 2 of Schedule 3 should be removed." should be recommended to the Working Group. Please note, while the majority of the task team supported this option, 4/7 of the producers/commodity association members present abstained from the vote.

RECCOMENDATION:

Option 1: Part 2 of Schedule 3 should be removed.

ANALYSIS OF OPTIONS

Question 2: Who should be able to determine where in Schedule 3 a crop is placed?

Option 1: The value chain should continue to be the group responsible for moving a crop from one Part of Schedule III to another.

Rationale:

This is the current system. The members of the value chain for the crop are the most knowledgeable in terms of market requirements production management and all aspects of growing and utilizing the crop. They have a stake in the success of the crop. Thus they are the most logical and knowledgeable expert group to make decisions on its placement in Schedule 3.

Pros/Benefits:

- The value chain are the subject matter experts when it comes to specific crops.
- This is a collaborative effort between government and industry.

Cons/Risks:

- The burden is on the crop-specific value chain members to initiate the process, and they are required to do the majority of the work.

Option 2: The CFIA should be responsible for moving a crop from one Part of Schedule 3 to another, without input or direction from the value chain.

Rationale:

This would potentially speed up the decision making process, especially if IbR were utilized for this purpose. It may also possibly make the decision less political.

Pros/Benefits:

- This could speed up the process of moving a crop from one Part to another

Cons/Risks:

- This removes the value chain from the decision process
- This removes many subject matter experts from the decision process
- This could potentially place a crop in a more burdensome Part, depending on the viewpoint of the CFIA.

DISCUSSION:

In general, the task team agreed that it made sense to have the ability to move crop kinds between the three Parts of Schedule 3. There was some discussion regarding a proposal from Seeds Canada to have Part 3 become the 'default' and only move crops to Part 1 if there was rationale and consensus provided to the CFIA by the value chain, however that proposal was voted down by the wider task team.

After reviewing the results of the voting, there was qualified consensus (unanimous) from the members present that "Option 1: The value chain should continue to be the group responsible for moving a crop from one Part of Schedule 3 to another" should be recommended to the Working Group.

RECOMMENDATION:

Option 1: The value chain should continue to be the group responsible for moving a crop from one Part of Schedule 3 to another.

ANALYSIS OF OPTIONS

Question 3: Should there be a process developed to add crop kinds to Schedule 3?

Option 1: A process needs to be developed by the CFIA to be able to add crop kinds to schedule 3.

Rationale:

There is currently no process to add crops to Schedule 3. Thus, there is no means of adding new crops. CFIA, on numerous occasions in the past, has not been able to accommodate stakeholders wishing to establish a new crop kind as subject to variety registration (e.g. quinoa (*Chenopodium* sp.), *Brassica carinata*) The decision to place crops in Schedule 3 should be up to the members of the value chain for that crop that can only be done if a process is developed to allow them to do that.

Pros/Benefits:

- This will provide more flexibility in the VR system by not being restricted to the crops currently subject to registration.
- This may facilitate more crop kinds being brought into the VR system.
- Adding crops to schedule 3 would allow them to take advantage of the benefits of VR

Cons/Risks:

- Industry may feel pressured into using the VR system

Option 2: There is no need to add crop kinds to schedule 3; no process should be developed.

Rationale:

The important field crops are already addressed in the variety registration system, and there is no need to add additional crops. Seed of these crops can be certified using CSGA's Form 300 process. This option would maintain the status quo.

Pros/Benefits:

- Maintains current system, no changes required.
- MORE PROS IF POSSIBLE

Cons/Risks:

- Only the current crop kinds in schedule 3 can be registered.
- This could be a barrier to entry of crop kinds into the marketplace.

DISCUSSION:

We had qualified consensus (unanimous) from the task team supporting putting processes in place to add crop kinds to Schedule 3. They acknowledged that there had been requests from

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crops that were not part of schedule 3 to enter VR, but they were turned away and went through CSGA's Form 300 process. While the details of these processes would have to be managed by the CFIA, the Task Team was united in their view that putting something in process is better than the status quo of nothing.

After reviewing the results of the voting, there was qualified consensus from the members present that "Option 1: A process needs to be developed by the CFIA to be able to add crop kinds to schedule 3" should be recommended to the Working Group.

RECCOMENDATION:

Option #1: A process needs to be developed by the CFIA to be able to add crop kinds to schedule 3.

ANALYSIS OF OPTIONS

Question 4: Should there be a process developed to remove crop kinds from Schedule 3?

Option 1: A process needs to be developed by the CFIA to be able to remove crop kinds from schedule 3.

Rationale:

There is no clearly defined process in place to remove crops from Schedule 3. There should be a process to accomplish this if it is the wish of the value chain.

Pros/Benefits:

- This will provide more flexibility in the VR system by allowing crops that no longer need government oversight to be removed from VR.
- Transparency for regulatory processes and requirements is needed by the seed sector.

Cons/Risks:

- There is the potential that not all of the value chain would agree with a crop being removed.

Option 2: There is no need to add or remove crop kinds from schedule 3; no process should be developed.

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Rationale: Consideration of Schedule 3 placement has already been given to the crop types grown in Canada, there is no need to have a process to remove them. This option would maintain the status quo.

Pros/Benefits:

- Maintains current system, no changes required.

Cons/Risks:

- This will force crop kinds that do not need oversight to be involved in VR.
- This could be a barrier to entry of crop kinds into the marketplace.

DISCUSSION:

The entire task team felt that there would be value added to the VR system if there were processes put in place to remove crop kinds from Schedule 3. While the details of these processes would have to be managed by the CFIA, the Task Team was united in their view point that putting something in process is better than the status quo of nothing.

After reviewing the results of the voting, there was qualified consensus (unanimous) from the members present that “Option 1: A process needs to be developed by the CFIA to be able to remove crop kinds from schedule 3.” should be recommended to the Working Group.

RECCOMENDATION:

Option 1: A process needs to be developed by the CFIA to be able to remove crop kinds from schedule 3

Additional discussion points:

While there was discussion on different types/forms of Regional restrictions, or the potential for having a crop in a different part of the Schedule 3 depending on what region you are in, it was decided that this discussion would be resolved when the Task Team reaches ‘Topic 12: Regional restrictions on National registrations’.

There was some discussion around the possibility of lbR’ing Schedule 3 and removing it entirely from the *Seeds Regulations*. Many were in favor of this, as it potentially meant that making any changes later to Schedule 3 would be quicker (1 year as opposed to 3). This discussion will be resolved when the Task Team discusses lbR in its entirety.

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Topic 4 Report (rdims# 15428780 v2)

**SEED REGULATORY MODERNIZATION
VARIETY REGISTRATION TASK TEAM
Topic #4: Varietal Purity
OPTIONS AND RECOMMENDATIONS REPORT
August 4 2021**

Topic #4: Varietal Purity

This is a narrow look at varietal purity as a larger discussion will be occurring in the Seed Certification Task Team. We currently have a trend in soybeans where the varietal purity (VP) standards that are set by AOSCA are not being adhered to. Soybean VP field standards are currently 99.7%.

However, we are seeing an increase in VP issues in oilseed soybeans at early generations of seed production. These issues could be due to soybeans being an extremely variable crop, or they could be the result of inattention at the breeder seed level that is exacerbated when the crop is multiplied up.

A potential solution may be to work with AOSCA to reduce the purity standard of oilseed soybeans to accommodate this increased variability.

Questions discussed:

- Should the purity standard for oilseed soybeans be adjusted?

ANALYSIS OF OPTIONS (Should the purity standard for oilseed soybeans be adjusted?)

Recommendation:

The CSGA should review the purity standards for oilseed soybeans with AOSCA.

Rationale:

By changing the purity standards we potentially will enable a wider allowance for variants, which should cope with the higher levels of variability within the oilseed soybean crop. This will decrease the amount of discussion with the breeder on the part of the VRO, and potentially aid the industry.

Pros/Benefits:

- Less time spent in communication with the breeder and CFIA, speeding up the process.
- Less potential for field declines when an identified off-type is actually of the variety

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- Potential to harmonize the AOSCA standard with the OECD standard (which is lower)

Cons/Risks:

- Potentially enables sub-par breeding if this issue is not related to the plant physiology.

DISCUSSION:

The field standards are set by CSGA, which are adapted when necessary from the AOSCA system. As these standards cannot be changed by the CFIA, a regulatory process recommendation is not necessary. However, the task team was in favour of CSGA working with AOSCA to review the standards. There was some concern that if this issue is not a plant physiology problem, we could be dropping the standard and creating more chaos.

After reviewing the results of the voting, there was unanimous consensus from the members present that this recommendation should be made. However, a note was made that this recommendation is put forward for consideration, assuming it does not directly counteract the recommendations of the Seed Certification Task Team.

Topic 5 Report (rdims# 15838548 v1B)

**SEED REGULATORY MODERNIZATION
VARIETY REGISTRATION TASK TEAM
Topic #5: One Variety, One Name
OPTIONS AND RECOMMENDATIONS REPORT
Dec 6 2021**

Topic #5: One Variety, One Name

Canada has a “one variety, one name” policy for variety registration (similar to the USA, though they are implemented and enforced differently in Canada). When a variety is registered in Canada, a verification is made to ensure that the proposed variety name meets several criteria (e.g. not false, not misleading, not offensive, will not cause confusion in the marketplace). The Canadian Seeds Regulations stipulate the fair and accurate representation of a variety in the seed market. Some other jurisdictions allow for more than one name for a given variety: synonyms. Should someone wish to register such a variety in Canada, all the synonyms must be disclosed to CFIA.

Questions discussed:

- Should the current policy continue in Canada or should it be changed?
- If we were to allow this in Canada, what restrictions or conditions should be met?
- Should there be full disclosure of synonyms?
- In instances where there are multiple agents, should there be full disclosure to multiple agents?

ANALYSIS OF OPTIONS

Question 1: Should the current policy continue in Canada or should it be changed?

Option 1: Maintain the current policy (one variety, one name)

Rationale:

The rationale for maintaining the current policy is for a number of reasons. Chief among those reasons is transparency both within the developmental stages and the eventual marketplace. There have been instances in jurisdictions where multiple names are permitted where a variety can end up pitted against itself due to marketing materials and different sales streams. This is

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not the case in Canada where we allow one variety to be known by only one name. This allows both varieties developers and producers the confidence of knowing exactly what they are buying and breeding with.

Pros/Benefits:

- The current system in Canada is transparent.
- The consistency of the name makes it simple to handle throughout the system, from seed production to cultivation and marketing. This prevents confusion.
- From a producer's perspective, this provides confidence that when one is changing to a different name, one is truly changing to a different variety – this transparency for producers is a fundamental advantage (i.e. knowing that a different name is associated with a different genetic package is key for a producer).
- Would facilitate the ability of a developer to license one of their varieties to more than one agent.
- For seed production, this enables to produce the seed lot in one location and distribute to different markets, all under the same name and the same tag.
- The one name, one variety policy is effective for breeding purposes, as it provides transparency. When looking at a specific cultivar that carries known genes or proven genes, breeders need to be absolutely certain that this is the line they are using.

Cons/Risks:

- The current lack of flexibility in naming varieties is a challenge.
 - When a specific name is submitted for registration, if there is any name in the world that is similar or close, the proposed name cannot be used. This can cause challenges in trying to find a suitable name.
 - Coming up with a name is becoming increasingly difficult. Greater flexibility on the restrictions on variety names would be desirable. This pertains to variety registration, however there is a connection with Plant breeders' rights (PBR) as well.
 - This could be a recommendation to CFIA to not be as rigid in the interpretation as it relates to the overlap with names in other crops and other jurisdictions (i.e. even in keeping one name, one variety, having greater flexibility in the naming would be helpful).
- The current one name, one variety policy does not provide the flexibility to market in different geographies or jurisdictions.
- The current system does not facilitate licensing to more than one agent.

Option 2: Changing the policy to allow multiple names for one variety

Rationale:

The rationale for changing the policy to allow for multiple names for one variety is mostly due to the want for flexibility when it comes to variety naming. Different markets (geographically or otherwise) will react differently to one name over another, causing a possible difference in performance solely due to the name being required to be the same across the board. This could potentially broaden the uptake of a new variety or re-invigorate a declining one, all by allowing a synonym.

Pros/Benefits:

- Allowing more than one name for a given variety would facilitate the licensing of a company who would want to license a variety they own to more than one agent.
- It would allow a variety owner more flexibility in their marketing strategy. For example, a company may wish to use a different name in Québec vs. in Ontario, for marketing purposes.
- An example was provided to illustrate how multiple brand names could work, along with a unique variety name:
 - In the USA seed business, there are examples of multiple brand names for the same variety. On the bag, there are both a brand name as well as a variety identifier (variety name, variety code) on the tag. This approach provides growers with the ability to identify the actual variety they are purchasing, by using the variety code; the approach also provides the flexibility to market under different brands.

Cons/Risks:

- In seed production, it would be confusing to have different names for the same variety.
- There is a risk of running out of possible names to name varieties, in context of the requirement to have different/unique names relative to varieties already registered internationally. If a variety can be given several different names, this can create challenges in finding names for new varieties.
- From a breeding standpoint, when marking up the lineage of a variety, having multiple names could be more complex; it could be confusing in an international academic science setting.
- With more than one name, there is a risk that someone could steal a variety that is perhaps licensed to someone else, and put it under a different name.

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- Multiple names can be misleading: if the traits are marketed differently under one name vs. the original name, this can be misleading for growers.

DISCUSSION:

There was discussion from the group at large as to whether there have been any problems with the current “one variety, one name” policy. While the CFIA was not present at these meetings, others indicated that many problems have been associated with handling varieties coming from jurisdictions allowing synonyms (not currently allowed under current rules). A vote was taken in absence of a complete report, and Option One (maintain the current system) was unanimously supported.

RECOMMENDATION:

Option 1: We have qualified consensus (unanimous) for maintaining the current policy (one variety, one name)

Topic 6 Report (rdims# 17836639)

**SEED REGULATORY MODERNIZATION
VARIETY REGISTRATION TASK TEAM
Topic #6: Variety Cancellation
OPTIONS AND RECOMMENDATIONS REPORT
September 15, 2021; amended June 2022**

Topic #6: Variety Cancellation

For the 53 crop kinds subject to registration, varieties can have their registrations canceled, effectively removing a variety from the market and removing any possibility of a common seed market for that variety. The current policy provides two paths for cancellation: 1) the Registrant requests their variety be canceled (most common path) or 2) for cause, by the Registrar (an enforcement action). When a variety is canceled it cannot be imported, sold, or cultivated in Canada. When a registrant (i.e. the organization that registered the variety) requests that their variety be canceled there is a CFIA consultation process with the Registrant and a notice of intent to the value chain; there is a waiting period so that anyone who is holding seed stock is given enough warning to move seed stocks of the variety out of the seed/grain system to avoid economic harm.

The question is: should the current policy continue? Cancellation for cause is likely to continue, however, the Task Team may wish to discuss what type of situations would be considered “for cause”. Should a third party (other than the registrant) be allowed to request a cancellation? In the context of “registration for life” (an alternative approach), who should maintain the cost of maintaining the seed and any regulatory fees when the owner of that variety does not want to maintain it? If a request to cancel a registration is refused, should the owner be required to maintain the variety themselves or to sell the rights to it?

Questions discussed:

- Should the current policy continue? Cancellation for cause is likely to continue, however, the Task Team may wish to discuss what type of situations would be considered “for cause”.

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- Should a third party (other than the registrant) be allowed to request a cancellation?
- In the context of registration for life, who should maintain the cost of maintaining the seed and the regulatory fees when the owner of that variety does not want to maintain it?
- If a request to cancel a registration is refused, should the owner be required to maintain the variety themselves or to sell the rights to it?

ANALYSIS OF OPTIONS

Question: Should the current cancellation policy continue?

Option 1: Allow for cancellation by request of the Registrant, and cancellation by the Registrar for cause.

Rationale: Cancellation upon request of the Registrant recognizes the registrant as the party effectively owning the registration (as the sole party responsible for the registration of that variety and having the ability to end that registration for their own purposes). The costs, responsibilities and liability are borne by the Registrant. In conducting their business they will be registering and cancelling varieties over time (seed product turnover).

Cancellation for cause (by the Registrar) is a tool used by CFIA (in rare circumstances), primarily where a variety presents a threat to crop production in any region of Canada. The Registrar also has a consultative expert committee to draw on in making these decisions (this is built into the regulations).

This option reflects the current regulatory approach to the cancellation of varieties.

Pros/Benefits

- It allows for the removal of problem varieties.
- It allows variety owners to manage the portfolio of their varieties.
- It helps clear the clutter of a large number of varieties in play.
- It creates a known environment for the registrant or the developer.
- Operating within a global market, when a variety is viewed as problematic by the export market, being able to cancel the registration is valuable in that global export market.
- It encourages the use of advanced genetics and technology. The time and money expended to develop new varieties that are better than older ones foster the advancement of agriculture (e.g. varieties that are more nutrient efficient, driving for greater sustainability, etc.). When varieties that are not as productive are de-registered,

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it fosters the use of new more efficient varieties, which contributes to advancing agriculture.

Cons/Risks

- Allowing varieties to continue on in instances where the Registrant wants to cancel the registration would create uncertainty (for the registrant or for the developer), and it would create an impediment to investment in Canada if registrants don't control their own variety.
- It does not allow producers to continue to cultivate varieties of their choice, e.g. older varieties that the registrant may want to take off the market.
- If a variety appeals to a niche market, with specific unmeasurable traits (such as better taste) de-registering that variety may discourage that niche market. Options to sell a variety to another marketer (rather than de-registering) would be useful.
 - If a company or breeder wants to discontinue a variety, anyone can approach them to license or sub-license, for a fee. This may not be a cancellation of registration question.
 - What if the owner of a variety did not want to continue to maintain a variety, what processes are in place to arbitrate that and to either compel the owner to produce it or to turn it over to another company?

Option 2: Change the current system to allow for parties other than the Registrant to influence cancellation of a variety. The Variety Registration Office of the CFIA shall notify potentially affected parties of the intent to cancel registration of a variety a minimum of one year prior to the cancellation date. The affected parties shall include the Canadian Seed Growers Association, commodity exporters, variety recommending committees, end-users, the Canadian Grain Commission (where applicable), commodity commissions and other parties with economic interests in commercial production and sale of the variety in question.

Rationale: The current practice of the CFIA is to publish lists of varieties intended for variety cancellation to forewarn parties other than the registrant of an impending variety cancellation. This enables the affected parties to plan for variety cancellation but gives them no direct input into the cancellation. If opposed to cancellation, the affected parties must convince the Registrant to postpone or revoke the planned cancellation. This change of policy would provide affected parties a formal opportunity to influence variety cancellation.

Pros/Benefits:

- This option provides a means for all parties with economic interests in production of a specific variety, be it pedigreed seed or commercial commodity, to have input into that variety's eligibility for continued production in Canada.
- This option would remove the exclusive economic interests of the registrant as the sole grounds for continued registration of a variety.
- This option would remove liability from the CFIA arising from negative impacts of cancellation of viable varieties.
- This option would not affect the cancellation of obsolete varieties for which there is no reason for continued registration.

Cons/Risks:

- It may be difficult to notify all potentially affected parties.
- There will be an on-going requirement to maintain a viable Breeder Seed registration sample. This may be largely solved by long-term storage at low temperatures.

Option 3: Cancel variety registration only when production of the variety is determined to cause harm.

Rationale: Variety registration is a requirement of the *Seeds Act* for the sale or import into Canada of seed of a variety of most agricultural field crops. The registration of a variety provides official verification that certification eligibility requirements and the requirements for variety registration have been met: 1) it is new and distinguished by common, described characteristics; 2) a sample of seed of the variety is submitted; 3) appropriate documentation to substantiate the identity of the variety and the responsible party(s) is submitted; 4) additional requirements, as the case may be, including any 'higher voluntary standards' for certification and requirements for varieties in Part 1 for support from a recommending committee as to the merit of the variety.

Pros/Benefits:

- Once registered, seed of a variety would be legal to import and sell in perpetuity unless it was determined to cause harm, in which case the registration could be cancelled.

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- The CFIA would not have to enforce the Seeds Regulations regarding the sale of common seed of previously registered varieties, as they would remain registered.
- Farmers would be able to receive the grain grade, and price, that is appropriate for the quality of the grain they deliver.
- Varieties that no longer have commercial value to seed distributors would still be available for use by farmers.

Cons/Risks:

- Older varieties that may not be as good as current varieties would depress the quality and value of the crop in aggregate.
- Private variety development parties may consider Canada a poor place to invest if they cannot prevent sale of seed of their varieties in the long run.

DISCUSSION

- Noted that there can be implications of variety cancellation for the common seed market/system. Previous (2019) discussions facilitated by AAFC and the Seed Industry where the concept of “seed variety use agreements” (SVUA) was debated; grain growers raised concerns about variety cancellation and common seed system impacts. Grain growers may see value in varieties that are being canceled.
- For publicly developed varieties, the institution that developed the variety now consistently retains both ownership and registration as the Registrant (not the agent) (source OIPC, AAFC).
- Noted that the focus of this task team is VR. **Common seed** issues/opportunities will be addressed by a different task team. However, this is a **linked topic** to our VR discussions.
- One member noted that the critical question is whether a Registrant should be allowed to cancel a variety without any rationale (are we focused on the right question?). At present, all CFIA discusses with the Registrant is their plan to ensure no seed stocks of the variety will be in the system three years out from the request (a notification-based policy designed to protect farmers).
- **Patents and PBR** can be impacted by variety cancellation (what would normally be released for use to the public can actually be removed by using variety cancellation; an **unintended consequence**).

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- There is currently no requirement in the system for variety owners to maintain a certain quantity of Breeder seed but there is a requirement to replenish the CFIA reference seed sample (for all registered varieties) when and if CFIA's sample is exhausted (this is a responsibility of registration). However, if a variety is canceled by the Registrant, that requirement no longer holds. With a canceled variety there will be a point where, in the absence of sufficient quantities of the CFIA Reference Seed Sample (for registration), that CFIA will not be able to fulfill their seed certification quality assurance work (grow-out of reference sample as a comparator) and the variety can no longer be supported in the seed certification system (not by action but by default – no seed, no certification).
- If a variety is canceled, it is relegated to the common seed market and strictly speaking cannot be legally imported or sold under a variety name. The result is that the grain/product cannot be delivered to line companies and can only be sold for feed (discounted).
- Developers requesting cancelation are in part seeking to reduce their liability.

RECCOMENDATION(s):

Vote from the September 29th Task Team meeting (taken in the absence of a complete report):

Voting for Option 1 – **11**

Voting for Option 2 - **4** (it is noted that these members represent primary producers/growers and reflect the concerns noted above)

Producers & Commodity value chain organizations (out of the 6 present 4 voted for option 2 (66%)) **Therefore OPTION 2 did not pass.**

CFIA indicated that the Working Group will be made aware that there is a no qualified consensus for Option 1 (maintain variety cancellation at the request of the Registrant) because a majority of producer stakeholders preferred the second option.

Industry (3 were present, all three voted for Option 1)

Breeders, Government, and Others: (Out of the 4 members present, all 4 voted for option 1)

This report was then deferred and was forwarded to the Task Team dealing with Common Seed to discuss and comment on the unintended consequence of variety registration cancellation on Common seed.

See **Appendix 5**, within Task Team Topic Report #6, for the **DRAFT report from the Common Seed task team** (without votes or recommendations). Five options were developed and discussed with regard to variety cancellation by Registrant and common seed.

The five options discussed by the Common Seed task team were:

- 1) *Status quo*,
- 2) Have registrations for life (as it was pre-1998),
- 3) establish a process whereby an interested party can become the variety maintainer of a variety pre-cancellation,
- 4) **Establish an application process for cancellations by Registrant with an appeal period***,
- 5) Do not allow hybrids based on male sterility genetics to be allowed for sale as common seed.

**this option (#4) appears to have the most support at the time, from the Common Seed Task Team*

As of June 24, 2022, the Common Seed Task Team had not voted on these options or made final recommendations.

At our June 29, 2022 meeting of the VR task team, this input from the Common Seed Task Team did not alter the options or recommendations previously developed.

Summary of recommendations: There was no qualified consensus on variety cancellation therefore no specific recommendation. Of note, the majority of producer stakeholders voted for Option 2 while the rest (majority) voted for Option 1 (keep the current system).

Topic 6 - ADDENDUM – 1 (Seed Industry input on variety cancellation)

Submission from the Canadian Seed Growers Association (CSGA), received Dec. 14, 2021 for inclusion in Variety Cancellation Topic Report (pasted “as-is” into this report and saved as RDIMS #15920750 in CFIA’s document database).

Potential concerns with Cancellation of variety registrations

SUMMARY

1. Should the Cancellation process be more transparent?

a) The present 3-year cancellation notification policy requires registrants to advise CFIA on specific steps they have taken regarding existing seed stocks.

- Should this specific information be shared by CFIA with ‘stakeholders’ involved with this variety?

- Enhanced disclosure of this information may facilitate opportunities for registration ‘transfers’ (instead of cancellation) and/or opportunities for potential registrations in the new ‘heirloom’ or ‘heritage’ categories.

b) Risk transparency for investors in variety development (especially producer organizations)

Should investors in variety development, especially producer organizations, be better advised of registrants’ disclosure requirements in the 3-year cancellation notification policy, such as steps the registrant has taken regarding existing seed stocks?

- Variety development funding agreements or contracts may require revision to adequately clarify options available to investors upon cancellation by the registrant.

2. Certification Eligibility

Cancelled varieties are still eligible for seed crop certification, as long as the CFIA lab has enough Breeder seed for the reference controls required for the variety verification testing program (which audits certification).

- Should the CFIA lab be responsible for notifying CSGA when Breeder seed of cancelled varieties is no longer available?

3. Linkage to Common Seed Task Team recommendations

As outlined in the BACKGROUND references below*, from the Variety Registration Task Team (VR-TT) meeting of Sept. 15, 2021, many concerns about cancellation directly involve common seed.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- Is there potential for heightened CFIA responsibility for enforcement of the Seeds Regulations requirements for selling, labelling, advertising, and importing common seed?

Topic 6 - ADDENDUM – 2 Producer input on variety cancellation

Submission from David Gehl (Producer Group), received Dec. 15, 2021 for inclusion in Variety Cancellation Topic Report (pasted “as-is” into this report and saved as RDIMS #15920750 in CFIA’s document database).

Cancellation of Variety Registration

Option 2

Change the current system to allow for parties other than the registrant to influence cancellation of a variety. The Variety Registration Office of the CFIA shall notify potentially affected parties of the intent to cancel registration of a variety a minimum of one year prior to the cancellation date. The affected parties shall include the Canadian Seed Growers Association, commodity exporters, variety recommending committees, end-users, the Canadian Grain Commission (where applicable), commodity commissions and other parties with economic interests in commercial production and sale of the variety in question.

Rationale

The current practice of the CFIA is to publish lists of varieties intended for variety cancellation to forewarn parties other than the registrant of an impending variety cancellation. This enables the affected parties to plan for variety cancellation but gives them no direct input into the cancellation.

If opposed to cancellation the affected parties must convince the registrant to postpone or revoke the planned cancellation. This change of policy would provide affected parties a formal opportunity to influence variety cancellation.

Pros / Benefits

- This option provides a means for all parties with economic interests in production of a specific variety, be it pedigreed seed or commercial commodity, to have input into that variety’s eligibility for continued production in Canada.
- This option would remove the exclusive economic interests of the registrant as the sole grounds for continued registration of a variety.
- This option would remove liability from the CFIA arising from negative impacts of cancellation of viable varieties.

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- This option would not affect the cancellation of obsolete varieties for which there is no reason for continued registration.

Cons / Risks

- It may be difficult to notify all potentially affected parties.
- There will be an on-going requirement to maintain a viable Breeder Seed registration sample. This may be largely solved by long-term storage at low temperatures.

Topic 6 - ADDENDUM – 3 seed industry input on variety cancellation

Submission from Michael Scheffel, Canadian Seed Growers Association (CSGA), received Jan. 14, 2021 for inclusion in Variety Cancellation Topic Report (pasted “as-is” into this report and saved as RDIMS #15964939 in CFIA’s document database). It is referenced at CSGA as: “Cancellation of VR_20220114.docx”.

Option X – Cancel variety registration only when production of the variety is determined to cause harm.

Rationale: Variety registration is a requirement of the Seeds Act for the sale or import into Canada of seed of a variety of most agricultural field crops. The registration of a variety provides official verification that certification eligibility requirements and the requirements for variety registration have been met: 1) it is new and distinguished by common, described characteristics; 2) a sample of seed of the variety is submitted; 3) appropriate documentation to substantiate the identity of the variety and the responsible party(s) is submitted; 4) additional requirements, as the case may be, including any ‘higher voluntary standards’ for certification and requirements for varieties in Part 1 for support from a recommending committee as to the merit of the variety.

Pros

- Once registered, seed of a variety would be legal to import and sell in perpetuity unless it was determined to cause harm, in which case the registration could be cancelled.
- The CFIA would not have to enforce the Seeds Regulations regarding the sale of common seed of previously registered varieties, as they would remain registered.
- Farmers would be able to receive the grain grade, and price, that is appropriate for the quality of the grain they deliver.
- Varieties that no longer have commercial value to seed distributors would still be available for use by farmers.

Cons

- Older varieties that may not be as good as current varieties would depress the quality and value of the crop in aggregate.
- Private variety development interests may consider Canada a poor place to invest if they cannot prevent sale of seed of their varieties in the long run.

Topic 6 ADDENDUM – 4 commodity group input on variety cancellation

Variety De-registration:

Comments by Laurie Friesen, Feb. 2, 2022

Option 1: Allow for cancellation by the registrant when requested and cancellation by the government for cause

This option has been fully discussed by the VR task team.

Option 2: Develop a compulsory consultation process for variety cancellation by the registrant.

Note: this option is for decisions on de-registration without cause

Rationale: The decision to de-register a variety by the registrant alone does not consider the needs of other stakeholders and a process is needed to allow input into the decision. Stakeholders could include:

- Sub-licensee granted rights to the variety: Consideration of the effort and expense put into marketing a variety and the opportunity for continued sales should be made before a decision to de-register a variety is made.
- Seed growers may still be selling seed of the variety and should be able to continue to market a variety until seed stocks are depleted and no further demand exists.
- Growers may still be growing a variety which performs well on their farm.
- Grain exporters/processor may still see value in a variety for end-use applications

Currently, communication of de-registration of varieties is lacking and needs to be addressed so all stakeholders are aware when a variety is to be deregistered.

Pros:

- This process allows continued access to a variety to those who have invested in marketing and continue to see a market for the variety.
- It allows growers to express interest in continued production of a variety and provide justification.
- It prevents deregistration of a variety solely for anti-competition reasons that still has value in the marketplace (e.g., to remove varieties that are not part of a value-capture system).
- It allows input from stakeholders that have invested in publicly developed varieties (e.g., levy dollars).
- It allows continued access to varieties with potential end-use niche markets (e.g., identified by processors or end-users).

Cons:

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- Variety developers should not be forced to continue to maintain a variety and hold liability of a variety in the marketplace. A process is needed to facilitate transfer of ownership of a variety to another party.
- Consensus may be difficult to attain with too many voices in the decision-making process. The process would need to limit the number of parties required to support de-registration
- Who would be responsible for seeking input from stakeholders? This needs to be identified.
- Investment into development of improved varieties may be reduced if older varieties are maintained in perpetuity. Perhaps a clause is needed to permit de-registration of varieties without consultation >20 years old unless it carries recently patent-protected traits that have come off-patent (this needs further input).

Proposed process:

- Registrant submits request to CFIA and marketing agent
- CFIA sends notification to crop commission
- Crop commission determines need for further consultation and directs process
- Marketing agent and crop commission submits approval or rejection for deregistration to CFIA
- If consensus is not reached, ownership of the variety can be transferred to either marketing agent (first right) or crop commission (second right). CFIA to facilitate transfer.
- If neither party wishes to obtain ownership, the request by the registrant to deregister is supported by CFIA.
- If deregistration is the final outcome, CFIA sends notification to marketing agent and crop commission as well as using the current system to inform stakeholders (e.g., growers).

Option 3: Cancel the registration of variety for cause only (i.e., registrants could not cancel their registration).

Pros and cons for this option have been fully discussed by the VR task team.

Topic 6 - ADDENDUM – 5 Copy of the Draft Common Seed Task Team Topic #2 DRAFT Report: Variety Registration and Cancellation Report (RDIMS # 16305398 v3A)

Note: this is a draft and as of June 24, 2022 the voting and recommendations from this team have not been completed. The comments/discussion is being shared here.

SEED REGULATORY MODERNIZATION

COMMON SEED TASK TEAM

Topic #2: Variety Registration and Cancellation Topic Report

[Schedule III](#) of the *Seeds Regulations* identifies the species, kinds and types of crops subject to variety registration in Canada. For these 53 crop kinds, both pedigreed and non-pedigreed (i.e. common) seed must be derived from a registered variety. Currently, seeds of species, kinds and types **not** listed in *Schedule III* are not subject to variety registration (e.g. hemp, corn, food-grade soybeans, chickpeas, etc.).

When a variety has its registration cancelled (syn. deregistered), at the request of the Registrant, for a seed crop kind or species listed in *Schedule III* then the sale, advertising for sale and importation of that variety is prohibited as per paragraph [3\(1\)\(b\)](#) of the *Seeds Act*. This includes each component of a seed mixture or varietal blend consisting of a *Schedule III* species, kind or type of crop when sold as common seed in Canada. Therefore, when a variety registration is cancelled it cannot be imported or sold in Canada, plus it removes any possibility of a common seed market for that variety. There are two paths that can result in variety cancellation:

- 1) by far the most common is for the Registrant to request their variety be cancelled; or
- 2) For cause, by the Registrar (an enforcement action).

Cancellation at the request of the Registrant was an amendment to the *Seeds Regulations* introduced back in the late 90's.

When a variety is registered it may contain patented technology or have [Plant Breeders' Rights](#) (PBR). When a patented technology or PBR expires then this is still available for farmers to use when a variety is registered. As soon as a variety registration is cancelled then there is no

opportunity for a farmer to experience the “public good” side of patents and PBR that occurs once rights expire.

The exemptions for importing seed of unregistered varieties of species, kinds or types listed in *Schedule III* into Canada are outlined in sections [41\(1\)](#) and [41\(2\)](#) of the *Seeds Regulations*. These exemptions are conditioning, research, seeding by importer or sale pursuant to subsection [5\(4\)](#) of the *Seeds Regulations*. Common seed does not meet the exemption in subsection [5\(4\)](#) as it only pertains to pedigreed seed. Currently, it is prohibited to import unregistered varieties of spring, winter or durum wheat into the provinces of Manitoba, Saskatchewan, Alberta and the Creston-Wynndell Area and Peace River District of British Columbia. This will be further discussed by the Import Task Team.

When common seed of an unregistered variety of a *Schedule III* species, kind or type of crop is imported for seeding by an importer or is produced domestically on a farm, this seed may be saved for planting in subsequent generations by the importer for their own use but must not be sold as seed as per section [3\(1\) \(b\)](#) of the *Seeds Act*. For instance, an unregistered (including deregistered or cancelled) *Schedule III* variety may be used for feed or grain purposes and saved by a farm but must not be used to produce common seed to share, sell or further distribute in Canada.

Grain delivered to an elevator must meet the standards and requirements under the authority of the [Canadian Grain Commission \(CGC\)](#). A potentially unintended consequences of a cancelled variety for growers could be that they will no longer be able to produce a variety and deliver it to the grain elevator.

The following considerations were discussed when determining the options:

- The sale of common seed for crops kind, species or types listed in Schedule III are linked to variety registration requirements, should there be additional requirements for crop kinds not subject to variety registration (i.e. not listed in *Schedule III*) be sold as common seed (e.g. chickpeas, food-grade soybeans, forage type rye, etc.)?
- What is the impact of a registered variety being cancelled by a Registrant in the common seed market?
 - What is the impact on niche markets (e.g. heritage varieties)?
 - What would the impact be if the policy went back to registrations being for life in Canada when the Registrant is no longer prepared to be responsible for a variety registration, absolving them of future responsibility of that variety, and there would be no responsibly party associated with the variety?
 - Who does this have a positive and negative impact on?

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- Is there a way to increase enforcement of common seed sold domestically of unregistered varieties?
- For hybrid crop kinds, species and types of registered varieties listed in *Schedule III* where the registered variety is the F1 certified seed generation and not the parent lines. When the F1 generation is grown out it would produce seed via selfing/sibbing of the F1 hybrid seed in subsequent generations which is **not** the registered variety. Should the *Seeds Regulations* clarify restricting the sale of these hybrid crop kinds to pedigreed seed? If the F2 generation does not meet the definition of a variety due to factors like stability, should common seed sales be enforced? Should this also be considered for hybrid seed crop kinds not subject to variety registration (e.g. hybrid corn)?
- What is the unintended consequence to the producer delivering grain to an elevator when a variety's registration has been cancelled?

Option #1: Maintain the current requirements for variety registration and cancellation with flexibility for the recommending committees to consider and accept other options to accommodate heritage, heirloom and alternate bred varieties in Canada.

Rationale: There is flexibility in the current system for recommending committees to adopt standards to recommend heritage, heirloom and alternatively bred varieties which deviate from mainstream varieties. A variety will be able to be cancelled upon request or for cause by the Registrant. This will allow a variety developer to cancel a variety subject to stewardship practices.

Pros/Benefits:

- Provides the flexibility to cancel a variety when there is a quality or disease issue occurring in common seed production which was not initially present at the time of registration.
- Registrants are required to be accountable for varieties subject to registration including in non-pedigreed seed production. Grain handling good practises will segregate unregistered varieties when destined to niche markets to mitigate the risk of mixing unregistered varieties at an elevator.
- Varieties can be removed from the market when there are issues with diseases, toxicity, etc. justifying a purpose for the seed not to be sold.
- Provides the opportunity for a Registrant to cancel a variety when quality issues arise after successive generations of production that were not observed when the variety was originally registered.
- Ability to cancel a variety when a global market issue arises (e.g. CDC Triffid flax) and it is economically beneficial to remove the variety from production.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- There is flexibility for end-users to determine the requirements of the grain they will accept and farmers are able to purchase seed based on these requirements.
- The grain sector will self-regulate to a degree if an end-user requires a registered variety and is able to manage products if they are aware of what is coming into the system.
- A Registrant may request to cancel varieties with herbicide tolerant traits under a stewardship program to ensure there are no issues with the trait in the environment or market.
- Recommending committees have flexibility to consider data generated outside of the regular system (e.g., alternatively bred organic crops) to determine and recommend these varieties for registration.
- Recommending committees have flexibility to consider alternative varieties if they do not cause harm to the seed industry and if there is value to producers.
- The risk of removing a variety is potentially mitigated by companies' valuing their reputation and consumer base.
- Varieties are able to be reinstated for registration once they have been cancelled.
- Removes old varieties that have not been used in years and decreases the additional costs of maintain varieties in the system.

Cons/Risks:

- Potentially increase non-compliant sales of heritage and heirloom varieties of unregistered varieties as niche markets expand and not recommended by registration committees.
- Organic varieties for crop kinds subject to variety registration may have issues meeting the standard requirements prohibiting the sale of these varieties as common seed when alternate options are not considered by recommending committees.
- Registrants are provided with the sole authority to cancel a variety's registration without further consulting to determine if a variety should be cancelled when there are no issues with a variety.
 - This could remove access to varieties and traits for the public good to be sold as common seed if there is no issue with the variety.
 - It may be difficult to determine if the registration is cancelled for specific causes versus the convenience of the marketer.
- If there are no issues of concern (e.g., health, safety, trade, stewardship practices affiliated with specific traits, etc.) with a variety the cancellation by the Registrant once a patent and/or Plant Breeders' Rights (PBR) privileges has expired would only benefit the Registrant.
 - Under PBR there could be restrictions on selling common seed of a specific variety and when these privileges expire then it would remove the opportunity to sell common seed of a variety if it is cancelled.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- Specific traits associated with a variety are no longer available for common seed once a variety is cancelled.
- If there is not issue with a variety the current system does not support the public domain when a variety is cancelled as it no longer is able to be sold as common seed.
- Unregistered varieties of grain qualify for lower grades, when a variety is cancelled this could potentially demote the grain to a lower grade at the elevator, negatively impacting the price a farmer would receive for grain.
- Cancelling a registered variety may have commercial implications including the ability to export the seed of a variety which is a viable variety grown in another country.
- Difficult to enforce the farm-to-farm sale of unregistered varieties that are not advertised for sale.
- Difficult to detect and enforce unregistered varieties and stewardship practices for varieties listed in *Schedule II* when the use of variety names are restricted on common seed sold for these crop kinds.
- Volunteers of unregistered varieties are difficult to control in the field potentially causing low level presence of unregistered varieties mixed into common seed sold and when grain is delivered to an elevator.
- Potentially deters recommending committees to approve varieties outside of the standard system due to the potential of losing their accreditation if they do not conform to recommending requirements.
 - There are issues comparing organic trials versus non-organic trials in the current system as they will perform differently due to the different growing conditions.
- Potential issues with breeder seed availability in older varieties when the variety is no longer in the certification system producing pedigreed seed. This could be an issue if a reference sample of the original variety is no longer available.
- There is a lack of understanding of the current variety cancellation system among companies and farmers.
- There is a lack of communication to understand the purpose of a variety cancelled upon the request of the Registrant.
- There is an increasing requirement to access varieties for niche markets in Canada.
- Potentially increases non-compliances of unregistered varieties of common seed sold in Canada.
- Potentially increases the difficulty to detect and enforce unregistered varieties and stewardship practices for varieties listed in *Schedule II* restricting the use of variety names on common seed sold.
- Each generation from pedigreed seed increases the probability that the common seed produced would no longer represent the variety or perform to the intentions of the breeder.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- The option for a variety to be maintained has been removed in the current system which could have extended the option for the variety to be sold as common seed.
- A variety may not be sold as common seed for a number of year from when it is cancelled upon request by the Registrant to when it is eligible to be reinstated as a heritage variety.

Option #2: Once a variety is registered it should remain registered for life and be accessible to sell as common seed in Canada unless it is cancelled for cause (e.g., health, safety, economic risk, etc.). Maintain the flexibility for the recommending committees to consider and accept other options to accommodate heritage, heirloom and alternate bred varieties in Canada.

Rationale: This will increase the access to good varieties and traits which have gone through the registration system to be sold as common seed in Canada. A variety may still be cancelled if there is cause to prohibit the sale of common seed. This will remove the requirement allowing a Registrant to cancel upon request from the regulations. It will maintain the flexibility to accommodate recommending heritage, heirloom and alternate bred varieties subject to variety registration to be sold as common seed in Canada.

Pros/Benefits:

- Allows for varieties to remain in the system to be sold as common.
- Provides continued access to traits when a variety is performing well in a specific region, niche market or on farm.
- Increases access to the traits benefits the public good when purchasing common seed in Canada.
- Allows for a variety to be cancelled for cause if an issue occurs with the variety or traits affiliated with that variety.
- Potentially mitigates a variety being cancelled only for the purpose to market a new variety.
- Potentially reduces the amount of unregistered varieties of common seed sold in Canada.
- Requires a responsible body for a variety if an issue arises.
- Varieties would remain available to purchase as common seed for a reasonable cost.
- Allows a variety to remain in the system to access as a farmers' privilege to sell and purchase as common seed.

Cons/Risks:

- Potentially increases the costs to maintain varieties, in the system, which are no longer being grown, processed or marketed in Canada for a number of years.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- Potential stewardship issues may arise with traits previously subject to these requirements.
- Forces the Registrant to continue to invest in maintaining varieties if they are only being produced and sold as common seed in Canada.
- Potentially decreases the interest for variety developer's to invest in Canada or to develop new varieties if they are required to maintain unpopular varieties.
- Potentially increases the amount of clutter in the seed system by requiring varieties to remain in the system just in case they will be sold as common seed.
- Potential issue preventing the spread of undesirable traits or prevent market access if a variety developer or responsibly body is not accountable to maintain a stewardship program.
 - There is a risk that a farmer may not be aware of stewardship practices affiliated with a herbicide tolerant trait in a common seed variety.
 - When a patent expires the stewardship practices become unregulated, this potentially could increase the incidences for stewardship practices not being respected by new users of the technology.
- Each generation from pedigreed seed increases the probability that the common seed produced would no longer represent the variety or perform to the intentions of the breeder.

Option #3: There should be flexibility built into the system to allow interested parties to become a maintainer of a registered seed variety upon request prior to the cancellation of the variety by a Registrant. Preserve the ability to cancel varieties from registration for cause. Maintain the flexibility for the recommending committees to consider and accept other options to accommodate heritage, heirloom and alternate bred varieties in Canada.

Rationale: This will increase access to varieties subject to variety registration in the system by transferring the responsibility for the variety over to another body. This process will allow for interested parties to become responsible for maintaining a variety to be sold as seed. If there is no interest to maintain a variety then it could be removed from variety registration. After the variety has been transferred, the ability to cancel a variety by the CFIA will remain in place if new evidence is presented that there could be issues with the variety. This could potentially allow deregistered varieties to enter back into the registration system. The recommending committees will have the flexibility to accept other types of data when considering recommending a heritage, heirloom or alternate bred varieties for variety registration.

Pros/Benefits:

- Allows for varieties to remain in the system to be sold as common seed.
- Requires a body to become responsible for a variety if an issue arises.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- Varieties would require interest to remain in the system to be sold as common seed prior to being cancelled and removed out of the public domain.
- Potentially reduce the amount of grain demoted to a lower grade at a grain elevator due to variety cancellation.
- Increases the availability of a variety that has been registered to be sold as common seed.
- Provides the ability for a variety to be cancelled by the CFIA if there is new evidence of harm for food safety, health, to be pre-emptive to market access issues where the variety's trait(s) may and issue, etc.
- Potentially increases access to varieties in Canada for niche markets.
- Potentially decreases non-compliant common seed sales of unregistered varieties in Canada.
- Potentially increases communications or understanding when a variety's registration will be cancelled.
- Commercial reason for cancellation may be mitigated allowing the variety to continue to be sold as common seed.
- Provides public access to continue to use varieties with desired traits in specific regions, markets and on farm.
- Varieties would remain available to purchase as common seed for a reasonable cost.
- Allows a variety to remain in the system to access as a farmers' privilege to sell and purchase common seed of that variety.

Cons/Risks:

- There may not be an interest for a variety to be maintained if it has not been sold for a number of years.
- Depending on the process, the request to maintain a variety could be rejected by the Registrant.
- It may be difficult to determine if the registration is cancelled for specific causes versus the convenience of the marketer.
- Potential issue preventing the spread of undesirable traits or prevent market access if a variety developer or responsibly body is not accountable to maintain a stewardship program.
 - There is a potential risk that a farmer may not be aware of stewardship practices affiliated with a herbicide tolerant trait in a common seed variety.
 - When a patent expires the stewardship practices become unregulated, this potentially could increase the incidences for stewardship practices not being respected by new users of the technology.
- Each generation from pedigreed seed increases the probability that the common seed produced would no longer represent the variety or perform to the intentions of the breeder.

Summary Report of the Variety Registration Task Team, CFIA Seed Regulatory Modernization Initiative

- A variety's reputation may be linked to the original seed developer or company which could be indirectly impacted if the variety is put up to tender and its performance is not adequately maintained by the new responsible body.
- Potential issues with breeder seed availability in older varieties when a variety is no longer in the certification system producing pedigreed seed. This could be an issue if a reference sample of the original variety is no longer available.
- Each generation from pedigreed seed increases the probability that the common seed produced would no longer represent the variety or perform to the intentions of the breeder.

Option #4: There should be an application process with an appeal period to cancel a variety by the Registrant. Preserve the ability to cancel varieties from registration for cause. Maintain the flexibility for the recommending committees to consider and accept other options to accommodate heritage, heirloom and alternate bred varieties in Canada.

Rationale: This would enable a Registrant to apply to cancel a variety with the ability of impacted stakeholders to provide justification for a variety to maintain in the system through an appeal process. After the appeal period, based on the information collected then it could be determined if there is a cause to accept or revoke the application to cancel the variety.

Pros/Benefits:

- Removes the requirement for the Registrant to be the sole party providing input when there is an application for a variety's registration to be cancelled.
- This could be more of a market driven decision and increase stakeholder feedback.
- Allows for varieties to go through an appeal process with the potential to remain in the system if they are of value.
- Varieties would be required to be of interest to remain in the system to be sold as common seed prior to being cancelled and removed out of the public domain.
- Provides the ability for a variety to be cancelled by the CFIA if there is new evidence of harm for food safety, health, to be pre-emptive to market access issues where the variety's trait(s) may and issue, etc.
- Increase the information requirements prior to variety cancellation.
- An appeal process could further increase transparency and potentially mitigate issues when unregistered varieties of common seed are sold in Canada.
- Potentially increase communications or understanding when a variety's registration will be cancelled.
- Removes varieties that have not been sold in a number of years out of the system if there is no market demand.

Cons/Risks:

- It may be difficult to determine parameters a Registrant would need to provide for a business case versus information provided by the stakeholder to decide if the variety should remain in the system or be cancelled.
- There may be an issue if a Registrant is forced to maintain a variety in the system if an application is rejected.
- Each generation from pedigreed seed increases the probability that the common seed produced would no longer represent the variety or perform to the intentions of the breeder.
- Potential issues with breeder seed availability in older varieties when a variety is no longer in the certification system producing pedigreed seed. This could be an issue if a reference sample of the original variety is no longer available.

Option #5: Certified seed of a hybrid variety produced directly from sterile and fertile parent lines of different varieties in the previous generation (e.g. hybrid canola, hybrid corn, hybrid cereals, etc.) should not be sold as Common seed in Canada.

Rationale: When certified seed is produced from a sterile and fertile hybrid production methods with different traits, the varietal traits in each generation after certified may segregate at a higher frequency impacting the stability of the variety produced in common seed. This potentially will increase consumer protection for undesirable traits in common seed sold when the traits of a variety are not stable in successive generations.

Pros/Benefits:

- Ensures traits will not segregate in common seed produced from a certified hybrid production method with sterile and fertile parent lines.
 - Decreases biological limitation when sterility segregates out in specific crop kinds which may increase the presence of ergot due to the increase sterility in the field.
 - Decreased the risk of quality traits (e.g. canola quality) separating out when grain is delivered to the elevator.
- Increase compliance on PBR protected hybrid varieties.
- Increase compliance with stewardship practices when there is a herbicide tolerant trait associated with the variety.
- Mitigates the risk of common seed sold not meeting part of the definition of a variety where it is required to retain its distinguishing characteristics when reproduced.

Cons/Risks:

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- Potentially increase restrictions as technologies advance in the future on crop kinds that may potentially produce a stable hybrid seed where traits may not segregate and be a viable option for common seed production.

DISCUSSION

There were concerns brought forward on the restriction of the use of variety names for *Schedule II* crop kinds sold as common seed and the ability to determine if seed sold would be of an unregistered variety. A similar concern was raised when considering herbicide tolerant traits subject to stewardship practices. Furthermore, the concern with common seed lots being misrepresented by sellers was raised during the discussion on crop kinds subject to restrictions on the use of variety names. This restriction increases the difficulty to detect and enforce unregistered varieties and stewardship practice when a variety is a crop kind listed in *Schedule II* is sold as common seed. This will be forwarded onto the Variety Names Task Team topic for further discussion.

It was clarified that the grain rules are based on variety cancellation. If a variety is cancelled for any reason, then it is only eligible for the lowest grade which tends to deter producers from growing it or seeking a market. For export purposes, Canadian wheat is sold by a statutory grade. CWS is probably one of the commodities cargos commonly traded but there is nothing allowed in a lot or a specification beyond the grade. There may be different requirements in contracts with foreign buyers with blending of classes and tolerances for the varieties.

It was mentioned that the grain industry may also help self-regulate common seed of unregistered varieties sold in Canada as there are legal implications, including penalties, under the federal *Canada Grain Act* if grain is knowingly declared incorrectly/misrepresented. Business contracts between buyers and sellers may further mitigate the misrepresentation of the grain being delivered under a contract agreement. There is flexibility in the current system for the industry and markets to adopt advances in technology (e.g., DNA analysis) to verify varieties when purchasing seed or grain from a farmer which may further enhance self-regulation and accountability when selling unregistered varieties of common seed in the future.

During the discussion the Variety Registration (VR) Task Team CFIA lead presented the recommendations on their Variety Registration Cancellation and Heritage/ Heirloom Lines, Heterogeneous Materials/ Populations and Alternatively Bred Cultivars options and recommendations reports to the Common Seed Task Team Members. During this discussion it was clarified that there is flexibility in the current variety registration system for recommending committees to accommodate heritage, heirloom and alternatively bred cultivars for variety registration. There is support from the Common Seed Task Team for these varieties to be

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accommodated into the variety registration system to be allowed to be sold as common seed during the discussions. It was suggested that there should be different criteria acceptable to recommend alternatively bred organic varieties as it is challenging to accommodate these varieties under the mainstream variety registration system. One consideration for this suggestion is the value in organic production for a seed developer and producer to sell organic seed to produce organic grain downstream as organic grain loses value once it is in the regular grain handling system. There was a concern that the different recommending committees inconsistently exercise their flexibility to accommodate alternatively bred varieties. It was suggested that CFIA should try to improve these inconsistencies between recommending committees to accommodate heritage, heirloom and alternatively bred varieties. There was support to build in the recommendation committees' flexibility to accommodate heritage, heirloom and alternatively bred varieties into options #1 and #2.

There was clarification on Plant Breeders' Rights (PBR) with respect to older variety not allowed to have PBR if the variety has been around for a specified number of years. It was also clarified that a variety would not qualify for PBR if there is no product to sell. There was also further clarification on the differences between a variety under PBR where the collective cells of the variety are subject to PBR versus a patent where a trait under at patent.

The Task Team members decided to remove the option of allowing unregistered varieties of common seed to be sold in Canada.

During the discussion on option #1 it was mentioned that the variety cancellation process is not well known and may require a qualification on what it means and on information provided, moving forward. There was a concern with the current cancellation process where the Registrant has the sole discretion to cancel a variety's registration. It was mentioned that varieties should be able to remain in the system [insert discussion& recommendations]

For option #2, [insert discussion& recommendations]

For option #3, there was a suggestion to have a process with parameters in place to ensure there is the ability for a variety to be maintained and sold as common seed in Canada. It was also suggested, as new evidence arises for harm or market issues, the proposed process should allow for varieties to be deregistered even if the responsibility is transferred to another body. [insert discussion& recommendations]

For option #4, [insert discussion& recommendations]

For option #5, this option may require further discussion during the Common Seed Sale topic. [insert discussion& recommendations]

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The Common Seed Task Team decided to defer the own-use import exemption to the Seeding by the Importer Common Seed Task Team Topic.

RECOMMENDATIONS: See introduction note.

Topic 7 Report (rdims# 16001706 v3)

SEED REGULATORY MODERNIZATION VARIETY REGISTRATION TASK TEAM Report Topic #7

The Parsing of crop kinds in Schedule III of the Seed Regulations. OPTIONS AND RECOMMENDATIONS REPORT February 2, 2022

Draft from Rob Darlington saved into CFIA RDIMS as #16001706 v1,
CFIA reviewed, edited version: **16001706 v1B**
Final version: **16001706 v3**

Approved February 2nd, 2022

Report Topic #7: *Parsing crop kinds in Schedule III of the Seed Regulations.*

Introduction:

In Schedule III of the *Seeds Regulations*, there are qualifiers listed for some crop kinds. The 53 crop kinds are subject to registration prior to import or sale of seed in Canada are listed in Schedule III. Fifteen of these crop kinds have qualifiers associated with them which require interpretation. This list determines what is subject vs. not to variety registration.

At the time, there was only merit-based registration recommending committee; so qualifiers were put into place to narrow down what had to go to the recommending committees.

Questions discussed:

- As the seed regulations are difficult to change, should we be looking at incorporation by reference so that changes can be made more easily change?

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- If separation is kept, what criteria definitions and clarity is needed so that regulatory system is clear cut for users?

ANALYSIS OF OPTIONS

Option 1 Parsing would be permitted for subsets of species which allows them to be treated differently. This is currently the situation for a number of species.

If parsing is to be maintained then it would be facilitated by using **Incorporation by Reference** to define the species and the subsets subject to parsing.

A review of the currently parsed species should be carried out to determine if parsing is still applicable to that species. Where parsing is appropriate then the definition of the subset and criteria to ascertain whether the subset fits or not should be reviewed so that it is clear to users and regulators.

Rationale: In a number of species there are subsets with quite different end uses and thus different requirements associated with those (e.g. linen flax and linseed flax). Parsing permits the subsets to be treated differently.

Pros

- Allows different subsets to be treated differently
- Recognizes that merit can be determined through means other than the requirements of the variety registration system

Cons

- Subset descriptors can be poorly defined.
- Sometimes presents CFIA with difficult interpretations.
- May require CFIA to make arbitrary decisions.

Option 2: No parsing is permitted and all subsets of a species are treated alike ¹.

Rationale: Decisions should be made as to how a species is to be treated and all components handled in a similar manner. This would clarify and simplify the system for the users and regulators of the system.

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Pros

- CFIA would not have to decide if a subset is in or out of the registration system.
- All varieties would be treated the same.
- Users would know the requirements for all variety types within a species.

Cons

- Does not permit subsets to be treated differently.
- Could place inappropriate criteria on a subset of a species (e.g. a specific fatty acid profile might be required of a linen flax)

¹ **Further to Option 2:** Move all crops currently under Part 1 to Part 3 of Schedule III, *Seeds Regulations*

Rationale: To eliminate concerns related to parsed crop kinds

Pros

- Eliminates issues related to parsed crop kinds
- Simplifies registration status of varieties within a crop kind
- Merit registration would not be required and as such farmers would be free to plant varieties that meet specific end use needs as determined by the marketplace within a crop kind
- Makes it easier for end users in their purchase decisions.
- Would accelerate new variety availability and adoption for growers who compete against farmers in other countries who benefit from faster access to new genetics.
- Would create market opportunities including new niche market opportunities that are not feasible today without exemptions, illegal purchase of crops, etc.
- Would create marketing freedom currently enjoyed in other crop kinds
- Maintains other aspects of the Seeds Act related to Certification to ensure seed quality and varietal integrity with certified seed.

Cons

- Changes the system from the status quo which would be uncomfortable to many and comfortable for those already taking advantage of Part III or exempt status in specific crops in the marketplace in Canada.

RECCOMENDATION:

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The Task Team in attendance at the January 19th, 2022 voted on the two options.

Chair moved for a vote on the options but emphasized option 1 would require some modifications such as a review of the currently parsed species. Results were recorded as follows:

Option 1 received the majority of votes but the majority of seed industry stakeholders on this task team supported Option 2; we therefore have a qualified consensus* for Option 1 (keep parsing of crop kinds but move Schedule III out of the *Seeds Regulations* to make parsing quicker/easier/more efficient).

Producers & Commodity value chain organizations (out of the 6 present 5 voted for option 1 and 1 abstained)

Seed Industry (5 were present, 2 voted for Option 1 and 3 for Option 2)

Breeders, Government and Others: (Out of the 5 members present, 3 voted for option 1 and 1 for option 2 and CGC abstained)

Summary of recommendations:

Other than Producers and Commodity Chain Organizations, where all members present voted option 1 (with 1 abstention), the other sectors split their votes between option 1 and 2. We therefore have a “qualified consensus” for Option 1 which is to continue the use of parsed crop kinds in Schedule III of the *Seeds Regulations* but to seek out subject matter experts on the rationale behind them and also to use Incorporation by reference and remove Schedule III (the official list of crop kinds subject to registration in Canada) from the *Seeds Regulations* in order to make changes to Schedule III, such as this, quicker and more responsive to Canada’s needs.

Definition of qualified consensus from T6 draft report:

*CFIA indicated that the Working Group will be made aware that there is **qualified consensus**. What we mean is that we record whether or not the majority of each stakeholder groups agree on an option/recommendation. If even one stakeholder group entirely disagreed, then we could not proceed to make a recommendation on a given topic. This would hold true even if the rest of the stakeholder groups clearly favoured a particular option.

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As an example, in this report, we have a qualified consensus situation supporting Option 1. It is a qualified consensus because one “Seed Industry” designated member voted for Option 1, whereas the remainders voted for Option 2.

Topic 7 - ADDENDUM – 1 Schedule III, *Seeds Regulations* and parsed crop kinds (qualifiers) listed

(From CFIA)

There is a “housekeeping issue” regarding Schedule III of the *Seeds Regulations*: the issue of parsed crop kind listing in Schedule III. The 53 crop kinds subject to registration prior to import or sale of seed in Canada are listed in Schedule III at the back of the *Seeds Regulations*. Fifteen of these crop kinds have qualifiers on them which require interpretation:

Fababean (**small seeded**) ~ small seeded is a reference to feed type fababean and excludes large seeded (the type used for canning/food – popular in Italian culture)

Flax (**oilseed**) ~ this is separating fibre-only flax (no registration) from oilseed flax (linseed and edible oil types)

Soybean (**oilseed**) ~ this is to distinguish from food-grade soy (natto/tofu, etc.) (no registration) from so-called “oilseed” types (note: soy is a meal crop, not an oilseed). Rationale for food-grade is that it is a highly integrated/contracted market where crop parameters are specified under contract.

Lentil (**grain type**) ~ intended for all lentils harvested for grain (dry lentil) as opposed to alternative uses such as green manure, crop cover, forage-feed use, etc.

Field pea (**commodity type**) ~ *this one is really tricky – what is “commodity type”? CFIA is left to interpret this (nothing in the regs) – it has been problematic (e.g. orange cotyledon peas – at introduction, no market – not a commodity by any definition – fast forward 9 years – market established – now a commodity but Canada Grain Commission needed to categorize it for delivery at elevator. It was a problem until they came back to us indicating they view all field pea (dry peas) as commodity. New definition moving forward now. I believe the original intent was to separate garden peas (field pea grown for fresh veggie use) from the dry pea (feed/food) use types.*

Oat (**grain type**) ~ *this excludes forage-only use oat varieties*

Rye (**grain type**) ~ *is there anything other than grain type rye? (Secale cereal). I suppose it excludes green manure-only types (if that is a thing).*

Tobacco (**flue-cured**) ~ *we currently only register non-hybrid and hybrid flue-cured tobacco: Author not certain of the origins of this but I take flue-cured to mean tobacco intended for the tobacco industry (smoking) and excludes all other use (ornamental, other?)*

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Topic 8 Report (rdims# 16005978 v3)

SEED REGULATORY MODERNIZATION VARIETY REGISTRATION TASK TEAM Topic #8

Regional Restrictions on National Registrations

OPTIONS AND RECOMMENDATIONS REPORT January 28, 2022

Approved Feb 2nd 2022, ver. 1B (edited)

Report Topic #8: Regional Restrictions on National Registrations

Introduction:

Currently, when a variety is approved for registration, it is given a national registration. For Part 1 registration crops (cereals, oilseeds, pulses, and canola) which are merit based and therefore require regional registration recommending committees, a committee recommendation is required. Typically a variety registers with one committee in Canada. CFIA processes the registration, initially granting it for the region that the recommending committee represents (e.g. the Prairies, Canada). For some crop kinds (cereals, pulses, canola) there are more than one regional recommending committees in Canada. Once a registration is granted for a variety CFIA then approaches each of the other committees, same crop kind, different region, and asks a simple question: Do you have any objection to the National registration of this variety? If a committee in a region (same crop) objects, then a regional restriction for that region is applied. By regulation, there can be one or two criteria for objecting: 1) based on disease reaction of the variety and 2) based on the quality characteristics of the seed/grain of the variety. The threshold for refusal is if the committee perceives a threat to crop production in their region if that cultivar is sole there. A typical pattern observed is spring or Winter wheats in Ont. and/or Quebec being refused by the PRCWRT out West for example. It often has to do with Fusarium Head Blight and DON toxin production in wheat. It has been over a decade since this was practiced in canola/rapeseed. Today regional restrictions are predominantly with wheat (spring and winter) and to a much lesser extent, Triticale and Oat. Also, today, it is completely driven by disease concerns, not quality.

Considerations brought forward from CFIA:

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- If regional restrictions are to be maintained CFIA in consultation with members of the value chain, should develop very well-defined criteria as to what constitutes potential harm. It is important that such decisions be consistently applied.
- If regional restrictions are to be maintained CFIA should initiate discussions to harmonize and integrate the activities of the three eastern sets of recommending committees.

ANALYSIS OF OPTIONS

Option 1 To continue to allow regional restrictions on variety registrations.

Rationale. This option would provide a means of protecting the production in a region from harm caused by a variety which may have the potential to cause harm to the industry in that area. (Possible examples might be due to disease susceptibility or interfering with quality segregation in the marketplace).

Pros

- Protects an area from potential harm from an inappropriate variety.
- Recognizes differences in the natural and marketing environments in different areas of Canada.

Cons

- Allows veto power of one region over another (albeit with prescribed criteria from CFIA).
- In Eastern Canada, there are three contiguous regions and the threats do not have natural geographic barriers. The area should be treated as a region but it has three separate Recommending Committees. This makes it difficult for variety developers who have to serve the criteria of three different committees.
- This presents CFIA with an extra regulatory burden to enforce a regional restriction on seed sales and advertising.

NOTE: A significant variation on this theme was presented (see Appendix 1) whereby crop placements in Schedule III (which crops go into which registration part (1, 2 or 3) where the Table (Schedule III) would be modified to allow for different crop placements in different regions of Canada (winter wheat is Part 1 in West region vs. Part 3 in Eastern region, as an example). On the one hand this further complicates the variety registration system in Canada and on the other hand it allows for more regional based flexibility for registering crops. A few members suggested that a simplified East/West approach to the regions might simplify the process without any untoward effects as compared to the current system.

Option 2 All registrations are National. No regional restrictions are allowed.

Rationale: This would simplify the registration system and make it easier for CFIA to manage. It would place the onus on variety marketers to sell varieties only in areas where they are adapted. It would also

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place the onus on variety users to ensure that a variety is appropriate for their conditions before they grow it. It would recognize that the registration system is not the best way to prevent inappropriate varieties from being grown in an area.

Pros

- It would be a simpler system and facilitate timely handling of registration applications.
- It would still require that a variety meet whatever registration requirements were in place for intended area of production.
- It would encourage variety developers to ensure that their marketing efforts were focused on areas appropriate to that variety.
- It would give extra weight to local adaptation recommending body recommendations.

Cons

- It would not allow use of the Variety registration system to restrict production of a variety in a region.
- It could potentially result in harm due to diseases susceptibility or market confusion due to quality issues, in a region.
- It may result in a developer using the “easiest route to variety support” by choosing to test in an area where the perception is that the criteria are not as rigid.

Option 3 Regional Restrictions should be permitted in select species. It would require that a process be developed to ascertain the status of each species.

From the minutes, Option 3: Case by case basis for any given species to determine whether regional restrictions would be allowed or not with suggestion that a process will have to be put in place if this option chosen.

Rationale: Regional differences are more important in some species than in others so that one size fits all is probably not necessarily a good fit for all species.

Pros

- Would be a compromise without imposing it on all species.
- Would permit each species to be treated differently.
- Would permit the value chain members to decide where their commodity fit in this regard.
- Would provide a means to prevent perceived harm in a given species in a given area.

Cons

- It would be a lot of work to set up and create administrative difficulties for enforcers.
- It may cause confusion amongst users.

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- Using the variety registration system to restrict production in an area may not be the best way to accomplish that end.

RECOMMENDATION:

The Chair asked whether the team was ready to vote. Voting by option or abstaining:

The vote was taken with results as follows:

Summary of recommendations:

We have a qualified consensus for Option 3 (**regional restrictions on registration, in select species**).

Producers & Commodity value chain organizations (out of the 6 present 5 voted for option 3 and 1 for option 1)

Seed Industry (5 were present, 3 voted for Option 2 and 2 for Option 3)

Breeders, Government and Others: (Out of the 5 members present, 3 voted for option, 3 and one for 2. CGC abstained)

Topic 8 - ADDENDUM – 1 Provided by Ellen Sparry, Seeds Canada/C&M Seeds (Seed Industry), Feb. 11, 2022 @10:21am, entered below, as-is:

[Note section was added to Option 1 in this report (T8) as it is actually a modification of Option 1]

Regional Placement of Crops

Option 2: To allow regional placement¹ of Part 1 crops into Part 1 or Part 3 of Schedule III²

Rationale: This option would provide a means for each region¹ to determine crop placement according to the needs of the value chain in the intended area of production.

Pros/Benefits:

- Offers flexibility for the value chain of each region to chose placement of crop kinds
- Allows regional value chains to take advantage of market opportunities not otherwise available
- Acknowledges the difference between use and end use markets in regions across the country
- Allows farmers in regions who want faster access to new varieties the opportunity to do so
- Will lead to increased investment in breeding activities, particularly for niche crops
- Provides a compromise without imposing one placement across all regions

Cons/Risks:

- More complex system of listing crop kinds within Schedule III
- Possible confusion for those not aware of the difference between regions
- Does not meet the need of those wanting the same rules across the country
- Possible enforcement challenge of seed of a crop type subject to regional restrictions, moving from a Part 3 area to a region where it is still Part 1 crop and not registered

Footnotes:

1. Assuming regional divisions are maintained as status quo, or may be changed to West and East
2. Assuming that Part 2 is removed from the Schedule

Topic 9 Report (rdims# 16172071 v2)

SEED REGULATORY MODERNIZATION VARIETY REGISTRATION TASK TEAM Topic #9

Use of Incorporation by Reference for Variety Registration

OPTIONS AND RECOMMENDATIONS REPORT Feb. 16, 2022

Report Topic #9: Use of Incorporation by Reference for Variety Registration

Introduction:

CFIA is now able to take advantage of a legislative tool that can allow removing parts of the *Seeds Regulations* from the regulations, replacing them with a “reference to an external document” and therefor avoid the cumbersome and time consuming regulatory amendment process (typically 1 to 3 years and sometimes longer). For Variety Registration, the biggest gain in speed and efficiency would come from incorporating Schedule III of the *Seeds Regulations*. This would allow for crop placements into different regulatory streams (Part 1,2,3) without having to go through the regulatory amendment process; cutting time to make change in half. This would be more industry responsive. It is possible that the lack of crop placements in the Flexible Variety Registration System might be because of the length of time and the work that has to go into making a crop placement in registration happen. This would simplify and speed up the process; lower the barrier for change. The **use of incorporation by reference to removed Schedule III from the *Seeds Regulations*** and to replace it with a process and an administrative document referred to by the regulations was one of the three outcomes of the last variety registration review (announced in 2016).

Another fundamental aspect with regard to incorporation by reference (IbR) is: who should hold the pen on an IbR document: the government (e.g. CFIA) or a non-government party? Regardless of who holds the pen, there is a process for changes to an IbR document which involves providing a rationale for the proposed change along with evidence of consensus on the proposed change. The government has oversight with IbR documents, as a minimum. The framework for changing an IbR document (meaning the requirements) is similar in many

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respects to the process for making changes to crop placement in Schedule III, *Seeds Regulations* except that a regulatory amendment process is not involved (saving time and effort).

Regardless of who holds the pen, there is a process for changes to an IbR document which involves providing a rationale for the proposed change along with evidence of consensus on the proposed change. The government has oversight with IbR documents, as a minimum. The framework for changing an IbR document (meaning the requirements) is similar in many respects to the process for making changes to crop placement in Schedule III, *Seeds Regulations* except that a regulatory amendment process is not involved (saving time and effort).

Considerations brought forward from CFIA

- For Part 3, *Seeds Regulations* (the section on “Variety Registration”), what parts of the regulations might be more efficient if removed from the regulations via incorporation by reference? Some items in Part 3 of the *Seeds Regulations* that you might consider are:
 - 1) The list of requirements for variety registration (**61. (1) to (4)**). and/or
 - 2) The description of the information required in a registration application (**67 (1) to (1.1)** inclusive).
 - 3) Schedule III, *Seeds Regulations* (the table listing which crops are subject to which type of registration in Canada).
- Who should hold the pen on an IbR document: the government (e.g. CFIA) or a non-government party?

ANALYSIS OF OPTIONS

Option 1 No changes to the current system.

Rationale

The current variety registration system works reasonably well in how various crop kinds are regulated

Pros

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- it works
- **it requires a detailed prescriptive process that is very thorough in that proposed change, the rationale for it and the proof of consensus among stakeholders is thoroughly documented**

Cons

- It is slow; not responsive to client demands (time-wise in particular). It does not operate at the speed of business.
- The current process for changes to Schedule III or any of Part 3 of the Seeds Regulations for that matter, requires a regulatory amendment process in government and this, by its nature, is time and resource intensive, ranging from 2 to 5 years to see through (on average).
- Delays in response to business needs in the seed sector, come at a cost to the industry.

Option 2 Incorporate by Reference Schedule III, *Seeds Regulations* (the table where the 53 crop kinds subject to registration are listed, as well as their qualifiers (parsing) and the type of registration (Part 1,2,3) they are subject to. CFIA to hold the pen on this document.

Rationale: The current system for crop placement (into Part 1, 2, or 3) can be made more industry-responsive by taking Schedule III out of the *Seeds Regulations*, making a reference to it in the regulations (as a referenced document) and then holding the document as an administrative document with a prescribed process for making changes to it. The process for change would have to meet the government requirements (which are the same ones CFIA currently uses), namely: 1) request the specific change 2) provide a rationale for the proposed change in your crop, and 3) provide evidence of consensus on the change proposal from your crop-specific stakeholders. It is anticipated that moving Schedule III to an Incorporated by Reference document with CFIA holding the pen, would reduce the current time to amend Schedule III by 2 to 4 years. It is also anticipated that the change mechanism would be no more than a year to complete (up to one year processing time by CFIA). This recommendation will also facilitate some items this task team has recommended in other reports such as entering new crops into variety registration and exiting existing crops from variety registration (more examples of improved responsiveness to industry).

Pros

- Faster (approx. a year or less) response to stakeholder-directed crop placement (changes of registration type (1, 2, 3)), potential entry and exit from variety registration.
- New process is still stakeholder-driven, CFIA facilitated, meets TB requirements; it is robust
- Facilitates some other changes this group has proposed (the ability to bring new crops into Variety Registration and for existing crops to leave variety registration)

Cons

- Some may argue that an expedited decision-making process such as IbR makes possible, is not as robust as a regulatory amendment process (checks and balances).

Option 3 None was determined. We examined other parts of Part 3, *Seeds Regulations* such as the list of requirements for eligibility for certification but none of the potential parts of Part 3 (the Variety Registration Section of the regulations) met the criteria of being a regularly amended list of things or even a regularly amended section of the Seeds Regulations. Schedule III was obvious to all.

RECOMMENDATION:

Chair asked whether the team was ready to vote. Voting by option or abstaining:

The vote was taken with results as follows:

Option 1: 1 vote

Option 2: 15 votes

Abstained: none

[Option #2 \(to IbR Schedule III, Seeds Regulations, CFIA holds the pen\) has consensus](#)

Summary of recommendations:

The Variety Registration Task Team developed a qualified consensus that CFIA use the Incorporate by Reference legislative tool to remove Schedule III, *Seeds Regulations* (the table where the 53 crop kinds subject to registration are listed, as well as their qualifiers (parsing) and the type of registration (Part 1,2,3) they are subject to. This will make Schedule III a referenced document in the regulations and make for a much faster change process for bringing crops into registration, having them leave registration, moving them to different levels of registration requirement, and parsing or qualifying crops in the Schedule. The task team also developed a consensus that the IbR document remain under the authority of the CFIA (CFIA holds the pen but the process is still crop-specific stakeholder-driven).

Topic 9 – ADDENDUM 1

A Q&A document from CFIA in response to questions arising from the Feb. 16, 2022 meeting of the VR task team. This was also supplied to the task team as a stand-alone document (rdims# 16106058)

Variety Registration Task Team Questions on incorporation by reference (IbR) February 16, 2022

Question 1: Should we utilize IbR and where would it be utilized beyond taking out Schedule 3?

Response: Please see section 8 of the [CFIA Incorporation by Reference policy](#) document. CFIA determines whether or not regulatory requirements and/or policy objectives are best met through incorporating a document, in whole or in part. CFIA is committed to the principles of accessibility, transparency, consistency, reasonableness, and clarity when using IBR in regulations.

Annex A of the CFIA Incorporation by Reference Policy document identifies a variety (though non-exhaustive list) of considerations for determining whether or not a document is appropriate for incorporation by reference, which includes how often a document will need to be modified, who is responsible for maintaining the document, accessibility, and whether or not the reference will be static (i.e. as the document existed on a certain date) or ambulatory (a document as amended from time to time).

Question 2: Who holds the pen on an IbR document?

Response: The document may be internal or external to CFIA. Because a document incorporated by reference has the same effect as if the wording appeared in the regulations, ambulatory references, in particular, need to be carefully considered. The document owner has the ability to change the regulations by updating a document incorporated by reference.

Annex B of CFIA's incorporation by reference policy identifies the process CFIA will follow when modifying an ambulatory incorporated document to ensure transparency, consultation, reasonableness, clarity etc. However, the ability for CFIA to follow-through on these commitments is limited in circumstances where the document is external to CFIA and the document owner has not informed CFIA in advance of the proposed changes. CFIA does not have final control over any changes made to an external document. If the changes were not acceptable to CFIA, CFIA would need to amend the regulations by either specifying certain portions of the document as incorporated or removing the incorporation altogether.

Question 3: Who could initiate the changing the regs by IbR and who would have the oversight or final say?

Response: Authority to IbR a document in the *Seeds Regulations* comes from s. 4.1 of the *Seeds Act*. Amending the regulations to incorporate a document follows the same process as all regulatory amendments with final approval by the Governor in Council. However, once incorporated, the document and any modifications are under the purview of the document owner.

Question/Comment 4: If CFIA holds the pen, they make the determination as to whether it meets the process requirements. But, if it's a different organization that holds the pen, they would determine if it has matched the process or not.

Response: The process that CFIA would follow to amend an IbR document is identified in Annex B of the CFIA Incorporation by Reference Policy. The process that and party external to the CFIA would follow when amending a document incorporated by reference would be evaluated prior to CFIA recommending the document be incorporated by reference. Nonetheless, CFIA cannot require an external party to follow (or even not change) their policy for making changes to the document. If changes are made to a document without CFIA's knowledge or if changes are made that no longer serve CFIA's stakeholders, CFIA's only recourse is to amend the regulations to remove the reference or specify a certain portion of a document as incorporated by reference.

Question 5: Could the process pertaining to the TB be briefly detailed.

Response: The following is an excerpt from Section 9 of the CFIA incorporation by reference policy outlining roles and responsibilities.

9. Roles and responsibilities

As part of the regulatory process, the Department of Justice (DOJ) will be asked to review the document(s) proposed for IBR, and advise CFIA of any related legal considerations, potential limits or risks. CFIA will then determine if it wishes to continue with the next steps to have the regulatory proposal referencing the IBR document(s) published in the Canada Gazette. TB must approve the proposal, which includes the supporting rationale for selecting the IBR document(s) in the RIAS. In addition, the proposal to include an IBR document needs to meet Canada's international obligations.

Once pre-published in the Canada Gazette, Part I, CFIA will notify stakeholders and provide an opportunity to comment on the regulatory proposal that includes the IBR document. CFIA will take the comments received into consideration, as appropriate, before final publication in the Canada Gazette, Part II. The Governor in Council, on the advice of the responsible Minister, makes the final

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determination of accepting or rejecting the regulatory proposal that includes document(s) incorporated by reference.

For proposed modifications to already incorporated ambulatory documents, the roles and responsibilities depend on the document's administrator. For CFIA-generated documents, CFIA will manage all proposed modifications. Any modification will only be made after thorough assessment, legal input (as noted above), and approval by the appropriate level within CFIA, as established by CFIA guidelines. CFIA will notify domestic and international stakeholders of all proposed modifications to CFIA-generated documents. An opportunity to comment will be provided, unless the proposed modification addresses an immediate risk to health or safety, a minor administrative adjustment or a consequential modification.

For external documents, the document's administrator is responsible for proposed modifications. Nevertheless, CFIA will endeavor to work with the responsible party to receive timely notice of any upcoming modifications and communicate them to stakeholders. Where possible, CFIA will direct stakeholders to consultations or comment periods held by the responsible party. Annex B outlines the process for modifying incorporated ambulatory documents.

Topic 10 Report (rdims# 16190783 v3A)

**SEED REGULATORY MODERNIZATION WORKING GROUP
VARIETY REGISTRATION SUB-TASK TEAM**
**Topic 10 Report: [Heritage/Heirloom Lines, Heterogeneous Materials/Populations,
Alternatively Bred Cultivars.](#)**
OPTIONS AND RECOMMENDATIONS REPORT

Topic: Heritage Cultivars/Heirloom Varieties, Heterogeneous Materials/populations Alternatively Bred Cultivars/Varieties

Context:

There are farmers and seed growers in Canada, predominantly small-scale organic, currently engaged in 1) breeding varieties on their farms of Schedule III crops and 2) circulating small amounts of seed and grain of unregistered heritage/heirloom varieties of Schedule III crops. SeedChange, a non-profit organization that works on a range of participatory plant breeding and seed conservation projects with farmers across Canada, put forward that the existing version of the *Seeds Regulations* could better support and accommodate farmers and seed growers who are working with heritage/heirloom varieties, heterogeneous materials, and cultivars bred by farmers for organic production. Furthermore, from the Needs Assessment Survey conducted by the SRMWG, 55% of respondents felt that accommodations should be made for both heritage and alternatively-bred varieties (the CFIA interpreted cultivars bred by farmers for organic production as “alternatively-bred varieties”).

This sub-task team was established to evaluate proposals for regulatory change that would accommodate these kinds of materials.

Topic 1: Heterogeneous Materials/populations

SeedChange put forward the concept of “heterogeneous material”, as adopted by the EU, being integrated into Canada’s *Seeds Regulations* definitions of “variety” to accommodate material with high levels of genetic and phenotypic diversity.

The sub-task team concluded that, unlike the EU (OECD Seed Schemes), Canada requires only “DS” or distinguishability and stability for a cultivar/variety, whereas the EU has a DUS (distinct, uniform, stable) requirement for “listing” (registration). In Canada, if the cultivar/variety can be described accurately and consistently (within accepted norms) from one generation to the next, it meets the basic definition of a variety. Canada does not require uniformity testing (from the DUS point of view) as part of the registration/listing process like the EU and the Plant Breeders’ Rights Office.

The current recommendation from the SRMWG-VR Task team is that the registration system can accommodate these Heterogeneous lines.

Topic 2: Alternatively bred Cultivars/Varieties

Alternatively bred (non-mainstream commodity) varieties.

The initial impetus for “alternatively bred” was about varieties bred by farmers for organic systems. There are farmers engaged in participatory plant breeding programs to develop new varieties. These growers require support to navigate the variety registration system.

Discussed and suggested recommendations for providing support to these breeders could include:

- A step-by-step guide developed by the CFIA and AAFC for how farmers/new breeders can navigate the variety registration system.
- Requests be made to the various Recommending Committees to review and possibly adjust their Operating Procedures to ensure there are no undue barriers preventing farmers or new breeders from submitting eligible material for variety registration.
- A topic also discussed was the potential for funding programs to be made available for farmers to sponsor the inclusion of farmer-bred varieties in co-op trials and/or for public plant breeders to assist farmers in navigating the variety registration process. However, it was deemed that this funding potential is **not** within CFIA’s mandate.

The current recommendation from the SRMWG-VR Task team is that the registration system can accommodate these Alternatively Bred lines.

Topic 3: Heritage/Heirloom Varieties

There are a small number of farmers and seed growers in Canada growing a range of unregistered heirloom and heritage varieties of Schedule III crops as *food* or *grain* for niche markets. Some of these varieties are also being sold as seeds in small amounts. These varieties are in circulation among farmers and gardeners because they often have special traits, unique end uses, cultural value, or historically significant origins and/or regional affiliations. They may be genetically and phenotypically heterogeneous, pure line selections from heterogeneous material, or varieties developed by traditional plant breeding techniques. Currently, the sale of seeds of these unregistered varieties is not permitted under the *Seeds Regulations*.

The sub-task team deliberated the following definitions of heritage and heirloom varieties:

Heritage Cultivars

Heritage Cultivars were previously registered Schedule III crops but later canceled. If

registration is canceled, they are “unregistered”. At present, there is no path to market and common seed sales are not allowed.

**There is a provision (an exemption) for farmers to import seed of an unregistered variety for their use on-farm in Canada but there is an exception to this for wheat and durum in what was formerly known as the Canada Wheat Board area (the three Prairie Provinces, as well as the Creston-Wynndell cultivation area and the BC side of the Peace River region in Canada).*

Heirloom Varieties

Heirloom varieties are Schedule III crops that have never been registered but have been previously grown in Canada or are currently in circulation. These are “unregistered varieties” and cannot be imported or sold as seed in Canada. An heirloom variety must not be a hybrid variety: it is open-pollinated or naturally pollinated.

These varieties were bred, or have been in production, 50 years or more ago. These historical varieties have been stewarded through generations of on-farm seed saving. These varieties may be grown because of special agronomic traits, unique end uses, cultural value, or historically significant origins and/or regional affiliations.

The sub-task team also deliberated the following options to accommodate heritage and heirloom varieties of Schedule III crops:

ANALYSIS OF OPTIONS

Option 1: Heritage and Heirloom Varieties

No change to the current system. Heritage/Heirloom Varieties can be accommodated by the current system

Rationale: The current registration system is flexible and can accommodate these varieties.

Options provided within the current system:

Full variety registration

Part I of Schedule III: Full-fledged merit assessment with a recommendation from Recommending Committee (though Recommending Committees could disregard certain elements such as quality or yield and possibly focus more on the disease aspects);

Part II of Schedule III: Recommending Committees do not decide as to merit, however, the proponent of the variety is required to test the variety in Canada, under protocols developed by the Recommending Committee;

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Part III of Schedule III: The proponent of the variety is required to provide information to the CFIA to substantiate the identity of the variety and a reference sample of the seed (i.e. no merit assessment required and no oversight by the Recommending Committee).

Pros:

- Cultivar registration through the current registration system would allow the Value Chain to legally grow and market/sell seeds of the Heritage/Heirloom variety,
- Special cases can be (and already have been) considered within the current system.

Cons:

- Registration may require the provision of current data compared to specific checks (testing may be costly/prohibitive to the majority of farmers and seed producers working with this material).
- The requirements of the current system may be challenging for someone new to the system.
- Because the Recommending Committees across Canada have slightly different Operating Procedures in place, some may be reluctant to consider these varieties for support for registration
- There is unpredictability regarding the potential success of gaining support for registration through the varied and independently operating Recommending Committees.
- Regional differences exist among the RCs, with varied criteria required and considered when requesting support for registration.
- Presumption of, or proof of, ownership may be difficult to ascertain (specific to registration)
- Determination of responsibility for navigating through the registration system may be elusive.

Option #2 – Heritage and Heirloom Varieties

Heritage and Heirloom varieties can be managed to utilize Schedule III Part II

Rationale:

This option proposes that crop kinds subject to registration under Schedule III Parts I and II, Part II (testing without merit assessment) be used to accommodate Heritage and Heirloom varieties.

For crops subject to registration under Schedule III Part I, the Recommending Committees (RC) would develop criteria for a basic data package for Heritage and Heirloom variety registration

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under Schedule III Part II, under the monitoring of CFIA. During regular meetings, the RC would verify that the data package met the criteria.

Heritage Varieties

Definition: Cancelled or “to-be-canceled” varieties of crops subject to registration under Schedule III in which the original registration is 50 or more years ago.

Process:

1. Crop kinds are subject to registration under Schedule III Part I (full merit assessment with endorsement by a Recommending Committee).
 - 1.1 Varieties in which registration has been canceled:
 - Proponents for a variety to be designated as a Heritage Variety would generate the required data package and present it to the RC for verification.
 - A Description of Variety (DoV) may or may not be required to meet current CFIA requirements but in practice, these descriptions should be on file.
 - If needed, a representative seed sample would be supplied to CFIA
 - CGC consultation on class placement will be required (e.g. wheat).
 - Varieties in which registration has been canceled for cause would not be eligible.
 - 1.2 Varieties in which a notification for variety cancellation has been received:
 - Determine if the variety meets the definition (i.e. is it at least 50 years old?)
 - If the definition is met, as part of the process, determine if the Registrant is comfortable with the variety being designated as a Heritage variety.
 - If the Registrant agrees, move the variety to Schedule III, Part II, without the need for additional data submission(s) to the RC and CFIA.
 - A DoV should not be required since the variety is currently registered, and a representative seed sample should be on file with CFIA.
 - **If the variety is less than 50 years old, the Heritage designation would not available.**
 - In some cases, CGC consultation on class placement may be required (e.g. wheat).
2. Crop kinds subject to registration under Parts II and III would not require any change provided that the variety meets the definition.

Heirloom Varieties

Definition: Non-hybrid varieties of crops subject to registration under Schedule III that have never been registered and were grown in Canada before 1970.

Process:

1. Crop kinds are subject to registration under Schedule III Parts I and II (either full merit assessment with endorsement by a Recommending Committee or the requirement for testing).
 - Proponents for a variety to be designated as an Heirloom Variety would generate the required data package and present it to the RC for verification.
 - A DoV will be required as is the case for all registered varieties.
 - CGC consultation on class placement will be required (e.g. wheat).
2. Crop kinds are subject to registration under Schedule III Part III ()
 - A Description of Variety (DoV), submission of a representative sample of seed, and payment of registration fee, sent to CFIA, would be the only requirements.

Other considerations

- Is a mechanism required for the industry to petition CFIA to cancel the registration of a Heritage or Heirloom variety for a cause? (i.e. industry harm)

Pros:

- Existing committees and expertise would be utilized.
- Requirements of growers to legally grow and market heritage or heirloom varieties would be accommodated.
 - For varieties that meet the definitions of heirloom or heritage, a basic data package reviewed by existing Recommending Committees would provide information to prospective growers on potential production risks and facilitate registration.
 - Varieties meeting the definitions of heirloom or heritage would not be subject to the more onerous process of merit registration (Part I).
 - A simple process to move currently registered varieties to heritage status would be established upon agreement by the registrant on record.
- A basic set of criteria to define the required traits and data requirements could be developed for all Canadian jurisdictions.
- Minimal additional oversight by CFIA.

Cons:

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- Generation of even a basic data package may be too onerous for some or those new to the system.
- Presumption or proof of ownership may be difficult to ascertain (specific to navigating the registration system and registration).
- The vast Canadian geography may make it difficult to agree on a common set of traits and data requirements for collection.
 - CGC consultation on class placement would be required for specific crops.

Option #3: Heritage and Heirloom Varieties

A special registration category should be available for registering Heritage and Heirloom varieties similar to the Garden Variety Potato Registration

Rationale: A Special Registration Category could be associated with restrictions – for example: on naming, use of the variety name, growing region, and propagation (maximum acreage/amount).

Pros:

- Special category, under the purview of the RCs, would potentially make registration simpler for proponents, depending on the restrictions placed on it.
- It would provide an alternative to current registration requirements/process, possibly with fewer testing requirements in support of registration.
- The Recommending Committee should be able to accommodate the registration of heirloom cultivars. Even if a special category was created, these varieties should still go through the registration Recommending Committee, however, different criteria could potentially be applied.

Cons:

- This could create a difficult system to oversee and regulate.
- There are questions associated with who would suggest or specify the restrictions. Would the CFIA be required to carry out consultations on each specific heirloom crop to deal with this?
- Would every specific crop Recommending Committee need to agree on all the details?
- Field crops do not fit easily into a “garden” concept; when many acres are planted, this is beyond the scope of a “garden”. The example of orange peas which became widespread illustrates the type of issues that can occur. Heritage field crop varieties should not be handled through a “garden variety concept”.

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- It is not desirable to have a “backdoor process” to allow growing varieties, however, there needs to be enough flexibility to allow growing for heirloom varieties, organics, etc.
- Restrictions and possibilities associated with the creation of a special category for heirloom varieties would need to be clear and justified.

Option #4: Heritage and Heirloom Varieties

Regulatory Exemption for Schedule III Heritage/Heirloom Varieties

Rationale and Background

The goal of the proposed solution below is to create accommodations for these farmers without removing the provisions that protect the public interest and preserve seed quality in Canada.

Proposed Regulatory Accommodation:

That heirloom and heritage varieties of Schedule III field crops in Canada be permitted to be sold as seed by variety name through a provision in the *Seeds Regulations* that enables the following:

- In consultation with an advisory body of farmers, seed growers, and Plant Gene Resources of Canada (PGRC), CFIA/AAFC develops a list of Schedule III heritage/heirloom varieties that are currently in circulation. This list could be included in an expanded Section 5 of the *Seeds Regulations*. Varieties on this list would be permitted to be sold by variety name without going through variety registration, or the pedigreed seed process managed by the CSGA, provided they are labeled when distributed by Section 30 of the *Seeds Regulations*.
- With the support of an advisory body, Description of Variety (DoV) forms for each variety based on available data would be generated. Given the phenotypic variability that may be present in several heritage/heirloom varieties in circulation, a range of characteristics exhibited by each heritage/heirloom variety would be documented in the DoV form to account for this variability.
- Similar to unregistered varieties of Schedule III crops, **heritage, and heirloom varieties would either not be eligible for delivery to licensed grain elevators, or only eligible to receive the lowest grade**. Changes could be made on variety declaration forms to ensure farmers declare whether they are growing a heritage/heirloom variety. These

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varieties would still be eligible as grain for sale to artisan millers, brewers, and other processors.

- If there is farmer interest in selling these varieties to a licensed grain elevator through a specific grain class, a process with the advisory body could be set up to move these varieties through the formal variety registration process like any other Schedule III crop. If there are valid reasons why these varieties should not be registered as commercial field crops (e.g. susceptible to serious disease, unacceptable for millers) there could be restrictions on where they are grown and buffer zones established between them and commercial crops.
- Heirloom varieties (e.g. Red Fife Spring wheat), and essentially derived varieties from heirloom varieties, shall not be eligible for Plant Breeders' Rights protection.
- For varieties to be added to the heritage and heirloom variety list, CFIA and AAFC could work with the advisory body to develop criteria for eligibility related to the following conditions:
 - Proof of production/circulation history before 1970
 - Description/documentation of cultural significance/heritage (verified by PGRC)
 - Basic agronomic, pest/disease reaction, and end-use testing as appropriate (potentially administered by recommending committees in each region)
- A reference seed sample would be submitted to the CFIA and PGRC.

Pros:

- The potential for advancing seed diversity conservation and creation using heirloom/heritage varieties for Canadian agriculture is promising. A small, but dedicated and skilled network of farmers, plant breeders, bakers, and chefs are advocating for regionally-adapted grains bred for flavor, nutrition, and part of a food system that supports ecological farming and climate resilience.
- Through supporting these activities, Canada can advance on its commitments to the International Treaty on Plant Genetic Resources for Food Agriculture (Plant Treaty). Specifically, Article 6 (Sustainable Use of Plant Genetic Resources), includes:
 - Broadening the genetic base of crops and increasing the range of genetic diversity available to farmers;
 - Promoting, as appropriate, the expanded use of local and locally adapted crops, varieties, and underutilized species;
 - Supporting, as appropriate, the wider use of a diversity of varieties and species in on-farm management, conservation, and sustainable use of crops.

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- This accommodation draws inspiration from the OECD Seed Scheme description of “Local Varieties” (“derives from a defined region of origin which has been shown by official tests to have sufficient uniformity, stability and distinctness to warrant recognition, but has not been produced as a result of breeding work”).
- Recommending Committees would not be required to evaluate these varieties, removing the uncertainty for success in obtaining registration

Cons:

- There exist many “versions” of some of these varieties which would need to be differentiated and properly labeled. Every source or claim would need to be unique, potentially tied to an individual proponent and/or production location.
- A specific commercial contract (e.g. closed-loop or identity-preserved) may need to be implemented for these varieties to be sold, to prevent entry into the licensed elevator system/commodity sales. If the produced seed did not meet the specifications as outlined in the commercial contract, it would have to be sold at the lowest available grade within the elevator system. To be clear here: we are referring to a private commercial contract between a producer of grain and a buyer of grain; this is not referring to “Contract Registration” as this is NOT an option for these types of varieties.
- A list of these varieties would be difficult to maintain, and difficult to prevent multiple lists from existing

RECOMMENDATION:

The vote was taken at the March 30, 2022 meeting of the VR task team, with results as follows:

<p>Option 1: 0 votes Option 2: 7 votes Option 3: 0 votes Option 4: 8 votes Abstained: 1 (CGC) Total: 15 votes/16 task team members at the meeting</p>
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There was no qualified consensus for any of the options developed. The VR task team was split, almost equally between **Option 2** (Heritage and Heirloom varieties can be managed to utilize Schedule III Part II) and **Option 4** (Regulatory Exemption for Schedule III Heritage/Heirloom Varieties). There are two viable options that CFIA could proceed with. **It is anticipated that the Seed Regulatory Modernization Working Group may have more input on this topic.** The report will be moved through the process as-is.

Summary of recommendations:

We do not have a qualified consensus on recommending to CFIA how best to deal with Heritage/Heirloom Lines, Heterogeneous Materials/Populations, or Alternatively Bred Cultivars.

Topic 10 – Appendix: The Draft Topic 10 Report with Comments embedded from CSGA (Submitted by the Canadian Seed Growers Association (CSGA), Randy Preater (Sent 2022-03-11 1:52 PM)). Comments have been embedded and identified as a member's comment.

**SEED REGULATORY MODERNIZATION WORKING GROUP
VARIETY REGISTRATION SUB-TASK TEAM**

Topic Heritage/Heirloom Lines, Heterogeneous Materials/Populations, Alternatively bred Cultivars.

OPTIONS AND RECOMMENDATIONS REPORT

Topic: Heritage Cultivars/Heirloom Varieties, Heterogeneous Materials/populations, and Alternatively bred Cultivars/Varieties

Context:

There are farmers and seed growers in Canada, predominantly small-scale organic, currently engaged in 1) breeding varieties on their farms of Schedule III crops and 2) circulating small amounts of seed and grain of unregistered heritage/heirloom varieties of Schedule III crops. SeedChange, a non-profit organization that works on a range of participatory plant breeding and seed conservation projects with farmers across Canada, put forward that the existing version of the *Seeds Regulations* could better support and accommodate farmers and seed growers who are working with heritage/heirloom varieties, heterogeneous materials, and cultivars bred by farmers for organic production. Furthermore, from the Needs Assessment Survey conducted by the SRMWG, 55% of respondents felt that accommodations should be made for both heritage and alternatively-bred varieties (the CFIA interpreted cultivars bred by farmers for organic production as “alternatively-bred varieties”).

This sub-task team was established to evaluate proposals for regulatory change that would accommodate these kinds of materials.

Topic 1: Heterogeneous Materials/populations

SeedChange put forward the concept of “heterogeneous material”, as adopted by the EU, being integrated into Canada's *Seeds Regulations* definitions of “variety” to accommodate material with high levels of genetic and phenotypic diversity.

The sub-task team concluded that, unlike the EU (OECD Seed Schemes), Canada requires only “DS” or distinguishability and stability for a cultivar/variety, whereas the EU has a DUS (distinct,

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uniform, stable) requirement for “listing” (registration). In Canada, if the cultivar/variety can be described accurately and consistently (within accepted norms) from one generation to the next, it meets the basic definition of a variety. Canada does not require uniformity testing (from the DUS point of view) as part of the registration/listing process like the EU and the Plant Breeders’ Rights Office.

The current recommendation from the SRMWG-VR Task team is that the registration system can accommodate these Heterogeneous lines.

Topic 2: **Alternatively bred Cultivars/Varieties**

Alternatively bred (non-mainstream commodity) varieties.

The initial impetus for “alternatively bred” was about varieties bred by farmers for organic systems. There are farmers engaged in participatory plant breeding programs to develop new varieties. These growers require support to navigate the variety registration system.

Discussed and suggested recommendations for providing support to these breeders could include:

- A step-by-step guide developed by the CFIA and AAFC for how farmers/new breeders can navigate the variety registration system.
- Requests be made to the various Recommending Committees to review and possibly adjust their model Operating Procedures to ensure there are no undue barriers preventing farmer (or new) breeders from submitting eligible material for variety registration.
- A topic also discussed was the potential for funding programs to be made available for farmers to sponsor the inclusion of farmer-bred varieties in co-op trials and/or for public plant breeders to assist farmers in navigating the variety registration process. However, it was deemed that this funding potential is not pertinent to CFIA.

The current recommendation from the SRMWG-VR Task team is that the registration system can accommodate these Alternatively Bred lines.

Topic 3: **Heritage/Heirloom Varieties**

There are a small number of farmers and seed growers in Canada growing a range of unregistered heirloom and heritage varieties of Schedule III crops as *food* or *grain* for niche

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markets. Some of these varieties are also being sold as seeds in small amounts. These varieties are in circulation among farmers and gardeners because they often have special traits, unique end uses, cultural value, or historically significant origins and/or regional affiliations. They may be genetically and phenotypically heterogeneous, pure line selections from heterogeneous material, or varieties developed by traditional plant breeding techniques. Currently, the sale of seed of these unregistered varieties is not permitted under the existing *Seeds Regulations*.

For this report, the sub-task team deliberated the following Definitions of Heritage and Heirloom varieties:

Heritage Varieties

Definition: Cancelled or “to-be-cancelled” varieties of crop kinds subject to registration under Schedule III in which the original registration is 50 or more years ago.

Since “unregistered”, Heritage varieties cannot be imported or sold as seed in Canada.

**There is a provision (an exemption) for farmers to import seed of an unregistered variety for their use on-farm in Canada but there is an exception to this for wheat and durum in what was formerly known as the Canada Wheat Board area (the three Prairie Provinces, as well as the Creston-Wyndell cultivation area and the BC side of the Peace River region in Canada).*

Heirloom Varieties

Definition:

Non-hybrid varieties of crops subject to registration under Schedule III that have never been registered and were grown in Canada before 1970.

Most heirloom varieties have been stewarded through generations of on-farm seed saving and maybe grown for special agronomic traits, unique end uses, cultural value, or historically significant origins and/or regional affiliations.

Since “unregistered”, Heirloom varieties cannot be imported or sold as seed in Canada.

The sub-task team also deliberated the following four (4) Options to accommodate Heritage and Heirloom varieties of Schedule III crops:

ANALYSIS OF OPTIONS

Option 1: Heritage/Heirloom Varieties can be accommodated by the current system, no changes

Rationale: The current registration system is flexible and can accommodate these varieties.

Options provided within the current system:

Full variety registration

Part I of Schedule III: Full-fledged merit assessment with a recommendation from Recommending Committee (though Recommending Committees could disregard certain elements such as quality or yield and possibly focus more on the disease);

Part II of Schedule III: Recommending Committees do not decide as to merit, however, the proponent of the variety is required to test the variety, under protocols developed by the Recommending Committee;

Part III of Schedule III: The proponent of the variety is required to provide information to the CFIA to substantiate the identity of the variety and a sample of the seed (i.e. no merit assessment required and no oversight by the Recommending Committee).

Pros:

- Cultivar registration through the current registration system would allow the Value Chain to legally grow and market/sell seed of the Heritage/Heirloom variety,
- Special cases can be (and already have been) considered within the current system.

Cons:

- Registration may require the provision of current data compared to specific checks (testing may be costly/prohibitive to the majority of farmers and seed producers working with this material).
- The requirements of the current system may be challenging for someone new to the system.
- Because the Recommending Committees across Canada have slightly different Operating Procedures in place, some may be reluctant to consider these varieties for support for registration
- There is unpredictability regarding the potential success of gaining support for registration through the varied and independently operating Recommending Committees.

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- Regional differences exist among the RCs, with varied criteria required and considered when requesting support for registration.
- Presumption of, or proof of, ownership may be difficult to ascertain (specific to registration)*
- Determination of responsibility for navigating through the registration system may be elusive.

*** Member comment: Ownership aside, the Seeds Regs. (and even Consumer Packaging & Labelling Regs) require a label to be accurate and not misleading. If seed of a Heritage/Heirloom variety is sold as a specific Name or varietal/genetic identity, then some party has to be identified who is responsible for that seed (labelled with that Name) actually being seed of that Name or varietal/genetic identity. For seed sold in Canada, the variety Registration process has traditionally identified that responsible party. To meet due diligence requirements, variety Registration has also required a Registrant to submit a sample of Breeder seed which is used as a control reference for the CFIA's variety verification testing program which audits the performance Canadian seed (varietal identity) certification system.**

Option #2

Heritage and Heirloom varieties can be managed to utilize Schedule III Part II

Member's comment: Assuming that Option 2 does not involve the 'special registration category' proposed in Option 3, Where will this 'Heritage designation' exist and how will it be communicated?

Rationale and Background

This option proposes that crop kinds subject to registration under Schedule III Parts I and II, Part II (testing without merit assessment) be used to accommodate Heritage and Heirloom varieties.

For crops subject to registration under Schedule III Part I, the Recommending Committees (RC) would develop criteria for a basic data package for Heritage and Heirloom variety registration under Schedule III Part II, under the monitoring of CFIA. During regular meetings, the RC would verify that the data package met the criteria.

Heritage Varieties

Definition: Cancelled or “to-be-canceled” varieties of crops subject to registration under Schedule III in which the original registration is 50 or more years ago.

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Process:

3. Crop kinds are subject to registration under Schedule III Part I (full merit assessment with endorsement by a Recommending Committee).

1.1 Varieties in which registration has been canceled:

- Proponents for a variety to be designated as a Heritage Variety would generate the required data package and present it to the RC for verification.
- A Description of Variety (DoV) may or may not be required to meet current CFIA requirements but in practice, these descriptions should be on file.
- If needed, a representative seed sample would be supplied to CFIA
- CGC consultation on class placement will be required (e.g. wheat).
- Varieties in which registration has been canceled for cause would not be eligible.

1.2 Varieties in which a notification for variety cancellation has been received:

- Determine if the variety meets the definition (i.e. is it at least 50 years old?)
- If the definition is met, as part of the process, determine if the registrant is comfortable with the variety being designated as a Heritage variety.
- If the registrant agrees, move the variety to Schedule III, Part II, without the need for additional data submission to the RC and CFIA.
- A DoV should not be required since the variety is currently registered, and a representative seed sample should be on file with CFIA.
- If the variety is less than 50 years old, the Heritage designation would not be available.
- In some cases, CGC consultation on class placement may be required (e.g. wheat).

4. Crop kinds subject to registration under Parts II and III would not require any change provided that the variety meets the definition.

Heirloom Varieties

Definition: Non-hybrid varieties of crops subject to registration under Schedule III that have never been registered and were grown in Canada before 1970.

Process:

3. Crop kinds are subject to registration under Schedule III Parts I and II registration (either full merit assessment with endorsement by a Recommending Committee or the requirement for testing).

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- Proponents for a variety to be designated as an Heirloom Variety would generate the required data package and present it to the RC for verification.
 - A DoV will be required as is the case for all registered varieties.
 - CGC consultation on class placement will be required (e.g. wheat).
4. Crop kinds are subject to registration under Schedule III Part III (aka listing)
- A Description of Variety (DoV) and submission of a representative sample of seed to CFIA would be the only requirements.

Other considerations??

- Is a mechanism required for the industry to petition CFIA to cancel the registration of a Heritage or Heirloom variety for a cause? (i.e. industry harm)

Member's comment: Related to this (and as suggested in the 2nd bullet under Cons: below), may be: 'CGC consultation on crop placement would be required for specific crops'

Pros:

- Existing committees and expertise would be utilized.
- Requirements of growers to legally grow and market these varieties would be accommodated
- Minimal additional oversight by CFIA.
 - For varieties that meet the definitions of heirloom or heritage, a basic data package reviewed by existing Recommending Committees would provide information to prospective growers on potential production risks.
 - A simple process to move currently registered varieties to heritage status would be established upon the agreement of the registrant.

Cons:

- Generation of even a basic data package may be too onerous for some or those new to the system.
- CGC consultation on class placement would be required for specific crops.
- There is unpredictability regarding the potential success of gaining support for registration through the varied and independently operating Recommending Committees.

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- Regional differences exist among the RCs, with varied criteria required and considered when requesting support for registration.
- Presumption of, or proof of, ownership may be difficult to ascertain (specific to registration)*

Member's comment: Ownership aside, the Seeds Regs. (and even Consumer Packaging & Labelling Regs) require a label to be accurate and not misleading. If seed of a Heritage/Heirloom variety is sold as a specific Name or varietal/genetic identity, then some party has to be identified who is responsible for that seed (labelled with that Name) actually being seed of that Name or varietal/genetic identity. For seed sold in Canada, the variety Registration process has traditionally identified that responsible party. To meet due diligence requirements, variety Registration has also required a Registrant to submit a sample of Breeder seed which is used as a control reference for the CFIA's variety verification testing program which audits the performance Canadian seed (varietal identity) certification system.

- Determination of responsibility for navigating through the registration system may be elusive.

Member's comment: Same comment as above regarding 'responsible party' required for each variety.

Option #3: A special registration category should be available for registering Heritage and Heirloom varieties similar to the Garden Variety Potato Registration

Rationale: A Special Registration Category could be associated with restrictions – for example on naming, use of the variety name, growing region, propagation (maximum acreage/amount).

Member's comment: Experience with this model in other countries (e.g. France) confirms (the 1st bullet under Cons) that overseeing and regulating 'maximum acreage' is very difficult with varieties of field crops.

Pros:

- Special category, under the purview of the RCs, would potentially make registration simpler for proponents, depending on the restrictions placed on it.
- It would provide an alternative to current registration requirements/process, possibly with fewer testing requirements in support of registration.
- The Recommending Committee should be able to accommodate the registration of heirloom cultivars. Even if a special category was created, these varieties

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should still go through the registration Recommending Committee, however, different criteria could potentially be applied.

Cons:

- This could create a difficult system to oversee and regulate.
- There are questions associated with who would suggest or specify the restrictions. Would the CFIA be required to carry out consultations on each specific heirloom crop to deal with this?
- Would every specific crop Recommending Committee need to agree on all the details?
- Field crops do not fit easily into a “garden” concept; when many acres are planted, this is beyond the scope of a “garden”. The example of orange peas which became widespread illustrates the type of issues that can occur. Heritage field crop varieties should not be handled through a “garden variety concept”.
- It is not desirable to have a “backdoor process” to allow growing varieties, however, there needs to be enough flexibility to allow growing for heirloom varieties, organics, etc.
- Restrictions and possibilities associated with the creation of a special category for heirloom varieties would need to be clear and justified.

Option #4 Regulatory Exemption for Schedule III Heritage/Heirloom Varieties

Rationale:

The goal of the proposed solution below is to create accommodations for these farmers without removing the provisions that protect the public interest and preserve seed quality in Canada.

Proposed Regulatory Accommodation:

That heirloom and heritage varieties of Schedule III field crops in Canada be permitted to be sold as seed by variety name through a provision in the *Seeds Regulations* that enables the following:

- In consultation with an advisory body of farmers, seed growers, and Plant Gene Resources of Canada (PGRC), CFIA/AAFC develops a list of Schedule III heritage/heirloom varieties that are currently in circulation. This list could be included in an expanded Section 5 of the *Seeds Regulations*. Seed of varieties on this list would be permitted to be sold by variety name without going through variety registration provided the crops

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are certified by CSGA to meet the *Source Identified* or *Selected* class requirements of AOSCA's Pre-Variety Germplasm standards and the seed is labeled when distributed by Section 30 of the *Seeds Regulations*.

●

Member's Comment: Might these PVG standards, traditionally used for native plant certifications, may provide a reasonable third-party oversight or verification framework to permit the use of variety names for non-pedigreed seed? AND potentially address some of the Cons.

- With the support of an advisory body, Description of Variety (DoV) forms for each variety based on available data would be generated. Given the phenotypic variability that may be present in several heritage/heirloom varieties in circulation, a range of characteristics exhibited by each heritage/heirloom variety would be documented in the DoV form to account for this variability.
- Similar to unregistered varieties of Schedule III crops, heritage, and heirloom varieties **would either not be eligible for delivery to licensed grain elevators, or only eligible to receive the lowest grade.** Changes could be made on variety declaration forms to ensure farmers declare whether they are growing a heritage/heirloom variety. These varieties would still be eligible as grain for sale to artisan millers, brewers, and other processors.
- If there is farmer interest in selling these varieties to a licensed grain elevator through a specific grain class, a process with the advisory body could be set up to move these varieties through the formal variety registration process like any other Schedule III crop. If there are valid reasons why these varieties should not be registered as commercial field crops (e.g. susceptible to serious disease, unacceptable for millers) there could be restrictions on where they are grown and buffer zones established between them and commercial crops.
- Heirloom varieties (e.g. Red Fife), and essentially derived varieties from heirloom varieties, shall not be eligible for Plant Breeders' Rights protection.
- For varieties to be added to the heritage and heirloom variety list, CFIA and AAFC could work with the advisory body to develop criteria for eligibility related to the following conditions:
 - Proof of production/circulation history before 1970
 - Description/documentation of cultural significance/heritage (verified by PGRC)
 - Basic agronomic, pest/disease reaction, and end-use testing as appropriate (potentially administered by recommending committees in each region)
- A reference seed sample would be submitted to the CFIA and PGRC.

Pros:

- The potential for advancing seed diversity conservation and creation using heirloom/heritage varieties for Canadian agriculture is promising. A small, but dedicated and skilled network of farmers, plant breeders, bakers, and chefs are advocating for regionally adapted grains bred for flavor, nutrition, and part of a food system that supports ecological farming and climate resilience.
- Through supporting these activities, Canada can advance on its commitments to the International Treaty on Plant Genetic Resources for Food Agriculture (Plant Treaty). Specifically, Article 6 (Sustainable Use of Plant Genetic Resources), includes:
 - Broadening the genetic base of crops and increasing the range of genetic diversity available to farmers;
 - Promoting, as appropriate, the expanded use of local and locally adapted crops, varieties, and underutilized species;
 - Supporting, as appropriate, the wider use of a diversity of varieties and species in on-farm management, conservation, and sustainable use of crops.
- This accommodation draws inspiration from the OECD Seed Scheme description of “Local Varieties” (“derives from a defined region of origin which has been shown by official tests to have sufficient uniformity, stability and distinctness to warrant recognition, but has not been produced as a result of breeding work”).
- Recommending Committees would not be required to evaluate these varieties, removing the uncertainty for success in obtaining registration

Cons:

- There exist many “versions” of some of these varieties which would need to be differentiated and properly labeled. Every source or claim would need to be unique, potentially tied to an individual proponent and/or production location.
- A specific contract may need to be implemented for these varieties to be sold, to prevent entry into the licensed elevator system/commodity sales. If the produced seed did not meet the specifications of the specific contract, it would have to be sold at the lowest available grade within the elevator system. To be clear, this refers to a commercial contract between two or more parties and had nothing to do with CFIA Contract Registration which would NEVER apply to these types of varieties (heritage and heirloom).
- A list of these varieties would be difficult to maintain, and difficult to prevent multiple lists from existing

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Member's comment: Might CSGA seed crop certification, to AOSCA Pre-Variety Germplasm standards, address the concern in this 1st bullet as well as the concern in the 3rd bullet?

Topic11 Report (rdims# 16191450 v2A)

SEED REGULATORY MODERNIZATION VARIETY REGISTRATION TASK TEAM

Topic #11 Report: Regionalized crop placements in Schedule III, *Seeds Regulations*

(crop placements within regions)

OPTIONS AND RECOMMENDATIONS REPORT March 11, 2022

Introduction:

Regional Placement of Crops

Currently, the seed regulatory system has the 53 crop kinds subject to registration in Canada listed in Schedule III of the *Seeds Regulations*. Further, this table of crop kinds is broken down into three categories of “type of registration required”: Part 1, Part 2, and Part 3 (the lowest level of requirements). Crops can be moved from one Part or requirement category to another via a process called “crop placement”. Simply put, this is a stakeholder-driven process that the government facilitates. The value chain for the crop can change its crop placement by providing a **rationale** for the proposed change and evidence of **consensus** in the value chain for that change. CFIA then undertakes the regulatory amendment process to make that change happen. The current system is National in scope. To date, it has not allowed for regional (e.g. Prairies, Ontario, Quebec, and Atlantic) differences in crop placements. This means that regional needs may not be met due to maintaining a National program (one size does not fit all arguments). An example of where this can be problematic (referring to a lack of regional accommodation) might be with pulse crops in Canada where the “East” is somewhat different than the “West” – e.g. the colored bean market (field bean) but there are other examples where the crop market is significantly different in different regions. The concept being explored here is to allow for more regional flexibility in how a particular crop is treated in each region of the country to better address variety developers, producers, and end-users specific needs.

ANALYSIS OF OPTIONS

Option 1: No change to the current system

Rationale: Currently crop placements (Part 1, 2, or 3 registration) within Schedule III are national in scope and thus have the same placement regardless of region of Canada.

Pros:

- A simple system
- Easy for CFIA to administer
- Treats a crop the same in all regions

Cons:

- Does not permit regional treatment of varieties (including sub-crop kinds such as colored beans within the field beans category within a crop.
- For rapid variety turnover markets (e.g. colored beans) the length of time to register is at odds with variety selection and commercial decisions which happen quickly (months not years). In such a system, if merit is already addressed (by end-user declaration) then the registration system is impeding a seed market due to regulation-related delays in getting to market (the registration system).

Option 2: To allow regional placement¹ of Part 1 crops into Part 1 or Part 3 of Schedule III²

Rationale: This option would provide a means for each region¹ to determine crop placement according to the needs of the value chain in the intended area of production.

Pros:

- Offers flexibility for the value chain of each region to choose the placement of crop kinds
- Allows regional value chains to take advantage of market opportunities not otherwise available
- Acknowledges the difference between use and end-use markets in regions across the country
- Allows farmers in regions who want faster access to new varieties the opportunity to do so.
- Will lead to increased investment in breeding activities, particularly for niche crops
- Provides a compromise without imposing one placement across all regions

Cons:

- More complex system of listing crop kinds within Schedule III
- Possible confusion for those not aware of the difference between regions
- Does not meet the need of those wanting the same rules across the country
- Possible enforcement challenge for the seed of a crop type subject to regional restrictions, moving from a Part 3 area to a region where it is still Part 1 crop and not registered
- Is not flexible in dealing with subgroups of crop kinds which may be a completely different market with unique needs in terms of regulatory requirements (e.g. colored bean market in the field bean sector is fast-paced, high variety turnover and merit essentially comes down to acceptability for canning market. If the two parties involved have a complete commercial arrangement it questions the need for determination of merit since it is a closed-loop system and the end-user is already buying that seed/grain (meaning merit is there – just not assessed by a committee).

Option 3 No Change to the current system but initiate change at the Recommending Committee level* to encourage an expedited pathway to market even though it is a Part 1 crop (e.g. pulses – create a special provision for colored beans whereby the committee trialing system is by-passed in favor of a developer/end-user documented agreement to work with the variety in the market).

**Does not require a change to the regulations but perhaps a change in CFIA policy and guidance to the recommending committees in Canada (at the least, a modification to the CFIA “MOPs” document for recommending committees.*

Rationale: To accommodate situations where the ‘normal’ registration process for one or more sub-groups within a crop is not flexible enough to accommodate the underlying seed/crop business in terms of requirements and time to market. It also addresses situations where a variety developer/marketer has an end-user lined up and is willing to take the production of their variety into their plant/processing facility. In such cases, the recommending committee involved COULD develop an expedited path to registration while still keeping all the sub-groups in the “Part 1 registration” basket. As an example, in pulses, the PRCPSC (Western pulse committee) and the OPCC (Ontario pulse committee) could create a one-year path to registration for colored beans (Phaseolus).

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Pros:

- Flexible, industry responsive, recognizes fast turn-over market and minimum risk situation
- Low risk – the end-user/processor in this scenario, has an agreement and there is no concern about the “merit” of the variety; it is a given. The committee can determine if disease and/or quality data is still required (their call).

Cons:

- The decision to recommend registration is only as good as the validity of the end-user/variety developer agreement (if the situation changes in the future, does that change the registration?)
- It operates on a reduced or minimal agronomic information model so growers may not have as robust growing information as

Footnotes:

1. Assuming regional divisions are maintained as status quo, or maybe changed to West and East
2. Assuming that Part 2 is removed from the Schedule
 - The description of the information required in a registration application (**67. (1) to (1.1) inclusive**).
 - Schedule III, *Seeds Regulations* (the table listing which crops are subject to which type of registration in Canada).

RECOMMENDATION:

The vote was divided between the three options with the majority going to Option 2 (To allow regional placement¹ of Part 1 crops into Part 1 or Part 3 of Schedule III²) and **Option 1** (No change to the current system). There was minimal support for Option 3 (No Change to the current system but initiate change at the Recommending Committee level*) to encourage an expedited pathway to market even though it is a Part 1 crop). **We did not have a consensus on any of the options.**

The vote was taken with results as follows:

Option 1: 5 votes

Option 2: 8 votes

Option 3: 3 votes

Abstained: nil

Total of 16 voting members

Summary of recommendations:

We have no qualified consensus on the Options we developed and cannot forward a specific recommendation. However, there are two options worth considering from the Variety Registration task team:

- 1) To allow regional crop placement such that, by region, a crop kind can be either Part 1 or Part 3 registration AND
- 2) No change to the system as it is felt that it meets the needs of the stakeholders.

Topic 12 Report

(rdims# 17836711; previously 17072579 v2B)

SEED REGULATORY MODERNIZATION VARIETY REGISTRATION TASK TEAM

Topic #12: Phenotype, Genotype, and the Variety Registration System

Topic Report

Phenotype, Genotype, and the Variety Registration System

Phenotype: the physical form of a living organism, typically described in detail, that is a product of genetics expressed in a given or set of given environments.

Genotype: the underlying genetic makeup of a living organism; the sum total of its genetic information contained within.

Although this discussion naturally could be extended to include the whole seed regulatory system (which is a predominantly visual/phenotypic based one), however, this VR Task Team will focus on **variety registration** and the requirements for **varietal eligibility, varietal identity** and **varietal purity** determinations (including “variants” and “off-types”). Some questions to ask are: Can we or do we want to shift our current technology base in the registration and certification space? What would be the advantages/disadvantages of the current visually based system? What competitive advantages might be gained by shifting to direct genotype assessment (use of **Biochemical Molecular Techniques (BMT)**)? What are the risks of this newer technology? Is there a path toward the improvement of the current system (time/cost/efficiency/degree of regulatory burden/optimizing the final outcome) for the benefit of Canadians? Should we be planning to transition from a phenotype first system to a genotype first system for the future?

Varietal eligibility: refers to meeting the definition of variety that is given in the *Seeds Regulations*: distinguishable from all other varieties of that crop kind in Canada and having a variety description that remains accurate over many generations of reproduction.
<Paraphrased>

Varietal identity: exactly as it sounds – identification of the seed of or an assemblage of plants of the variety in question against its registration and/or certification-only identity.

Variety purity: refers to the purity of variety in a seed sample and/or an assemblage of plants in question. This is not physical (seed based) purity per se; it refers to genetic purity (the % of seed or plants that are “of the variety”).

Biochemical and Molecular Techniques (BMT): is the catch-all term used by The International Union for the Protection of New Varieties of Plant (UPOV) and the International Seed Testing Association (ISTA), as well as others, to include all biochemical based methods of assessing the identity of a living organism and certainly includes DNA based methods such as “fingerprinting”, “DNA bar-coding”, “whole genome sequencing”, etc. It is an internationally recognized term for referring to molecular based assessment of the identification of plant varieties.

The current variety registration system in Canada is primarily visually based by design (crop inspection, reference seed sample grow-outs, visual descriptions of varieties). Variety eligibility (e.g. is it a variety?/is it distinguishable?/is it stable?) is determined by a combination of information from the breeder: **breeding history, generation at which breeder seed was declared, pedigree of the variety, reference seed sample of variety from the breeder to be grown out** and compared against the **official description of the variety** (from the breeder). The

sum total of this information is used to make a judgement as to the line being a variety or not at the registration level.

There is also a phenomenon with plants which are part of the variety but which may stand out from other plants in the variety; **variants**. Variants are plants which are part of the variety which may contain one or more traits (physically observable aspects to the plant) which the breeder neither selected for or against but which “came along for the ride” in the breeding program. These are considered part of the variety in the Association of Seed Certifying Agencies (AOSCA) Seed Schemes. They are certainly recognized and accounted for in the OECD Seed Scheme although they do not use the same terminology. A common example would be hilum colour variants in oilseed soybeans; they are often, but not always, present depending on the parents chosen and the breeding program in question. Variants are to be expected given that plant breeders historically have bred for only for a handful of simply inherited traits and a few complex multi-gene traits such as yield (subject to minor differences between crop kinds). There are thousands of “other” genes in the variety which are not being manipulated directly by the plant breeder so it is expected that many genes may be expressing differently in different plants within a variety (the breeding technique(s) used will affect this as well). Yes, in most breeding programs there is an effort toward “self pollination of successive generations of plants to drive them toward homozygosity/purity” or “backcrossing plants to more genetically pure/homozygous lines, again, driving the breeding material toward homozygosity/purity” as an aspect near the end of development of the new variety or in the case of hybrids, the new inbred line.

The current seed system is visual or phenotypic so data is gathered via a combination of paper/electronic tracing, purity/identity field grow-outs, tests for PNT-GM trait purity, tests for hybridity (where applicable), and observations against the breeder’s submitted variety description. This system arguably has worked well for many decades and continues to, to this day. It has evolved somewhat to include supplemental tests such as protein assessments (electrophoresis based) for variety profiling and more recently DNA based methods for hybridity determination and PNT trait determination.

On the registration side of the program, we do have the ability to use chemical and/or molecular genetic techniques to help in assessing varietal eligibility as well as purity and identity. CFIA currently operates on an unwritten policy of using molecular genetic or genotype- based assessment and information only as a supplement to visual observations. The approach is that phenotype must corroborate genotype for the data to be used and for us to be able to make a call.

The registration program is supported by the CFIA Variety Verification Program, Science Branch where every year we DNA fingerprint varieties base on their reference seed samples and every

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year we grow out close to 1,000 plots of reference seed of registered and Form 300 (CSGA) certification only varieties.

Looking to the future of seed regulation and in particular, variety registration, the question to ask is: Is there a faster, simpler, smarter way of assessing varietal eligibility, varietal purity, and most important: varietal identity? Is it possible to move to an all-marker based system (all lab testing based) to improve accuracy and speed of processing? What would be the cost/benefits? Do we have the technology (across all 53 crop kinds) to make this happen?

Molecular markers in Variety Registration

(Below is the submission of Dr. Bryan Harvey, Chair of the VR task team, as promised (in the context of summarizing a discussion held by the task team) from our previous meeting. (Dr. Harvey's submission reference: RDIMS# 16256568 v1)

Canada is a world leader in the development and use of BMTs in variety development, variety identification, variety description and grain handling. The Task team discussed their use in variety registration and makes the following recommendations.

CFIA should pursue means of utilizing these technologies as an additional descriptor tool in Variety registration.

Canada should continue to play a lead role in international discussions related to use of these technologies in the seed regulatory framework.

CFIA should pursue the exchange of information and technology with other Government Agencies with due regard to privacy and security of data.

Canada should ensure that no barriers are created to the use of molecular tools in the regulatory use of these technologies.

Option #1: No Change to the existing system (includes CFIA policy on use of genotype information: that genotyping support/corroborates phenotypic information (not the other way around)).

Rationale: The current registration system is fit for purpose, being visually based and cost-effective. There is close to 100 yrs. of experience behind it.

Pros/Benefits:

- The current system is a proven one: historically it has had manageable issues (mostly to do with declaration of variants in the variety)
- Historically, the system has been cost-effective versus any alternative system
- Similar systems are being used globally; our system fits well into existing certification systems around the world (harmonization).

Cons/Risks:

- In the present system CFIA does not fully complete their due diligence on registrations until after a field grow out of the reference seed sample from the breeder; this can be up to a full growing season after registration meaning any issues identified are occurring (typically) AFTER the variety is in seed certification (costly to all concerned when the timing is off). Impurities are identified late in the game, particularly for those engaged in certified off-shore pedigreed seed production (e.g. the winter seed production of Canadian canola, corn, oilseed soy that is conducted annually in Chile by the seed Industry).
- New technologies (e.g. molecular genetic editing tools such as CRISPR Cas9) enable rapid variety generation and create a scenario where future varieties may typically differ by only one or two expressed gene(s) which may or may not translate to visually detectable traits (plant based visual observations) but still meet the definition of distinguishability for a variety. This is a direct challenge to the visually based certification system (hence to the description of variety on the registration side). This issue already exists at a minor level: (1) iron chlorophyll deficiency in oilseed soy varieties; where the only distinguishing trait between some varieties, is the visual aspect in an iron-deficient soil (in all other instances the two lines would appear identical). We have another example (2) of this with the Innate™ brand potato varieties (all are PNTs) which are based on underlying public varieties (their distinguishing trait(s) cannot be used in the field; only in a laboratory).

Option #2: CFIA is encouraged to look toward the increased the use of BMTs on the variety registration program and to change the *Seeds Regulations to incorporate molecular genetic characterization tools as a recognized tool to use in their existing work. To make clear a vision for the increasing future use of BMT based assessment of varietal identity and varietal purity, recognizing that the industry is well out in front of this technology and already creating innovative new varieties.**

Rationale: The variety development landscape is changing. There are new technologies using directed genetic changes to plant genetic information (genotype). Gene editing is one such example; a rapidly developing technology. The result of this type of innovation is much more

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rapid variety development, more accurate varietal development (precise targeting) and as a result, a much higher anticipated variety pipeline from developers. This will present challenges to the existing system in the future. One way to rise to the challenge on the regulatory side is to shift, over time to using genetic information profiling of varieties.

Pros/Benefits:

- It would eliminate the generation lag in the current visually based purity and identity assessments that take place in Registration (and also certification); it would allow data generation and decision-making faster and potentially cheaper but also more flexible, in terms of timing (marker work does not require growing plants in the field/greenhouse – while they certainly can be used, depending on availability, you can also easily sample seed for variety purity and variety identification).
- It would increase the efficiency (work over time) of the current system. Canada already has an exponential growth in variety registrations (10 yr. trend) and this is expected to accelerate with the use of new plant breeding tools (BMTs); improved efficiency is critical, particularly for time and cost considerations.
- It allows for a continual transition from a visually based system to a more blended system (phenotypic assessment coupled with genotypic assessment) such that the right tools are available to be used for varietal eligibility determination (distinguishable and stable).

Cons/Risks:

- Challenge: to get the variety developers to agree to what “tools in the tool chest” are acceptable to all, within a given crop sector. CFIA would have to be using DNA based tools that have the confidence of the industry (agreement). There are also international harmonization concerns in this space that would need to be addressed. Depending on the crop and the parties involved, this may prove challenging (at first).
- Cost to transition (for CFIA): the new technologies (gene editing) being used are anticipated to require a shift to more molecular data based generation, storage, analysis and appropriate security of data precautions. It will require changes to CFIA’s new digital variety registration solution (pending) in order to accept this type of data in its various forms. In terms of infrastructure, it will require significant investment in specialized data storage and analysis equipment and software (capital costs).
- Moving to a more or a complete genotype-based system in Canada would have International repercussions; currently, over 100 countries in the world operate on a similar (phenotype-based) definition of “variety” and it is not genotype-based. This would also require a crop-by-crop approach; not a single change to the system.

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**Seeds Regulations, Part 3: Variety Registration, 67 Applications for Registration (1) (iv) “...a detailed description of variety including, where applicable, morphological, agronomic, pathological, physiological and biochemical characteristics,” add BMT reference here?*

Option #3: Transition immediately to an all-genotype based system for variety registration (use of BMTs exclusively).

Rationale: Anticipating where the registration/certification space is heading (the future), take the leap now and move to a modern, rapid, accurate system of variety identification and purity assessment through exclusive use of BMTs. This would put Canada on the leading edge (only Argentina is working in this space at present). With sign-on from the industry, this could put Canada in the lead and provide a competitive advantage over other phenotype based systems around the world.

Pros/Benefits:

- Eliminates current generation-lagging data generation; it moves the data generation (and decision-making) close to real-time (time of planting, time of harvest); an efficiency improvement over the current system which allows the regulator to be more pre-emptive and provides quicker decisions to the regulated party.
- It would put Canada in the lead position on use of new technologies for registration and also (assuming it would force the certification system in the same direction) certification.

Cons/Risks:

- Elimination of phenotypic assessments from the process (for registration: removing the reference seed sample grow-out comparison to the description of variety (DoV)) would require a major program restructuring at CFIA (decreasing the field program and increasing the Genobot lab throughput/capability/informatics resources). The transition period could prove quite challenging.
- Changes to the registration process would have knock-on effects to the seed certification program, forcing it in the same direction; this would be a disruptive change by any measure: a complete re-working of the certification system (e.g. elimination of crop inspection, elimination of CFIA’s monitoring program for crop inspection (check inspections), a shift from assessing plants in the field to assessing seed planted and seed harvested (genotypic analysis).
- A thorough cost/benefit analysis and careful transition planning would be an absolute requirement before contemplating a game changing shift such as this. There would need to be clear, defined benefits of heading in this direction as a country.

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- There will be industry concerns around the security and use of the molecular genetic characterization (the data set for a variety). This must be clearly defined, including the precautions to put in place and the prescribed use of this data. While the industry will want to protect its intellectual property to maintain competitive advantage and to be able to capitalize on their invention (variety), the public and the government are in favour of “open data” and transparency of government functions. There needs to be a very clear understanding of data concerns and usage in this space (in writing).
- Similar to the cons/risks cited in Option 2, above, Moving to a more or a complete genotype-based system in Canada would have International repercussions; currently, over 100 countries in the world operate on a similar (phenotype-based) definition of “variety” and it is not genotype-based. This would also require a crop by crop approach; not an over-arching change.

Options voting results:

Option 1 (no change to current system – maintain visual based system with supplemental “other” techniques to corroborate visual based data)

Support: 0

Do not support: 0

Abstain: 0

Option 2 Encourage CFIA to pursue a vision of increasing use of BMTs for variety registration; to specifically enable the use of BMTs in the *Seeds Regulations*. To pursue a strategy of transition toward a genotype based system of variety registration, keeping pace with the variety development innovations in the crop sector.

Support: 13

Do not support: 0

Abstain: 1 (was not able to vote)

Option 3 Transition immediately to an all-genotype based system for variety registration (use of BMTs exclusively).

Support: 0

Do not support: 0

Abstain: 0

Summary of results

The task team reached a qualified consensus for **Option 2** with 13 votes (one person abstained by default). In summary, 13 out of 14 voting members present voted for Option #2 (a minor change to the *Seeds Regulations* to recognize and allow for use of BMTs (bio-molecular techniques) to support the current visually based system and to allow for its increasing use in the future)

Final Recommendations

It is recommended that CFIA change the following part of the existing *Seeds Regulations* as follows: **Part 3: Variety Registration, section 67. Applications for Registration (1) (iv)**...to include a reference to “bio-molecular techniques (BMTs)” to pave the way for the current use of genotype-based assessments and to provide for increased future use of these techniques within the registration system. The term BMT is internationally recognized in the seed trade (e.g. OECD, AOSCA, UPOV, ISF, and ISTA) and is therefore recommended.

This amendment will add clarity to the use of DNA-based methods for variety purity and variety identification in the seed regulatory system. It does not change the phenotype-based seed certification system that is currently in place; however, it enables the regulator to conduct more genotype-based assessments within both registration and certification.

Topic 12 Report, Appendix 1 - Submission from Canadian Seed Growers Association (CSGA)

Email from Randy Preater, CSGA to Mark Forhan (CFIA) and Dr. Bryan Harvey (Chair, Variety Registration Task Team, part of Seed Regulatory Modernization)

Note: CSGA has placed comments on a copy of a slide from a presentation on use of molecular markers in variety registration (provided by Dr. Curtis Pozniak, U of SK., Crop Development Centre).

Date: April 27, 2022 (day of meeting 24 of VR task team)

The following slide (from Curtis) may enhance the Team's Topic 12 discussion, especially Option 3:

IMPLEMENTATION CHALLENGES

- What marker platform should we use? – crop specific, information vs cost (cost not really an issue)
- How many markers? Genome size, relatedness, ascertainment bias
- Changing marker technologies – data cross talk
- Database management, who is the “keeper”?
- Public availability of marker sets is a prerequisite – level playing field
- IP related - Ownership?
- Define the minimum required distance for distinction – how close is too close
- Define realistic uniformity/stability

WHO DECIDES?

The solution (technology) can not be a barrier....



Randy Preater

SPECIAL ADVISOR

CONSEILLER SPÉCIAL

Canadian Seed Growers' Association • Association canadienne des producteurs de semences

Editor's note: these “cons” or caveats apply to the use of BMTs in general (so applies to all options considered in this report).

Topic 13 Report

(rdims# 17836853; previous version: 17072619 v1C)

SEED REGULATORY MODERNIZATION VARIETY REGISTRATION TASK TEAM

Topic #13 Report

CFIA Recognition of Foreign Variety Registrations and their Equivalent
(harmonization on registration requirements)

OPTIONS AND RECOMMENDATIONS REPORT June 22, 2022

Introduction:

From the CFIA Primer (April 2022)

Recognition of and acceptance of foreign equivalent to variety registration for the Canadian variety registration process for Part 3 registration crops (currently 23 forage species, oilseed soybean, non-ornamental sunflowers, and potatoes).

At present, CFIA does not consider foreign market assessments of varieties (equivalent to variety registration) toward meeting our domestic registration requirements. There may be some advantages (reduced time, effort) to having foreign party variety evaluations and data be acceptable to CFIA for variety registration applications of Part 3 registration (non-merit based) crops. This would or could also include data from The International Union for the Protection of New Varieties of Plants (UPOV) organizations (plant breeders' rights offices around the world). For example, we see many potatoes and forage crop species from the EU which have a rigorous registration system (or the equivalent thereof). The data submitted for listing there would certainly be the same or very close to the same as what is required in Canada (meet the definition of variety: distinguishable and stable, have an acceptable name, provide pedigree and breeding history, provide a seed sample and a variety description, disclose novel traits, GMO status, etc.). It would be more challenging, depending on crop kind, with US commercial varieties having the requisite data package for Canadian variety registration but there is certainly a large body of information that could be considered. The acceptance of US-

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generated data for variety registration in Canada, in whole or in part, would certainly be of help for forages and oilseed soy. The AOSCA Variety Review Board system in the US would factor into this as well (see Option 2, below).

This approach would differ by region, depending on the local registration or listing system (the goodness of fit). The requirements for eligibility for registration for Part 3 registration crop kinds are identified in the *Seeds Regulations*. What is missing is text around foreign data acceptance for meeting the requirements of our domestic registration system (Part 3 crops only). This would require a simple regulatory amendment (one sentence) to the *Seeds Regulations* to allow acceptance of non-domestic data for Part 3 registrations.

Changes to enable foreign data acceptance would create a framework for engaging in this space. There would be new work taken on by CFIA to put this into effect: a clear written explanation of the standard of acceptance by each country's data package would be assessed, for acceptance. The process must be transparent to the variety developer. It assumes that the variety developer has access to the data package in the foreign country (CFIA would not negotiate that for the applicant).

The implications of this proposed change would need to be explored: Import/Export considerations (WTO notification?), suitability of various country's data packages toward meeting Canada's Part 3 registration requirements (CFIA assessments), suitability of this system under OECD and AOSCA Seed Schemes. Suitability of description of varieties (DoV) from foreign sources toward meeting Canada's DoV requirements (particularly important for seed certification). A discussion of the "real value" of this proposal would be in order to clarify if stakeholders for forages, potatoes, oilseed soy, and sunflowers view this as a worthy regulatory amendment proposal.

Finally, the requirement for the designation of the "Canadian Representative" at the time of application, would remain. The Canadian Representative becomes the Registrant after registration completes. This entity must be a Canadian resident (it can be a corporation or person). The definition of resident is the same one used by Canada Revenue Agency (half a year plus a day residing in Canada as a minimum).

ANALYSIS OF OPTIONS

Option 1: No change to the current system (domestic requirements do not change)

Rationale: The current Part 3 registration requirements are the minimum information required by CFIA to register a variety; it is a minimal and streamlined system as it stands. Changes are not required for the foreign variety application as our domestic requirements are minimal at present.

Pros:

- It is resource neutral to the regulator
- Potential reduction in regulatory burden to some variety developers (applicants)
- Clear, defined stream for registering Part 3 registration crop kinds
- Basic variety data, as is captured in Part 3 registrations, is, for the most part*, not specific to any geographical region; risk to Canadian crop production is low/negligible

Cons:

- Does not recognize and utilize registrations or their equivalent from foreign markets; it assumes a new application is required for Canada. Good variety data is being ignored.
- A lack of harmonization with similar jurisdictions performing similar or identical functions with regard to registering a variety for the market
- Regulatory burden – despite this being the minimum level of registration, not involving committees and assessment of merit, it still is a regulatory burden, it takes time and effort to apply and get a registration. This is a con when there is a more streamlined, less time consuming method of achieving the same end result.
- There is a risk, however small, borne by the variety developer and the producers in Canada, if the variety in question turns out to be unsuitable for cultivation in Canada (note: it is recognized that most variety developers mitigate this risk by assessing the varieties in the target market area prior to deciding to commercialize).

**plant disease resistance data (if claimed by the applicant) can be race/strain/geography dependent so some detailed knowledge would have to be applied in this instance. This is a caveat. The applicant always has the option of dropping any disease claims.*

Option 2: Modify the list of registration requirements in Part 3, *Seeds Regulations* (Variety Registration), for Part 3 Registration crops (as listed in Schedule III) to allow for recognition of

foreign registration equivalence such that foreign data packages could be used by CFIA to meet Canada's registration requirements. Canada would still perform their own variety eligibility determination (distinguishability and stability) based on this data.

Rationale: Simplify the process for foreign registered/listed varieties of Part 3 registration crops (forages, oilseed soy, sunflowers, and potatoes), reduce the time/effort of variety registration applicants where a variety is already commercialized in a foreign jurisdiction, and harmonize with other countries/same crop as much as possible. Savings in time, effort, cost to applicants

Pros:

- For some variety developers seeking registration in Canada could reduce the overall regulatory burden – mostly in **time savings** and avoidance of duplicate work. The dollar cost is neutral (same).
- There is the possibility that, in harmonizing with other countries, those countries may decide to take reciprocal action (to be able to receive Canadian registered varieties under similar circumstances). This has a modest potential to improve international seed trade for Canada.
- For oilseed soy varieties that go through an AOSCA Variety Review Board¹ process outside of Canada, there is potential to streamline into Part 3 registration in Canada based on the same data and conclusions.

¹ The purpose of the Variety Review Board system is to determine if the new crop varieties meet the eligibility requirements of the AOSCA (The Association of Seed Certifying Agencies) genetic seed certification standards. The Boards accomplish this by providing a central, standardized, and non-biased procedure followed by all plant breeders submitting review applications to AOSCA. VRB membership is comprised of representatives from seed certification agencies, USDA, and the seed industry, thus offering a peer review process for new varieties.

<https://www.aosca.org/variety-review-boards/#>

Cons:

- Maintenance of the system is a concern: the foreign registration or variety review bodies may change their requirements over time and fall out of synch with Canadian standards but this is deemed a low risk given the basic nature of the data collected here.
- The corollary of the “Pro” above: Those other countries will not follow suit and accept Canada's Part 3 registered crop varieties in a similar fashion.

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- Time/effort/cost to the regulator – this does come at a price to set up but it is an upfront cost, and once established, would be cost neutral or slightly cost saving to the regulator.
- Cost/benefit: the degree to which this proposal would help Canadian Seed Companies doing business domestically and abroad might not be significant versus the cost to the regulator; that is a consideration.

Option 3 Complete acceptance of foreign registration packages or their equivalent in lieu of Canadian Part 3 registration (acceptance as equivalent). Acceptance as equivalent would be on the basis of meeting the core information requirements: varietal eligibility determination, data to support claims in variety description, seed sample, variety description, “tombstone information” on the principals involved in the registration (Breeder, Canadian Representative (syn. Registrant), Variety Maintainer, Variety Owner, etc.). A streamlined Part 3 registration process would be put in place (shorter processing time – less than 8 weeks).

Rationale: For some jurisdictions, the registration process or its equivalent (equivalent to Part 3 registration in Canada that is) the exact same information is being collected on a variety prior to registration. If Canada had a reasonable comfort level with the work done in those jurisdictions, then accepting a complete foreign data package for registration is the next logical step; why duplicate the work of others?

Pros:

- Saves time and money; avoids duplication of processes
- Expedites registration of foreign previously registered crops (for Part 3 registration crop kinds)
- Gets more innovative varieties onto the Canadian market; provides more choices for producers

Cons:

- Is dependent on another jurisdiction and its practices, which may change in time. Therefore, maintenance of the systems must be a consideration for the regulator.

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- Time/cost burden for the regulator; it could be that the benefit does not outweigh the cost however, the cost is to the regulator and the benefit is to variety developers and producers (different market segments).

RECOMMENDATION:

The vote was taken with results as follows:

Option 1: 0

Option 2: 12/12

Option 3*: 0

Abstained: 0

** This option was not on the table when the vote was taken – it was discussed at our June 29th, 2022 meeting and there was no support from the task team members. The Chair mentioned that the missing members (12 of them) could submit their votes and have them added to the votes recorded in the meeting.*

Originally there was a total of 8 voting members (May 25, 2022)

Finally, there was a total of 12 voting members on the re-vote, June 29, 2022

Summary of recommendations:

There is qualified consensus (12 members, unanimous) for **Option 2** which is to have CFIA modify the *Seeds Regulations*, Part 3 (list of registration requirements) to allow for the acceptance of foreign registration data (or its equivalent) to allow those same data packages to be submitted for Canadian Part 3 Registrations. Canada would still perform their own assessment of variety eligibility but it would be on the foreign data provided.

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Appendix 1: VR Task Team Membership and Affiliation

Variety Registration Task Team Members		
Name	Organization, Assoc., Group, Independent, etc.	Sector
Dr. Bryan Harvey (chair)	OC, SOM, FAIC, PHD, PAG, U of SK	Seed Industry*
Dr. Paul Hoekstra (co-chair)	Grain Farmers of Ontario (Alternate: Dr. Josh Cowan, GFO)	Producer Group
Stephen Denys	Maizex Seeds, ON.	Seed Industry
Dave Harwood	Corteva, Seeds Canada	Seed Industry
Randy Preater (Mike Scheffel, alternate for Randy at CSGA)	CSGA staff	Seed Industry
Laurie Hayes or Michael Shewchuk	Saskatchewan Seed Growers Association (Alternate: Laurie Hayes, Mitchell Japp, Shawn Fraser)	Seed Industry
Ellen Sparry	C & M Seeds, Seeds Canada	Seed Industry
Dr. Lauren Comin	Alberta Wheat Commission, Alberta barley (<i>later left and joined Seeds Canada as an employee</i>).	Commodity or Value Chain Association
Caalen Covey	Canadian National Millers Association	Commodity or Value Chain Association
Laurie Friesen	Saskatchewan Pulse Growers	Commodity or Value Chain Association
Bill Gehl	Saskatchewan Wheat Development Commission	Commodity or Value Chain Association
Dr. Curtis Rempel	Canola Council of Canada	Commodity or Value Chain Association
Dave Gehl	National Farmers Union (NFU)	Producer Group
Fred Greig	Producer, Grain Growers of Canada, Chair of MB Crop Alliance (Alternates: Pam de Rocquigny, Branden Leslie)	Producer Group
André Lussier	Producteur de semences et de grains au Québec	Producer Group
Brenna Mahoney OR Neil Van Overloop	Keystone Agricultural Producers	Producer Group
Dr. Duane Falk	U of Guelph (retired) Professor, Independent Plant Breeder; Ecological Farmers Association of Ontario	Other non-government
Dr. Jennifer Mitchell-Fetch	Retired AAFC plant breeder (oats), Chair of sub-group on heritage, heirloom, heterogeneous varieties and alternative breeding	Other non-government
Dale Burns	Bayer Crop Science, Seeds Canada, plant breeder (canola)	Variety Developer, Seed Industry

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Variety Registration Task Team Members		
Name	Organization, Assoc., Group, Independent, etc.	Sector
Dr. Robert J. Graf	AAFC, Research Branch, Lethbridge- Public Breeder (wheat)	Variety Developer, Government
*Nathan Gerelus in support of Kris Wonitowy who replaced Daryl Beswitherick (original member) Nathan is non-voting.	Canadian Grain Commission (CGC)	Government, Grain Sector (non-voting, backup to Kris Wonitowy)
Kris Wonitowy (voting member for CGC)	Canadian Grain Commission (CGC)	Government, Grain Sector
*Wendy Jahn	National Manager, Seed Section, Canadian Food Inspection Agency (CFIA), Registrar , Co-Chair of Seed Regulatory Modernization Working Group (SRMWG)	Government, Seed Sector
*Mark Forhan	Team Leader, Variety Registration Office, Canadian Food Inspection Agency (CFIA), plant breeder	Government, Seed Sector
*Heather Ryan	Specialist, Variety Registration Office, Canadian Food Inspection Agency (CFIA)	Government, Seed Sector

*non-voting members

25 members; 21 stakeholder-members: **20* voting members**

Voting stakeholder-members breakdown:

Seed Industry (6), Producer groups (5), Commodity or Value Chain Associations (5), Other, non-government (2), Government, grain sector (1), Government, variety developer (1).

*the Chair (Dr. B. Harvey) only votes on a tie – this never occurred throughout the whole process.

Appendix 2: Reference Documents for the Variety Registration Task Team available upon request.

Document A: CFIA Primer on Canada’s National Variety Registration System (RDIMS # 15099236 v1B)

Document B: 80 Years of Variety Registration, Grant Watson, Senior Advisor, Plant Products Division, 10/09/2003 (RDIMS # 1087087)

Document C: AAFC Document: Crop Variety Registration in Canada; Issues and Options (posted on-line) (AAFC no. 12064E, Catalogue No. A34-21/2013E-PDF, ISBN 987-1-100-22572-2)

(Released in 2013 as part of the 2013-2015 AAFC-Led National Review of the Variety Registration System in Canada (an initiative of the Minister of Agriculture's Office))

Document D: Variety Registration Task Team Topics from the Seed Regulatory Modernization Working Group (SRMWG)

Document E: CFIA Presentation on Incorporation by Reference (IbR) presented to all the Seed Regulatory Modernization Task Teams (for reference) (RDIMS # 1521034)

Document F: Variety Registration Task Team Questions on Incorporation by Reference (IbR), Feb. 16, 2022...with answers from CFIA regulatory experts (RDIMS # 16106058)

Document G: CFIA Primer on: Phenotype, Genotype and the Variety Registration System (RDIMS# 16177627 v1A)

Document H: MY THOUGHTS ON MOLECULAR MARKERS FOR VARIETY REGISTRATION, Dr. Curtis Pozniak, Professor and Director, Crop Development Centre, U. of Saskatchewan
(pdf of PowerPoint presentation). Saved into CFIA system as: RDIMS #17652652

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