

A Streamlined Seed Program (Single Window)

ISSUE / IMPEDIMENT	IMPACT	WHAT SHOULD BE DONE
<p>The de-centralized structure of the Canadian seed regulatory system creates inefficiencies and reduces seed program effectiveness. In the process it imposes administrative and regulatory burden and unnecessary costs on users.</p> <p>Multiple entry points for pre-market assessment of new events and varieties are managed by different entities within the CFIA, Health Canada, and CSGA; including those related to the Plant Breeders' Rights Office, the Variety Registration Office, the Feed Section and the Plant Biosafety office in CFIA, the Food Directorate in Health Canada and variety eligibility for certification in CSGA.</p> <p>Supporting data bases and IMIT systems remain for the most part separate and there is limited if any scope currently for workload sharing or joint assessments. The potential to apply a growing array of technology solutions and related IMIT systems design improvements to address both regulatory and client driven needs is severely limited as are the related prospects for reduction of regulatory and administrative burden.</p>	<p>Multiple entry-points means multiple pre-market submission processes are necessary. Absence of data connectivity and supporting systems (ex. variety profiles) means high levels of administrative and regulatory burden that could otherwise be removed remain. The opportunity costs of inaction are high.</p> <p>Initial conservative estimates of some of the opportunity costs of inaction are:</p> <p>The Single Window</p> <p>Estimated benefits currently forgone include (1) entering information only once, (2) minimizing the need to provide annual variety updates and (3) lower costs associated with providing information. Annual cost savings ranging from \$300,000 and \$1.0 million.</p> <p>Variety Profiles</p> <p>Conservative early estimates indicate that improved availability of variety profile information to value chain users would generate annual cost savings through lower search costs by an estimated \$1.5 million. The improved information would also reduce the use of common seed. If common seed use in cereals and pulses fell by 2%, certified seed use would increase by 6.6%. The net change in sales would be \$9.3 million. Overall, the range in net benefits ranges between \$6 and \$19 million per year.</p>	<p>The Seed Synergy partners are actively examining merger and other policy and operational coordination options required to create a single window. To succeed, we need governments as partners; open minded, fully engaged and committed to achieving mutually agreed objectives through all reasonable means at their disposal. This submission is effectively a request that Government commit to an agreed single window objective for seed regulation and allocate the required resources to its design and implementation, jointly with the Partnership.</p> <p>A single window model would, inter alia :</p> <ol style="list-style-type: none"> 1. Allow product developers and seed companies to enter on-line product data, such as for registration, eligibility for certification, variety listing, and PBR protection once. 2. Facilitate joint work processes and streamlined procedures for seed safety assessments among the 3 current responsibility centres. 3. Facilitate consolidation of key seed regulatory and related program services (ex. seed quality assurance, phytosanitary inspections, certification) within a single third party delivery vehicle 4. Accelerate system redesign to incorporate technology enablers and to integrate regulatory and other services that add value for users.

The design of the current system makes it difficult to effect timely system improvements, as it is very difficult to establish and sustain consensus and coordinate action around even mutually agreed upon outcomes for long enough to effect meaningful change, except in exceptional circumstances.

There is at best weak coordination of regulatory policy, program design and program delivery priorities and objectives, among the Seed Synergy organizations and their various CFIA counterparts and no overarching planning framework to guide joint priority setting.

Similarly, seed policy and standards development and variety registration merit assessment programs are also delivered less efficiently and effectively than they would be if the type of single window and variety profiling approaches that we see in other jurisdictions existed in Canada. For example, CFIA, CSGA and CSTA all rely heavily on separate crop specific expert and member committees (often drawing on the same individuals and organizations) to provide input on variety performance, crop certification standards, and a range of seed policy decisions. This is one of many areas ripe for streamlining.

The government organizations currently responsible for the delivery of the seed program, the plant breeders' rights program, the food, feed and environmental safety assessment programs, and the plant health program need to work with the Partners and others to develop an integrated approach to pre-market assessment of new events and varieties.

In parallel, a variety profile data management strategy to link pre-market assessments with other downstream regulatory and business services such as seed certification, seed tests, royalty collection, phytosanitary and other additional certifications needs to be developed; as part of a broader technology enabled regulatory and information service window for the seed industry, its customers and the public.

A user-friendly variety profile platform enabled single window would connect the end user to the breeder and everyone in between. Such a platform, could begin as an offshoot of the current Plant Breeders' Rights, Variety Registration and Variety Eligibility for Certification data bases. It could contain (1) required varietal identity, (2) intellectual property features, (3) product developer, (4) distributors, (5) other regulatory features, (5) agronomic characteristics, (6), geographic areas for production, (7) stewardship requirements (8) agronomic performance information on a variety, (9) relevant end-use and (10) other business information.

A Predictable, Aligned and Risk Based Seed Safety Assessment Program (Plant Breeding Innovation)

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<p>Canada’s globally-unique regulatory approach for novel plants, as currently administered, is a significant impediment to crop innovation in Canada.</p> <p>Canada is the only country in the world to subject conventional plant breeders to the same type of pre-market safety assessments that other countries apply to genetically-modified organisms. Over 20 per cent of the “plants with novel traits” approved for cultivation in Canada would have required no such oversight in any other country and would have reached the market 1 to 4 years earlier, at a lower cost.</p> <p>In addition, the case-by-case approach used to determine which new varieties are subject to pre-market assessments causes great uncertainty for the plant breeding community. Plant breeders report that they cannot be sure if their products require approvals, and if so, how much this will cost, what data they will need and how much additional time it will take to do field research and obtain an approval. Researchers are told they must “talk to the regulator” to find out if they are subject to regulation.</p>	<p>A recent survey of Canadian plant breeders indicates nearly half change or scale-back their R&D activities to avoid falling under Canada’s pre-market regulatory programs for novel products. In some cases, R&D projects go unfunded or do not make it past the proposal stage due to regulatory uncertainty.</p> <p>When plant breeders curtail their best efforts to innovate, Canada loses out on opportunities to nurture the development of innovative small businesses (as we are seeing emerge in the US and Australia), to increase agricultural yields of grain (up to 90% of which are exported) and to make a wider selection of healthier food products available to Canadian consumers.</p> <p>Canada is a relatively small market and our global competitors (US, Brazil, Australia, Argentina and others) are moving quickly to put clear and practical regulatory approaches in place for cutting-edge methods of plant breeding innovation, like gene-editing systems (CRISPR). Canada is already falling behind with significant acreage of crops developed using cutting-edge techniques in the US this year, while Canada has none.</p> <p>The opportunity cost of not having access to high performing traits that benefit from these cutting edge techniques is potentially very high.</p> <p>Recent analysis of farmer benefits associated with delays in approval of high performing traits suggest lost opportunities in the range of \$12-55 million per trait per year.</p>	<p>There is a pressing need to update the delivery of Canada’s regulatory programs for plants with novel traits, novel foods and novel feeds, to ensure Canada remains competitive with its trading partners and receives its share of investment in plant breeding innovation.</p> <p>Our recommendations do not require regulatory change and can be accomplished through process improvements.</p> <p>Desired outcomes would include administrative changes to the process that:</p> <ol style="list-style-type: none"> 1) Clarify Canada’s regulatory trigger for PNTs, novel foods and feeds, so that our plant breeders can confirm within a reasonable time frame whether their products are subject to pre-market assessment. 2) Aligning with our like-minded trading partners to the extent practical, e.g., to avoid unnecessarily regulating products that were, or could have been, achieved through conventional breeding. 3) Provide for a tiered approach (with service standards), so that “novel” but lower-risk products can move through the approval process more quickly, with sufficient but less onerous data requirements than products that are more complex, less familiar, or potentially higher risk.

While the administration of Canada's "novelty" approach has been an irritant for many years, the advent of new breeding methods such as genome-editing will amplify the problem. We are already starting to see examples of products being commercialized in the US or elsewhere where regulatory regimes for plant breeding innovation are clearer, instead of in Canada. For instance, in many countries in Latin America, plant breeders using gene-editing have access to a two-page form and a twenty-day process to determine if their product requires a pre-market assessment. By contrast, a similar product in Canada has recently required multiple rounds of questions and back-and-forth interactions with three separate regulatory offices for over 12 months, without a final determination of whether or not the product is regulated.

These losses can add up quickly in a situation like we are facing today, where for all intents and purposes, the pipeline is dry. Moreover, this impact is felt by all firm sizes, including small and medium size seed businesses that are losing promising investment and growth opportunities.

A Strengthened Intellectual Property Regime (Value Creation)

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<p>Within Canada, there are essentially two seed supply chains. One is the canola, corn, and soybean seed supply chain where the private sector supplies most of the new varieties. The other is the cereal and pulse crop seed supply chain where public sector research supplies most of the new seed products.</p> <p>The first supply chain is made up of either hybrid crops and/or crops with patented traits, resulting in very effective intellectual property rights (IP), high rates of innovation and high returns to the seed sector and to the respective downstream value chains.</p> <p>In cereals and pulse crops, there is less effective IP protection and the self-pollinating nature of most of these crops have a significant effect on private sector investment, since farmers can save seeds for planting next year's crop.</p> <p>The current Plant Breeders' Rights Regulations legitimizes the use of farm saved seed of protected varieties. Levels of investment and innovation are consequently less than they are in crop value chains where use of farm saved seed is less common.</p>	<p>The impact of inaction is the opportunity cost of losing a significant stream of potential net benefits to both the seed industry and the downstream value chain, including primary producers. This is borne out by international comparisons.</p> <p>In addition, impact assessments conducted for the Seed Synergy Collaboration project and based upon a future scenario where recently protected varieties represent 50% of total acreage, a trailing contract system would result in a total of \$24.2 million in annual royalties (\$10.3 million from FSS royalties and \$13.9 M in certified seed royalties). The incremental FSS royalties of \$10.3 million can generate future producer benefits of at least \$70 million per year and an economy wide impact of \$140 million per year.</p> <p>While only an estimate based on a hypothetical future case scenario, it provides a reasonable indication of what current inaction is costing the Canadian economy.</p>	<p>Proposed changes to the Plant Breeders' Rights Regulations would facilitate collection of royalty payments on farm saved seed (FSS) of protected varieties. The farm sector, the seed sector, and government have all recognized the need for additional investment in varietal development in cereals and pulses. There are currently two approaches being considered for this sector to incentivize more investment.</p> <p>One approach is an end point royalty (EPR) system where first receivers of grain collect an EPR (such as \$1.00/t) on delivered grain, which is then distributed back to the breeder/product developer.</p> <p>The second approach is a royalty paid on FSS where farmers with their purchase of Certified seed enter into a contractual agreement with the product developer/breeder with the obligation to pay a FSS royalty (e.g., 1¢/lb. or \$0.50 per 50-lb. unit) on any FSS used in subsequent crop years. Contracts of this nature are already used with terms on FSS in Canada; however none with an FSS royalty.</p> <p>In recent analysis undertaken for the Seed Synergy Collaboration Project (see Economic Impact and Risk Analysis at https://www.seedsynergy.net/whatsnew/) the use of contracts and EPRs to collect royalties on FSS in cereals in Western Canada were compared. The conclusion was that a FSS trailing royalty model generates a larger impact.</p>

		<p>Besides providing more money for plant breeding through higher royalties the contract system (compared to an EPR system) was also judged to: 1. be more efficient in collecting the royalties; 2. be more acceptable to producers and seed companies; 3. have a lower per acre cost to producers; and 4. provide a better linkage to traceability.</p> <p>It is also noteworthy that this is an area for potential experimentation with advanced royalty tracking and collection systems that could be employed to facilitate cost effective implementation, as part of a larger single window IM/IT systems integration</p>
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A Modernized Seed Certification Program (Enhanced Traceability)

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<p>The pedigreed seed system is meant to ensure that seed of over 50 crop kinds meets product quality requirements such as varietal identity and purity, grade standards and associated performance characteristics. The system is designed to provide basic genetic traceability from high through lower generation seed to commercial crops. In some cases (e.g., Identify Preserved Crop Value Chains) it is a foundational component of high value crop production and export chains.</p> <p>However, the Canadian system is unnecessarily complex administratively. Rather than being delivered by one entity, which is the international norm, the Canadian system is delivered by three organizations (CFIA, CSGA and CSI). Given the resultant separation of roles and responsibilities system efficiency and effectiveness suffers.</p> <p>Rigidities stemming from the systems multiple administrative components and related connectivity and coordination issues has hampered its responsiveness to evolving business models, seed cleaning technologies and market demands. For example, regulatory decisions related to the issuance of crop certificates based on problems in the field cannot currently factor in downstream mitigation options, adequately.</p>	<p>Not modernizing an outdated seed certification system model carries significant opportunity costs and growing risks.</p> <p>Critical Mass</p> <p>Currently, many of the organizations that make up the “seed regulatory family” are one or two layers deep at best and by extension one departure removed from losing critical leadership, policy and/or technical expertise. Key staff departures in one area can therefore significantly impact overall system performance. Increasing critical mass through consolidation is a low cost risk mitigation option.</p> <p>System Redesign</p> <p>With respect to opportunities forgone with an outdated model, the structure and composition of the seed industry continues to evolve, and the seed certification system needs to evolve with it. The current division of system oversight roles between the crop certification phase where CSGA efforts are focussed and the final certification phase where CSI operates needs to be bridged. CFIA is well positioned to facilitate the necessary changes.</p> <p>Recent economic impact assessments indicate that certification models that rely less on third party field inspections and more on quality management system certifications and audits could generate savings of \$2-\$4 million dollars annually while improving the global competitiveness of the system.</p>	<p>Explore the feasibility of creating one third party delivered seed certification program, within a new national seed organization, that partners with governments on a single window approach.</p> <p>The Seeds Regulations should be reviewed and seed and labelling standards and potentially other requirements should be removed from the text of the regulation, instead providing for incorporation by reference.</p> <p>The government should delegate all quality related seed standards to the named third party as well as any other authorities required to facilitate the operation of a unified third party delivery model.</p> <p>Government should continue to provide regulatory oversight and enforcement support as well as science support to the seed certification system; with an expanded role for accredited labs in the latter case.</p> <p>A new third party delivery model should be technology-enabled to facilitate comprehensive electronic seed certification.</p>

<p>Not surprisingly, the Canadian seed certification system has also been unable to take full advantage of IMIT and related technology solutions that could make the system more responsive and cost effective if operated under a unified administrative model.</p>		
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