| A Streamlined Seed Program (Single Window) | | |
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| **ISSUE / IMPEDIMENT** | **IMPACT** | **WHAT SHOULD BE DONE** |
| 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.<br><br>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.<br><br>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. | 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.<br><br>Initial conservative estimates of some of the opportunity costs of inaction are:<br><br>The Single Window<br><br>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.<br><br>Variety Profiles<br><br>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. | 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.<br><br>A single window model would, inter alia :<br><br>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.**<br><br>2. Facilitate joint work processes and streamlined procedures for seed safety assessments among the 3 current responsibility centres.<br><br>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<br><br>4. Accelerate system redesign to incorporate technology enablers and to integrate regulatory and other services that add value for users. |

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| 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.<br><br>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.<br><br>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.<br><br>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.<br><br>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)

| ISSUE / IMPEDIMENT | IMPACT | WHAT SHOULD BE DONE |
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| Canada's globally-unique regulatory approach for novel plants, as currently administered, is a significant impediment to crop innovation in Canada.<br><br>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.<br><br>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. | 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.<br><br>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.<br><br>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.<br><br>The opportunity cost of not having access to high performing traits that benefit from these cutting edge techniques is potentially very high.<br>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. | 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.<br><br>Our recommendations do not require regulatory change and can be accomplished through process improvements.<br><br>Desired outcomes would include administrative changes to the process that:<br><br>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.<br><br>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.<br><br>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. |

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| 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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| **ISSUE / IMPEDIMENT** | **IMPACT** | **WHAT SHOULD BE DONE** |
| 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.<br><br>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.<br><br>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.<br><br>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. | 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.<br><br>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.<br><br>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. | 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.<br><br>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.<br><br>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.<br><br>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. |

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| | | 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.<br><br>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 widow IM/IT systems integration |

| A Modernized Seed Certification Program (Enhanced Traceability) | | |
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| **ISSUE / IMPEDIMENT** | **IMPACT** | **WHAT SHOULD BE DONE** |
| 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.<br><br>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.<br><br>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. | Not modernizing an outdated seed certification system model carries significant opportunity costs and growing risks.<br><br>Critical Mass<br><br>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.<br><br>System Redesign<br><br>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.<br><br>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. | 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.<br><br>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.<br><br>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.<br><br>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.<br><br>A new third party delivery model should be technology-enabled to facilitate comprehensive electronic seed certification. |

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| 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. | | |

Regulatory Review
Regulatory Affairs Sector
Treasury Board Secretariat of Canada
90 Elgin Street, 5th floor
Ottawa, Ontario
K1A 0R5

September 15, 2018

RE: **SEED SYNERGY PARTNERS SUBMISSION TO THE 3-YEAR TARGETED REGULATORY REVIEW PROCESS FOR AGRI-FOOD AND AQUACULTURE.**

The Seed Synergy Partners are six major national seed industry organizations: the Canadian Seed Growers' Association (CSGA), the Canadian Seed Trade Association (CSTA), the Canadian Seed Institute (CSI), the Commercial Seed Analysts Association of Canada (CSAAC), the Canadian Plant Technology Agency (CPTA) and Crop Life Canada. These organizations represent the certified seed system value chain beginning with research & development, marketing, production & processing, through to sales & distribution.

The Partnership was formed to initiate positive change in the overall Canadian seed system and is guided by a vision of a reformed, industry-led, government-enabled seed system that effectively attracts investment, fosters innovation, and delivers new and tailored seed traits to customers efficiently. The goals and objectives embedded in this vision recognize the opportunity that exists now to move forward with the kind of improvements to the seed regulatory system that will position producers, innovators, and ultimately the entire agricultural value chain to succeed in a highly competitive and innovation driven global marketplace.

The recent work of the Partnership has produced a promising package of mutually reinforcing seed policy and regulatory and institutional reform proposals. These proposals provide a potential road map for attracting increased investments to plant breeding innovation in Canada. Their adoption and implementation would serve to ensure that Canadian farmers receive the uninterrupted stream of seed based innovation they require to remain economically viable and internationally competitive in the future, in the process supporting Canada's ambitious agriculture sector growth targets.

**Proposals**

Each of the four appended issue profiles describes a priority area where the seed sector and governments urgently need to work together to advance policy and regulatory review and reform.

They are:

1. An Integrated and Streamlined Seed Program (Single Window)

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

3. A Strengthened Intellectual Property Regime (Value Creation)

4. A Modernized Seed Certification Program (Enhanced Traceability)

The anticipated outcomes of pursuing these reforms are respectively:

1. A more efficient organization and utilization of public and private sector resources devoted to seed system governance and management, enhanced system transparency and traceability, increased system responsiveness and value added to users, and reduced administrative and regulatory burden on users.

2. Faster and more predictable access to safe, cutting edge seed innovation and the associated economic benefits.

3. A stronger intellectual property regime that offers improved return on investment for breeders of protected varieties of key crop kinds, enhanced system transparency and traceability, and more cost effective enforcement.

4. Increased system responsiveness and value added to users, lower system operating costs, reduced administrative and regulatory burden on users, enhanced system transparency and traceability, increased system responsiveness and value added to users, and more efficient and effective regulatory oversight.

The appended issue profiles are designed to respond to the question:

- "In your view, are there existing regulatory requirements or practices that impede economic development, competitiveness, or growth for your firm or sector? What are their impacts? How should the Government address these irritants?"

In responding to the aforementioned core question, we attempt to respond to the following supplementary questions, where applicable:

- "Are there existing or emerging technologies, processes, or products in your firm or sector facing barriers because of federal regulations? What changes or tools should the Government consider to facilitate the development, integration, or approval of these technologies, processes, or products for Canadians?"
- "Do you see opportunities for regulatory experimentation in your sector, and if so, what would this look like.

## Background

### The Economic Importance of the Seed Sector

The Canadian seed industry is large. It employees nearly 60,000 Canadians and accounts for $3.2 billion in seed sales to Canadian farmers and to overseas customers. In addition to providing advanced genetics for commercial farm operations, this value of sales supports over $6.0 billion in annual economic activity and employment in many value added sectors of the economy. These seed sales are an integral input into the $33 billion in annual crop production sold by farmers into markets, as well as the crops used as home-grown feed and forages on livestock operations.

The seed sector is key to continued productivity improvements in the Canadian agriculture and food sectors. A steady stream of new varieties that increase yields, offer pest and drought resistance and other qualities that improve farmers per acre returns and provide attributes required by buyers of grains and oilseeds are required to ensure the competitiveness of the agriculture sector in domestic and export markets.

### Seed Regulation and Investment in Innovation

Over the course of the last 40 years the leadership focus, design and delivery of Canada's seed regulatory system has evolved substantially, with: legislative and regulatory authorities transferred from Agriculture and Agri-food Canada to the Canadian Food Inspection Agency; the establishment of intellectual property protection for new plant varieties through the enactment of and recent amendments to the Plant Breeders Rights Act ; the introduction of a globally unique "novel products" approach for ensuring the environmental, food and feed safety of new plant genetics entering commerce and; the delegation of government responsibility for the regulated components of seed quality assurance to an increasingly fragmented array of para-public and private entities.

In parallel, while investment in government and producer funded breeding programs in Canada continues at substantial levels (current estimates $80 million/year), its overall relative importance to Canadian agriculture has diminished as private sector investment in plant breeding innovation has grown (current estimates $125 million/year). Increasingly, the future of plant breeding innovation in Canada and the associated profitability and growth potential of Canadian crop based agriculture is dependent upon attracting higher levels of private sector investment to plant breeding and varietal development and ensuring that public sector investment is directed to where it is most needed as a catalyst for private sector growth.

**The Seed Synergy Collaboration Project**

The Seed Synergy Collaboration Project body of work is well documented and accessible via our website, https://www.seedsynergy.net/home/ . It includes: the product of initial efforts to accurately describe and explain the operation of Canada's complex seed system to those less familiar with it; the identification of issues affecting the performance of the system and the exploration of remedial options (the Green Paper); stakeholder feedback from consultations on the Green Paper; and recommendations stemming from a comprehensive economic assessment and risk analysis of options derived from it, including international comparisons.

It is important to note that while stimulating investment to unlock the innovative potential of the Canadian seed and agricultural sectors is a core Seed Synergy Collaboration Project driver, it is not the only one. Others include: increasing transparency within the system; meeting diverse customer needs and driving growth throughout the agriculture value chain; enabling industry to assume a more coherent focussed and effective role in seed regulatory system management and governance; and allowing government to re-allocate resources to areas of highest risk and collective benefit.

**The Project's next step is the development of a successor White Paper that aspires to translate the insights and learning of the last three years work into a detailed blueprint for seed policy, regulatory and institutional reform that are aligned with priority Government of Canada regulatory and innovation policy objectives.**

**Optimizing Regulatory Resource Allocation – Third Party Delivery**

Re-allocating resources to areas of highest risk and collective benefit is of critical importance to any regulatory program, with the ongoing operation of CFIA's seed related regulatory programs being no exception. Housed within an Agency on the front line of managing and mitigating enormous food safety, animal health and plant health program risks, "lower risk" seed related regulatory programs have historically faced ongoing resource pressures.

These challenges were met in a variety of ways over time, including through relatively high rates of cost recovery in such areas as Plant Breeders Rights administration. However, by far the most impactful strategy for dealing with cost pressures has been to privatize specific seed program elements, in the process freeing up government resources for reallocation to higher priority areas, most notably with the authorization of private, accredited seed laboratories to test seed for import release purposes (1976) and then for official certification purposes (1986), followed in 1997 by the creation of the industry governed Canadian Seed Institute and again in 2012 with the decision to privatize seed crop inspections.

Arguably, the policy decisions made between 1976 and 2012 were consistent with the original seed program privatization decision in 1904, when the Canadian Seed Growers' Association (CSGA) was established. Over time, the CSGA assumed legislative authorities and regulatory responsibilities within the formal seed certification regulatory framework and now works in partnership with the CFIA, the CSI, the new authorized seed crop inspections services, Canada's plant breeding community and its other Seed Synergy partners to deliver the Canadian seed certification program.

In retrospect, what is perhaps most surprising is that responsibility for the entire seed certification system was not transferred to a third party much sooner and in a planned way. If it had been, Canada's seed system of today may have resembled more closely that of the world leading Dutch and French models where core seed system functions are delivered efficiently and effectively through robust national seed organizations and broadly supported industry governance models.

While subject to strict regulation and close government oversight, these organizations (the NAK in Holland and GNIS in France) deliver or facilitate seed quality assurance certification, seed phytosanitary certification, royalty collection, market development, training and education and other important functions that drive investment in their agriculture sectors. These vibrant third party delivery models are the product of decades of evolution and iterative change that benefitted from a foundational vision; where the respective roles and responsibilities of industry and government in the partnership were well defined, understood and broadly supported from the start.

**Recognizing that this is perhaps what Canada now needs to ensure that in the near future others will be inspired by our story; the Seed Synergy Collaboration Project partners offer the outcome of our work to date as a starting proposal for a new dialogue with government on a road map for comprehensive seed system regulatory and institutional reform.**

Sincerely,

CSTA ACCS
Canadian Seed Trade Association
L'Association canadienne du commerce des semences

Canadian Plant Technology Agency

Canadian Seed Institute | Institut Canadien Des Semences

CSGA ACPS
Canadian Seed Growers' Association
Association canadienne des producteurs de semences

CropLife CANADA

SEED COMMERCIAL ANALYSTS ASSOCIATION CANADA INC.