

Canada's Seed System

A Summary Description

DRAFT

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Executive Summary

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New and improved varieties of plants provide immeasurable value to society. Whether it is higher yielding, pest resistant wheat varieties or ornamental plants for public or private gardens, new plant varieties can be valuable contributors to societal improvement.

Canada's seed system can be considered to be the sum total of the policies, laws, regulations, rules, procedures, organizations and individual choice that result in the availability of seed for planting.

Before Canadian seed can be sold or planted, it goes through a number of important steps. Many of these steps are specified in regulations, policies, and guidelines, and together they make up the lifecycle of a seed in Canada.

Developing a new seed variety

New seed varieties are regularly being developed by large and small plant breeding institutions, both in Canada and abroad. There are a number of ways in which new seed varieties are developed, including conventional plant breeding, utilization of recombinant DNA (rDNA) technologies, and more recently, gene-editing techniques.

Intellectual property rights are a recognition of the efforts to bring new and beneficial innovation to Canadian society. Inventors have the "right" to protect their inventions (intellectual property) and to be remunerated for their use. This encourages further innovation to make better use of resources and generate wealth for Canadian society as a whole.

Variety registration

Variety registration is a process that results in the official verification that a seed variety is new, distinguishable from other varieties, relatively uniform in its essential characteristics, and stable. The identity of a variety is determined by its breeding history and is defined by the description of variety (DoV) and a legal reference sample. The variety registration process requires that a legal reference sample of seed of the variety be submitted to the Canadian Food Inspection Agency (CFIA). The CFIA validates the draft DoV submitted by the plant breeder by growing plants and confirming the distinguishing characteristics described in the DoV.

Growing seed crops

Initially, only a small quantity of seed of a new variety is available. In order to produce the quantities needed to commercialize a new variety, several years of seed production are required. This "multiplication" of seed of the variety is undertaken by seed growers, in accordance with specific regulations and procedures for growing pedigreed seed crops in Canada, outlined in a document called Circular 6.

Seed crop inspection and certification

In order for seed to be certified, the seed crop from which the seed is derived must undergo an inspection. If the Report of Seed Crop Inspection indicates that the requirements of Circular 6 have been met, the Canadian Seed Growers Association (CSGA) will issue a Seed Crop Certificate indicating the crop met the certification requirements of the CSGA.

Harvesting, cleaning and conditioning seed

The seed grower is responsible for the harvest and initial handling of the seed crop and ensuring that it does not become mixed with any other seed. The processing of pedigreed seed is strictly controlled and subject to the *Seeds Regulations*. Only the grower of the seed or an establishment registered as an approved conditioner is permitted to “prepare” seed of pedigreed status, that is, to clean, treat, sort, size, package or any other activity that changes the nature of the seed lot.

Sampling, testing and grading of seed

There are three recognized methods for seed sampling and testing in the *Seeds Regulations*, the purpose of which is to ensure that a seed test result is a reliable estimate of the average seed lot quality. Canada has a grading system for seed, which means that most seed is labelled with a grade name when it is sold in Canada. There are also requirements for seed quality, including sampling and grading, packaging, labelling and importation of seed.

Importing, exporting and selling seed

Imported seed must meet the minimum standards established for seed, most often the Common No. 2 grade standard, unless it is imported for the expressed purpose of cleaning/conditioning. However, all imported seed must be free of prohibited noxious weed seeds. Imported seed is exempt from most labelling requirements at the time of import but must be labelled before sale. If imported seed has been treated with a pest control product it must be stained and labelled accordingly at the time of import.

Exported seed is exempt from most requirements but if treated with a pest control product it must be properly labelled. Canada exports both pedigreed/certified seed and non-pedigreed/common seed. Certified seed is labelled with either official Canadian certification tags/labels if it has adhered to the requirements of the AOSCA seed certification system or official Canadian OECD tags/labels if it meet the requirements of the OECD Seed Schemes.

Seeds Act and Seeds Regulations

The Canadian Food Inspection Agency (CFIA) is responsible for the administration and enforcement of the *Seeds Act* and the *Seeds Regulations*. The *Seeds Act* sets out the broad parameters of Canada’s seed regulatory framework while the *Seeds Regulations* describe in detail the requirements for compliance. There are many other laws, regulations and rules that apply to seed and agricultural products in general.

Introduction

Canada's seed system can be considered to be the sum total of the policies, laws, regulations, rules, procedures, organizations and individual choice that result in the availability of seed for planting. This document will focus on the formal seed sector governed by the *Seeds Act*, its related regulations and policies and other federal and provincial legislation. There is an emphasis on the institutional frameworks that include both federal government agencies and private sector organizations that make and administer rules. There is also an informal or 'alternative' seed sector that tends to operate on the margins or outside of the formal regulatory framework and this will also be discussed briefly.

The purpose of this document is to describe the Canadian seed system in sufficient detail so that seed sector stakeholders have a common understanding of the current system and can participate in a consultative process to determine the need and desire for changes.

The Lifecycle of a Seed

Before Canadian seed can be sold or planted, it goes through a number of important steps. Many of these steps are specified in regulations, policies, and guidelines, and together they make up the lifecycle of a seed in Canada.

These steps include: 1) New seed variety is developed, 2) Variety is approved/registered, 3) Seed crops are grown, 4) Seed crop is inspected and a crop certificate is issued, 5) Seed is harvested, cleaned and conditioned, 6) Seed is sampled, tested and graded, 7) Seed is certified, 8) Seed is imported, exported, and sold.

This simplified model is represented by the diagram on the following page, and outlines the major steps of the mainstream seed system as it currently exists in Canada. The section that follows the illustration of the model explores each of these steps in greater detail.

Note: The model represented on the next page is a simple representation of a complex system; as such, it does not delve into a number of complexities, including the different scope of resources required for each step, or overlapping provincial regulations and international treaties. The first layer represents the steps, the second layer represents the key players involved and the outer layer illustrates the primary acts, regulations or procedures involved.

A simplified illustration of the current seed system in Canada

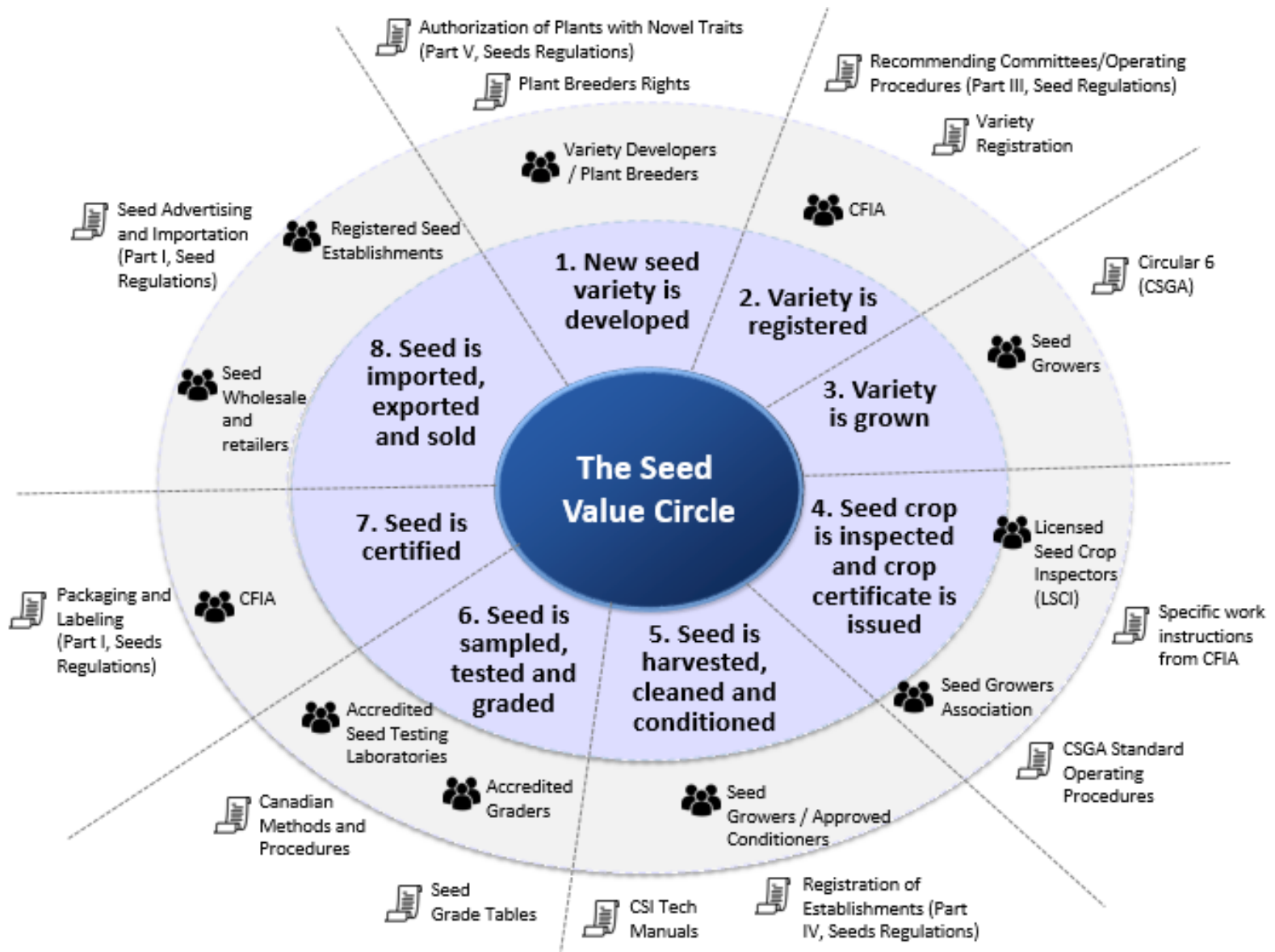


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1. A New Seed Variety is Developed

New and improved varieties of plants provide immeasurable value to society. Whether it is higher yielding, pest resistant wheat varieties or ornamental plants for public or private gardens, new plant varieties can be valuable contributors to societal improvement. New varieties of agricultural crops may be higher yielding, more resistant to pests or have improved quality/processing traits.

What is Variety Development?

New seed varieties are regularly being developed by large and small plant breeding institutions, both in Canada and abroad. There are a number of ways in which new seed varieties are developed, including conventional plant breeding, utilization of recombinant DNA (rDNA) technologies, and more recently, gene-editing techniques.

Variety development continues to rely on conventional breeding techniques that identify genes and traits, introduce beneficial genes, modify existing genes and remove detrimental ones, including the use of a range of very precise tools, increasingly including protein-based marker assisted and DNA-based genome assisted breeding. Additional plant breeding innovations are also used in breeding programs such as r-DNA and gene editing techniques. Genetic engineering (GE) via rDNA, which produces genetically modified (GM) plants (sometimes referred to as GM organisms or GMOs), is perhaps the most talked-about plant breeding innovation.

There are various activities that contribute to the development of new, innovative varieties including:

- 1) Trait discovery
- 2) Elite germplasm development and maintenance
- 3) Plant breeding, including gene introgression and marker or genome assisted selection
- 4) Variety finishing/evaluation/characterization

History of Variety Development

For most of the 19th and 20th centuries, federal or provincial/university scientists and technicians conducted plant breeding of the major agricultural field crops in Canada. For example, the breeding of wheat at the Central Experimental Farm in Ottawa began soon after the farm was established in 1886. The Marquis cultivar, released in 1909, matured earlier and was more resistant to disease than Red Fife, the predominant wheat at the time. By 1918, Marquis was planted on more than 20 million acres from southern Nebraska to northern Saskatchewan.

By the 1970s and into the 80s, private sector plant breeding began to play a more prominent role. Starting with hybrid corn and then moving into soybeans and canola, private sector investments in plant breeding continued to grow, reaching \$110 million by 2012 (Canadian Seed Sector Profile, 2014).

Beginning in the 1990s, varieties derived through rDNA technologies began to be commercialized in Canada, primarily to confer novel herbicide tolerance to the modified plants but also to incorporate insect resistance traits (e.g. Bt corn) and introduce genetics that enabled hybrid canola seed production in an effective and efficient manner. However, GM traits are prevalent in only a small number of the crop types grown in Canada, although they are widely grown, e.g., canola, soybean and corn. Opposition to GE/GM plants and food derived from them soon began to grow, however, especially in Europe, which has approved GE/GM for food and feed purposes but few for cultivation. For the past 20

years, GM seed issues related to adventitious presence (unintended low levels of GM seed in non-GM seed) and asynchronous approvals, including Starlink corn and Triffid flax, have challenged the international seed and grain trade.

Latest Technologies in Variety Development

We are now on the verge of commercializing a whole new generation of plant varieties derived from the latest technologies – gene editing. Currently three main systems for gene editing have been developed:

- 1) Zinc-Finger Nucleases (ZFN)
- 2) Transcription Activator-Like Effector Nucleases (TALENs)
- 3) Clustered Regularly Interspaced Short Palindromic Repeats – CRISPR-associated protein-9 nuclease (CRISPR-Cas9) system

These systems enable the rapid introduction of targeted genetic modifications in existing genes. Recently, the CRISPR-Cas9 system was named by the journal *Science* as the Breakthrough of the Year for 2015.

These technologies may not be subject to regulation the same way that GM technologies are. The legislation/regulations in many countries specify rDNA technologies as the process that is subject to regulation and this will need to be changed if a jurisdiction decides to regulate crops derived from these newer technologies. In Canada, the regulatory trigger is the ‘novelty’ of the trait, crop or food and is therefore product based, meaning products derived using these new processes may be subject to regulation depending on whether the product is novel or not. However, the regulatory system, developed in the mid-1990s remains ambiguous to plant breeders and trait developers.

Canada’s Current Seed Intellectual Property (IP) Toolbox

Intellectual property rights are a recognition of the efforts to bring new and beneficial innovation to Canadian society. Inventors have the “right” to protect their inventions (intellectual property) and to be remunerated for their use. This encourages further innovation to make better use of resources and generate wealth for Canadian society as a whole.

The Seed Intellectual Property Toolbox currently available to plant innovators contains five distinct tools that attempt to protect innovation investments in the seed sector:

- 1) Plant Variety Protection (found in the *Plant Breeders’ Rights Act*)
- 2) Trade secrets
- 3) Trade-marks
- 4) Contracts
- 5) Patents

Canada’s *Plant Breeders’ Rights Act* was first introduced in 1990 and recently updated in 2015. The holder of a plant breeder’s right has exclusive rights in relation to propagating material of their variety.

Under the updated *Plant Breeders’ Rights Act* the exclusive rights available to the rights holder are expanded to include reproduction, export, import, conditioning and stocking of propagating material of the plant variety. The rights also extend to harvested material, but only in cases where the harvested material has been obtained through the unauthorized use of propagating material and the rights holder has not had reasonable opportunity to exercise their rights.

The *Plant Breeders' Rights Act* complies with the international treaty for protection of plant varieties referred to as UPOV. The UPOV treaty was developed specifically by governments for the international seed industry and reflects seed business practices and the technology available.

Four of these tools – trade secrets, contracts, trade-marks and patents – are broadly used to protect innovation in many industries. Their use to protect seed innovation is currently limited as they must be adapted for their effective application in the seed business.

1) Plant Variety Protection, as set out in the *Plant Breeders' Rights Act*

A plant variety protection right is granted to the breeder of a new plant variety that gives that breeder exclusive control over use of the propagating material of the new variety for a limited number of years. The breeder must demonstrate the new variety is distinct, uniform and stable to receive this right. In Canada, plant variety rights are granted to breeders pursuant to the *Plant Breeders' Rights Act*.

2) Trade Secrets

Trade secrets consist of certain information, expertise or knowhow that has been developed by innovators. This knowledge gives developers a competitive edge in the market and once known, can be broadly used by others.

3) Trade-marks

A trade-mark is a word (or words), a number (or numbers), a design, or a combination of these, used to identify the goods or services of one person or organization.

4) Contracts

A contract is an agreement between parties to do or not do something. Contracts are commonly used to outline the terms of the transfer of goods and services. Valid contracts consist of an offer, acceptance, and consideration. Parties to the contract must be capable of contracting and must signify the intention to create a legal contract.

5) Patents

A patent is a right, granted by government, to exclude others from making, using, or selling your invention in Canada. A patent consists of a set of exclusive rights granted to an inventor for a limited period of time, in exchange for the public disclosure of the invention. Patents are issued by the Canadian Intellectual Property Office (CIPO) if specific requirements are met by the applicant.

A patentable trait or event is defined as “a distinguishable and useful characteristic of an organism that is the product of human intervention.” As such, the patented article can be claimed as a gene or a set of genes that operate within the plant by conferring a beneficial trait.

A patentable plant cell /plant variety is defined as “a distinguishable and useful assemblage of genes that is the product of human intervention.” As such, the patented article can be claimed as a set of genes that operate within the plant by conferring a beneficial set of traits.

2. The Variety is Registered

What is Variety Registration?

Variety registration is a process that results in the official verification that a seed variety is new, distinguishable from other varieties, relatively uniform in its essential characteristics, and stable. The identity of a variety is determined by its breeding history and is defined by the description of variety (DoV) and a legal reference sample. The variety registration process requires that a legal reference sample of seed of the variety be submitted to the Canadian Food Inspection Agency (CFIA). The CFIA validates the draft DoV submitted by the plant breeder by growing plants and confirming the distinguishing characteristics described in the DoV.

History of Variety Registration

In Canada, the legal prohibition on the sale of seed of varieties that had not been registered began in 1923. Prior to this the Canadian Seed Growers' Association (CSGA) registered seed crops and varieties on a voluntary basis. Agricultural field crops as well as vegetable varieties were initially subject to variety registration or licensing as it was called at the time.

By 1927, the *Seeds Act* had been amended to allow for the refusal to register varieties of “inferior quality”. Over time, this changed so that new varieties had to be “better than” the average varieties of the day. This was later changed to “equal to or better than”.

In 1996, the *Seeds Regulations* were amended and the list of crop kinds subject to variety registration (Schedule III) was created. Prior to this, only vegetables, roots, flowers, herbs, trees and shrubs were exempt from variety registration. Several years later, at the request of stakeholders, hybrid corn and turf-type varieties of grasses were exempted from variety registration. Since then, as new crop kinds were introduced to Canada (e.g., Carinata, Camelina, Hemp) it would have taken an amendment to the *Seeds Regulations* to bring them into variety registration and this was never done.

Over the past 15 years, Canada's variety registration system has been the subject of almost continuous review. In 2009, amendments to the *Seeds Regulations* introduced a three-tiered, flexible variety registration system and in 2014 oilseed soybeans and forage crops were moved from Part I of Schedule III (which requires testing and merit assessment under an approved recommending committee) to Part III (which requires basic information and a sample to be provided to the Variety Registration Office of the CFIA). The CFIA has also recently introduced model operating procedures for variety registration recommending committees.

The most recent round of consultations on the variety registration system confirmed that pre-market characterization of quality is especially important to the success of new varieties, especially for the majority of stakeholders in those crop sub-sectors where quality is a determining factor affecting commercial acceptance (e.g., milling wheat, malting barley, oats, canola).

There are examples where the commercialization of new varieties in Canada/North America was delayed pending foreign market approvals. This can be very expensive for companies, as they may have invested substantially in the new varieties (\$10sM) and have to wait an additional year or more to begin

to get a return on that investment. The corn, soybean and canola sectors have all had to manage the commercialization of varieties with new traits that had not yet received authorization in export markets.

Form 300

For varieties of crop kinds that are not subject to variety registration in Canada (e.g., corn, chickpeas, food grade soybean, etc.) the CSGA has implemented a system for the determination of the eligibility for seed crop certification¹ of new plant varieties. The Form 300 process is only required where the variety has not previously been accepted for certification by a foreign official seed certifying agency. So, for example, a hybrid corn variety that has previously been certified by the Illinois Crop Improvement Association would not have to complete the Form 300 process prior to production in Canada. In order to produce such a variety in Canada, however, an official description of the variety (and its inbred components in the case of hybrids) must be provided to the CSGA. The CFIA may also request a standard sample of the variety from the seed certifying agency for variety verification purposes.

3. Seed Crops are Grown

Initially, only a small quantity of seed of a new variety is available. In order to produce the quantities needed to commercialize a new variety, several years of seed production are required. This “multiplication” of seed of the variety is undertaken by seed growers, in accordance with specific regulations and procedures for growing pedigreed seed crops in Canada, outlined in a document called Circular 6.

Circular 6

The CSGA is responsible for the *Canadian Regulations and Procedures for Pedigreed Seed Crop Production*, commonly known as Circular 6. This document sets out the requirements to produce pedigreed seed crops in Canada including conditions respecting previous land use, isolation of the seed crop from contaminating pollen sources and freedom from prohibited noxious weeds. Circular 6 sets out standards for varietal purity as well as relative freedom from plants whose seeds are difficult to separate from the seed crop.

The CSGA’s Standards and Circular 6 Committee has been established to review, evaluate and propose revisions to Circular 6 on an annual basis. In addition to seed growers drawn from the CSGA’s Board of Directors, the Committee’s members include representatives from the CFIA, the Canadian Seed Trade Association (CSTA), the Commercial Seed Analysts Association of Canada (CSAAC), provincial departments of agriculture and public plant breeders.

The CSGA assures Breeder seed quality through its *Canadian Regulations and Procedures for the Production of Breeder Seed Crops*, which include requirements for professional recognition of Breeders, audited Quality Management Systems, and seed lot testing for adherence with federal seed grade standards. The CSGA’s Plant Breeders’ Committee has a formal process for recognition of plant breeders. Only CSGA recognized plant breeders can enter Canadian developed varieties into the Canadian seed certification system. Seed of foreign varieties is eligible for certification in Canada if

¹ Certification: the provision by an independent body of written assurance that the product, service or system in question meets specific requirements.

certified in the country of production or if the seed has been recognized by the CSGA as Breeder or Select seed.

4. The Seed Crop is Inspected and a Crop Certificate is Issued

In order for seed to be certified, the seed crop from which the seed is derived must undergo an inspection.

Applying for Seed Crop Certification

Seed growers submit applications for seed crop certification to the CSGA. CSGA staff review applications for seed crop certification upon receipt. If the application is incomplete or if there are any discrepancies, CSGA staff will request additional information. In some cases, the application may indicate that the crop is not eligible for certification (e.g., if the previous land use does not allow for certification of the proposed seed multiplication).

Once an application for seed crop certification has been accepted by the CSGA it is forwarded to the authorized seed crop inspection service (ASCIS) identified in the application by the applicant. The ASCIS has two business days to accept or reject the request for services.

An application for seed crop certification must include information pertaining to the seed that has been planted that enables the CSGA to verify its eligibility to produce a pedigreed/certified seed crop. This information may take several forms and depends on the type of seed and other variables.²

What is Crop Inspection?

The principal elements of a seed crop inspection include verification of previous land use, the isolation of the seed crop from contaminating pollen sources, potential mechanical impurities and the varietal purity of the crop. Field inspection of a growing seed crop is intended to check that the distinguishing

² This information may take several forms:

- 1) In most cases, a copy of the official CFIA tag indicating that the seed planted was Foundation or Registered class seed duly certified and purchased either in sealed containers or, if in bulk, delivered by a bulk storage facility.
- 2) In cases where a seed grower is using "own seed", the seed does not have to be certified but a crop certificate must have been issued in the name of the seed grower for the seed planted.
- 3) In the case of imported seed, the seed will have been imported with certification labels from an official seed certifying agency that is a member of AOSCA or that participates in the OECD Seed Schemes.
- 4) Plant breeders recognized by the CSGA can enter Breeder class seed of varieties into the seed crop certification system for the production of Breeder, Select, Foundation, Registered or Certified seed, depending on the crop kind; in order for seed to be recognized by the CSGA as Breeder class seed the plant breeder must submit a completed *Application for Breeder Seed Crop Certificate* (Form 43).
- 5) Plot producers accredited by the CSGA can enter Select class seed of varieties into seed crop certification for production of Breeder, Select, Foundation Registered or Certified seed crops, depending on the crop kind; in order for a seed crop to be recognized by the CSGA as Select class the plot producer must submit a completed *Report on Plot Production* (Form 50) and a sample of the seed for variety verification testing.
- 6) The CSGA will also pedigree seed of experimental lines (pre-variety germplasm); this initial documentation of the multiplication of seed enables further production and future certification should the line demonstrate commercial potential; experimental lines are often designated 'EXP' followed by a numerical code.

characteristics of the variety are present (varietal identity) and to ensure that other varieties/off-types (varietal purity) and species that are difficult to separate or identify in a laboratory (species purity) are within acceptable tolerances.

Seed crops may be inspected frequently during the growing season but all seed certification systems require that an authorized seed crop inspector inspect the seed crop at least once. The inspection is normally scheduled when the varietal identity and varietal purity are best assessed. Many crops are inspected during the flowering period but some (e.g., soybean) are best observed at full maturity.

In order to assess varietal purity, inspectors select six sample areas within the seed crop comprising of approximately 10,000 plants and make detailed observations within this sample area. Off-type plants and acceptable variants (as described by the plant breeder and included in the description of variety) are noted as well as certain other “difficult to separate” crop kinds and weeds. The general condition of the field and the presence of “objectionable weeds” is also noted.

Report of Seed Crop Inspection

A Report of Seed Crop Inspection is completed by the inspector and submitted to the CSGA for appraisal. The appraisers are particularly interested in the isolation of the seed crop from adjoining crops, the results of the six counts and difficult to separate crop kinds and weeds. In general, for Certified status the average number of off-types/other varieties per count shall not exceed 5 with the exception of soybeans where the number is 20. These are exceptionally high standards (99.95 and 99.8 per cent varietal purity, respectively). Under the Association of Official Seed Certifying Agency (AOSCA) rules, the equivalent numbers are 10 and 50 while under the OECD Seed Schemes the minimum standards are 99.7 and 99 per cent varietal purity in the field, respectively.

Privatization of Seed Crop Inspection

Historically, the inspector has been an employee of the official seed certifying agency (e.g., the CFIA in Canada) but beginning in the mid-90s some jurisdictions began experimenting with private inspection under official supervision. In Canada, some hybrid seed corn inspections were permitted under a “first party” model (inspection by employees of the seed production company) in the late 90s followed by hybrid seed canola inspections under a “third party” model. In total, these amounted to about 5 per cent of the acres/fields in certification.

In 2012, the Canadian government decided that seed crop inspection should be largely privatized. Alternative service delivery (ASD) of seed crop inspection was one of 33 CFIA Deficit Reduction Action Plan (DRAP) projects. It was intended to save \$1.8 million annually with a reduction of 20 full time equivalents (FTEs) beginning in 2014.

As a result, the CFIA and the seed sector (as represented by the CSGA, the CSTA and the CSI) worked together to develop and implement ASD of seed crop inspection based on a third party model with 9 seed crop inspection regions across Canada. Authorized seed crop inspection services (ASCIS) employing licensed seed crop inspectors (LSCI) conducted 89 percent of the seed crop inspections in 2014, rising to 94 percent in 2015, and 96 percent in 2016.

Issuing a Crop Certificate

If the Report of Seed Crop Inspection indicates that the requirements of Circular 6 have been met, the CSGA will issue a Seed Crop Certificate indicating the crop met the certification requirements of the CSGA. The certificate identifies the seed grower, the field number, and the area of production.

5. The Seed is Harvested, Cleaned and Conditioned

The seed grower is responsible for the harvest and initial handling of the seed crop and ensuring that it does not become mixed with any other seed. This requires extreme care to make sure that all equipment, especially the combine but also augers and bins, are completely cleaned prior to handling the seed crop. There are no specific rules or regulations governing this step in the seed certification process and it is not subject to inspection. However, it is one of the most critical control points in the whole system.

The seed grower must sign the crop certificate, attesting that the seed has not become mixed with any other seed while in the grower's possession and declare of the quantity of seed that has been harvested, before it is cleaned.

The processing of pedigreed seed is strictly controlled and subject to the *Seeds Regulations*. Only the grower of the seed or an establishment registered as an approved conditioner (AC) under part IV of the *Seeds Regulations* is permitted to "prepare" seed of pedigreed status, that is, to clean, treat, sort, size, package or any other activity that changes the nature of the seed lot.

When a seed grower delivers pedigreed seed to an AC for cleaning the grower must provide the operator of the AC, or the accredited grader at the premises, with the signed Crop Certificate attesting that the seed has not become mixed with any other seed while in the grower's possession and the quantity of seed harvested from the area indicated on the certificate. Meanwhile, the operator or the grader at the AC must also sign off on the total quantity of seed conditioned and eligible for grading, tagging and sealing (seed certification).

Seed Conditioning involves applying a seed treatment to the seed. In many cases, the seed is conditioned with pesticide seed treatments. This is where the pesticide is embedded in an inert applied coating to each seed which offers significant health and environmental benefits over other modes of application (e.g. foliar sprays). For example, by applying the pesticide directly to the seed, significantly less active ingredient is required to treat a given area, reducing the overall amount of active ingredient used and minimizing potential impacts on non-target and beneficial organisms.

Pesticides intended for use as seed treatments are subject to the federal *Pest Control Products Act* (PCPA) in Canada. As such, they are subject to an extensive pre-market regulatory approval process that assesses their safety, efficacy, and value before they can be registered for sale or use in Canada. Since the pesticide and the proposed use pattern are both evaluated during this process, pesticide-treated seeds themselves are exempt from registration under Schedule II of the *Pest Control Product Regulations* (the Treated Article Exemption) so long as certain key requirements are met ([these are outlined in more detail here](#)).

6. The Seed is Sampled, Tested and Graded

Methods for Sampling and Testing

Recognized standard methods for seed sampling and testing are defined in the *Seeds Regulations* as one of the following:

- 1) The *Canadian Methods and Procedures for Testing Seed (M&P)*
- 2) The *Rules for Testing Seed* published by the Association of Official Seed Analysts
- 3) The *International Rules for Seed Testing* published by the International Seed Testing Association

Although the three rules differ in some details, the purpose of each is to ensure that a seed test result is a reliable estimate of the average seed lot quality. The Canadian M&P is specifically designed to provide assurances that Canadian seed regulatory requirements have been met under the Canadian seed grading system.

Seed Grades

Canada has a grading system for seed, which means that most seed is labelled with a grade name when it is sold in Canada. The grading system has been a feature of Canada's seed regulatory framework for over 100 years. It provides a simple but effective way to communicate seed quality information from the seller to the buyer. The grade name conveys information about the pedigreed status of the seed (e.g., Foundation, Registered, Certified or common) and it contains an indication of the relative quality of the seed (e.g., No. 1 or No. 2).³

Seed grades have been a feature of the Canadian seed regulatory framework since its earliest days. In contrast, seed labelling requirements in the United States are based on "truth in labelling" meaning that the seed must be labelled with information as to its germination and weed seed content.

Under the *Seeds Act* the term "grade" includes any class of seed. Thus, both pedigreed and non-pedigreed (common) seed may be required to be graded and to be labelled when sold with the appropriate grade name. Anyone can label seed with a non-pedigreed grade name but only individuals accredited by the CFIA as graders are allowed to assign a Canada pedigreed grade name to a seed lot.

Seed Standards

Part I of the *Seeds Regulations* prescribes the requirements for seed quality - including sampling and grading – packaging, labelling and importation of seed. The specific standards for germination, weed seeds and other crop seeds are found in Schedule I to the Regulations, commonly referred to as the Grade Tables. There are 22 different tables with seeds of similar size and use being grouped together (e.g. Table VII has black, brown and white mustard, canola, oilseed radish and forage radish).⁴

³ For example, Canada Certified No. 1 wheat seed cannot have any noxious weed seeds per kilogram, a total of up to 3 other weed seeds per kilogram and must have a germination of at least 85% whereas Common No. 2 wheat seed can have up to 4 noxious weed seeds per kg, as many as 20 other weed seeds per kg and a germination rating as low as 70%.

⁴ The *Seeds Regulations* require that all seed meet minimum standards for seeds of other species and for labelling of seed when sold. In particular:

- 1) All seed shall not contain prohibited noxious weed seeds – paragraph 7(1)(a).

7. The Seed is Certified

What is Seed Certification?

The CFIA is the official seed certification body for Canada. Seed derived from a seed crop that meets both the process and product standards specified by the CSGA (Circular 6) may be labelled with an official seed certification label/tag by an RSE that is audited by CSI if it is handled and processed as specified by the Regulations and meets the product standards set out in the Regulations.

The main aspects of the seed certification system include many of the steps previously outlined in this document, specifically the following:

- 1) Planting eligible stock seed and adherence to the requirements of Circular 6;
- 2) Inspection of the seed crop by an authorized seed crop inspector;
- 3) Seed processing by an establishment registered by the CFIA as an Approved Conditioner;
- 4) Seed sampling by an individual licensed by the CFIA;
- 5) Seed testing by a CFIA accredited analyst working in a CFIA accredited seed testing laboratory;
- 6) Seed grading by an individual accredited to do so by the CFIA;
- 7) Seed labelling (official tags) by or under the supervision of a licensed operator of a registered seed establishment or an accredited grader.

Seed that is officially certified must be sold in sealed packages unless it is delivered by an establishment that is registered by the CFIA as a Bulk Storage Facility.

Labelling Pedigreed Seed

A pedigreed seed declaration must be completed by the operator/grader within 30 days of conditioning or grading seed of pedigreed status. The pedigreed seed declaration includes detailed information pertaining to the seed lot including the seed grower's name, crop certificate number, quantity of seed and the quality of the seed. The act of assigning a Canada pedigreed grade name and the subsequent labelling of seed with an official certification label/tag is the point at which seed is certified.

All pedigreed seed when sold in Canada must be labelled with an official certification tag/label. These are issued or approved by the CFIA or, in the case of imported seed, by the official certifying agency in

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- 2) All seed shall have been subject to appropriate mixing, blending and processing techniques so that it is as uniform as practicable – paragraph 7(1)(a.1).
 - 3) Seed of the kinds set out in Schedule I shall meet the standards set out in that Schedule – subsection 6(1)
 - 4) Seeds of kinds not set out in Schedule I shall meet the standards for “other species” set out in the appropriate table of Schedule I based on seed size – subsection 6(2).
 - 5) All seed shall be sampled and tested in accordance with a recognized standard method – paragraph 11(1)(c) and subsection 12(1).
 - 6) Seed shall not be labelled with any incorrect or misleading information or mark – paragraph 15(2)(b).
 - 7) Every package containing 50 g or more of seed (25 g in the case of tobacco) shall be marked with the net quantity of seed – subsection 19(1).
 - 8) Every package containing more than 5 kg of seed shall be marked with the lot designation of the seed – subsection 19(5).

the foreign country. Seed in sealed (fastened) containers is labelled with an official tag while seed that is sold and delivered in bulk may have a bulk pedigreed seed statement issued in respect of the seed. About 10 years ago, the CFIA began authorizing companies to print official tags pursuant to a contract. Currently, 31 companies are authorized to print over 9 million official tags annually.

8. The Seed is Imported, Exported and Sold

Seed is harvested in Canada beginning in July (winter cereals and some forage crops) through to November in some locations (soybeans). Seed may be conditioned soon after harvest or many months later. In either case, and no matter when the seed was tested and then subsequently sold, it is the vendor's responsibility to ensure that the seed, when sold, meets the guarantees implicit in the grade that the seed has been labelled with.

Seed of small-seeded crop kinds (e.g., forage grasses and legumes, canola) is normally sold in 25 kg sealed packages whereas large-seeded crop kinds such as wheat are usually sold "in bulk" or by the truck-load. Hybrid seed corn is usually sold in "units" of 80,000 kernels and often by contracted farmer-dealers; soybeans are often sold in "mini-bulks" of 1,000 kg which may be sealed and labelled with an official tag. There were 849 bulk storage facilities (BSF) registered in Canada in 2015. Only BSF are permitted to "deliver" certified seed to a purchaser in bulk; the authorization of a BSF by the CFIA to store seed graded with a Canada pedigreed grade name in bulk is essentially an exemption from the requirement that such seed be in "fastened" containers. Anybody can sell certified seed in sealed containers but only a BSF can sell certified seed in bulk.

The definition of "sale" in the *Seeds Act* is very broad and includes "agree to sell, or offer, keep, expose, transmit, send, convey, or deliver for sale, or agree to exchange or to dispose of to any person in any manner for a consideration". This broad definition has sometimes been problematic when trying to determine exactly when a sale takes place and whether all of the requirements of the Act and its regulations are in fact satisfied at that time.

Imported seed, and seed grown for export, are exempt from certain requirements that pertain to domestic seed but must follow specific processes.

Imports – Regulatory Requirements

Imported seed must meet the minimum standards established for seed, most often the Common No. 2 grade standard, unless it is imported for the expressed purpose of cleaning/conditioning. However, all imported seed must be free of prohibited noxious weed seeds. Imported seed is exempt from most labelling requirements at the time of import but must be labelled before sale. If imported seed has been treated with a pest control product it must be stained and labelled accordingly at the time of import.

Imported seed must be accompanied by an import declaration providing information on the kind, quantity, variety name, lot designation, importer and exporter and by a seed test report showing the seed has been tested as required by the Regulations. Small lots (under 500 g for small seeded kinds or under 5 kg for large seeded kinds) are exempt but must still meet the minimum seed quality standards. Authorized Importers can provide the required information after importation. All others are subject to a seed import conformity assessment by the CFIA prior to distribution or sowing of imported seed. Imported seed is subject to Canadian phytosanitary requirements and may require a permit from the

CFIA or be accompanied by a phytosanitary certificate issued by the appropriate authority in the country of origin of the seed.

Exports – Regulatory Requirements

Exported seed is exempt from most requirements but if treated with a pest control product it must be properly labelled. Canada exports both pedigreed/certified seed and non-pedigreed/common seed. Certified seed is labelled with either official Canadian certification tags/labels if it has adhered to the requirements of the AOSCA seed certification system or official Canadian OECD tags/labels if it meet the requirements of the OECD Seed Schemes.

There are some RSE that have been authorized to certify seed pursuant to the OECD Seed Schemes under the official supervision of the CFIA. These Authorized Exporters can sample seed lots and submit samples to an Authorized Exporter Laboratory, usually for testing under the ISTA Rules for seed destined for Europe. This program was established in response to complaints from stakeholders that CFIA export certification services were not timely.

Non-pedigreed, Common and Other Types of Seed

Canada's seed regulatory system recognizes both pedigreed/certified seed as well as non-pedigreed/common seed. Pedigreed/certified seed is seed that has been produced and handled according to strict procedures established and administered by the CFIA and the CSGA; non-pedigreed/common seed has to meet minimum quality standards for weed seeds, germination and labelling but is not subject to packaging or processing requirements. Seed of most agricultural field crops cannot be sold by variety name unless the seed has been certified.

Canada is unique in so far as it permits the sale of non-pedigreed (common) seed but does not allow it to be sold by variety name. This is in contrast to other jurisdictions, for example the European Union, that do not permit non-certified seed or the United States where non-pedigreed (common) seed can be sold by variety name.

The prohibition on the use of the variety name when selling common seed has been interpreted by some, as permission to sell unregistered varieties as common seed. This is not, in fact, the case and all commercial seed in Canada of crop kinds that are subject to variety registration should be derived from registered – or at least, previously registered – varieties.

Common seed is subject to seed standards and labelling requirements, both of which are less onerous than those for pedigreed seed. Individuals do not need to be accredited nor establishments registered to engage in activities that result in the sale of common seed. Over the past 20 years, CFIA data has consistently shown that common seed is (with the addition of tolerances) only 85 per cent compliant with the Regulations while pedigreed seed, which has to meet higher standards, is 95 per cent in compliance.

At one time, common seed was not just a synonym for “non-pedigreed” but actually inferred that it was of unknown, or at least uncertain, origin. These days, it may be quite clear that the seed in question was grown from Certified seed of variety X and is in fact variety X, but it is common seed and cannot be sold by variety name (in most situations).

In addition to pedigreed seed of the agricultural crop kinds grown in Canada, there are other “groupings” of seed that need to be considered to more completely portray the Canadian seed system. These can be broadly summarized as follows:

- 1) Farm-saved seed – the vast majority of western Canadian cereal and pulse acres are planted with farm-saved seed. This is seed that, for the most part, is one to several years removed from Certified seed. This is – or should be – seed of registered varieties.
- 2) Commercial common seed – this is seed of the main agricultural crop kinds, including cereals, pulses and forage seed that is sold to farmers for crop production. It is generally, and certainly should be, seed of (or derived from) registered varieties and graded with the Common No. 1 or Common No. 2 grade name when sold. It cannot, in most cases, be sold by variety name.
- 3) Vegetables, Herbs and Flowers – there are two distinct markets for vegetable, herb and flower seeds: the home gardener and the commercial producer. This seed is generally not pedigreed for varietal identity and varietal purity but it can be sold by variety name.
- 4) Lawn and Turf – the main market for common seed of lawn and turf species is the home gardener. Commercial producers, e.g., golf courses, sod producers, landscape architects, etc., are inclined to use Certified seed and to demand product specifications that exceed the requirements of the *Seeds Regulations*.
- 5) Native plants, land reclamation, heritage varieties, complex mixtures etc. – is a small but growing segment of the Canadian seed system. There is huge potential for further growth especially in light of local food initiatives, eco-agriculture trends and climate change initiatives on the part of governments.

Native Plant or Pre-Variety Germplasm Certification

Native seed sold for restoration of wetlands, reseeding of highway roadsides and revegetation for mines and pipelines may require third party assurance certification of origin or identity. Several U.S. states have native plant certification programs that certify to the Pre-Variety Germplasm standards of the Association of Official Seed Certifying Agencies (AOSCA). The CSGA has developed a similar native plant certification program for Canada.

Many important seed sources in the native plant industry have no place within the traditional pedigreed seed certification system because they simply do not fit the legal definition of a variety. Varieties are legally defined as distinguishable, uniform and stable and often require a long term investment in plant breeding and testing which is difficult to justify for native plants with limited acreage market potential. More importantly, the selection intensity of traditional crop breeding programs is often not appropriate for native plant species where maintaining genetic diversity (for reclamation and conservation plantings) may be more valuable than specific agronomic characteristics.

Informal Seed Sector

Around the world, many groups are working to improve seed supply to farmers in developing countries in order to increase agricultural productivity, nutrition and rural well-being. From 2007 to 2012, for example, 50 per cent of the World Bank’s 191 projects promoting sustainable agriculture, totaling \$513 million, had a seed system component.

At the international level, the informal seed sector has been defined as the total of seed production activities of farmers, mostly small scale farmers, and includes plant selections, seed multiplication, storage and limited distribution. It may sometimes be referred to as a ‘local’ or ‘farmers’ seed system.

In many developing countries, this is the source of most seed for planting and it is, therefore, of extreme strategic importance for national food production and security.

In Canada, in addition to the formal seed sector, which includes variety registration, seed certification and official oversight, there is a growing informal sector comprised of seed savers, seed libraries, participatory plant breeding, heritage varieties and new and/or exotic crops. Much of the attention is directed to vegetable crops but there is also interest in “ancient grains”, heritage varieties of wheat, and new crops. While some of the activities associated with these interests is clearly exempt from the *Seeds Regulations* (e.g., varieties of vegetable crops are exempt from variety registration) some of them are not (all wheat varieties are subject to variety registration). In all cases, seed must meet weed seed standards when imported or sold.

Seed Sector Legislation and Regulation

History of the Seed Legislative Framework

The formal seed system in Canada is a modern, complex structure that has developed over more than 100 years in response to the needs of the agriculture and food system. Its origins can be traced to complaints from farmers in the early 1900s about the quality of (mostly forage) seed that was available for planting. The Dominion Department of Agriculture conducted surveys of commercial seed and established a seed testing laboratory in 1902. The results demonstrated that the farmers’ complaints were well founded and in 1905 parliament passed the *Seed Control Act*. This first legislation was focused on the control of weed seeds in commercial grass and legume seeds intended for pasture and hay production. By 1923, cereals, vegetables and root crops were subject to regulation and variety registration was introduced as the importance of new and improved varieties gained prominence.

The *Seeds Act* has been amended on three separate occasions over the past several years:

- 1) *Budget Implementation Act* of 2012 - included amendments to the *Seeds Act* to ensure that there was clear authority for the CFIA to license seed crop inspectors in anticipation of the privatization of this activity in 2014.
- 2) *Agricultural Growth Act*, 2015 - included many amendments of a “housekeeping” nature. Of particular note are i) regulation making authority “requiring persons to prepare, keep or maintain documents and to provide the Minister or an inspector with, or with access to, those documents” and ii) authorization of incorporation by reference as a regulatory “tool”.
- 3) *Safe Food For Canadians Act* – included amendments resulting from the revocation of the *Canada Agricultural Products Act*, which has provided the authority to make regulations respecting seed laboratory accreditation and the registration of seed establishments. This does not come into force until regulations are made (expected in 2017).

Seeds Act and Seeds Regulations

The Canadian Food Inspection Agency (CFIA) is responsible for the administration and enforcement of the *Seeds Act* and the *Seeds Regulations*. The *Seeds Act* sets out the broad parameters of Canada’s seed regulatory framework while the *Seeds Regulations* describe in detail the requirements for compliance.

The *Seeds Act* focuses on two principal “prohibitions”:

- 1) No seed shall be imported into or sold in Canada unless it meets minimum requirements set out in the Regulations with respect to quality (e.g., relative freedom from weed and other crop seeds; minimum germination levels; disease) and is packaged and labelled as required;
- 2) No seed of a variety of a crop kind listed in Schedule III to the Regulations shall be imported into or sold in Canada unless the variety has been registered as prescribed by the Regulations.

The main emphasis of the *Seeds Regulations* is on agricultural seed although all seed, including vegetables, herbs, flowers, turf and other miscellaneous seeds, are subject to standards for weed seeds. The Regulations do provide for some exemptions to the above noted prohibitions for specified purposes such as seed production of unregistered varieties in anticipation of variety registration or for export.

The layout of the *Seeds Regulations* is as follows: :

- 1) Section 2, Interpretation - Over 45 words, terms and expressions are defined in s. 2, from “biotechnology” to “variety name”.
- 2) Part I, Seeds other than Seed Potatoes - deals with seed standards, sampling, testing, grading, packaging and labelling as well as the use of variety names. There are also sections on advertising, seed crop inspection and seed importations.
- 3) Part II, Seed Potatoes – sets out the requirements for certification of seed potatoes, including standards, testing and labelling requirements. The CFIA is wholly responsible for seed potato certification including field production standards/inspection as well as tuber standards/inspection, although some tuber inspections are conducted by authorized producers under official supervision.
- 4) Part III, Variety Registration - the requirements for the Minister to approve recommending committees are set out in s. 65.1. Applications for registration, eligibility requirements of varieties and other requirements are set out in Part III.
- 5) Part IV, Registration of Establishments that Prepare Seed and the Licensing of Operators - there are three types of registered seed establishments: i) approved conditioners that prepare (clean, process, pack, treat, etc.) seed of pedigreed status; ii) bulk storage facilities that store seed graded with a Canada pedigreed grade name in bulk (i.e., not in sealed containers) and iii) authorized importers that are able to import seed on minimum documentation and ensure that an import conformity assessment has been completed before further distribution or planting.
- 6) Part V, Release of Seed – deals with seeds with novel traits and the requirements for notification, information, decision of the Minister, confined releases and unconfined releases.

Other Acts and Regulations

There are many laws, regulations and rules that apply to seed and agricultural products in general. Of particular note are the following:

Plant Breeders’ Rights Act

The *Plant Breeders’ Rights Act* is administered by the Plant Breeders’ Rights Office of the CFIA. Plant Breeders’ Rights (PBR) are a form of intellectual property rights by which plant breeders can protect their new varieties. Amendments to the Act in 2015 brought Canadian legislation into conformity with the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 91). An effective plant breeders' rights system is intended to create an environment that encourages and supports the development of new plant varieties.

Plant Protection Act

The purpose of the *Plant Protection Act* is to protect plant life and the agricultural and forestry sectors of the Canadian economy by preventing the importation, exportation and spread of pests and by controlling or eradicating pests in Canada. The Plant Protection Division in the Plant Health and Biosecurity Directorate of the CFIA has various sections that deal with grains and oilseeds, horticulture, forestry and international standards. The CFIA is Canada's National Plant Protection Organization (NPPO) and represents Canada at meetings of the International Plant Protection Convention (IPPC).

Pest Control Products Act

The purpose of the *Pest Control Products Act* is to protect human health and safety and the environment by regulating products used for the control of pests. It is administered and enforced by Health Canada's Pest Management Regulatory Agency (PMRA). A pest control product is defined as "a product ... that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects'.

Fertilizers Act

The Fertilizers Act is administered and enforced by the CFIA and regulates both fertilizers and supplements. A fertilizer is defined as any substance or mixture of substances, containing nitrogen, phosphorus, potassium or other plant food, manufactured, sold or represented for use as a plant nutrient; a supplement means any substance or mixture of substances, other than a fertilizer, that is manufactured, sold or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields.

Feeds Act

The Feeds Act is administered and enforced by the CFIA and regulates feed for livestock which means horses, cattle, sheep, goats, swine, foxes, fish, mink, rabbits and poultry and includes "such other creatures as may be designated by regulation as livestock" for the purposes of the Act.

Food and Drugs Act

The Food and Drugs Act is an Act respecting food, drugs, cosmetics and therapeutic devices.

Oversight of the Seed Sector

The CFIA is responsible for the administration and enforcement of the *Seeds Act* and its regulations. A key component of this responsibility includes its oversight of the seed certification system and in particular those persons who have been authorized to conduct seed quality determinations in support of certification. This includes:

- 1) Licensed seed crop inspectors (LSCI) and Authorized Seed Crop Inspection Services (ASCIS) – approximately 10 per cent of seed crops are "check inspected" by official CFIA inspectors to monitor the ongoing competency of the LSCI. In addition, ASCIS are subject to an annual audit to ensure that they continue to implement their documented quality management system.

- 2) Licensed samplers, accredited graders and licensed operators of registered seed establishments (RSE) – the CFIA has an agreement with the Canadian Seed Institute (CSI) whereby the CSI is authorized to monitor the RSE system and recommend individuals and companies for annual renewal. RSEs are subject to a CSI audit on a frequency determined by its past performance. The CFIA will also conduct “spot” check inspections of RSEs and draws samples of pedigreed seed as part of its marketplace monitoring program.
- 3) Accredited seed testing laboratories and accredited analysts – seed testing labs are accredited by the CFIA. The CFIA’s Seed Science and Technology Section (SSTS), Saskatoon Laboratory is responsible for the initial audit and accreditation of seed labs and the CSI is responsible for subsequent audits. The SSTS works closely with the Commercial Seed Analysts Association of Canada on proficiency testing programs for seed labs/analysts to ensure ongoing competency.

Another key oversight activity is the variety verification program. Every year the CFIA grows up to 2,000 small plots of between 500 – 5,000 plants, depending on the crop kind, as an overall check on the seed certification system. This program has three main objectives:

- 1) To verify the breeder’s description of newly registered varieties and ensure that the legal reference sample meets requirements.
- 2) To verify the identity and confirm the varietal purity of samples drawn from Select and Foundation plots.
- 3) To verify the identity and confirm the varietal purity of samples drawn from both random and targeted seed lots of Foundation, Registered and Certified status.

Legislative Areas of Interest to the Seed Sector

Two aspects of the above noted legislation are currently of particular interest to the seed sector and agriculture in general:

Novelty

The *Seeds Regulations* regulates seed with novel traits (most often referred to as plants with novel traits or PNTs), the *Feeds Act* regulates novel feeds and the *Food and Drugs Act* regulates novel food. Canada has a “no split approvals” policy in respect of novel products, which means that approvals are required under each legislative framework (seed, feed and food). This may result in duplication of effort and delays for approval of innovative plant products.

Agricultural Biologicals

Interest in and development of innovative agricultural biologicals are expanding rapidly. Some products may fall under the regulatory authority of both the *Fertilizers Act* and the *Pest Control Products Act*, which can complicate the approval process and result in delays.

Seed Sector Actors

There are a number of important actors that sustain the seed sector in Canada. Some of these actors have legislated authority as part of the oversight of the seed system. Other associations and industry players are similarly essential to the success of the sector.

Actors with Regulatory Authority

CFIA – Seed Section within the Policy and Programs Branch of the CFIA is responsible for the overall coordination and management of the Seed Program, that being the regulatory components of Canada’s seed system, with an emphasis on variety registration, standards and seed certification. The Plant Biosafety Office (PBO) is responsible for the administration of the confined research field trial program and regulating the unconfined release of seed with novel traits. Seed Section and the PBO work closely with Operations Branch (inspectors) and Science Branch (analysts and risk assessors) to achieve their objectives.

Canadian Seed Growers’ Association – The CSGA was founded in 1904 with the objective to “encourage the general use of improved seed with a view to increasing the yield and quality of the field crops of Canada.” It was the outgrowth of the MacDonald-Robertson Seed Growers’ Association, which had demonstrated over the previous six years that “much may be accomplished by care in growing and selecting of seed, according to a system planned and applied with intelligence.” The CSGA was essentially, in its early days, an organization of on-farm breeders. The CSGA is a private, not-for-profit organization with 3,500 members who grow pedigreed seed for crop production purposes.

The CSGA requires that everyone who grows a seed crop for certification in Canada be a member of the Association. Applications for seed crop certification must include detailed information on previous crops that have been grown on the land that has been planted to the seed crop to be certified, farm maps and evidence that the planted seed is eligible to produce a pedigreed seed crop (e.g., Breeder, Select or official tags; crop certificates).

Canadian Seed Institute (CSI) – the CSI was established in 1998 by the CSGA, CSTA and CSAAC in response to cost recovery initiatives of the government of Canada. The purpose of the CSI was to provide quality system verification/oversight of the seed sector in place of official inspections by the government. The CSI is recognized by the CFIA as an approved conformity verification body.

Today, approximately 1000 RSEs follow CSI’s Seed Program Quality System Standard which must be implemented by approved conditioners, bulk storage facilities or authorized importers in order for CSI to recommend the RSEs for accreditation. Active in these RSEs are over 1700 Operators and over 1000 Graders that have been evaluated and recommended by CSI for accreditation. CSI also designs training programs for Operators and Graders of RSEs and delivers them in collaboration with CSAAC. CSI also does the ongoing audits of the 31 CFIA accredited seed labs.

Registered Seed Establishments (RSEs) – In the 1960s, the *Seeds Regulations* were amended to allow the Director of the Plant Products Division to authorize persons to label packages of seed with official tags and/or to sell Certified seed of large seeded crop kinds in bulk.

Today, the CFIA registers seed establishments, and renews that registration annually, on the recommendation of the CSI. There are three kinds of RSEs:

- 1) **Approved Conditioners** – are establishments that are permitted to process (condition) pedigreed seed. This includes any treatment that could possibly alter the nature of the seed lot, e.g., cleaning, treating, sorting/sizing, coating or any other similar activity.
- 2) **Bulk Storage Facilities** – are establishments that are authorized to store seed that has been certified (graded with a Canada pedigreed grade name) in unsealed containers (e.g., bins) for delivery to a buyer while maintaining the pedigreed status and grade.
- 3) **Authorized Importers** – are establishments that are able to import seed on minimum documentation and to make an import conformity assessment but are required to report that import to the CFIA within 30 days.

An RSE can only operate if it has a licensed operator, an individual responsible for the RSE adhering to its documented quality management system.

Accredited Seed Testing Laboratories – In 1976, the government of Canada began to accredit private seed laboratories for seed import conformity assessment purposes. In 1980, there were four private accredited labs and 18 accredited seed analysts. In 1985, Canada began accepting foreign lab results for import purposes and allowed private labs to test pedigreed seed for certification purposes. Today, the CFIA accredits seed laboratories pursuant to its Seed Laboratory Accreditation and Audit Protocol. CFIA also trains, evaluates and accredits seed analysts. The initial quality system audit of a seed laboratory is conducted by the CFIA; subsequent audits are performed by CSI auditors.

Authorized Seed Crop Inspection Services (ASCIS) and Licensed Seed Crop Inspectors (LSCI) – In 2013, the CFIA began to formally license entities that provided seed crop inspection services as ASCIS and individuals as LSCI in anticipation of the privatization of seed crop inspection in 2014. In 2016, there were 27 ASCIS and approximately 300 LSCI operating in Canada.

Associations and Other Actors

Seed Growers In conjunction with the official seed certification system administered by the CFIA, CSGA members produce a dependable and affordable supply of quality seed of a wide range of varieties and crop kinds for both the domestic and export markets.

Canadian Seed Trade Association (CSTA) – the CSTA is a private, not-for-profit organization with more than 130 members ranging from small and medium sized enterprises to large integrated multi-national life science companies. CSTA members engage in seed variety research and development, production, marketing and trade both domestically and internationally.

Commercial Seed Analysts Association of Canada (CSAAC) – the CSAAC is a private, non-for-profit organization with more than 100 members in Canada and the US. Seed analysts test seed according to recognized standard methods to ensure that seed lots meet the minimum requirements set out in the *Seeds Regulations*. Seed analysts may also provide additional seed testing services for non-regulated quality parameters such as certain diseases or variety identification.

CropLife Canada - CropLife Canada is the trade association representing the manufacturers, developers and distributors of plant science technologies, including pest control products and plant biotechnology, for use in agriculture, urban and public health settings.

Canadian Plant Technology Agency (CPTA) – The CPTA was established to protect intellectual property rights pertaining to crop variety development. It seeks to promote an environment within Canada where a robust and globally competitive framework for intellectual property protection is valued and respected. The CPTA monitors and enforces seed intellectual property issues and has a significant communications and education mandate.

Seed distributors, brokers, exporters and retailers – Most vendors of certified seed are either members of the CSTA or the CSGA or are agri-retailers who sell seed that has been packaged and labelled at an Approved Conditioner. Common seed may also be sold, including farmer-to-farmer sales. Canadian exports of seed were estimated to be approximately \$450 million in 2012. The majority is seed, both certified and common, exported to the US, but a significant amount of OECD certified seed of European forage varieties is sent to the EU every year.

Others – there are a number of other organizations that have an interest in the seed system including, provincial governments, farmer organizations and civil society. During the CFIA-led Seed Program Modernization Initiative in the mid-'90s the CFIA received input from the National Farmers Union, the Canadian Biotechnology Action Network, the Catholic Women's League of Canada, a Metis organization and the Canadian public.

Conclusion

As the seed sector looks ahead to 2020 and the possibility of new regulatory and structural frameworks for seed in Canada it will be important to engage all seed stakeholders to ensure that an all-encompassing vision for Canada's seed system is achieved.

Appendix 1 – International Organizations

Canada participates in a number of international seed organizations that are involved in the regulation, testing and certification of seed:

- 1) Organisation for Economic Cooperation and Development (OECD) Seed Schemes – is an inter-governmental organization with its headquarters in Paris, France. Canada has been a participant in the OECD Seed Schemes since they were founded in 1958. OECD certification of seed facilitates the international trade in seed by establishing harmonized standards and procedures, thereby reducing transaction costs.
- 2) Association of Official Seed Certifying Agencies (AOSCA) – founded in 1919 as the International Crop Improvement Association, AOSCA is an association of seed certifying agencies based in the US and comprising 44 US state agencies as well as agencies in Canada, Chile, Argentina, Brazil, South Africa, New Zealand and Australia. The CSGA represents Canada at AOSCA but the CFIA and CSI are also members.
- 3) Association of American Seed Control Officials (AASCO) – is an organization of federal and state seed regulatory officials of North America. Participants meet to exchange information on seed regulatory issues and to update the Recommended Uniform State Seed Law (RUSSEL) to enhance seed regulatory harmonization in the US. The CFIA participates in AASCO.
- 4) International Seed Testing Association (ISTA) – was established in 1924 and is responsible for the *International Rules for Seed Testing* and an international seed laboratory accreditation system. Harmonization of seed sampling and testing provides confidence in seed test results and facilitates the international movement of seed. CFIA is an active participant in ISTA.
- 5) Association of Official Seed Analysts (AOSA) – represents official seed laboratories and their analysts and is responsible for the *AOSA Rules for Testing Seed* which are aligned with the requirements set out in the Federal Seeds Act of the US. AOSA works closely with the Society of Commercial Seed Analysts (SCSA) to promote professionalism in seed testing. CFIA's Seed Science and Technology Section, Saskatoon Laboratory is an active participant in AOSA.
- 6) International Union for the Protection of New Varieties of Plants (UPOV) - is an inter-governmental organization whose members administer legislation granting intellectual property protection (plant breeders' rights) to owners of new varieties.
- 7) International Plant Protection Convention (IPPC) – is an international plant health agreement, established in 1952, that aims to protect cultivated and wild plants by preventing the introduction and spread of pests. The Commission on Phytosanitary Measures is the governing body of the IPPC and located at the Food and Agriculture Organization of the United Nations in Rome.

Appendix 2 - Amendments to the *Seeds Regulations*

The following represents the list of amendments that have been made to the *Seed Regulations* over the past few years:

SOR/85-903
SOR/86-849
SOR/86-850
SOR/87-62
SOR/88-242
SOR/88-854
SOR/89-368
SOR/91-609
SOR/93-162
SOR/96-252
SOR/96-273
SOR/97-199
SOR/97-292
SOR/97-534
SOR/2000-183
SOR/2000-184
SOR/2001-93
SOR/2003-6
SOR/2007-223
SOR/2008-228
SOR/2009-186 Flexible variety registration
SOR/2012-13 Varietal blends
SOR/2012-286 Housekeeping; French corrections
SOR/2014-114 Soybeans and forages to Schedule III, Part III; removal of suspension of registration
SOR/2015-55 Housekeeping; French corrections

Appendix 3: Fees

There are many fees and charges that participants in the seed system must pay. These are generally for a specified service but may also be categorized as a right, product, privilege or use (e.g., of a facility). Most CFIA fees are set out in the *CFIA Fees Notice*. CSGA and CSI fees are published on their web sites. Other fees, e.g., seed crop inspection, seed testing or audit fees of CSI accredited auditors, vary depending on the service provider.

CFIA Fees

Most CFIA fees for the Seed Program are currently based on a \$60 per hour base rate with a \$90 minimum. Fees for export certification purposes are half this. As part of the OECD Seed Schemes, the CFIA charges \$15 for post-control (variety verification) testing of seed lots of varieties that are maintained in Canada and \$60 per seed lot for those varieties that are not. Seed importers who are not Authorized Importers pay for import conformity assessments for any seed lot that is more than 5 kg (large seeded kinds) or 500 g (small seeded kinds) - \$15 for lots that are 1,500 kg or less and \$0.01 per kg for lots that are larger.

The fee for the review of an application for variety registration is \$875 unless it is for interim registration in which case the fee is \$200. Annual renewals of interim registration are \$100, variety name changes are \$200 and the reinstatement of a suspended or cancelled variety registration is \$200.

The fee for the accreditation of a seed testing laboratory is \$1,100.

The fee for the evaluation required under section 111 of the *Seeds Regulations* for the confined release of a seed with novel traits is \$400 and in the case of an unconfined release, \$2,000.

The CFIA has indicated that it may begin consultations with stakeholders on user fees before the end of 2016. The CFIA's intent is to move towards a fee structure that is reflective of the cost to provide its services and allows for service recipients to be charged appropriately for the services they use.

CSGA Fees

CSGA fees can be found in the application support document under the Seed Grower tab on its web site: http://seedgrowers.ca/wp-content/uploads/2016-Application-Support-Document_2016422.pdf Please note that the 2016 annual general meeting approved increases in the fees for 2017. This includes an increase in the annual membership fee from \$100 to \$200 and an increase in acreage fees of \$0.15 per acre. Together, these two fees bring in approximately \$1.35 million, the bulk of CSGA's retained revenue. CSGA also collects fees on behalf of the Branches and on behalf of seed growers who continue to receive seed crop inspection service from the CFIA. Other fees apply for plots, late applications, incomplete applications, land use inspections and re-inspections.

CSI Fees

There is an application fee of \$300 required from all new facilities requesting registration as an Approved Conditioner (AC), Bulk Storage Facility (BSF) or Authorized Importer (AI). Operators and

graders pay \$96 per year while AC pay \$300 plus volume based variable fees, BSF pay \$200 and AI pay \$950 per year. The variable fees for AC are based on the number of seed lots that they handle ranging from \$50 for up to 10 lots and increasing to \$550 for over 100 seed lots.

Seed testing laboratories pay a \$350 annual renewal fee, US Exporters pay \$950 and there are interval fees of \$100.

Total CSI revenues for its seed programs is approximately \$0.8 million per year.

Other fees

In order to market seed, fees for additional “regulatory services” may be required including seed crop inspection, seed testing and quality system audits. A conservative estimate of these costs would be in the order of \$5 million annually.

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Appendix 4 - Federal Resources for the Seed Program (CFIA)

The 2016-17 CFIA Report on Plans and Priorities indicates that there are 104 FTEs⁵ allocated for the Seed Sub-program (Sub-Program 1.3.2) in 2016-18, 2017-18 and 2018-19. Planned spending is set at \$9.97 million in 2017-18 and 2018-19 vs. \$12.91 million in 2016-17.

The information below is from the CFIA RPP.

Sub-Program 1.3.2: Seed

Description

The Seed sub-program aims to ensure that seeds sold in Canada meet established standards, that seeds are properly represented in the marketplace and that most agricultural crop kinds are registered before entering the marketplace. The program achieves its objectives by verifying that seeds meet quality, biosafety, labelling and registration standards as set out in the relevant governing acts and regulations. Regulating the environmental release of plants with novel traits contributes to environmental sustainability and the health and safety of Canadians. Furthermore, quality assured and accurately labelled seeds contribute to a prosperous agricultural production system and to domestic and international confidence in Canada's seeds.

Budgetary Financial Resources (dollars)

2016-17 Planned Spending	2017-18 Planned Spending	2017-19 Planned Spending
12,912,971	9,968,461	9,968,461

The Planned Spending for the Seed sub-program decreases by \$2.9 million from 2016-17 to 2018-19. This decrease is primarily related to the sunsetting of funding for the Federal Infrastructure Initiative.

Human Resources (FTEs)

2016-17	2017-18	2017-19
104 FTE	104 FTE	104 FTE

Source: <http://www.inspection.gc.ca/about-the-cfia/accountability/reports-to-parliament/2016-17-rpp/eng/1453472983491/1453472984734>

⁵ FTE: Full Time Equivalent

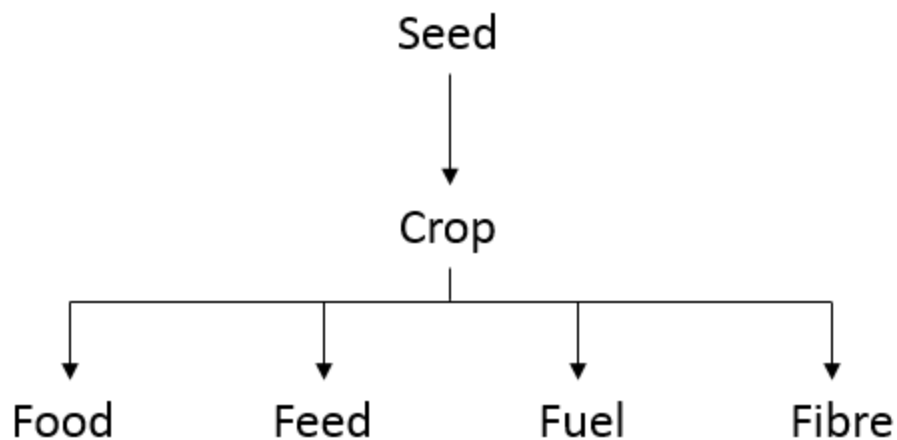
Appendix 5 – Seed → Crop → Food, Feed, Fuel, Fibre

“Seed is the critical first link in the agri-food value chain. Seed is the starting point for growing crops that produce food, feed and other bioproducts such as feedstock for biofuels. Much of the innovation for increased productivity and market opportunities for farmers is delivered by seed.”

Canadian Seed Sector Profile, July 2014

Source: <http://www.agr.gc.ca/eng/industry-markets-and-trade/value-chain-roundtables/seed/canadian-seed-sector-profile/?id=1405967530785>

A simplified illustration of how seeds are the starting point for crops that become food, feed, fuel or fibre is shown below:



Note: in a future revision of this document, this appendix can be expanded upon further if needed.