

**INDUSTRY WORKSHOP**

# **FUTURE OF PLANT BREEDING OVERSIGHT IN CANADA**

**OTTAWA MAY 30, 2017**

PRESENTED BY:



# EXECUTIVE SUMMARY

## OVERVIEW

CropLife Canada, the Canada Grains Council, and the Canadian Seed Trade Association convened a value-chain workshop on the plant breeding oversight system in Canada, on May 30, 2017. The workshop brought together a diverse array of experts representing small, medium, and large industry players, industry associations, academia, international guests, and representatives of the federal government policy and regulatory departments.

## OBJECTIVES OF THE WORKSHOP

- Clarify Canada's current regulatory and policy framework for plant breeding oversight
- Take stock of the system's strengths and weaknesses
- Identify the advancements in science, trade considerations and other factors that are drivers for change
- Identify principles to follow and potential options for an improved regulatory framework
- Clarify the next steps toward making Canada a global leader in plant breeding oversight

## CONCLUSIONS

- New plant breeding techniques offer enormous potential benefits for farmers, consumers and the rest of the agri-food sector.
- Our ability to adopt innovation hinges on having a clear, predictable and consistent regulatory environment both in Canada and in all significant export markets.

- Canada's current system needs to evolve to avoid stifling innovation, and to help unlock the untapped potential of the agriculture sector.
- This is supported by Canada's Advisory Council on Economic Growth (the Barton report), which urges the Government to take clear policy actions to overcome obstacles such as excessive or outdated regulations, to improve agriculture's competitive position and prospects for growth.
- Canada is well-positioned to adapt to new emerging methods of plant breeding, thanks to a focus on regulating novel products rather than the processes used to develop them. However, there are a number of opportunities for improvements to the system:
  - With products of biotechnology in use for more than 20 years with no safety incidents, regulators can leverage their experience and familiarity to make the system more transparent and accessible.
  - Efficiency is a pressing concern, with the prohibitive cost and lengthening time frames required to navigate the regulatory system being especially disadvantageous to small players and causing a drag on innovation.
  - The new products that will enter the regulatory system in coming years will span a wide range in terms of their familiarity and complexity. Although case-by-case approaches have worked well in the past, gains in knowledge and experience now allow for a more predictable, tiered system to be defined.
  - Defining data requirements and time frames up-front will encourage plant breeders, particularly new players, and those developing familiar or low-risk products, to keep their R&D in Canada. It will also help ensure similar products are subject to similar requirements, year-to-year, and reviewer-to-reviewer.

- As regulatory approaches evolve, engagement between Canadian regulators and their counterparts in other countries can help build international consistency and clarity of requirements. This is important both for maintaining market access and to help support the global adoption of regulatory best practices.
- Over and above science-based regulatory systems, Canadian and global public trust remains a major driver of market acceptance and global regulatory approaches.
- Governments, industry representatives, consumer groups and academia all play a role in building consumer confidence by communicating the benefits of plant breeding innovation and the strength of the regulatory programs in place to protect food safety and the environment.
- In addition, it is important for information about products in the developmental pipeline to be made available well in advance of their actual entry into the marketplace. Countries that are early adopters of new technologies use this lead-time to identify and mitigate export market risks.
- We can envision a Canadian, product-based regulatory system that assesses new products in a timely manner at a level commensurate with their potential risk, with predictable tiers for defined levels of risk.

## DESIRED OUTCOMES FOR PLANT BREEDING OVERSIGHT IN CANADA

- Continue to provide the public with assurance on safety
- Enable far more product innovation at an accelerated pace. Areas of particular interest include tackling challenging phytosanitary issues, advancements in small/hard to manage crops
- Support innovation as a driver of economic growth throughout the agriculture and agri-food sector
- Allow Canada to assume a global leadership role in the creation of regulatory programs that provide clear and predictable paths to market for innovative products, while export market risks are mitigated

*This report features highlights from each presentation, as well as the major points from the group discussion. The full content of the small table work-books is also included as an annex.*

*It should be noted that the summaries of the presentations are not the works of the authors themselves. In addition, none of the ideas expressed here have the expressed or implied endorsement of the government representatives present at the workshop.*

# THEME:

## TAKING STOCK – OUR SYSTEM TODAY

**PANEL 1 – How the Canadian system for plant breeding oversight works today: perspectives on the strengths and weaknesses of the current system.**

### DR. JOHN ARMSTRONG

Research Manager,  
Okanagan Specialty Fruits

Dr. Armstrong shared his experience navigating the regulatory system from the perspective of a small, product-focused company. Put simply: “if we don’t get products through regulatory approval we can’t bring them to market”.

The Arctic Apple is a new product and species, and Okanagan Specialty Fruits (OSF) had to go through the entire regulatory process from scratch. In Canada this took approximately 1200 days, and Dr. Armstrong estimates that some two years of that time was spent with the ball in the court of the regulator.

This particular case was challenging in that apple is a highly-managed horticultural crop, resulting in discussion about field trial organization, agronomic traits, yield versus quality, and statistical analysis. In addition, there was no consensus document for apple biology, so OSF prepared a document that became the basis for a CFIA Biology Document for apple.

Overall, practice showed the system to be functional and accessible. In the OSF experience, in spite of some challenges, the regulatory system is not broken. And CFIA and Health Canada were able to adapt and deal with new traits on a reasonable timeline.

Some suggested outcomes include standards for next generations sequencing. For ORF analysis and allergenicity formerly public databases are now privately held, and therefore not accessible to small companies. There is a need for consensus documents for biology, nutrition & composition, modified trait, and modified process. Finally, improved transparency of the regulatory process. The United States has all changes and questions summarized in final documents, and is a model that could prove useful for Canada.

### DR. STEPHEN YARROW

Vice President of Plant Biotechnology,  
CropLife Canada

Dr. Yarrow began with a confirmation of the shared global objectives of plant breeding systems everywhere: ensuring safety and driving innovation to ensure farmer access to better seeds and enable growth around the world.

Understanding the Canadian context begins with understanding novelty triggers, which differ across the Seeds, Feeds, and Novel Foods regulations. In some interpretations the trigger for regulatory review is “newness” whereas in others it is “newness” and “risk”.

Today’s risk assessment regime differs from traditional risk assessments (which evaluate specific hazards and exposure levels) as there is no hazard to evaluate.

Rather, the system is largely focused on confirming a lack of hazard in potential unintended effects. However, the track record of the last twenty years has shown that regulated products have stood up to oversight, and have proven to be safe.

Dr. Yarrow then presented a set of strengths and weaknesses of the current system in the following categories: predictability, the case-by-case evaluation model, costs, regulatory capacity, and self-determination of novelty. Specific points are featured in the embedded presentation. Overall Canada boasts an effective system, however its focus on novelty (which is the objective of all plant breeding) can be too blunt a regulatory instrument, and results in either over-assessment of some products, while largely ignoring all other products deemed not to meet the regulatory trigger.

Where to go from here? Maintain the product-based approach, but where potential risk, not novelty, is the regulatory trigger. Develop a tiered approach where familiarity of the product and breeding technique informs the tier of evaluation. Develop a more focused safety assessment, centred on investigating the intended change.

In addition, Dr. Yarrow suggested that the system include a feature whereby products not deemed novel could be officially recognized as such by the government of Canada, so as to address export market requirements.

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## DR. GRAHAM SCOLES

Professor of Plant Sciences,  
University of Saskatchewan

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Dr. Scoles reviewed the history of the regulatory scheme, and how we got to where we are today. Deriving useful genes from other species/genera or through mutation was an accepted practice.

However, public and policy-making attitudes have changed significantly, which came as a surprise to plant breeders.

With the BSE crisis, consolidated corporate power and resultant suspicion, and a far more affluent and health conscious society, genetic engineering of plants lost public trust. Society demanded regulation of possible health and environmental effects, and regulation in accord with the precautionary principle.

In addition, some scientists actually oversold the potential of genetic engineering, promising a transformative technology far beyond the reality, which increased both hopes and fears, and argued for regulation. The result is a regulatory scheme triggered by novel traits. The definition of “novelty” has resulted in ambiguity and slowness. In addition, there is also ambiguity over the precise definition of a “trait”. Often a trait is simply a higher or lower level of a property already present in the species, and not new per se.

Overall we can see that product-focus is a good approach, however the current system entails excessive cost and time for oversight. We need to ask ourselves how health and environmental outcomes are being served by the current scheme, and whether we might introduce a model more focused on risk for the next generation of products.

## GROUP DISCUSSION

- ✿ What are the key strengths and weaknesses of the current system?
- ✿ Who are the key stakeholders of the regulatory system and what do they expect?

### Strengths

- ✿ Dialogue and partnership attitude between regulators and regulatees.
- ✿ Flexibility and ability to put something in front of the regulators and have them help you in pre-submission before you go through the whole process
- ✿ Regulatory staff are pragmatic, professional, and dedicated. Compared against global perspective we are lucky, some countries don't have this.

- ☀ Canadian decisions and oversight is respected globally, by consumers and governments
- ☀ Regulations based on end product characteristics is the right approach. There is general support for this approach, provided that definitions are clear.

## Weaknesses

- ☀ Unpredictability around regulatory triggers. You don't know when it will kick in and this can limit innovation or create uncertainty
- ☀ The public should know the value of what the regulatory system brings to the industry. Demonstrating to the public what regulation is bringing to the process.
- ☀ On pesticides we have an extremely open system with public consultation, but this doesn't necessarily equal public confidence. Need the regulators to engage and explain to achieve public trust.
- ☀ Need clear specific protection endpoints. Food and feed don't have clear protection endpoints. Why would they care about yield? They should be interested in allergens and toxins.
- ☀ Interpretation of regulation is inconsistent. Seeds and Feeds regulations have same definition of novelty. Seeds regulation definition is interpreted as novelty and risk, Feeds regulations definition is just novelty.
- ☀ System needs to stay science-based, and not introduce socio-economic criteria into decision making.
- ☀ Today's focus on unlikely risks, too risk averse.
- ☀ In some data generation the data is developed by companies, so there is a confidentiality consideration. If it's submitted as private it has to remain private.
- ☀ First person to go through the gate for a new type like pumpkins, for example, has to bear a large cost in doing environmental assessments etc., and they are more likely to be small companies
- ☀ Once we've triggered a review it's a one size fits all style, that tries to address all the questions. Some products we have a great deal of familiarity with and we don't need to do everything, because the knowledge already exists
- ☀ Reconciliation with other countries who regulate on a process-based model. We risk being out of sync with the rest of the world
- ☀ Early research is getting pushed out of Canada into other jurisdictions like the US which have friendlier regulatory schemes
- ☀ Cost is a limiting factor for public breeders/ universities who don't have the resources to go through the regulatory process.

# THEME:

## DRIVERS FOR CHANGE

### PANEL 2 – Drivers for Change: value-chain and international landscape

#### DR. KOFI AGBLOR

Managing Director,  
Crop Development Centre

Dr. Agblor set out some of the major drivers for the industry. First are a set of global challenges that will, in fact, be opportunities for plant breeding. Climate change, dwindling traditional energy resources, and limited food production are all issues with strong negative connotations. However, they may not be insurmountable challenges, and can provide significant opportunities for plant science to fill evolving and emergent needs. Similarly, biological approaches to pest control will be in demand as pesticides may become less effective in the future.

Modern breeding techniques can target outcomes such as improved yield, timely maturity (especially relevant for Canada with its limited growing seasons), enhanced resistance to biotic and abiotic stressors, tolerance to herbicides, and improved nutritional end-use profiles. All of this is to say that there exists a great deal of opportunity. However, costs are prohibitive for small acreage crops, and smaller players. Moreover, today's uncertain and lengthy regulatory scheme causes breeders to try to work around triggering regulatory oversight, and diminishes public-private partnerships. The result is that, for some – particularly nice – crops genetic improvement is slow and potential gains are not fully realized.

Looking to the future, Canada will want to address several key questions: what have we learned based on accumulated evidence? And how can we apply this knowledge? What do we now know that we didn't before? Are we on par with our competitors? Can we find harmony between trade, regulations, and technologies? Can we synchronize regulatory requirements with agriculture research priorities?

#### TYLER BJORNSON

President,  
Canada Grains Council

Mr. Bjornson spoke about the political environment for food innovation and the potential impacts on market access and trade. Plant breeding innovation will be a major driver of growth, and the attainment of social, economic, and environmental goals. However, our ability to adopt innovation hinges on a clear, predictable and consistent regulatory environment in all significant markets.

The enormous potential of innovation is obvious to the industry, but not to the public and many policy-makers. Food innovation is viewed by some with suspicion, and consumers often do not trust the underlying science. Powerful traditional or wholesome seeming images can be used against innovative food products and stifle market acceptance. Most critically, the answer to this challenge is not more science; we need to accept the situation and work within the constraint.

Public attitudes are important domestically, but international perceptions are just as important. This is so because Canada is heavily dependent on trade, and because international markets are an interdependent network. The EU, China, and Japan are large markets for Canadian grains, and are also very sensitive to public perception of food innovation. Transparency is critical for keeping markets open and addressing consumer concerns.

With up to 90 percent of some crops ending up in export markets, if just one or two significant markets experience disruption due to regulatory issues, adoption of plant breeding innovation will grind to a halt around the world. Furthermore, if numerous countries each take a different regulatory approach, this only increases the complexity of concerns over market predictability & trade. Canada is well positioned: our regulatory framework is fundamentally sound, even if it does require improvements on predictability and a stronger risk orientation. Strong Canadian leadership could help deliver greatest consistency amongst our trading partners in the future.

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## **MICHAEL KELLER**

Secretary General,  
International Seed Federation

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Mr. Keller talked about the overall goal of expanding the breeder's toolbox, in order to enable the best possible outcomes for increasing traits like yield, disease and pest tolerance, climate adaptability, resource use efficiency, nutritional value, and quality. In this way selection breeding, genetic engineering, cross breeding, genome editing, and hybrid breeding are all valid tools available to meet breeding needs.

However, systems with high regulatory burden will have the unintended effect of limiting the use of these tools to the largest companies, and freezing out smaller firms. In addition, overly burdensome regulatory systems will tend to focus investment on the highest value crops and on a more limited number of traits. In so doing, a regulatory system may limit innovation, and society will lose out on potential benefits.

Consistent and clear regulatory criteria have benefits around the world, for various stakeholders. Academic institutions: opportunities for international collaboration, public private partnerships. Farmers: access to better seed, sustainable production. Plant breeders: access to the latest methods, legal certainty. Traders: consistent supply, fewer trade barriers. Consumers: high quality and wide variety, affordable prices.

The high level roadmap for consistent international policies is based around a simple principle: Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier methods.

## PANEL 3 – Drivers for Change: science and regulatory experience

### DR. FRED GOULD

University Distinguished Professor of Entomology and co-director of the Genetic Engineering and Society Center at North Carolina State University

Dr. Gould provided an overview of the conclusions of the National Academies of Sciences, Engineering, and Medicine report Genetically Engineered Crops: Experiences and Prospects. The objective of the Committee and its report was to 1) assess the evidence for purported negative effects of genetically engineering crops and their accompanying technologies; and 2) assess the evidence for purported benefits of genetically engineered crops and their accompany technologies.

The major findings of the report are that we have learned a great deal in the last 20 years, and the field has evolved. Today there is no longer a clear distinction between crop improvement approaches, and it is not possible to make sweeping generalizations about the benefits and risks of GE crops. Looking at the history, the science, and the outcomes we can see a general pattern of safety. However, it is impossible to prove that a technology or use is entirely without any risk, and this was not the purpose of the report.

With respect to regulatory approaches, the Committee concluded that “...a more effective regulatory approach would give premarket scrutiny to plants that express traits that are new to established, cultivated crop species and that pose a potential for environmental harm, regardless of the process used.” And that “In concept, that is the approach adopted by Canada for plants with novel traits.”

In terms of how to move to a more risk-based approach, Dr. Gould suggested that – Omics technologies have enormous potential for providing a “fingerprint” of a plant’s composition. These technologies can detect unintended changes and should be further developed and used to better understand risks.

### DR. NICK STORER

Global Leader for Scientific Affairs  
Biotechnology Regulatory and Government Affairs, Dow AgriSciences

Dr. Storer spoke about the regulatory experience in bringing a GE trait to market. Today this is a very expensive (\$136M USD) process, which can take over a decade from early discovery to approval, and wherein regulatory costs make up a quarter of overall costs. Dozens of papers have found that GM crops do not have greater unintended effects than other breeding techniques, nor does transgene insertion unduly increase endogenous allergen levels. However, unintended effects studies typically provide of 50,000 data points and costs exceed \$1M, all while providing little to no new or useful information.

Because of the integrated global market, a new crop will often have to be approved in 15 to 20 jurisdictions before coming to market. Each such jurisdiction has multiple review agencies, looking at agriculture, human health, animal, and the environment, with their own processes for submission, review, and approval. We would expect that with familiarity the regulatory would decrease over time, however the opposite has occurred, as regulators now have more and more questions and tests in spite of the positive safety record.

North America has been the leader in developing and commercializing GM traits, and other countries will continue look to the leaders for guidance on appropriate regulation. Overly politicized regulatory systems do great disservice to the agricultural sector, rural economies, consumers, and the environment. Alternatively, governments should seize opportunities to “right size” regulatory oversight of breeding, proportionate to plausible risks to human and animal health and the environment.

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## DR. JIM BRANDLE

CEO,  
Vineland Research and Innovation Centre

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Dr. Brandle noted that the recent Barton Report found that Canada’s agriculture and food sector has the potential to contribute 2% GDP growth. Doing so will require us to move to 2nd in agriculture exports and 5th in ag & food, in the world to realize that potential. Government, industry and the broader public sector need to build consensus around the obstacles to growth and then “clear the path”. One of the ways to drive growth is to build the technology base for primary production.

In Canada we are generally innovation takers, in that we purchase technologies. Plant breeding is an area where we could become technology exporters, however we are limited by regulation and access to new traits. Now might be the time to develop new business models like not-for-profits corporations.

It is expensive to bring a PNT to market today, and this cost limits the scope of innovation and the potential benefits we might gain collectively. We need to think seriously about our experience with mutation-based traits in crops, and ask whether the risks justify the cost to society and industry. This is particularly relevant if we take the growth challenge of the Barton Report seriously.

## GROUP DISCUSSION

- ✿ What have we learned about plant breeding innovations in the last 30 years?
- ✿ What do we know about the state of innovation?
- ✿ How could the current system better leverage this knowledge?

### What have we learned?

- ✿ We have an excellent safety record
- ✿ Early loss of public confidence can be difficult to recover from
- ✿ Regulatory burden has increased
- ✿ Communicating on safety is just not enough
- ✿ There’s an emotional conversation and a science-based approach conversation. And you can’t use science to address the emotional concerns.
- ✿ Message is important, but how you deliver the message matters too. We’re moving to social media, for example. Opportunity for AAFC to step up and tell people that Canada has an excellent regulatory system
- ✿ ASTA has come up with a whole new communications strategy and language
- ✿ Food manufacturers and retailers have their own agendas, and they can interfere with that message that industry wants to send. i.e. getting onto the anti GMO bandwagon

### State of innovation

- ✿ Very crop focused, it’s hard to predict what the market will want in 10–15 years. We’re constantly playing regulatory catch up, we modernize and then we’ll be out of date quickly
- ✿ Enormous potential, but there have only been a few crops commercialized. Is it regulations?

- ☀ Public perception? Something else?
- ☀ SMEs have strengths but not good at taking things to market, maybe they have to be bought out to do it?

### **Better leverage knowledge?**

- ☀ Clearer distinction of triggers etc. maybe a tiered system of some kind.
- ☀ Better telling the story of our successes, from industry to regulators, we each have a role, to bring consumers along with us
- ☀ Innovation: we have tonnes of tools, but we haven't innovated in terms of products. There are reasons, but we need to actually produce products.
- ☀ Maybe an arctic apple resonates more than the big commodity products in terms of explaining the benefits to consumers
- ☀ Science has evolved, we know what we're doing and we have more capability
- ☀ Leveraging our knowledge can help the industry maintain and build public trust; perceptions and social license can drive regulatory agendas
- ☀ In general, we want to bring our message to the general public, not address the small percentage of staunch opponents who will always oppose the industry, regardless of the facts

# THEME:

## IMPLICATIONS FOR CHANGE

### GROUP DISCUSSION: CONCEPTUALIZING THE PLANT BREEDING OVERSIGHT SYSTEM OF THE FUTURE

- What are the key opportunities for Canada?
- What endpoints are expected of a modern Canadian oversight system?
- What are the threats – what will stand in the way of success?

#### Key opportunities

- Canada is well-placed to lead in regulatory best practice, contributing to consistent and transparent global approaches
- Improve efficiency of the regulatory system, it's effective already
- Transparency in impact assessments

#### Expected endpoints

- Producers are going to want timely access to new technologies to remain competitive
- Support of public databases
- Sufficient clarity on process and the path for regulatory approvals, so there is still flexibility, and not too restrictive
- Clarity for novelty and how risk is evaluated. Tiered system that would allow products to go to market quicker and provide transparency and predictability

- Adoption of a regulatory approach that facilitates access to export markets
- Do not want to see a registration system
- Public perception – the public should hear more about how they have a world class system
- Value proposition like eliminating inputs, diesel fuel, etc.

#### Threats and barriers

- High costs, if we don't get costs down we won't penetrate the market enough to get these products into the market and thereby build consumer comfort
- Doing nothing is a big threat
- Export market risks increase if product introduction outpaces the development of regulatory programs and a clear path to market
- Lack of transparency of innovative products approaching commercialization
- Canadian regulatory approaches that do not meet importing country domestic requirements (e.g. notification vs assessment)
- Resources. Making the system efficient. We have a good system but our capacity to process everything is limited.
- We've patted ourselves on the back on safety, but maybe it's because our regulators did a good job in 1996

## GROUP DISCUSSION: THE DELTA

- What changes may be necessary to achieve desired endpoints?
- What are implications for systemic change – what is required to support change?
- Can we establish some guiding principles for change?

### What needs to change

- Tiered system that establishes data requirements, etc. not just in or out of regulation, but a tiered process so that it would be based on the product you're coming up
- What would industry self-regulation look like?
- We'd like a more formal tiered risk based assessment, that's more clearly defined, not more prescriptive.
- Triage based on familiarity with the crop, distance of change from existing species, and importance of service standards for each of the tiers
- Resources training, capacity building, for developers
- Scheme has to be justifiable for the regulators
- Not just risk-based, but a science-based approach. Because science is the bedrock of trust.
- All three groups involved in assessing our submissions carry out similar tests, and there are opportunities for efficiency
- Needs to be recognition that governments adequately resource regulatory agencies, they have to have adequate resources to do the job they're asked to do.

- To get to where we want to be there could be more public documents, to build trust domestically and internationally, enhanced transparency
- Consensus document or biology document for crops, maybe develop documents before new crops hit the regulatory steps
- International harmonization and use of OECD documents
- Stopping data requirements around unintended effects, would dramatically decrease costs
- Risk assessment should focus on evaluating the change which was intentionally made to the plant rather than unintended change
- More clearly defined science-based criteria for triggers, around novelty etc.
- Discuss this with our partners, make sure that we align with those we need to
- Public trust, maybe one way to address it is to have a forum to have everyone to discuss it. Maybe we could try to think about how we'd develop a formal forum to do that.

### Next steps

- Move forward on exploring the tiered risk assessment approach opportunity
- Establish biology documents, especially for new and emerging crops
- Possibly establish an industry or industry/government working group to advance these ideas
- Engage with senior levels of government to raise the importance of addressing the items identified in this workshop