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The state of genetically modified crop regulation in Canada

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Genetically modified (GM) crops were first commercialized in Canada in 1995 and the 2014 crop represents the 20th year of successful production. Prior to the first commercialization of GM crops, Canada reviewed its existing science-based regulatory framework and adapted the existing framework to allow for risk assessments on the new technology to be undertaken in a timely and efficient manner. The result has been the rapid and widespread adoption of GM varieties of canola, corn and soybeans. The first decade of GM crop production precipitated 2 landmark legal cases relating to patent infringement and economic liability, while the second decade witnessed increased political efforts to have GM crops labeled in Canada as well as significant challenges from the low level comingling of GM crops with non-GM commodities. This article reviews the 20 y of GM crop production in Canada from a social science perspective that includes intellectual property, consumer acceptance and low level presence.

Introduction

The advent of modern genomic sciences certainly have their originals in the work of Watson and Crick in the 1950s, but the research and development phase was a considerably long one, with over 2 decades of laboratory research prior to the first proof of concepts. Watson and Crick[1] published their seminal piece on DNA in 1953 and it was not until 1975 that the Asilomar Conference[2] was held to discuss the safety concerns about genetic modification procedures and processes. It took another 20 y for genomic sciences to graduate from microbes to plants as the first commercial production of a genetically modified (GM) crop occurred in 1992 in China, involving 100 acres of transgenic tobacco for the purposes of seed multiplication.[3] The first commercial production of a GM crop for food purposes occurred in 1994 in the USA with 10,000 acres of delayed-ripening transgenic tomatoes.[4] Commercial production of GM varieties of canola, corn, cotton and soybeans commenced the following 3 y in Canada and the United States. These 2 countries now have 20 y of GM crop production and correspondingly, 20 y of regulation experience and knowledge.

As part of the adaption of its previous variety approval regulatory framework, Canada created a new classification of plant varieties, plants with novel traits (PNTs). PNTs can be plants that do not have a history of use in Canada or created via conventional, mutagenic or transgenic methods, possessing a trait that is expressed beyond the normal band of expression for that trait.

In Canada, GM crops were commercialized into a market with little fanfare. The adoption of GM canola, corn and soybeans was widespread, with full adoption for GM canola and corn occurring within the decade. GM canola was produced under an identity preserved production and marketing (IPPM) system for the first 2 y of production to ensure international market acceptance.[5] Once the Japanese regulatory system approved GM canola for import and consumption during the winter of 1996–97, this IPPM system was discontinued.

After 20 y of GM crop production in Canada, the science-based regulation of PNTs has not changed. GM crop varieties are still treated as PNTs and are approved in an efficient and timely manner. The adoption of the 3 GM commodities produced in Canada has provided numerous economic and environmental benefits. Consumer demands for labeling of GM products has never been strong, however there are sustained efforts to have this implemented by some individuals and organizations. Investment in crop research and development is strong, the regulatory system functions fluidly and Canadian society supports biotechnology. For a more detailed review of biotechnology regulation in North America, see Wozniak and McHughen.[6] At a global level, Canada is considered to be an early and leading adopter of biotechnology and its resulting products.

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The article provides an overview of GM crop regulation in Canada and society's responses. Section 2 provides a summary of the adoption trends for the 3 GM crops produced in Canada. Section 3 examines 3 important issues that developed following the commercialization of GM crops, intellectual property, labeling and comingling. Section 4 updates some of the recent regulatory changes. Section 5 provides a short concluding comment.

GM Crop Adoption Trends

Canada approved GM canola in 1995, GM corn and flax in 1996 (GM flax was only commercially grown for seed multiplication purposes) and GM soybeans in 1997. All 3 of these commodities were quickly adopted by farmers as is illustrated in **Figure 1**. GM canola experienced the most dramatic uptake, with over 50% market adoption after 5 y. There is a small amount of mutagenic-developed herbicide tolerant (HT) canola produced, so when this figure is included, all of the canola production in Canada is currently with HT varieties. GM corn adoption was substantial in the initial 3 y, plateaued slightly for 2 y, then increased rapidly, reaching almost full market adoption in 2012. GM soybean adoption is presently about 80% of the market.

The adoption of GMHT canola in Western Canada has resulted in substantial economic and environmental benefits. Gusta et al.[11] and Smyth et al.[12,13] report on a spring 2007 survey of nearly 600 canola farmers in the 3 prairie provinces of Western Canada. Producers were asked about their crop production experiences for 2005 and 2006 and expected crop planting for 2007. The survey revealed that the new technology generated between $1.063 billion and $1.192 billion net direct and indirect benefits for producers over 2005–7, partly attributed to lower input costs and partly attributed to better weed control. Prior to the introduction of GMHT canola, weeds were controlled by herbicides and tillage as the leading herbicides at that time required tillage to allow for soil incorporation of the herbicide. Much of the tillage associated with GMHT canola production has been eliminated as 64% of producers were using zero or minimum tillage as their preferred form of crop and soil management. An estimated 1 million tonnes of carbon is either sequestered or no longer released under land management facilitated by GMHT canola production, as compared to 1995. A reduction in the total number of chemical applications over the 3-year period was reported, resulting in a decrease of herbicide active ingredient being applied to farmland in Western Canada of nearly 1.3 million kg annually. When comparing canola production from 1995 when GMHT canola counted for only a fraction of 1% of total canola production with 2006 GMHT canola production, the environmental impact of herbicides applied to canola decreased 54% and producer exposure to chemicals decreased 56%. Consumer exposure through surface and run-off water was reduced by 42%. The cumulative environmental impact was reduced 53% with the use of GMHT canola.

The adoption of GM corn in Canada has been steadily upwards, save for a slight decline at the turn of the millennium. This strong adoption trend of initially single trait varieties, but increasingly of stacked trait varieties, that possess traits for both herbicide tolerance and insect resistance, is evident. By 2010, 70% of the GM corn produced in Canada utilized stacked-trait varieties.[14] In 2013, it is estimated that adoption of GM corn is 98%. This adoption level is based on seed sales as farmers are planting stacked corn varieties and using single trait HT varieties as their refugia that have the same herbicide tolerance as the stacked varieties. The corn growing region in Canada has expanded from the standard corn producing region of southern Ontario into Western Canada with over 150,000 ha of corn produced in Manitoba in 2013, up from 120,000 in 2012.[15] Small amounts of feed corn are also being produced in Saskatchewan, about 20,000 acres in 2013.[16]

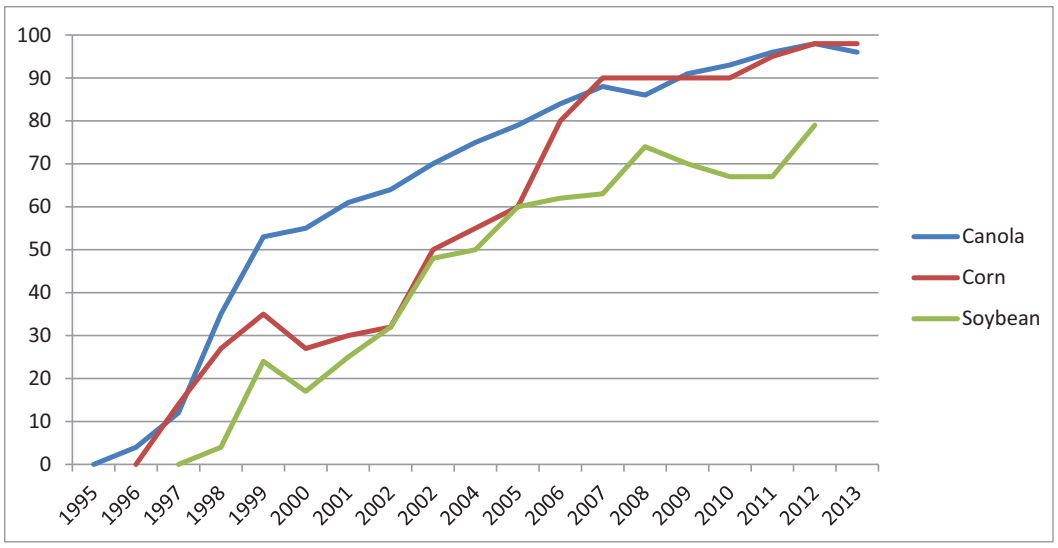

Figure 1. Adoption percentage of GM crops in Canada.[7-10]

Soybean production was traditionally confined to Ontario and Quebec, but the commercialization of GM soybeans has resulted in farmer adoption in Western Canada. In 2012, Manitoba passed Quebec as the second largest soybean producer in Canada and by 2013, produced 50% more soybeans than Quebec with Manitoba producing 23% compared to 16% in Quebec. The commercialization of GM soybeans has resulted in a noticeably larger soybean producing region as for the first time in 2013 Saskatchewan farmers planted nearly

70,000 ha of soybeans, representing 4% of Canadian soybean production. Ont-ario is by far the dominant soybean producer, producing 55% of Canada's soybeans.[7]

Leading Impacts from GM Crops

Over the 20 y of GM crop production in Canada, 3 leading policy issues have emerged as dominant impact adoption issues. The first issue to arise was one of intellectual property rights and the related policy of whether plants could be patented in Canada. This issue arose in the late 1990s with the filing to 2 lawsuits and both cases were resolved after protracted legal proceedings. The second issue has been the political pressure brought to bear on the Canadian government to initiate mandatory labeling policies for GM products in Canada. This pressure has been driven from 2 sources, environmental non-governmental organizations (eNGOs) and by the philosophical left of Canada's political parties, the New Democratic Party. The third policy issue is that of comingling between conventional, organic, GM and non-GM crops. Canada is a global leader though its current efforts to develop a domestic low level presence policy regarding the import of agricultural commodities. Each of these 3 policy issues are explained in greater detail and context in the subsequent subsections.

Intellectual property

Patentability and the laws pertaining to it in Canada, are noticeably different in one specific aspect from those in the USA. Notably, in Canada it is not possible to patent a higher life form. Based on the ruling in a case involving Abitibi and microbial life forms,[17] Canada does allow patenting of lower living life forms, but not multi-cellular organisms. Current Canadian legislation does have protective mechanisms to afford very practical protection with the equivalent result as is obtained in the USA. The protection offered by protein, gene and cell patents allow patent applicants to receive process patents in Canada, allowing protection of the entire array of methods to create a modified higher life form, but not protection of the end product.[18] This method of protecting intellectual property (IP) has worked well as one patent analysis of oilseed herbicide tolerance patents in 2006 found that 38 patents existed at that time.[18] While intellectual property rights (IPRs) were well recognized a decade after the initial commercialization of GM crops in Canada, the issue was not without its challenges within that first decade.

The first legal challenge that resulted from the commercialization of GM canola in Western Canada was that of a patent infringement case involving a farmer that illegally planted Monsanto's patented Roundup Ready variety of canola without paying the appropriate technology licensing fees. This protracted legal dispute with Saskatchewan farmer, Percy Schmeiser, played out over several years, with the case ultimately reaching Canada's highest court.[19]

While GM canola was produced in both 1995 and 1996, it was predominantly seed multiplication with relatively small acreages. By 1997, general commercial production was feasible due to the increased volume of GM canola seed. Prior to the spring planting of the 1997 growing season, Schmeiser illegally obtained a bag of GM canola seed from a neighboring farmer, which would have allowed Schmeiser to plant a few acres of GM canola. The few acres of seed were harvested and subsequently replanted the following season on over 1,000 acres. It was at this point that Monsanto started to receive anonymous phone calls about Schmeiser's fields of GM canola to its tip-line that was set up to report the illegal production of GM canola. It was alleged that over 20 different farm neighbors reported Schmeiser's illegal GM canola production. Officials from Monsanto had the canola tested, verifying that it was indeed the Roundup Ready variety of canola and approached Schmeiser about paying the $15 per acre licensing fee. Schmeiser was quite indignant about this and is reportedly to have told Monsanto to 'sue me'. So they did.

While Schmeiser's illegal purchase of seed was not proven in the initial trail, it is the only logical conclusion based on the proof found in this trial.[20] Monsanto presented expert evidence that canola seed would blow less than 30 feet from a grain truck, which is how Schmeiser claimed the GM canola reached his field. In Saskatchewan, the crown has public rights for all roads, in the case of farm access roads it is 100 feet and for grid roads it is 150 feet. A grain truck driven down the center of a road at a minimum would have require the canola seed to have to travel 50 feet to reach the boundary of Schmeiser's property. Expert witnesses for Monsanto also observed that windblown canola does not germinate the following year on over 1,000 acres at a range of 95–98% pure Roundup Ready canola, in perfectly straight rows. Anyone with any knowledge of crop agriculture can quickly deduce that the only means for Schmeiser to have over 1,000 acres of virtually pure GM canola in straight rows was to have bought seed from a neighbor.

Monsanto filed legal action against Schmeiser for infringement of their technology, seeking compensation of $15 per acre for each of the roughly 1,000 acres. Schmeiser alleged that the seed blew into his field from a neighbor's passing truck during the 1996 harvest. The provincial court, in its ruling, found Schmeiser's arguments that over 1,000 acres of GM canola was due to a few seeds that might have blown off of a passing truck, as not believable, thus ruling in favor of Monsanto. Schmeiser appealed this decision and lost. Down to his final legal option, Schmeiser once again appealed the ruling to the Supreme Court of Canada, this time arguing that he had not violated Monsanto's patent as he had not 'used' the technology as Monsanto had not been able to prove that he had sprayed his fields of Roundup Ready canola with the herbicide Roundup. The Supreme Court decided to hear the appeal and after lengthy deliberations, ruled in a 5–4 majority that a patented invention does not need to be actively 'used' but merely present for an infringement of the innovation to have occurred.[19]

In a humourous note of irony to this legal action, Schmeiser's wife sued Monsanto Canada for polluting her 'organic' garden with GM canola. The court found the allegations somewhat mind-boggling given that her husband had been found guilty of illegally growing in excess 1,000 acres of the very plant that Mrs. Schmeiser was alleging to be pollution. Perhaps she should have sued her husband.

The second legal dispute to arise following the commercial production of GM canola was claims of lost organic markets due to the comingling of GM canola with organic canola and the resulting demands for financial compensation. Two Saskatchewan organic farmers, Hoffman and Beaudoin, on behalf of all registered organic farmers in the province of Saskatchewan filed a class action lawsuit against the developers of GM canola, Bayer CropScience and Monsanto Canada. The 2 organic farmers sought damages for all of the members of the Saskatchewan Organic Directorate (SOD) under claims of negligence, nuisance, trespass and strict liability.[21] In particular, they argued that the comingling of GM canola had destroyed the export market for organic canola due to the inability to certify that canola exports (particularly to Europe) were free of GM canola.

The plaintiffs sought damages on behalf of all 1,250 member of the SOD, regardless of whether they had ever grown organic canola or not. Indeed, it was revealed in the trial that many organic farmers had never grown organic canola. During the trial, the court heard from an organic farmer that still produced and exported organic canola. Based on this evidence, the judge opined that the evidence did not demonstrate that a majority or even a significant minority of the proposed class of organic farmers had suffered loss because of the inability to produce canola sufficiently free from GM contamination to be marketed as organic, as 10 y after the introduction of GM canola, some organic farmers were still growing organic canola and finding markets for it.[22]

Based on these 2 important precedent setting cases, it was determined in Canada that GM crops would not constitute a liability within the production of any form of commodity production, should that be non-GM, conventional or organic. More importantly, the courts upheld Canada's laws on IP, in ruling that the ability to patent the processes to create a genetically modified plants were indeed within the law and that patent infringement did not require 'use' of the technology. Following these 2 decisions, there have been no further lawsuits filed by or on behalf of farmers, seeking redress from technology developers for the commercialization of GM crops in Canada.

Labeling

In Canada, it has been estimated that GM foods and food ingredients are detectable in 11% of foods consumed and might be present (but often not detectable) in up to 75% of the processed foods sold in stores.[23] Examples range from GM papaya and GM sweet corn that are directly consumed, to sucrose and fructose from GM corn that are used as ingredients in a wide variety of products, such as soft drinks and baking. Although regulators around the world have ruled that there is no scientific evidence to support claims that these foods involve any new or magnified risks, many civil society groups and a large portion of consumers are simply not convinced. Even though definitive long-term studies are beginning to show these foods are safe,[24] civil society groups and consumers seek mandatory labeling for GM foods in response to heightened apprehension about food safety issues. The feasibility of such demands run counter to the ability of science to prove that any food product is 100% safe. The reasons offered in defense of mandatory labels include: consumers' right to know what is in their food; giving consumers the ability, at point of sale, to choose or avoid GM foods; and enhancing long term monitoring and surveillance of GM foods.

The demand from consumers to know what is in their food is not a standalone issue, but part of a greater societal movement pertaining to our proximity to food. Witness the recent concern about horsemeat being secretly included in beef products in Europe, mandatory nutrition and country of manufacture labeling in many countries, the inclusion of calorie counts for meals in restaurants and the rise of urban gardening as a means of shortening food chains. All of these examples indicated that consumers are increasingly concerned about potential risks related to their food consumption habits, and perhaps more importantly these examples indicate that consumers want recourse to accountability in food systems that traceability and other documentation are intended to support. Whether they are willing to pay for this is another matter as evidenced by California consumers rejection of Proposition 37 in 2012 that would require mandatory labeling of GM foods and food products.[25]

While advances have been made regarding the labeling of many of the above examples, labeling for GM content has been more problematic. The European Union (EU) requires labeling on products that contain greater than 0.9% GM ingredient or processing content, such as oils and sugars. However, the GM event has to be approved for food use in the EU otherwise the food product will be rejected. Even something as seemingly straight forward as putting a label on a product becomes very problematic as considerable challenges become apparent when one stops to consider questions about how to label and the extent to which labeling should be applied throughout a food system – does it apply from papaya to processed corn to enzymes and yeasts? Enzymes used in the production of cheese are often from genetically modified bacteria, as are yeasts that are used in most baked products.[26,27] Based on product fractionation of GM corn and soybeans, hundreds of food and drink products in the EU contain GM content.[28]

When Canadians (and most citizens in OECD countries) are asked if they would prefer to have information about whether their food is GM, or contains GM ingredients, nearly all will say they want the information. This result is consistent with research into the public's information needs regarding new technologies, for example in the energy, health care and biotechnology sectors. The issue of labeling, whether it is mandatory or voluntary, spans the full spectrum of opinions. Environmental groups and critics of biotechnology claim that greater than 95% of consumers responding to surveys indicate that they want GM content to be

labeled, but other surveys show that only 2% of unprompted consumers ask for GM labeling.

Following commercial production of GM crops in Canada, various calls for labeling began to be issued. In 2001, a backbench member of the governing Liberal Party of Canada, submitted a private members bill calling for the labeling of GM food products in Canada. Liberal Member of Parliament (MP) Charles Caccia introduced Bill C-287, *Labeling of Genetically Modified Foods*.[29] The discussion relating to this bill, which would make labeling of GM food products mandatory in Canada, allowed many of the opponents to biotechnology to voice their concerns about the consumer lack of choice. This bill was defeated by a vote of 125 to 91.

In response, the federal government tasked the Standing Committee on Agriculture and Agri-Food to study the issue and to report back to Parliament. In June 2002, this committee released their report, *Labeling of Genetically Modified Food and its Impact on Farmers*.[30] This report found that approximately 70% of Canada's agri-food exports are to countries where labeling for GM content is not mandatory and that imposing mandatory labeling on Canada's agri-food industry would be a needless cost, hence the Committee recommended voluntary labeling. Based on this recommendation, in 2004, the Standards Council of Canada officially adopted the *Standard for Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering*.[31] This meant that firms that so choose, could label their products as containing GM ingredient, however no firms have availed themselves of this option as consumer demand is simply not strong enough to justify the additional costs of GM labeling.

In Canada, efforts to have food products labeled for GM content have come from numerous environmental non-governmental organizations (eNGOs). Various eNGOs have been involved in this action such as the Canadian Biotech Action Network, Greenpeace Canada and the Sierra Club. The success of these calls for labeling have been marginal at best as successive Liberal and Conservative governments have responded by saying that Canada's regulatory system is one of the strongest in the world and only products that are safe for the environment and human consumption are approved, hence the lack of need for labeling. Some aging, but formerly notable, environmentalists such as David Suzuki, have joined in the call for labels.

More recent champions of the demands for labeling have come from the left side of the political spectrum, the New Democratic Party (NDP). In 2007, an NDP MP, Alex Atamanenko introduced a private members bill, Bill C-456 *An Act to amend the Food and Drugs Act (mandatory labeling for genetically modified foods)*.[32] A vigorous discussion occurred in Canada regarding this bill with the eNGO community strongly campaigning for labeling, while the agricultural industry lobbied strongly against the bill. Hearings were set up at various cities across Canada, with experts from both sides of the debate invited to speak. Ultimately, existing government policy was felt to be sufficient with this bill being defeated by a vote of 156–101. In 2011, Atamanenko was once again advocating on behalf of the eNGO community by introducing yet another private members bill, Bill C-257 *An Act to amend the Food and Drugs Act (mandatory labeling for genetically modified foods)*.[33] This bill was identical word-for-word to the bill that he introduced in 2007 and is presently still in front of the Canadian Parliament, although it would appear to have stalled at the committee level as no action has been taken on this bill since First Reading in 2011. At time of writing, some 3 y later, this bill has not progressed beyond First Reading.

For a full decade, from 2004–2014, Canada has had a voluntary labeling standard in place for food products containing GM ingredients. While the NDP and various eNGOs continue to champion this cause, there is clearly very little public support for this type of initiatives. Canada is a strong adopter of GM crops and Canadians have a high level of confidence in the existing regulatory capacity regarding GM crops and foods, resulting in there being minimal support for GM labels. There is little reason to believe that the philosophical left in Canada will move away from continuing their pursuit of mandatory GM labeling in Canada, conversely, there is little reason to believe that future efforts will be any more successful than previous efforts.

Comingling and low level presence

In recent years, trade patterns have been disrupted in corn, flax, rice and soybeans due to the low level presence of GM events. The forecasts of both further crop innovations and greater diffusion of production into new markets increases the potential that markets will be even more destabilized by incomplete coexistence systems within and between major producing, exporting and consuming regions of the world.

The current view is that the number of events that could complicate trade is rising. Stein and Rodriquez-Cerezo[34] and Graff et al.,[35] reported that the number of commercialized GM traits would increase within 5 y from the current 40 to in excess of 125. While there have been more than 144 events proposed for commercial release, the evaluation, uptake and use of these technologies is quite spotty.[36] Soybeans and corn have the highest penetration rates, averaging around 10% of the total countries producing those crops. Nevertheless, those countries adopting GM varieties account for an estimated 73% of global soybean area and 30% of global corn area. Canola is only substantially produced in a small number of countries, such that the adoption of GM canola accounts for only 13% of global canola production but the majority of global trade.

The EU policy of zero tolerance for the sale or importation of GM products that have not received official approval for production and sale within the single market extends to unintended comingling of both unapproved GM products with non-GM products and unapproved GM products with approved GM products. Zero tolerance is the policy whether the comingling takes place within product groups (unapproved GM soybeans with non-GM soybeans) or across product groups (unapproved GM rice with non-GM corn). There are 2 categories of unapproved GM-product events. The first is low level presence (LLP) where the GM product is approved in the export market but not in the import market. The second form of event is known as adventitious presence (AP), occurring when the GM product is not approved in any

market (i.e. is an experimental product or is cultivated under confined field trials). In both cases, the official maximum amount of comingling allowed is zero. Unapproved GM events are becoming more common as the commercial production of GM crops has spread around the globe, with individual countries having different authorization and regulatory procedures, resulting in non-simultaneous approval of new GM crops.

By 2013 GM crop adoption soared to 175 million hectares in 27 countries.[37] The rapid global adoption of GM crops would not be an issue, were it not for the zero tolerance policy for unapproved GM traits in commodity imports in the EU, the world's largest import market. Markets cannot and do not function at a level of zero percent threshold for comingling of GM and non-GM crops. Smyth et al.,[38] identify that the EU's rigid adherence to enforcement of zero percent thresholds has cost the international commodity trade industry in excess of $1 billion. In particular, this policy has cost the Canadian flax industry nearly C$30 million in losses.

In July 2009, the EU reported that a Canadian shipment of flax had tested positive for the NPTII marker indicating a GM event. At this point, it was assumed that GM canola or another GM crop variety had comingled in the shipment. However, by September 2009 the EU's Rapid Alert System for Food and Feed (RASFF) was notified by a German company that its bakery/cereal products had tested positive for Triffid, a Canadian variety of GM flax. This variety of flax had last been grown in fields in 1999 and in 2001 it was deregistered as a variety. No commercial production of GM flax had occurred in Canada. Notification on the RASFF system is equivalent to an air siren going on in the EU. It is an incredibly effective communication tool. This notification in September was the first of more than one hundred over the next several months that would report Triffid in bakeries, cereals and other products made by companies throughout the EU.

Further confusing the issue was that no confirmation could be provided that it was Triffid flax as none of the assays conducted could conclusively confirm this. In fact, continued testing of flax found that statistical confirmation of Triffid flax in Canadian flax exports was problematic.[39] Ultimately this entire trade barrier problem could have been nothing more than a series of false positives that were detected, costing the flax industry on both sides of the Atlantic, millions of dollars in costs and lost sales opportunities.

The Canadian seed-trade industry was quick to respond to the initial notification. Industry stakeholders – Flax Council of Canada, the Canadian Food Inspection Agency and the Canadian Grain Commission – moved in quickly to try to mitigate the impacts of what threatened to shut market access for Canadian flax producers. With winter approaching and the looming closing of the St. Lawrence Seaway, there was an impetus to ensure that markets opened before the winter freeze-up, usually sometime in December. This export option is not available for the 3 winter months of January, February and March. **Figure 2** shows the crop year export figures for Canadian flax to Europe, highlighting the impact of Europe's zero-tolerance policy. Canadian flax exports to Europe were down by 51% when compared to the crop year prior to the detection of GM flax. As is evident, the final quarter of the calendar year is the peak export period for flax to Europe.

Ryan and Smyth[40] document the economic impact of the Triffid issue for the Canadian producers and for broader industrial actors. A key tool in their study, was a grower survey, administered in early spring 2011, resulting in a total of 272 surveys available for analysis. Fifty-2 of the total 272 respondents (19%) indicated that the amount of flax that the grower sold in the 2009 crop year was reduced after the Triffid issue. Of those, 83% indicated sales were reduced by 50% or more. More than half of the growers (of the 52) lost 100% of their sales in the 2009 crop year, but were able to sell their flax at a later date, but had to incur on-farm storage costs for extended periods of time.

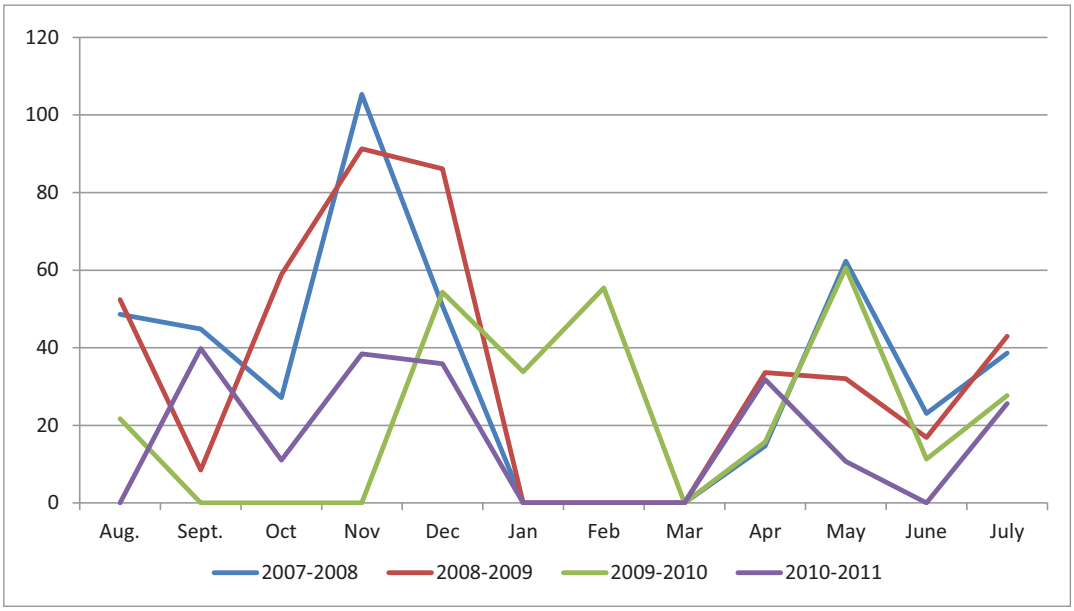

Figure 2. Month-over-month flax exports to the EU (000s tonnes).[40]

Between October 2009 and October 2011, over 26,000 tests to identify GM flax were conducted on over 10,000 seed lots. Results indicate that 0.0498% (n = 548) of seed lots sampled (n = 10,982) tested positive for Triffid. The on-farm testing costs are borne by farmers, reaching approximately $4 million (**Table 1**). Additional segregation costs have been incurred all along the supply chain for flax, costing Canada nearly $30 million. Not all of the costs of this LLP

Table 1. Total estimated costs associated with the Triffid event in Canada[40]

Cost category		Notes	Source
Demurrage/quarantine costs	$12,000,000[a]	As of September 2010	Authors' calculations
Testing costs	$3,900,000[b]	2009 to 2011	Authors' calculations
Cost of segregation, other costs for: breeders, certified seed suppliers, producers, grain companies, AAFC and SaskFlax	$13,185,217	2009 to 2011	Dayananda 2011
Total Estimated Costs:	$29,085,217		

[a]This cost estimate is calculated as follows: $30,000 per day which is equivalent to $1million per month. We conservatively estimate a total of 12 months with this level of costs.
[b]Based on the number of tests conducted (26,000) as reported by the Flax Council of Canada and assuming a conservative (average) cost per test at $150, we estimate total testing costs (2009 to 2011) at almost $4 million.

incident were borne by Canada, COCERAL/FEDIOL has estimated that the cost to the European flax processing industry was in excess of 39 million euros coupled with the loss of over 600 jobs.[41]

Officials from the Canadian government and agriculture industry have been working for several years on developing a domestic LLP policy. The objective of such a policy would be to minimize trade disruptions with key trading partners should the LLP of an unapproved GM event be detected in a Canadian commodity import. Various round table discussions have been held as regulators and representatives from the agriculture and grain trade industries review and comment on drafts of proposed legislation have been developed. However, given Canada's science-based regulatory framework, there is a significant challenge in determining an agreeable threshold. The challenge is that there is no scientific justification for establishing a threshold at any level and ultimately should one be set, it would be a political decision. It was a political decision taken by the EU to set their threshold for labeling of GM content at 0.9% for GM events approved for the EU, there is no scientific rational for this threshold, it is simply a number that the EU member states could politically agree to.

Recent Policy Changes

The above identifies some of the policy issues that have been dealt with and resolved following the commercialization of GM crops in Canada. One further change of note bears mentioning and that is the change in the structure of Canada's regulatory framework.

The Canadian Food Inspection Agency (CFIA) was initially a branch within Agriculture and Agri-Food Canada during the development of the regulatory framework that oversaw the regulation of GM crop varieties in the late 1980s and early 1990s. In 1997, the CFIA was established as an independent agency of the government, reporting to Parliament through the Minister of Agriculture and Agri-Food. The CFIA is responsible for risk assessment of all crop varieties submitted for unconfined release in Canada, regardless of the technology used to develop them and for issues related to food safety. Based on the second mandate, the CFIA has inspectors in most of the meat processing plants in Canada.

In April 2013, the federal government announced that the political oversight of the CFIA would switch from Agriculture and Agri-Food Canada to Health Canada.[42] This regulatory structural adjustment did not have anything to do with the crop regulation aspect of the CFIA, but everything to do with the food safety aspect. Canada has experienced some food safety problems in recent years and Health Canada already oversaw some aspects of Canada's food safety system and the movement of the CFIA to Health Canada simply put all of the food safety oversight capacity under one branch of government.

Conclusions

Canada has reaped the benefits of 20 y of GM crop production. Farmers have gained billions in terms of improved production and reduced chemical costs, while the environment has also benefited from the reduced application of pesticides and insecticides. The adoption rates for GM canola and corn can be seen as full market adoption, while 80% of soybean production in Canada is now done using GM varieties. Clearly, farmers are receiving substantial benefits from GM crops, otherwise the adoption rates for GM varieties would be declining rather than continuing to increase or remaining at full adoption.

The commercial production of GM crops in Canada did create some policy issues that required resolution. The Supreme Court of Canada upheld existing intellectual property laws regarding the patenting infringement and 'use' of a technology. While there was a cost to industry in seeking a resolution to this issue, the benefits have justified this investment as sound business strategy as more technology development firms are investing larger amounts of capital for variety development in Canada.

In a similar vein, the development of voluntary labeling standards for products of biotechnology have been in place now for a decade and are clearly meeting the needs of consumers as the demands for mandatory labeling of GM products have been increasingly muted. Sporadic efforts by members of the New Democratic Party can be viewed merely as political posturing by the party in an attempt to attract left-wing voters to the NDP and away from the emerging Green Party. The vast majority of calls for labeling come from Canada's 3 largest cities: Montreal,

Toronto and Vancouver; with virtual silence on the issue from the rest of Canada.

Where policy-makers are challenged is in situations where politics has overtaken science-based regulation, such as in determining acceptable low level thresholds for unapproved GM varieties. The EU's threshold for comingling of 0.9% is purely political as it was a number that the EU Member States could agree upon, it has no scientific merit. Likewise, Canada is struggling to determine a threshold level for LLP in commodity imports. This aspect has stalled Canada's LLP policy for nearly 3 y and it is unlikely that this issue is going to be resolved in the near future.

The key observation to take away from a review of the Canadian regulatory situation following 20 y of commercial GM crop production is that the market is capable of managing issues without government regulation and is able to inform government as to when legislation is required. This situation is the polar opposite of the situation in the EU, where governments are attempting to regulate the most insignificant aspects of the technology and have created a situation of complete paralysis, where no new GM crop varieties are able to proceed through the regulatory system. The Canadian government revised patent legislation in the 1980s, which were upheld by the Supreme Court, the government facilitated the development of voluntary labeling standards when asked by the food industry and the government has been cautiously proceeding with LLP policy to reassure international trade partners. The role of government in the regulation as demonstrated by the actions of the Canadian government highlight the actions of a responsible approach to the regulation of GM crops, unlike the efforts of the EU, which is (unsuccessfully) attempting to micro-manage the technology.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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