Closed Loop Identity Preservation Systems and Successful Co-existence

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Abstract

Canada has experienced successful co-existence between genetically modified (GM) and non-GM soybeans. However, the conditions that allowed for this successful co-existence are not likely to be replicated in all other crop types. Where these conditions do not exist, closed loop production and handling systems may contribute to successful co-existence. A three year cooperative government-industry pilot project involving a new and unique wheat variety was carried out to determine if it could be successfully contained within a closed loop identity preserved (IP) system. The results of this pilot project demonstrate that closed loop IP systems can be difficult and costly to maintain and do not guarantee 100 percent containment.

Introduction

Canada has a stringent science-based regulatory system designed to evaluate and manage food safety, livestock feed safety and environmental safety risks associated with novel plants prior to approval. Economic and market implications are not considered in this regulatory process. This means that consumer concerns about genetically modified (GM) plant products and the associated market sensitivities have the potential to result in market loss and disruptions for conventional and organic supply chains. In the case of soybeans however, a premium niche market for non-GM soybeans emerged with the introduction, commercialisation and wide-spread adoption of GM soybeans. The Canadian food grade soybean industry was able to take advantage of these niche market opportunities through the development and implementation of identity preservation (IP) systems for non-GM soybeans. As a result, Canada experienced successful co-existence between GM and non-GM soybeans.

This paper examines the conditions that allowed for this successful co-existence and demonstrates that these conditions can not always to be replicated in other crop types and suggests that closed loop production and handling systems may contribute to successful co-existence in these cases. The paper then turns to an analysis of closed loop IP systems based on a three year cooperative government-industry pilot project involving a red spring wheat cultivar that did not meet variety registration regulatory requirements and was therefore registered for restricted commercial production in Canada. The results of the pilot project are reviewed and its implications for the potential of closed loop IP systems to foster successful co-existence are summarised in the conclusions.

Conditions for Successful Co-existence between GM and non-GM Soybeans

Co-existence between Canadian GM and non-GM soybeans has been successful in that both are produced, handled, transported and marketed such that all participants in each of the two value chains are able to sell their products at prices that cover costs and provide a reasonable return on investment. This success has been largely dependant on the ability of the IP systems for non-GM soybeans to consistently deliver products that meet buyers’ specifications.

Prior to the commercialisation of GM soybeans, food grade soybeans were already a small premium market relative to soybeans destined to the oil crush or feed markets. When GM soybeans were first commercialised, niche premium export markets soon emerged for food grade non-GM soybeans where there was consumer resistance. The Canadian industry was well positioned to meet the increased specificity of these markets because of their experience with variety specific delivery programs for food grade soybeans. However, the programs to deliver non-GM soybeans were now required to be IP production and delivery programs. That is, the programs were now concerned about contamination from the larger commodity crop at specific levels established by buyers. Without a price premium, it would not be economically feasible for Canadian exporters to deliver non-GM soybeans into the marketplace because of extra costs associated with operating IP systems.

In addition to the price premium for non-GM, other factors that have contributed to the successful operation of these IP systems over the past 12 years include:

- the expertise of all participants in the non-GM IP supply chain in keeping the IP product segregated from the commodity product;
- the agronomic and physical characteristics of soybeans (i.e. larger seeds) that allow it to be kept isolated in the field and cleaned out of seeding, harvesting, transportation and storage equipment and facilities;
- a physical grain handling and transportation system infrastructure that enables handling and segregation of IP and non IP products;
- the small size of the non-GM soybean market relative to the GM commodity market;
- achievable and measurable tolerances for GM content;
- the GM event present in GM soybean varieties grown in Canada is approved in most importing countries; and
- no risk of market harm to GM markets if non-GM soybeans are not completely contained within the IP system.

While all these factors are important for the successful operation of IP systems for non-GM soybean, the first three have the potential to be replicated in other crop types if there are buyers willing to pay a compensatory premium for the IP product and there are practically achievable and measurable tolerances for GM content.

Typically, Canadian IP non-GM soybeans are sold in foreign markets under contract specifications that allow for 0.5 to 1.0% GM content. Furthermore, the efficacy of industry's IP processes in place to meet the specified tolerances can be verified easily and inexpensively by a simple strip test. This combination of achievable tolerances and an economically viable test method for the presence of this GM event allows industry to determine the price premiums necessary to offset the added costs of growing, handling and exporting a non-GM product that meet contracted specifications.

While price premiums and attainable tolerances for GM content are essential to the success of the IP supply chain for non-GM soybeans, successful co-existence also depends on the presence of an acceptable market for those non-GM soybeans that do not meet buyer quality specifications, including excess GM content. In the soybean case, there is no potential harm to GM markets if non-GM soybeans from the IP supply chain is sold or leak into the feed or oil crush markets. The focus of non-GM IP systems for soybeans is on keeping GM soybeans out. All of the costs associated with keeping GM soybeans out of the non-GM supply chain rest with those that are capturing the price premium for the non-GM product.

Closed Loop Identity Preservation Systems

It is important to note that the main distinction between IP systems and closed loop IP systems is that while IP systems attempt to prevent contamination of the IP product, closed loop IP systems also have the objective to prevent leakage out of the system. There is a need therefore, to consider potential harm to the non-IP supply chain if product escapes or leaks out of the IP system. This harm includes significant price discounts or possible rejection of individual shipments of the non-IP product as well as the potential for long term harm to the reputation of an entire industry and the resulting loss of markets.

Where the conditions that fostered successful co-existence in soybeans through IP systems are not replicated for other crop types, closed loop IP systems have been considered as a mechanism to allow for GM products to be commercialised. A government-industry pilot project conducted in Canada over the 2006/07 to 2007/08 crop years provided an opportunity to assess the operational requirements and efficacy of a closed loop IP system within Canada's grain handling and transportation system and to investigate those factors that impact on product containment.

Pilot Project Conception

In Canada, variety registration is regulated by the government through Canadian Food Inspection Agency (CFIA), on the advice of recommending committees consisting of industry, producer, and government representatives. New plant breeder's lines of most grain crops, including wheat, must meet various agronomic, disease and quality merit criteria before they can be registered, and subsequently grown by farmers for delivery into the commercial grain handling system. For western Canadian milling wheat, the merit criteria include end-use quality characteristics important to buyers and processors in both domestic and export markets. Lines which do not meet the established merit requirements are not supported for full registration. In addition, for wheat grading and quality assurance purposes, a government agency, the Canadian Grain Commission (CGC), publishes a list of those registered wheat varieties eligible to be delivered and graded into the top milling grades of one of the nine wheat classes. Non registered and ineligible wheat varieties delivered into the grain handling system are graded as feed and priced much lower than varieties eligible for the milling grades.

A major European buyer of Canadian milling wheat expressed a strong interest in purchasing commercial quantities of a certain plant breeder's wheat line that was not supported for full registration. Even though this line did not meet some of the traditional end use quality merit criteria, the buyer indicated that its quality characteristics would meet their specific processing needs. The processor had been purchasing Canadian wheat varieties segregated as part of an IP program for several years and wanted to include this line as part of its variety specific production and delivery IP program.

Concurrently, the Canadian wheat industry had approached Canadian government agencies and the Canadian wheat marketer requesting an avenue and mechanism to register and commercialise new wheat types that had novel or specialty characteristics that would maintain the integrity of the conventional milling wheat classes. Contract registration was proposed as the potential mechanism to meet industry's request. Contract registration is a form of variety registration designed to accommodate varieties with biochemical or biophysical characteristics that distinguish them from most registered varieties and where delivery of the resulting commercial crop into conventional value chains may cause an adverse effect on those value chains. Contract registration imposes regulatory requirements including: a closed loop IP system for the production, transportation and handling of the variety; a documented quality management system for the closed loop IP system; and associated risk mitigation measures to prevent leakage of the variety into conventional grain handling and transportation channels.

A pilot project was planned to test the practical implementation and efficacy of this process. The plant breeder's wheat line noted above was chosen for the project because its end use quality characteristics were close to those of the Canadian hard red spring wheat class of milling wheat. Therefore, leakage of small quantities of this line into conventional wheat shipments would not pose a significant risk to the integrity of the conventional wheat value chain.

Pilot Project

The government regulatory agencies involved in this pilot project were the CFIA, which is responsible for administering the legislation associated with variety registration, and the CGC, which is responsible for administering the legislation associated with the grain quality assurance system. To facilitate the pilot project, CFIA agreed to interim contract registration of this IP wheat cultivar, while the CGC agreed to monitor the efficacy of the closed loop IP system designed and implemented by the Canadian grain company which was producing, handling and shipping the new wheat cultivar to the processor.

The grain company submitted its proposed quality management system for the closed loop IP system to the CFIA, CGC and the Canadian Wheat Board, which is responsible for marketing the crop, for review and approval. This system was designed to ensure that any seed or harvested product within the closed loop IP system would not enter the conventional wheat value chain.

Once the quality management system was approved, a monitoring plan was developed. After the first year of commercial production, an on-site audit was conducted by government officials at three of the 18 grain facilities that accepted delivery of the IP wheat cultivar from the contracted growers. The objective of this audit was to verify adherence to the procedures associated with contracting, purchasing, receiving, handling and shipping of the IP wheat cultivar.

The CGC also monitored conventional wheat shipments for potential leakage out of the closed loop IP system through random sampling and biochemical variety identity testing of railcars and ship cargos during the three years of the pilot project.

Risk Assessment for Closed loop IP

An industry-government committee was formed to oversee the pilot project. Part of the work carried out by this committee was identification of the factors that would contribute to the risk of harm to the conventional wheat supply chain. The committee followed the standard approach to risk assessment: Risk = Hazard x Exposure. In this case, hazard was defined as the deviation between the quality of the new cultivar and conventional wheat quality parameters, and exposure was defined as those factors that could impact the likelihood that the IP cultivar would leak out of the closed loop system. Hence, risk was defined as the potential for industry harm from the IP wheat cultivar leaking into conventional wheat shipments.

Table 1 provides a summary of the identified exposure factors along with the potential mitigation measures. Not surprisingly, many of the mitigation measures factors identified by the committee are also identified above as the conditions for successful IP of non-GM soybean. However, of particular interest to this project were those factors that are important to keeping a product within a closed loop.

Table 1. Exposure Factors and Mitigation Measures for Closed loop IP Systems

Exposure Factor	Mitigation Measures
Outcross Potential	Self pollinating species have a lower risk of escape from a closed loop IP system than out crossing species
Persistence in the field (Volunteers)	Crop types that have low propensity to maintain viability are less likely to contaminate crops grown in subsequent years
Seed source	Seed controlled by the company contracting with growers helps to ensure that it is all used and that crop produced by growers is not kept to be grown in subsequent years
Availability of Testing to Detect Leakage	A low cost, reliable and quick test to detect leakages into the conventional crop will encourage more frequent testing for leakage and thereby reduce the impact on the conventional crop.
Grower Return	A price premium for growers will reduce the incentive for growers to deliver outside of the closed loop IP system.
Number of Growers	The higher the number of growers contracted to grow the specialty product, the higher the likelihood of leakage.
Dispersion of Growers	The more geographically dispersed the growers, the higher the likelihood of leakage.
Acreage	The higher the number of acres of the IP product grown, the higher the likelihood of leakage
Production relative to conventional crop	The higher the percentage the IP product grown relative to the conventional product, the higher the likelihood of leakage.
Separate supply chain	The more dedicated the supply chain for the IP product (e.g. production delivered directly to the end-user) the lower the likelihood of leakage.
Market for non-conforming product	If there is an identified market outlet for the portion of the IP cultivar crop that does not meet buyer specification, then it can be disposed of by commercial means and does not need to be destroyed. Members of the supply chain then do not have an incentive to sell or leak the product outside the closed loop IP supply chain.
Existing QMS post farm	Companies with successful experience in process control and quality management systems are less likely to make errors in segregating IP from conventional cultivars and in control and oversight of closed loop IP systems.
Existing QMS on farm	Growers with experience in process control and quality management systems (e.g. seed growers, on-farm HACCP systems, IP contract growing) are less likely to make errors in segregation

The grain company responsible for the closed loop IP system participated in the development of this table of exposure factors and mitigating measures. The concepts formed the basis for their design of the system.

Pilot Production Details

Preliminary seed increase of the new wheat variety took place in 2005, and commercial crop production began in 2006. Contracted acres of the IP wheat cultivar increased from approximately 20,000 to 30,000 over the three years of the pilot project concomitant with a corresponding increase in production (Table 2). The number of growers involved in the pilot also increased, but the number of grower delivery sites decreased from 18 in the first year to nine and 10 in the second and third years. Delivery sites were located in the provinces of Manitoba and Saskatchewan in western Canada (Figure 1). From these delivery sites the IP wheat cultivar was shipped by railcar to a grain elevator located at Thunder Bay, Ontario. From there, the product was moved by vessel to a transfer grain elevator at Sorel. Quebec on the St. Lawrence River, where it was transferred to ocean going vessels for shipment to the buyer in the European Union.

Data recorded by the CGC for shipments of both the IP wheat cultivar and conventional wheat shipments indicated that the IP wheat cultivar comprised a small percentage of total wheat shipments (3% in 2006, 6% in 2007, and 6% in 2008, see Table 3).

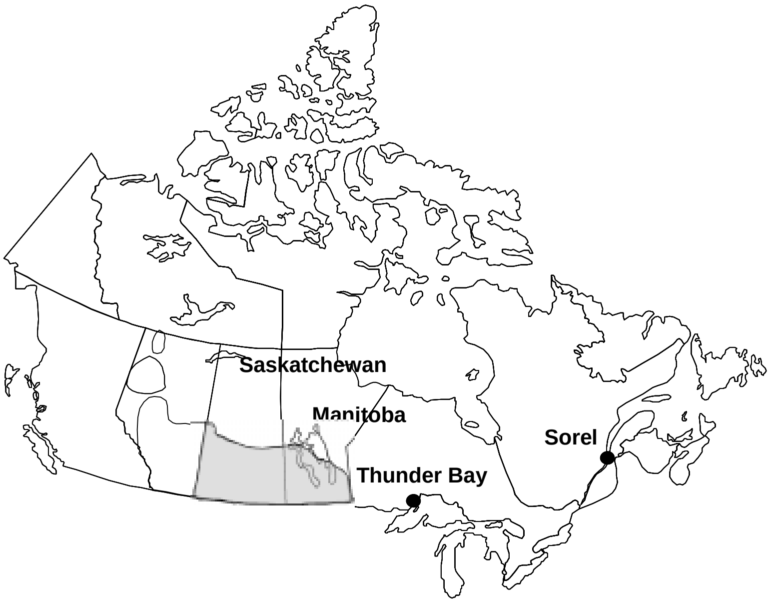
Table 2 – Summary Data for the Pilot Project

	2006/07	**2007/08**	**2008/09**
Number of Grower Delivery Sites	18	9	10
Number of Contracted Growers	66	98	92
Contracted Acres	20,042	30,471	31,320
Estimated Production (tonnes)	18,990	28,872	31,540

Table 3 – Rail cars and tonnes of conventional wheat and new wheat variety shipped through Thunder Bay, by Crop Year

	2006-07	**2007-08**	**2008-09**
Number of railcars of conventional wheat	6,571	4,966	5,827
Number of railcars of IP wheat cultivar	220	301	366
Tonnes of conventional wheat	599,958	456,894	538,896
Tonnes of IP wheat cultivar	19,894	27,578	33,998
Percent of total railcars and tonnes that were the IP wheat cultivar	3%	6%	6%

Figure 1. Map showing growing areas in western Canada (in grey) and transfer sites.



Pilot Project Monitoring Results

A total of 15 incidents of leakage out of the closed loop system were detected, one during seed production in 2005 prior to the start of the pilot project, three in the first year of commercial crop production, five in the second year, and six in the third year. Eight of these incidents were detected in vessel shipments of conventional wheat destined for export markets. Based on the levels of the IP wheat cultivar found in conventional shipments, it was estimated that these detected leakages represented a maximum of approximately 2000 tonnes, or about two percent of the total production of the IP cultivar over the three year pilot project.

In depth investigations were conducted to determine the cause of the seven largest leakages detected. These seven leakages were large enough to cause potential grading problems for conventional shipments. In three of the seven investigated instances, the sources of the leaks were traced back to producers. These producers did not fully adhere to production contract requirements. In one case, a seed grower delivered screenings to another company, in another it was thought that the grower did not clean his equipment adequately, and in the final case, the grower stored his crop incorrectly.

Two other investigated leakages indicated the source of the leak to be at the transfer elevator on the St. Lawrence River handling the product under contract with the grain company shipping the product. The grain company did not provide adequate oversight to ensure that the transfer elevator was following segregation procedures that were sufficient to keep the variety segregated.

One of the two final investigated leakages was traced back to a binning error made by staff at one of the facilities taking deliveries from the farmers. The other was found to be a result of staff at the Thunder Bay terminal not following the rail car unload procedures established for the specialty wheat.

Analysis

Table 4 identifies the planned mitigation measures put in place by the grain company responsible for the closed loop IP system. The findings of the leakage investigations provide an opportunity to assess the effectiveness of mitigation measures designed to reduce the likelihood of leakage outside the closed loop IP system.

Table 4. Exposure factors and mitigation measures used in the pilot project.

Exposure Factor	**Mitigation Measures**
Outcross Potential	Wheat is a self pollinating species; outcross potential is low.
Persistence in the field (Volunteers)	Wheat has a high propensity to maintain viability in the field. Contracted growers were required to ensure that wheat was not grown in the field used for the IP cultivar in the subsequent year.
Seed source	Seed was produced and controlled by the by IP company and supplied directly to the contracted growers.
Availability of Testing to Detect Leakage	A reliable test to detect leakages into the conventional crop was available, but it was not quick or inexpensive. Testing for leakage was limited by cost.
Grower Return	A price premium was provided to the growers.
Number of Growers	The number of growers contracted was relatively small.
Dispersion of Growers	The growers, though in two provinces, were all in close proximity to the delivery sites.
Acreage	Acreage of the IP wheat was relatively low.
Production relative to conventional crop	The percentage of the IP product grown relative to the conventional product was very small.
Separate supply chain	The supply chain was not dedicated to the IP wheat.
Market for non-conforming product	The contracting IP company was responsible for all of the IP wheat that did not meet customer specification and had an agreement with the marketer to find a market for non-conforming products or production that exceeded the buyer's demand.
Existing QMS post farm	The IP company has a certified quality management system in place, though initially the IP program for the project was not incorporated into this system.
Existing QMS on farm	The contracted seed growers had experience with process control and quality management systems.

The most striking finding of the leakage investigations is that all seven of the investigated leakages were attributed to human error. Human errors can be reduced (although not eliminated) through training and careful control of processes. This attests to the importance of existing quality management systems or other experience with process controls throughout the supply chain. While the grain company accepting grain delivery did have a mature quality management system and several years of IP experience, this pilot was their first experience with a closed loop IP system. Two of the human errors that lead to detected leakage were made by staff of this company. Interviews conducted with staff during the on-site audits indicated that some did not fully appreciate the need to focus on keeping IP wheat cultivar within the closed loop as well as keeping other wheat out. The review of the company's training records indicated that training material specific to the closed loop IP program was not standardised across all company locations involved in the program. The audit also revealed that the company's procedures to ensure the IP product does not leak into conventional product could be strengthened to limit the opportunity for human error.

The three leakages attributed to growers also suggested the need for more stringent quality management procedures regarding the selection and oversight of growers. The audit indicated that while the company did select these growers on the basis of their experience with other IP production contracts, there were no records of this practice. Training of the growers was another area that was identified as needing improvement.

Staff errors at the transfer elevator were the source of the final two investigated leakages. This facility did not have a quality management system and, as indicated above, was not sufficiently overseen by the grain company that contracted their services.

Despite the leakages detected during the course of the pilot project, many of the potential causes were effectively controlled. The grain company controlled the seed supply of the IP wheat cultivar by making it available only to those growers who signed a production contract. This allowed them to keep track of all seed and ensure that the seed did not end up in the hands of non-contracted growers. There is no indication that the detected leakages were caused by non-contracted growers.

The production contracts with growers included a price premium so that growers had no economic incentive to deliver the IP wheat to another grain company outside the closed loop IP system. In addition, if a grower's crop did not meet the quality specification of the buyer, or if there was any production not needed by the buyer, the marketer in consultation with the quality assurance agency (CGC) agreed to make its best efforts to sell this production at the best price possible. All leakages traced to growers were due to human errors, rather than to economic incentive.

While the increase in the number of leakages in the second and third year of the pilot project does correlate with an increase in number of growers, and the size of production relative to the conventional crop, three years of data are not sufficient to draw any definitive conclusions from this observation. Nor did the pilot project provide any insight to the relative importance of wheat's low outcross potential or its high propensity for volunteer growth in subsequent crops.

It is reasonable to assume however that the potential for leakages would be significantly reduced and limited to those caused at the farm level if the IP wheat cultivar had been cleaned, stored, and transported to the buyer in a dedicated supply chain, rather than the same physical infrastructure used for conventional wheat. Creating a separated physical infrastructure is not economically feasible in this case, but could be considered for products shipped directly from the farm to the end user in containers, for example.

Testing for leakages during the pilot project was conducted by the CGC and associated resource costs were not passed on to the industry participants. These costs limited the amount of testing that the CGC carried out. It is possible that additional leakages would have been detected if more tests on conventional wheat shipments had been conducted.

Conclusions

The most important factors supporting the successful co-existence between Canada's GM and non-GM soybeans are price premiums for non-GM IP soybeans, attainable tolerances for GM content in non-GM shipments, and the absence of market harm if non-GM soybeans enter GM shipments. Experience has demonstrated that these conditions are not necessarily replicated for other crop types, and that it is the potential for market harm to the co-existing supply chain that is the most likely reason that a closed loop IP system is proposed as a potential mechanism to achieve successful co-existence.

Although the pilot project described in this paper involved closed loop IP of a non-GM wheat cultivar, comparable results would undoubtedly be obtained in a GM/non-GM situation. The results demonstrate that preventing leakages from a closed loop IP system is challenging. Human error was shown to be the most likely cause of leakages outside a closed loop IP system. The audit of the quality management system and the leakage investigations identified areas where the mitigation measures could be strengthened if this model were to be used to contain a higher risk product. Increased training, careful oversight of all participants in the supply chain, and efforts to continually improve the closed loop IP system, as well as the increased experience of growers and grain handlers, are factors that would improve the rigor of the system and reduce the incidence of human error. However, this increased rigor would increase the cost of operating the closed loop IP system.

Tight control of the seed of the IP wheat cultivar as well as commitment on the part of the grain company responsible for the closed loop IP system to account for all production, including the disposal of any production that was not sold to the European buyer were important factors in containing the IP wheat. In the pilot project, alternative markets were available for the IP wheat cultivar because of its end use quality attributes. This may not be the case for a higher risk product. Depending on the quality of a higher risk product, production not sold to the designated buyers may have to be sold in a much lower value market such as feed, or may have to be destroyed. This would further increase the cost for a closed loop IP system for a higher risk product.

The pilot project demonstrated the importance premiums to offset the costs of a closed loop IP system, and to remove the economic incentive to deliver the IP product outside of the closed loop system. However, leakage out of closed loop IP systems also imposes market harm costs on participants in the conventional value chain who do not have access to these premiums. In addition, as the risk of the IP product to the conventional value chain increases, the potential market harm costs also increase. Reducing those risks requires tighter and more costly mitigation measures within the closed loop IP system, but there may not be sufficient economic incentive for the participates in the closed loop IP value chain to reduce those risks. This suggests that each participant in the closed loop IP system must be held liable for the costs of leakages for which they are responsible in order to ensure that effective risk mitigation measures are put in place and the conventional value chain is compensated for the market harm risks.