

# Transitions in Agbiotech: Economics of Strategy and Policy

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## PART FOUR: Regulation and Trade

### **21. The BioSafety Protocol and International Trade in Transgenic Canola: An Economic Assessment of the Impact on Canada**

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## Chapter 21

### **The BioSafety Protocol and International Trade in Transgenic Canola: An Economic Assessment of the Impact on Canada**

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#### **Introduction**

Agricultural commodity trade is in transition. The application of biotechnology to conventional commodities is both deepening, as modifications to particular varieties become more sophisticated, and widening, as more crops are genetically modified (GM). Along with the increase in genetic modifications, there has been increase in concern about the risks of GM varieties to biodiversity. To address these concerns, negotiations have been underway to create the BioSafety Protocol (BSP). In this sense, agricultural commodity trade is in transition as it becomes more explicitly linked to environmental objectives.

This transition has not been smooth. The BSP negotiations have revealed that different negotiating parties have different perceptions of the appropriate scope of the protocol. This ranges from a limited BSP focused on the risks to biodiversity from the transboundary movement of living GM products to a comprehensive BSP focused on biodiversity, food safety, economic development and moral, ethical and religious concerns associated with all GM products. The protocol scope that prevails may have significant trade implications for GM agricultural commodities. The purpose of this paper is to identify the potential economic and trade impacts of the BSP upon Canadian canola exports with respect to four specific protocol scenarios, which may prevail in the final BSP. The paper then examines possible strategies to minimize those costs.

#### **Background to the BioSafety Protocol**

The BioSafety Protocol negotiations are an international effort under the auspices of the 1992 Convention on Biodiversity (CBD) of the United Nations Environment Program (UNEP). The CBD was the culmination of a decade-long effort, begun at the Third World Congress on National Parks and Protected Areas in Bali, Indonesia in 1982 (Swanson, 1997). The objective of the CBD was to develop an international convention, which outlined the commitment of the global community to conserve and protect biodiversity. In June 1992 the CBD was included as Agenda 21 of the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, the 'Earth Summit', and was signed by participating countries at the Conference. Presently, 171 countries (about 88% of all the countries in the world) have signed the Convention and it has been ratified by 134 countries. The main holdout is the United States, which has failed to ratify the CBD in the US Congress.

In order to protect biodiversity, the initial scope of the BSP, according to the CBD, was to develop legally binding international rules governing the testing, importation and exportation (transboundary movement or TM), deliberate release and commercial use of living modified organisms (LMOs). Specifically, the Advance Informed Agreement (AIA) principle was to be applied to TMs. This meant that the Party of Import would be notified prior to a shipment of LMOs. Further, the LMOs would be subject to a process of scientific risk assessment (SRA) conducted by the Party of Import prior to shipment, in order to identify any potential risk(s) to the biodiversity of the importing region. The Party of Import, upon completion of a SRA, could allow or restrict the importation of the LMO because of identified risk(s) to biodiversity. It is important to note that while the CBD explicitly used the term living modified organisms, no consensual definition was developed or adopted when the Convention was signed in June 1992.

Although the BSP is not explicitly intended to be a trade agreement, the fact that its scope includes export and import activities makes it an implicit or *de facto* trade agreement associated with the international trade of transgenic organisms and products. Successful completion of the BSP has the potential to positively influence international trade in three significant ways. First, trade transparency will be increased through the use of the AIA principle. Second, trade will be more fair because scientific risk assessment is intended to ensure that biodiversity risks from GM products, whether domestic or foreign, are assessed using consistent, credible procedures. If biodiversity risks are identified using SRA procedures, then, and only then, trade barriers may be erected that are commensurate with the identified risk. Currently because there is no universal agreement on the transboundary movement of LMOs, countries, if they wish, can unilaterally impose barriers to imports simply by claiming environmental risk. As well, with no international agreement, exporters face a different set of rules from each potential Party of Import—Canada, for instance, exports wheat to more than 100 different countries. Third, an international protocol could overcome the lack of domestic regulations in those countries with little or no experience with regulating GM products (Mulongoy 1997). In this sense, the successful negotiation of the BSP could be a win-win outcome. The global benefit, shared by all countries, would be the overall conservation and protection of biodiversity. From an industry perspective, successful completion of the BSP would potentially increase predictability and market access opportunities for GM products, which would support further research, development, adoption and commercial use of agricultural biotechnology.

The administrative center for the BSP negotiations, the seat of the CBD Secretariat, is in Montreal, Canada. There are over 120 countries involved in the BSP negotiations. The current state of the BSP negotiations can be characterized as uncertain and fraught with differences of opinion. Six negotiating sessions have been completed to date: July 1996, Aarhus, Denmark; May 1997, Montreal; October 1997, Montreal; February 1998, Montreal; August 1998, Montreal; and February 1999, Cartagena, Columbia. The sixth negotiating session was to be followed by the Extraordinary Conference of the Parties to the Convention where the final draft BSP was to be presented for signing. However, on 24 February 1999, after it became clear that a final

draft protocol was not going to be established, the negotiators decided to push back the deadline for the final protocol for 18 months.

The negotiations began with the discussion of general issues, including who should be involved in the negotiating sessions (i.e. signing parties, industry representatives, environmental non-governmental organizations) and with a request for draft protocol submissions by October 1996. Ethiopia submitted a draft protocol on behalf of the African delegation and the Third World Network in October 1996. This draft protocol, considered as representative of the views of many developing countries, used as a framework the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (McDonald 1997). As a result, the draft protocol treated shipments of LMOs with the same degree of prescriptive regulation as shipments of toxic or nuclear waste. Further, this draft protocol placed enormous burdens upon exporters and the Party of Export to ensure biosafety and to gain approval before any shipment of LMOs. Not surprisingly, export countries reacted negatively to this draft protocol.

In response to the draft protocol submissions, the second negotiating session involved parties staking out their positions. The third session, in October 1997, was characterized by the emerging awareness of the agricultural commodity trade issue and the potential impact of the protocol upon the international trade in products of modern biotechnology. The fourth and fifth sessions primarily involved the elaboration of crucial definitions and issues, including the definition of LMOs, the roles of the Party of Export, the exporter, the importer and the Party of Import, the opportunity for exemptions, and the scope of the AIA. Many of these issues remain unresolved after the sixth session in Cartagena.

Although all the Parties share the objective of protecting biodiversity, differences exist in how they propose to do this and what should be considered under the scope of the BSP. Mulongoy (1997) portrays the negotiations as generally reflecting two predominant views—the view of biotechnology shared by developed countries versus the view of biotechnology shared by developing countries. The group of developed countries, including the UK, the US, Canada, and Japan, has experience with domestic biosafety regulation. Further, the global application of biotechnology in the agri-food sector is largely driven by the private interests in these countries. This group of countries is seeking a BSP that will not harm their trade interests. As a result, they wish to limit the BSP to address only transboundary movements; this type of international regulation would complement and not compete against their current domestic regulations. The rest of the world, with little or no experience with domestic biosafety regulations is counting on the BSP to ensure protection against any adverse impact of GMOs. This group wants the BSP to cover R&D, transfer, handling, testing, use and disposal of any GMO. Essentially, developing countries want an international BSP in order to overcome their lack of domestic biosafety regulations and their lack of capacity to assess the risks of GMOs to biodiversity, by placing the burden of responsibility of AIA upon the exporter or Party of Export (Mulongoy, 1997; Hodges and Herity, 1998).

Once a final BSP is completed and signed, a (yet-to-be) specified number of countries would have to ratify the BSP domestically, which could take several years (Hodges and Herity, 1998). Once ratified, the BSP will become an international legal instrument and all ratified countries will be considered signatories.

### **The BSP and Trade Implications: The Canadian Perspective**

In Canada, the government, the industries that apply biotechnology and consumers support the objective of protecting biodiversity and, in December 1992, Canada was the first industrialised country to ratify the CBD. Canada also supports the AIA principle that Parties of Import must be notified and allowed to conduct a scientific risk assessment prior to an importation of products posing a risk to biodiversity. Canadian regulators remain confident that the regulatory framework in Canada pertaining to product importation meets, or even exceeds, the framework for assessment proposed in the BSP, so that Canadian biodiversity is well protected from either domestic or imported GM products. However, as many Canadian agricultural commodities are exported, there is significant concern that the BSP may have adverse effects upon market access for a wide range of Canadian export products. Any disruption to export market access may be detrimental not only to international trade, but also to product research and development, technology transfer and the basic scientific research activities which underlie Canadian biotechnology.

The fundamental problem with the BSP, from a Canadian perspective, is that the draft protocols have not adequately considered the realities of international trade. This failure has resulted in a broadening of the protocol scope beyond the protection of biodiversity. That is, some Parties are attempting to conclude an agreement that will govern environmental biodiversity and also human health, food safety, economic development as well as cultural, social and ethical issues regarding the use of biotechnology. The Canadian position on the BSP to date has been focused on ensuring export market access for Canadian GM products through attempting to balance environmental biodiversity concerns with the realities of international trade (Canadian BioSafety Working Group). In particular, there is concern that the current BSP proposals do not include provisions for dispute resolution in the event that exporters are dissatisfied with the AIA decision of the Party of Import. In so far as the BSP is a *de facto* trade agreement, the view is that it should recognize that trade disputes do occur. Although the dispute resolution mechanism in the WTO is not perfect, it is considered by many to be a triumph of trade diplomacy. The concern is that the BSP will circumvent both the right to appeal trade decisions through a dispute resolution mechanism and the overall rights and obligations of countries according to international trade rules.

This has led Canadian negotiators to articulate five firm positions or negotiating fences that represent the Canadian position on the BSP. As contravention of these fences will likely result in a loss of Canadian support for the BSP, they are treated as parameters in this paper. First, Canada has stated that the BSP should ensure the preservation of biodiversity but exclude issues of human health, food safety, economic development and moral, ethical and religious views on biotechnology. Second, the view is that the BSP

should ensure regulatory sovereignty, focusing on transboundary movements of LMOs and not on ‘domestic’ regulatory issues of domestic handling, testing and containment. Third, Canada has stated that in disciplining the transboundary movements, the BSP must remain congruent with the WTO rights and obligations and should not circumvent the WTO trade agreements. Fourth, given that the US may choose to not sign the Protocol, Canada has argued that there should not be a ‘non-signing party’ article in the BSP prohibiting trade between signing and non-signing parties. Finally, Canada has argued that the scientific risk assessment procedures for AIA should be transparent and based on universally-accepted scientific principles. Inside these fences there are several crucial concerns or issues. The outcomes of these issues will significantly influence the scope of the BSP and its subsequent impact upon Canadian canola exports. Therefore, they are examined in more detail below.

The first, and perhaps most important, is the definition of LMO that prevails. Article 19.3 of the CBD states that an international protocol should be created to address the transboundary movement of “living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.” This definition explicitly links LMOs with modern biotechnology and implies that it is the use of modern biotechnology that potentially creates risk to biodiversity. In contrast in Canada, novel organisms, which may be created by the use of either biotechnology or traditional plant breeding techniques, are viewed as the source of potential risk to biodiversity and are the focus of regulatory efforts. This difference is illustrated in Table 1. There are three categories of plant varieties to consider; plants with novel traits (PNTs), plants derived from PNTs, and plants that contain a transgenic modification. The first type, PNTs are those varieties that are novel to the species in the Party of Import. Such a variety may be derived through rDNA technology (modern biotechnology) or through traditional plant breeding. The second type of plant varieties are those derived from a PNT and, again, this can include varieties of plants derived using biotechnology or traditional plant breeding using a PNT parental line. These derived varieties are not novel because they are no longer new or unique—the parental line has come before. The third type of plant varieties are those that contain a transgenic modification. These plants are explicit products of modern biotechnology because they are derived with a gene inserted through rDNA technology. However, if the inserted gene-trait is not novel, then the GM plant is not a PNT.

Table 1 indicates that Canadian regulations are not explicitly focused on varieties created through the use of modern biotechnology. Instead, varieties that are novel are the focus of regulatory oversight (moving horizontally across Table 1 from PNT). On the other hand, the proposed focus of the BSP is on the use of modern biotechnology. Therefore, unlike Canadian regulations, in-scope plant varieties of the proposed BSP includes PNTs, varieties derived from PNTs and GM varieties. From Table 1, the proposed BSP regulations move vertically down the “modern biotechnology” column because the use of modern biotechnology determines what is in-scope.

**TABLE 1 Differences in Regulatory Focus—Canada and the BSP**

	Modern Biotechnology	Traditional Plant Breeding	
Plant with novel trait	CAN and BSP	CAN	←Canada: NOVEL
Derived from PNT	BSP	(Neither CAN or BSP)	
Contains Transgene	BSP		
	↑ BSP: Products of Modern Biotechnology		

*Source:* Compiled by authors.

LMOs must also be distinguished from genetically modified organisms (GMOs). Generally, products derived from the application of the techniques and procedures of modern biotechnology are known as GMOs or GM products (Phillips and Isaac, 1998; Mulongoy, 1997). LMOs are a sub-set of GMOs because they are those GMOs that retain metabolic activity or remain viable. An often-used example is a genetically modified canola seed. As a seed, it retains metabolic activity, and so it would be both a GMO and a LMO. However, when canola is crushed into oil and meal it is no longer viable and is not a LMO. If the entire crushed seed is used in a product (e.g. bread), then that would be a GMO. Although many view the refined oil as a GM product, in the strictest sense it is not because none of the rDNA is present in the oil—it remains in the meal. Most of the developed countries in the BSP negotiations, including Canada, tend to argue that products that have lost the capacity to replicate are no longer LMOs. Therefore, LMOs would be only those plant varieties found in the ‘modern biotechnology’ column in Table 1 that are still living. Developing countries have proposed including in the definition of LMO the caveat of “products thereof” and hence attempting to capture non-viable GMOs as LMOs under the BSP. In an Information Note (August 12, 1998) the Executive Secretary of the Open-Ended Ad Hoc Working Group on Biosafety concluded that the use of the term ‘products thereof’ exceeds the scope of the BSP as laid out in the CBD. Whether this will effectively conclude the debate on the scope of the term LMO remains to be seen so the definition will be one of the issues examined further.

A second issue is whether the BSP scope pertains to first-time transboundary movements of LMOs or to all shipments of LMOs. The Canadian position is that AIA should be limited to the first movement of LMOs only. Closely associated with this issue is whether AIA must be obtained only from the final import destination or whether AIA must be obtained from any and every jurisdiction that the LMO passes through in transit. The Canadian position, recognizing that exporting can be a complicated process involving many intermediaries, is that AIA should be required only for the final import destination.



Third, the BSP could apply to all shipments of LMOs or only to those shipments intended for deliberate environmental release. Given that the BSP is intended to protect and conserve the biodiversity of Parties of Import from transboundary movements of LMO material, it follows that biodiversity is only at risk when LMO material is released into the environment. Not all shipments are intended for release. The reasons for importing LMOs are varied, including for R&D in contained laboratories, for confined field trials, for production and for processing (Table 2). Only the portion of shipments destined for deliberate environmental release present an explicit risk to biodiversity. However, it remains unclear to what degree the BSP will differentiate between LMOs destined for environmental release and those not destined for environmental release. If the broadest definition of LMOs prevails, the so-called ‘products thereof’ definition, then LMOs would include agricultural and industrial commodities intended for further processing. Although these products present very little risk of environmental release, they would nevertheless fall within the scope of the BSP.

**TABLE 2 Intended Uses of LMOs in Party of Import**

Plant Product LMOs: Includes agri-food commodities and nursery stock products	Low risk of release	Intended release
LMOs for R&D in contained laboratory	X	
LMOs for deliberate but confined release for field testing or seed propagation		X
LMOs for deliberate unconfined release for production		X
LMOs for further processing; food or industrial use	X	

*Source:* Compiled by authors.

Fourth, it is unclear who will be responsible for notification for both AIA and subsequent shipments. There are two types of notification to consider. The first is notification for AIA that involves the Party of Import performing a complete scientific risk assessment (SRA) on the LMO to determine potential risk(s) to biodiversity. This type of notification requires the party responsible to provide all the information required by the Party of Import to fully assess the LMO for the first time. The second type of notification is for the subsequent transboundary movement of an LMO that has already been assessed under the AIA. Although the Party of Import has previously approved the LMO for importation, the responsible party for notification must still notify the Party of Import of the intended shipment. Canadian negotiators have argued that the importer should be responsible for both types of notification because: the Party of Import has legal jurisdiction over its importers, but not over exporters; the importer knows the intended use of the LMO, including whether or not it is intended for deliberate environmental release; an assessment done by the Party of Export would be done relative to the biodiversity of that country, which may vary significantly from the importing country; the identity of the exporter is not always clear as international trade does not simplistically involve one exporter and one importer—there may be several ‘handlers’ of

the product beyond the exporting country and prior to the final destination; importer notification is consistent with international trading practices; and under export notification, the Party of Export would have to enact legislation to ensure that exporters notify the Party of Import.

There are costs associated with the process of notification so that the greater the number of notifications, the greater the cost to those responsible for notification. In Canada, for unconfined releases of PNTs the cost of preparing and supplying the necessary information has been estimated at C\$50,000 or more, depending on the information needed to completely characterize the novel traits (CFIA, Biotechnology Regulations, Procedures for Unconfined Release Approval). With respect to first-time notifications for AIA, the full documentation for the first Party of Import would need to be prepared for each new variety considered to be a LMO. Once the portfolio of information has been put together it would need to be submitted to the intended Party of Import (and any clearing house mechanism). Subsequent shipments of the specific LMO variety to the initial Party of Import or first-time notifications to other Parties of Import for the same new LMO variety might then be made using the same information (perhaps slightly tailored to address differences in biodiversity).

Fifth, there is an issue of segregation of GM varieties from non-GM varieties. Without this ability, there is no way to ensure that co-mingling has not occurred. As a result, all production, both GM and non-GM varieties, would be considered to be GM, according to the precautionary principle, and would be subject to the BSP. In the short-term, the development of an Identity Preserved Production (IPP) system is unlikely. Although Buckwell (1999) argues that IPP systems are feasible, almost all participants in the Canadian grains and oilseeds industry insist that the present Canadian distribution system makes it logistically impossible to segregate GM product from non-GM product (Hart, Vincent & Bubber, 1997), a view shared by both US and European industry participants (Agrevo, Nov. 1997; GAFTA, May 1997; Central Soya, Dec. 1996; NOPA, Dec. 1996; ASA, Dec. 1996 and Sparks Companies, Sept. 1996). Further, the economic feasibility of such a system is seriously questioned by industry. An experimental IPP system for GM canola was implemented in Canada in 1995 and 1996. From this experiment, it was identified that an IPP system created incremental costs of between \$34-37/MT (Manitoba Pool Elevators, 1997). Other estimates suggest that developing and implementing an international IPP system would require a commodity price rise of between 140-180% (EuropaBio, June 1997). Further, even if segregation could be ensured on the production or supply-side and the costs could be passed along to consumers, industry participants argue that many import countries simply lack the capacity to ensure no co-mingling once the commodity is imported.

These issues have significant potential implications for the overall economic and trade impact of the BSP upon Canadian genetically modified trade, which is examined in the next section.

## **Analysis of Potential Economic and Trade Impacts of the BSP**

The objective of this section is to estimate the potential economic and trade impact of the BSP upon Canadian canola exports. According to the unresolved debates examined in the previous section it is possible to identify four potential scope scenarios for the final BSP. The first scenario is the broadest case, assuming that LMOs are defined as all GM products, so that any shipment of any GM variety of a commodity must be notified even if it is not novel nor intended for deliberate release. Without an IPP system, this definition includes all GM and non-GM export products. The other three scenarios consecutively narrow the potential scope of the BSP. Scenario two assumes that LMOs are defined to include all GM products so that any first-time shipment of any GM variety of a product must be notified (but not subsequent shipments), regardless of intended use in the Party of Import. This scenario assumes that an IPP system is present, so that GM and non-GM products may be segregated. The third scenario assumes that LMOs are defined as Plants with Novel Traits (PNTs), where only first-time shipments must be notified, regardless of intended use in the Party of Import. This scenario assumes that an IPP system is present, so that GM and non-GM products may be segregated. Finally, the fourth scenario assumes LMOs are PNTs but that only first-time shipments intended for deliberate release must be notified (i.e. seeds exported for field-trials, propagation or first time production in the Party of Import). This scenario assumes that an IPP system is present. The potential trade and economic impact declines as the definition of LMO narrows.

This section examines the impact of the four scenarios on canola trade in Canada and then extends the analysis to estimate the impact on Canada's total commodity seed trade.

### ***The Product***

Canola is actually two plants commercially produced in Canada: *Brassica napus* L. and *Brassica rapa* L. A third plant, *Brassica juncea* is currently being researched for commercial production. As of 1998, 138 varieties of the two plants, both GM and non-GM, have been registered for commercial planting in Canada. Canola is a prime target for innovation, with more than 30 new varieties being registered annually and the largest amount of transgenic work for any commodity in Canada. Canola was the first GM commodity in Canada to receive approval for unconfined environmental release. The adoption of GM varieties in Canada has been rapid. In 1998, approximately 47% of all canola was produced with GM varieties and in 1999, the adoption is projected to rise to 75% (PBI Bulletin, Sept.1998, <http://www.pbi.nrc.ca/bulletin/sept98/index.html>). Such high rates of adoption fuel research and development into the further application of biotechnology to canola and the other agricultural commodities.

### ***Overview of Production and Export Activity***

Canola is Western Canada's second most valuable crop. In 1997 more than 60,000 farmers collectively planted 4.8 million hectares, producing 6.2 million tonnes of canola worth an estimated C\$2.7 billion. In 1997, over 45% of Canadian canola production was exported (Table 3). In 1997, there were 13 export destinations, which was down from 22 countries in 1995. The drop between those two years was due to the loss of the EU market. Exports of canola to the EU, which had averaged 141,000 tonnes in 1991-93, were stopped in 1997 when genetically modified canola was co-mingled in the Canadian system. Without regulatory clearance in the EU, exports to Europe ceased because of the inability to ensure the segregation of GM canola from non-GM canola in the shipments. Based on the markets served and the capacity of the transport system, it is estimated that there were between 107-385 separate canola export shipments in 1997.

**TABLE 3 Canola Production and Exports (1997)**

Production (1997)	millions C\$ <sup>a</sup>	Production <sup>b</sup> (‘000 MT)	Area Harvest (HA)	Seed (‘000 MT)
	2,734	6,198	4,812,900	35
Exports (1997)	millions C\$ <sup>a</sup>	(‘000 MT)	# Destinations <sup>c</sup> (1997)	# Shipments <sup>d</sup> (1997)
	1,235	2,801	13	107-385

<sup>a</sup>Production and Export values based on 1996/97 Winnipeg Commodity Exchange Twelve-Month Summary Price found in Canada Grains Council Statistical Handbook, 1997/98.

<sup>b</sup>Production numbers: FAO, Production of Commodities by Country Statistics.

<sup>c</sup>Export destinations: *Strategis Trade Data* ([http://strategis.ic.gc.ca/sc\\_mrkti/tdst/engdoc/tr\\_homep.html](http://strategis.ic.gc.ca/sc_mrkti/tdst/engdoc/tr_homep.html)).

<sup>d</sup>Author's estimate of number of shipments.

Although the majority of canola exports are crushed domestically, the Canola Council of Canada reports that in 1997 Canada exported 420,000 MT of ‘canola feed, seed and waste.’ Of the seed that was exported, some of it was intended for crushing in the Party of Import while some of it was indeed intended for deliberate environmental release (i.e. field testing, seed propagation or first-time cultivation). Canadian Seed Trade Association Export Statistics for 1996 show that canola seed for deliberate environmental release accounted for only 0.5% of total exports and was exported to only five destinations (the US, Australia, Belgium, Finland and South Africa). This small amount is not surprising because many of the GM canola varieties have been developed for the Canadian climate and growing conditions. Canadian seeds may be crossed with

local seeds in different countries, but there are few wholly Canadian varieties that are viable in the different ecological conditions existing in other countries. Hence, there is a small volume of Canadian GM canola exported for deliberate environmental release. Also, with respect to the shipments of seed for deliberate release, the volumes tend to be smaller than bulk commodity shipments (i.e. holds in freighters or a hopper car). Instead the shipments often were in bags on pallets in containers.

### ***Extent of Genetic Modification of Canola***

The research effort underlying the application of modern biotechnology to canola is substantial. Up to and including 1997, 138 varieties of canola have been registered in Canada (a further 28 varieties were registered in 1998 and 32 in 1999). The 138 varieties include both GM and non-GM varieties. It is important to identify the proportion of varieties that are GM since the final definition of LMO in the BSP may include all GM varieties and not just PNT varieties of canola.

Field trial data (Table 4) for canola in Canada is broken into single-, double- and triple-trait stacking categories of transgenic modifications. For example, a transgenic modification category for herbicide tolerance is single-trait stacking, herbicide tolerance and nutritional change is double-trait stacking and herbicide tolerance, nutritional change and oil composition represents triple-trait stacking category. Up to 1998, 12 single-trait transgenic modifications have been approved in Canada, involving three single-trait stacking categories: herbicide tolerance, oil composition and hybridization. Therefore, so far, on average, four transgenic modifications are associated with each trait category (12/3).

The 12 approved single-trait transgenic modifications have been used to produce 31 GM varieties of both *b.napus* and *b.rapa* canola. Thus, approximately 3 GM varieties (31/12) are required in order to 'cover the market.' The 31 GM varieties of canola in Canada include four varieties approved as PNTs or novel varieties. The remaining 27 GM varieties are either derived from a PNT parental variety using traditional plant breeding techniques or are varieties that contain a non-novel transgenic modification. In short, an estimated 13% (4/31) of GM varieties are PNT varieties.

Using these benchmarks derived from the relationship between canola research and actual commercialization, it is possible to develop estimates of the potential future biotechnology activity based on the current biotechnology research effort. The field trial data for 1997 (Table 4) indicates that significant work is underway in recent years. Furthermore, the trials reveal that while the focus on single-traits has risen from three to four categories, there is significantly more work on double- and triple-trait stacking categories. There have been trials involving 25 categories of double-trait stacking in recent years and nine categories of triple-trait stacking. The past biotechnology effort indicated that on average four transgenic modifications were possible for each trait-stacking category and that subsequently three new GM varieties were required to 'cover the market' for each new transgenic modification. Therefore, Table 5 indicates that for

both double- and triple-trait stacking the potential stock of new GM canola varieties is 408 while the potential number of new PNT canola varieties is 54.

**TABLE 4 Confined Field Trials for Transgenic Canola in Canada**

Year	B. napus trials	B. rapa trials
1989	39	0
1990	57	0
1991	141	0
1992	225	0
1993	389	6
1994	608	14
1995	234	71
1996	311	173
1997	317	220

Source: Field Trials data from CFIA Plant Biotechnology Office, Summary of submissions and field trials of Genetically Engineered Plant Material, 1988-1997, found at [www.cfia-acia.agr.ca/english/plant/pbo/Trial88.html](http://www.cfia-acia.agr.ca/english/plant/pbo/Trial88.html).

**TABLE 5 Estimated Annual Release of New Canola GMOs and New PNTs**

<b>Assumptions:</b> <ul style="list-style-type: none"> <li>• 4 transgenic modifications/category</li> <li>• 3 varieties/transgenic modification</li> <li>• 13% of GMO varieties are PNT varieties</li> </ul>
<b>Estimated new GMOs/year (both B. napus and B. rapa):</b> <ul style="list-style-type: none"> <li>• double-trait stacking = <math>[(25 \times 4) \times 3] = 300</math></li> <li>• triple-trait stacking = <math>[(9 \times 4) \times 3] = 108</math></li> <li>• Total = <math>(300 + 108) = 408</math></li> <li>• Total/year = <math>408/7 = 59</math></li> </ul>
<b>Estimated new PNTs/year (both B. napus and B. rapa)</b> <ul style="list-style-type: none"> <li>• Double-trait stacking = <math>300 \times 13\% = 39</math></li> <li>• Triple-trait stacking = <math>108 \times 13\% = 15</math></li> <li>• Total = <math>(39 + 15) = 54</math></li> <li>• Total/year = <math>54/7 = 8</math></li> </ul>

Source: Compiled by authors.

However, it is the estimated flow of new GM and PNT varieties each year that is important for this analysis. The field trial data for Canadian canola indicates that there was a 7-year lag between the initial field trials of transgenic canola modifications and the

approval for unconfined environmental release. Although this has narrowed somewhat in recent years, this analysis adopts this seven-year lag as a benchmark for establishing the commercial flow of new varieties. It is estimated in Table 5, with the current research effort and the seven year lag, that 59 potential new GM canola varieties, including an estimated eight potential new PNT varieties, could be released each year. In fact, this may be an under-estimate because it assumes only single-, double-, and triple-trait stacking and it ignores potential higher-order stacking creating new categories of transgenic modifications and, hence, new GM varieties.

One concern is whether the market can absorb the 59 potential new GM varieties each year. The application of modern biotechnology to agricultural products increasingly allows for customized varietal development. GM canola varieties may be developed both for food use and industrial use, to exhibit specific traits perhaps tailored to particular geographical conditions or with targeted end-use attributes. As such, it is increasingly likely that the overall production of canola in Canada may indeed be composed of a vast array of customized varieties and it is increasingly likely that the market may be able to absorb such a large number of new varieties.

### ***Trade Implications of BSP Rules***

In Table 6 the export sensitivity of canola is combined with its current and potential biotechnology activity, in order to establish the export exposure of Canadian canola shipments to the BSP. The estimated export exposure is the potential amount of canola exports at risk of being held-up, delayed or restricted pending the decision of the Party of Import, because they fall under the scope of the BSP. There are four possible scope scenarios to consider and each involves a different level of potential export exposure.

**TABLE 6 Impact of BSP on Canadian Canola Exports**

	Approved for release (Can)	IPP system in Canada	Scope of BSP: What is LMO?
Scenario 1	Yes	No	All first TM of GMOs; No IPP
Scenario 2	Yes	Yes	All first TM of new GMOs; IPP
Scenario 3	Yes	Yes	Only PNTs; regardless of intended use
Scenario 4	Yes	Yes	Only PNTs for deliberate release
	Amount of annual exports affected C\$ millions		Thousands of tonnes annually
Scenario 1	\$1,235		2,801
Scenario 2	\$371		840
Scenario 3	\$48		109
Scenario 4	\$6		14

*Source:* Compiled by authors.

In scenario one, the definition of LMO includes any GM-varieties of canola approved for environmental release in Canada but we assume that there is not an appropriate IPP system in place to ensure segregation of exports of GM varieties from non-GM varieties. In that case, all exports of canola would be considered LMO, since GM-free exports cannot be ensured. If this prevails, then, according to 1997 figures, C\$1.2 billion or 2.8 million tonnes and between 107-385 shipments of canola would be subject annually to potential hold-up, delay or restriction under the BSP. Essentially, until an IPP system can be ensured, all Canadian exports of canola would have to be notified under the BSP.

In scenario two, the definition of LMO includes any new GM varieties of canola approved for environmental release in Canada but we assume that there is an IPP system. Given that a potential 59 canola GMs/year may be developed and assuming an average market share on introduction, based on 1997 figures, would mean that, in a particular year, 30%  $[59 / (138 \text{ stock} + 59 \text{ flow})]$  of the export market would be comprised of new varieties. This would be equal to C\$371 million or 840,000 tonnes that would be in-scope and exposed to potential export hold-up, delay or restriction.

In scenario three, the definition of LMO includes new PNT varieties, regardless of intended use in the Party of Import and there is assumed to be an IPP system. Then the potential exposure of Canadian canola exports to the BSP would be 109,000 tonnes valued at C\$48 million (equal to 13% of the GM trade).

In scenario four, the definition of LMO includes only new PNT varieties intended for deliberate environmental release and it is assumed that there is an IPP system. The potential export exposure of Canadian canola is estimated to be 0.5% of total exports or 14,000 tonnes valued at C\$ 6 million. In this scenario, the impact of the BSP on Canadian canola exports is minimized.

### ***Notification***

The final part of the commodity analysis is associated with the requirements for the responsible party of notification given the potential export exposure of canola to the BSP. Since this issue remains unresolved, it is assumed that exporter notification with some degree of Party of Export responsibility for regulatory oversight prevails.

The estimated annual costs for full notification for AIA is equivalent for both scenarios one and two and for scenarios three and four (Table 7). Under scenarios one and two, LMOs include all new GM varieties in a particular year. For each one of the new GM varieties, a full information portfolio is needed for AIA. Since an estimated 59 GM varieties may be released per year, and assuming that the cost of generating such a portfolio for each variety is C\$50,000, then the estimated annual cost of full notification of new GM varieties is C\$2.95 million. Under scenarios three and four, LMOs include only new PNT varieties in a particular year. With an estimated 8 new PNT varieties per year, the estimated annual cost of full notification for AIA is C\$400,000.



Table 7 also indicates the potential number of separate annual notifications for the transboundary movement of LMOs according to the four scope scenarios. Scenarios one and two will require the equivalent number of separate annual notifications. Each market/Party of Import would have to be notified about each new GM variety, estimated to be 59 per year. Therefore, it is estimated that between 1,298 and 1,770 separate notifications of transboundary movements would be required annually under scope scenarios one and two. Also, if the exporters were responsible for notification, the Canadian federal government would be responsible for ensuring that exporters were indeed notifying the Party of Import and for monitoring the approvals.

**TABLE 7 Potential Transboundary Movements for Notification Under BSP**

Annual impact	Exports 000 MT	Cost C\$000	# markets	# relevant events	# notifications <sup>a</sup>
Scenario 1: All First TM of new GMOs	2,801	2,950	22 – 30*	59	1298 – 1770
Scenario 2: All first TM of new LMOs	840	2,950	22 – 30*	59	1298- 1770
Scenario 3: All first TM of new PNTs	109	400	22 – 30*	8	176 – 240
Scenario 4: All PNTs deliberate release	28	400	5	8	40

*Source:* Compiled by authors.

<sup>a</sup>Number of notifications per year is the product of the number of markets and the number of relevant events (i.e. the estimated potential new LMO varieties that may be released in a year.

\*The number of markets is pending EU approval for LMO varieties of Canadian canola. In 1997, the number of export destinations for canola was 13.

\*\*The number of shipments and markets of PNT seed under scenario 4 is assumed to be 5 relatively small transboundary movements to five different Parties of Import.

Under scenario three, the definition of LMO only includes new PNT varieties regardless of intended use in the Party of Import. Each market/Party of Import would have to be notified of the potential transboundary movement of each new PNT variety, estimated to be 8 per year. In this case, between 176 and 240 separate notifications would be required annually.

Under scenario four, only first transboundary movements of PNT seeds destined for deliberate environmental release would have to be notified. In the case of canola seeds, there were only five relevant Parties of Import for these exports. Therefore, it is

estimated that 40 separate notifications for potential transboundary movements would be required under scenario four.

Although the rules behind the Party of Import's deliberations and decision on AIA have not been fully established yet, it is worth noting that it took the EU three years to approve three varieties of Canadian canola. Under scenarios one and two, where up to 1,770 notifications per year are potentially necessary, the issue of exporter notification indicates a potentially severe regulatory barrier to Canadian exports.

### ***Analytical Extensions***

The potential trade impact of the BSP and the potential economic impact of exporter notification upon Canadian canola producers can be extended to include three other major biotechnology-mediated Canadian export commodities: flax, wheat and barley. As well, scenario four is broadened to illustrate the impact on all Canadian seed exports with biotechnology activity in Canada. These commodities include: canola, flax, wheat, barley, maize, peas, soybeans, alfalfa and broccoli.

Table 8 indicates the annual potential trade impact of the BSP according to the four scope scenarios and including Canadian canola, flax, wheat and barley. In the broadest scope, \$6.4 billion worth of Canadian exports would be subject to the BSP while in the narrowest scope \$31 million worth of exports would be subject to the BSP. Also, Table 8 indicates that under scenario 4, \$115 million worth of annual Canadian PNT seed exports for deliberate release would be subject to the BSP.

**TABLE 8 The Potential Annual Trade Impact of the BSP**

Scope Scenarios and costs in millions of C\$	Cost
Scenario 1: All GMO and PNT varieties are LMOs; without an IPP system	\$6,378
Scenario 2: All first-time GMO and PNT varieties are LMOs; with an IPP system	\$1,399
Scenario 3: Only first-time PNTs are LMOs; with an IPP system	\$182
Scenario 4: Only first-time PNTs for deliberate release are LMOs; with an IPP system	\$31
Scenario 4: Seed Trade Analysis	\$115

*Source:* Compiled by authors.

With respect to the estimated annual cost of notification for AIA, Table 9 indicates that under scenarios one and two the aggregate cost is estimated to be C\$18.55 million for the canola, flax, wheat and barley sectors. Under scenarios three and four, where it is assumed that the definition of LMO includes only new PNT varieties, the estimated annual cost for notification of these four commodities falls to C\$700,000.

**TABLE 9 Potential Economic Impact of Exporter Notification**

Scenarios	Estimated Notifications/year	Estimated Annual Cost of Notification (C\$ 000)
Scenarios 1 and 2: Notification for all GMO varieties	4670 – 5142	18,550
Scenario 3: Notification for only first-time TM of PNT varieties	637 – 701	700
Scenario 4: Notification for only first-time TM of PNT varieties intended for release	84	700
Scenario 4: Seed Trade Analysis	179	1,300

*Source:* Compiled by authors.

With respect to the estimated number of aggregate annual exporter notifications, Table 9 indicates that under scenarios one and two the number ranges between 4,670 and 5,142 separate annual notifications. Under scenario three, for the canola, flax, wheat and barley sectors, the estimated number of notifications required per year would range between 637 and 701. It is estimated that, under scenario four, the canola, flax, wheat and barley exporter would be responsible for 84 annual notifications. Finally, with respect to the broader seed trade analysis, it is estimated that the annual cost of exporter notification for first-time AIA for the Canadian seed export sector would be C\$1.3 million, while the estimated number of separate notifications is 179 per year.

### Conclusions and Policy Recommendations

The canola analysis, combined with the analytical extensions, indicates that the BSP may have significant impact upon Canadian exports of agricultural commodities. The research reveals that a key to minimizing the potential impact of the BSP is to limit the scope of the protocol, which involves limiting the definition of LMO. This section examines negotiation strategies aimed at developing the BSP in a manner that is congruent with the Canadian regulatory framework and sensitive to Canadian agricultural trade interests. We also identify three domestic strategies that may be employed by government or by the commodity sectors to minimize their potential exposure to the BSP.

With respect to negotiation strategies, the research indicates that there are two elements to a BSP that would minimize its potential trade and economic impact upon Canadian exports of agri-food commodities. A BSP scope limited to the first trans-boundary movement of novel seeds intended for deliberate environmental release and combined with importer notification would appear to effectively minimize the potential impact of the BSP upon Canadian export commodities without unduly risking biodiversity. This would be even more effective if Parties of Import could be induced to

manage notification and risk assessments on a regional basis. Efficiencies could then be gained by both exporters and by Parties of Import. Exporters could reduce the cost and effort of notifications for both first-time AIA and subsequent notifications for trans-boundary movements while Parties of Import could pool resources for conducting scientific risk assessment based upon risks to their shared biodiversity.

A number of domestic strategies could also be adopted to minimize the potential impact of the BSP upon export sectors. Three domestic strategies are worth considering: developing IPP systems capable of identifying and segregating varieties; establishing a simultaneous approach to regulatory approval in the Party of Export and the Party of Import; and, undertaking more processing in Canada so that the exports of GM based agri-food products fall outside the scope of the BSP. The third strategy will likely happen based on the economics of opportunities, so warrants little further discussion. The other two strategies may require collaborative industry action or government support, and are worth some discussion here.

Segregation may now be necessary to proceed with further biotechnology based agri-food development. It has been argued that the inability to ensure segregation of GM from non-GM varieties is a short-term issue created by the current structure of both the Canadian grains and oilseeds distribution system and the current Canadian regulatory structure (Yarrow, 1998; Mutch, 1998). As customized varieties involving particular transgenic modifications are developed to meet specific industrial or food-use requirements, greater segregation will have to occur in order to ensure that the industrial or food processors receive the customized variety they have contracted for. Under such commercial demands, these sectors may be required to move away from bulk distribution and handling into niche-oriented contracting of knowledge-based, specific-use agri-food products. Therefore, the long-term strategic commercial interests may make varietal segregation and IPP systems increasingly necessary. Quality assurance in the industry, however, is a quasi-public good and cannot be assured by firms acting alone—either government will need to impose regulations upon the industry or the firms will need to collaborate to regulate themselves.

Either in conjunction with an IPP system, or in lieu of it, industry could approach the regulatory challenge more proactively. Hollebone and Duke (1994) categorize the general regulatory procedure for agricultural products of modern biotechnology according to four steps. The first step is contained research followed, in order, by confined research trials, unconfined research trials and then commercial release. No specific approvals are required for research or green-house trials. Canadian developers first require approval when they want to take their product into the fields—they must seek and acquire approval for field trials. Assuming a positive outcome, this is then followed by approval for unconfined seed release in Canada for production. There are also Canadian regulations pertaining to the end use—approval must be gained before the product is used in foods, as an animal feed or as a feedstock for the pharmaceutical industry. If all the approvals are gained then there is no problem with unconfined environmental release for commercial production in Canada and, hence, co-mingling with conventional products occurs (varieties with industrial or pharmaceutical elements

always require IPP contract systems to segregate them). Finally, if there is potential to export, regulatory approval in another country is then sought. If regulatory approval is not gained in the export market, that export market will most likely be closed to the GM product. But, without an IPP system, even non-GM varieties would be denied access because it is impossible to assure foreign regulatory authorities that the product is GM-free. The problem here is the step-wise approach of the Canadian regulatory approval procedures. Seeking AIA when the GM variety is already in widespread and unconfined release in Canada (or will be shortly), and therefore co-mingled with conventional products, is the root of the problem. As most of the Canadian products of modern biotechnology are exported, AIA should instead be sought from the most likely export destinations at the same time as regulatory review is sought for deliberate release in Canada. Employing a simultaneous approach to regulatory approval would circumvent the segregation issue. This strategy requires more study. One difficulty is that companies are unlikely to adopt such an approach without some protections for their intellectual property (e.g. field trial data), which may require further intergovernmental negotiation.

In the end, however, it is possible that approval for unconfined release may still be denied by one or more potential Parties of Import. Although this threat is indeed real, it in fact provides support for concluding a BSP. If a Protocol is successful in harmonising the manner in which SRAs are performed for GM products, there would be a much lower chance that a GM product will be approved for unconfined commercial release in all but one or a small number of Parties of Import. A BioSafety Protocol, ultimately, would yield a more predictable and effective protection for biodiversity and for companies seeking to commercialise bioengineered agri-food products. In the absence of a Protocol, a patchwork quilt of regulations would impose higher costs, with lower compliance and greater risk to both the environment and biotechnology development.

### Endnote

<sup>1</sup>Grant E. Isaac is Ph.D. Candidate, London School of Economics and Peter W. B. Phillips is NSERC/SSHRC Chair Professor, University of Saskatchewan. The article includes material originally in the study Isaac, Grant E. and P.W.B. Phillips. "Assessment of the Potential Impact of the BioSafety Protocol: The Canadian Agricultural Commodities Case." Study commissioned by the Canadian Food Inspection Agency (CFIA), submitted 1 March 1999. Contacts: G.E.Isaac@lse.ac.uk and phillips@duke.usask.ca.

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