

POST-MORATORIUM EU REGULATION OF GENETICALLY MODIFIED PRODUCTS: TRIFFID FLAX

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1.0 Introduction

Beyond the issue of approvals of GM-products as discussed in the companion paper, *Post-Moratorium European Union Regulation of Genetically Modified Products: Trade Concerns* (Viju et al., 2011), there is another issue where the evolving EU regime for GM-products needs to be examined in the context of barriers to international trade. This is the case where an imported non-GM product is contaminated with an unapproved GM-product. There are two categories of unapproved GM-product events. The first is commonly known as a *low-level presence* (LLP) where the GM product is approved in the export market but not in the importing market. The second form of GM 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)¹. 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. This discrepancy leads to *asynchronous authorizations* where a GM crop may be fully approved for commercial use in one country, but not in others.

The stated EU policy is 0.9 percent threshold of tolerance for *authorized* GMO LLP in non-GM food and feed products. Any conventional product found with 0.9 percent GM comingling must consequently be labelled as GM. The EU maintains zero tolerance for the LLP of *unauthorized* GMOs in conventional food products meaning there can be no imports when any co-mingling is found. Zero tolerance, however, must be operationalized. As it is commercially impossible to test every individual grain of an imported shipment, sampling and testing methods as well their thresholds must be specified for exporters. In other words, potential exporters need to be informed as to what they must do to satisfy the EU that their shipments of non-GM products are free of contamination.

While there have been other examples of non-GM imports into the EU being contaminated with GM material, in 2009 there was a major LLP event where the exporter had a clear desire to continue to have access to the EU market. This case provides an excellent opportunity to assess this aspect of the EUs regulatory regime for GM products. On September 8, 2009, Germany issued an EU-wide Rapid Alert notification confirming the presence of GM-flax in some samples of flax imports from Canada. Imports of Canadian flax were embargoed until Canadian exporters could satisfy the EU regulators that shipments conformed to EU standards. The process of satisfying EU regulators entailed the development of a detailed sampling and testing regime. The GM-flax product that co-mingled with non GM-flax is the variety known as CDC² Triffid. The examination of the Triffid flax case provides considerable insight into what exporters to the EU can expect if they are found to have shipments contaminated with unapproved GM material.

¹ While there are no universally agreed definitions, current industry and government parlance uses adventitious presence (AP) to describe co-mingling of GM material that is not approved in any jurisdiction while low level presence (LLP) is used to describe instances of where GM material is found that is not approved in the country of import but approved in another jurisdiction. The authors have chosen to use these definitions, though others may disagree.

² CDC stands for the Crop Development Centre at the University of Saskatchewan in Canada where the Triffid variety was developed.

The EU regulatory regimes for both new approvals of GM products and GM contamination are in disequilibrium – the former due to the difficulty in finding a politically acceptable compromise and the latter due to technical improvements in detection. In the case of Triffid, flax shipments from Canada could have been co-mingling for up to a decade but there were no Triffid-specific tests which could detect it. While unauthorized but known GMs are often detected with the same methods used for authorized GMs, it is unlikely that the appropriate detection methods are always readily available. As a result, the regulatory processes have not been transparent. The findings of this paper should improve the transparency for both exporting firms and those interested in trade policy.

2.0 Low Level Presence³ of Triffid Flax

There are two main types of commercially cultivated flax. Fibre flax is grown primarily for its long fibres that are used in the production of linen cloth. Oil seed flax (also known as linseed) is largely grown for industrial use, with the oil used in the manufacture of linoleum and paint. CDC Triffid is an oil seed variety. The flax seed is crushed to extract the oil, with the residual meal used as an animal feed. Small quantities of oil seed flax are also consumed by humans. The human market for flax seed has increased in recent years as it has been discovered that consuming flax can impart considerable health benefits. There is no segregation of seed to be used for industrial use from seed destined for human consumption in export shipments. In the case of oil seed flax shipments from Canada to the EU, flax for human consumption is sourced from common cargo.

In most years, Canada is the world's largest flax producer - approximately 750,000 metric tonnes annually. Less than 20 percent of Canadian flax production is consumed domestically. Until the incident when the LLP of Triffid flax was detected in the EU. approximately 70 percent of Canada's flax exports were destined for the EU. With the detection of Triffid flax, imports of all Canadian flax were first embargoed and then, with Canada's development of a testing and monitoring Protocol which was subsequently accepted by the EU, the embargo was lifted. As yet, Canadian exports of flax to the EU have not fully recovered. In the short run, as the Protocol was being put into operation – and risks were high for Canadian exporters – much of the Canadian flax surplus to domestic requirements apparently moved to China at prices much lower than were typically received in Europe. This suggests firstly, that the testing Protocol may be costly to implement, making alternative markets more lucrative for some Canadian producers. Secondly, any shipment that tested positive for Triffid could not be offloaded in the EU. Therefore Canadian exporters had no alternative but to divert these shipments to other markets, at whatever price they could obtain (usually discounted). As the operation of the Protocol has become transparent and refined, Canadian exports to the EU have begun to recover.

³ For this discussion, the authors have classified the Triffid GM event as LLP. The case of Triffid is unique as it was approved by both Canada and the US on a scientific basis but is no longer marketed as it was withdrawn by the developer due to concerns over the potential loss of the EU market for flax. In other words, there is no scientific reason for it no longer being approved. The science underlying the approval has not been questioned in this case of 'approved and then withdrawn'. As Triffid was previously approved and the science behind the approval has not been disputed, the authors have interpreted the Triffid GM event as LLP. Others may believe it should be classified as AP.

The Triffid variety of flax was developed through publicly funded research at the University of Saskatchewan's CDC in the mid-1980s. The genetic modification made the Triffid variety resistant to soil residues of sulfonylurea-based herbicide – a herbicide commonly used on cereal crops which persists in the soil until the next growing season. Field trials of Triffid flax began at the end of the 1980s and the regulatory approval process was initiated by the CDC in 1994. Triffid received official approval for use as animal feed in 1996 and for human consumption in 1998. Approval was also obtained in the United States.

By the late 1990s, however, it was apparent that GM-products were becoming an important political issue in the EU. While future developments in the EU were not clear, segments of the Canadian industry became concerned about continued market access for Canadian flax in the EU. The CDC, Triffid's developer, decided to voluntarily deregister the Triffid variety from the market to pre-empt potential problems with export markets, particularly the EU (EC, 2010e). At that point, Triffid had not yet been commercially grown but seed companies were in the process of growing the Triffid variety to produce seed destined for commercial sale to farmers. A recall and crush of these initial seed stocks was undertaken in 2001. The germ plasm and other materials held by the CDC were incinerated. The CDC Triffid variety was deregistered in 2001. Thus, Triffid flax was never grown commercially and thought to have been removed from the ecosystem. Tests did not exist that could detect the presence of Triffid, but testing technology is not static.

In July 2009, GM material was found in a shipment of flax in the EU. Initially it was thought that the material was the result of cross-contamination from Canadian GM canola. This event, however, led to an increased detection effort in the EU. In September 2009 Triffid was identified in bakery goods in Germany, the first of in excess of one hundred positive tests reported through the EU's Rapid Alert system for Food and Feed (RASFF). Contamination was widely dispersed geographically in cereal and bakery products made by EU firms. The EU market was closed to Canadian flaxseed. The Canadian Grain Commission (CGC) initiated its own testing which confirmed the presence of trace amounts of Triffid material in some Canadian flaxseed shipments.

From the Canadian perspective, a mechanism was required that would allow renewed exports of Canadian flax to the EU. A Protocol was developed by CGC in consultation with the Flax Council of Canada⁴ and DG SANCO, the European Commission Directorate for Health and Consumer Affairs. The Protocol puts in place a mechanism for documenting, sampling and testing for the presence of Triffid flax in the supply chain of Canadian flaxseed destined for the EU. The Protocol satisfies the zero tolerance policy for LLP GMOs as currently interpreted in the EU, i.e. maximum acceptable level of risk of CDC Triffid is at the 0.01 percent level. The 0.01 percent detection level established by the Protocol is linked to a level that can be accurately and reliably detected by the Triffid-specific test. However, the threshold represents a very high commercial risk as it has proven nearly impossible for the grain storing and handling companies to achieve it and, thus, is of considerable economic importance.

⁴ Agriculture and Agri-Food Canada (AAFC), Foreign Affairs and International Trade Canada and the Canadian Food Inspection Agency (CFIA) were also involved (CGC, 2010a).

Testing all along the supply chain began in the fall of 2009 and by April 2010, over 5000 tests had been conducted. A widespread but extremely low level presence of Triffid was found in the Canadian flax production and distribution system. One hundred and seventy four (3.4 percent) of the samples tested positive at 0.01 percent while another 300 (6 percent) tested positive at less than 0.01 percent. Of the 213 tests conducted on pedigreed seed, 6.5 percent tested positive at 0.01 percent (Stephens, 2010). However, the level of detection has dropped in 2011. Only 7 percent of 4,003 samples in 2010-2011 were found positive compared to 10 percent positive samples out of 6,013 farm samples tested in 2009-2010. For pedigree seed, the positive samples decreased from 7 percent in 2009-2010 to only 2 percent in 2010-2011. Similarly, for farm-saved seeds, only 6 percent of samples proved to be positive in 2010-2011 compared to 14 percent in 2009-2010 (Vakulabharanam, 2011).

All of this was done without any scientific justification regarding the imposition of trade restrictions nor a risk assessment. Triffid is not commercially grown and, in fact, may be technically obsolete because the main herbicide it was bred to resist has been supplanted by superior products in the marketplace for herbicides. Thus, no application for approval in the EU for Triffid will ever likely be made. Hence, it is not clear how EU policy toward Triffid flax fits within the EU's SPS obligations.

3.0 EU GMO Traceability and Detection

The EU has introduced a number of regulations to ensure GM safety, detection and traceability and labelling (Table 1). While the process of food safety assessment is the responsibility of the European Food Safety Authority (EFSA), the operation of GM food control systems is performed by the European Commission through the Community Reference Laboratory (CRL) and the competent authorities of individual member states. The EU regulations on traceability are the most stringent rules when considered in an international context. The traceability and labelling regulations facilitate the enforcement of the EU's policies of zero tolerance for unauthorized GMOs and adventitious presence as discussed previously. Davison and Bertheau (2007) describe a typical GMO decision tree utilized under EC labelling regulations (Figure 1). It may serve as a general model or be modified for safety purposes.

3.1 Zero Tolerance and Adventitious Presence

In the EU, when either the LLP of an *unauthorized by the EU*, or AP of a GMO occurs, the product is considered an illegal substance by EU officials and can trigger a significant reaction including emergency measures⁵. The European Commission food safety Regulation

⁵ The unintentional and seemingly unavoidable co-mingling of trace amounts of one type of seed, grain or food product with another during growing, harvesting, transport or processing is a common occurrence. When applied to the situation where GMOs are co-mingled with conventional products, two scenarios can occur within the European Union context. Keeping in mind the definitions of LLP and AP as discussed in footnote 1, the first situation is when *authorized (by the EU)* GMOs are found in non-GM products and is commonly referred to as low level presence (LLP) by the EU. The second is when *unauthorized (by the EU)* GMOs are found and can be either LLP (as in authorized in other jurisdictions) or adventitious presence (AP) (as in not authorized anywhere). The EU has a 0.9 percent threshold of tolerance for *authorized* (by the EU) GMO LLP in non-GM food and feed products. Should authorized GMO amounts greater than 0.9 percent be detected in non-GM products, the product must be labelled as GM. For seed products, the EU maintains a maximum threshold limit of 0.5 percent of GMO content for a specified

Table 1. EU Legislation and Regulations Governing the Authorization Process for GMOs			
Directive	Regulates the deliberate release of GMOs into the environment, including through cultivation, and		
2001/18/EC	requires a thorough environmental and health risk assessment		
Directive	Amends Directive 2001/18/EC on the deliberate release into the environment of GMOs by		
2008/27/EC	introducing references to the new regulatory procedure with scrutiny. Adopted by the Council and Parliament, March 2008		
Directive 2009/41	Recast Directive 90/219 concerning the common measures for the contained use of genetically		
D	modified micro-organisms for the purposes of protecting human health and the environment		
Regulation 2004/65	Established a system for the development and assignment of unique identifiers for genetically modified organisms		
Regulation 178/2002	Resulted in the creation of EFSA and the system of traceability with the concept of at least one step forwards and one step backwards in the food chain		
Regulation	Establishes procedures for the authorization, supervision and labeling of genetically modified food		
1829/2003	and feed and aims to guarantee a high level of protection for human life and health, animal health, the environment and consumers' interests while ensuring that the internal market functions properly.		
Regulation	Broadens the concepts contained in 1829/2003 and includes all types of foodstuffs containing or		
1830/2003	produced from GMOs (e.g. proteins), additives and flavorings for human consumption, and GMO animal feed.		
Regulation	Concerns the transboundary movement and accompanying documentation for living modified		
1946/2003	organisms destined for deliberate release, or for food and feed or for immediate processing, under the terms of the Cartagena Protocol on Biosafety		
Regulation	Amends 1829/2003 to accommodate Community Reference Laboratory for GMOs		
1981/2006	This is 1025/2005 to accommodate community reference Eaboratory for Gives		
Regulation 2008/298	Amends 1829/2003 to confer power to the EC to determine whether a GMO product would be		
	assessed according regulatory procedure with scrutiny in the areas of lowering thresholds for the		
	requirements		
Regulation 2004/641	Provides the detailed rules regarding an application for the authorization of new genetically modified		
	food and feed, the notification of existing products and adventitious or technically unavoidable		
Regulation 298/2008	Amends regulation (EC) No 1829/2003 on genetically modified food and feed as regards the		
	implementing power conferred on the Commission. March 2008		
Recommendation	Sets guidelines for the development of national strategies and best practices to ensure the coexistence		
2003/556/EC	of GMOs with conventional and organic farming, in order to help Member States develop national		
	implementation of such national measures (COM (2006)104).		
Recommendation	The Commission proposed to confer to Member States the freedom to allow, restrict or ban the		
2010/C200/01	cultivation of Genetically Modified Organisms (GMOs) on part or all of their territory. While		
Proposed July 2010	keeping unchanged the EU's science-based GM authorization system, the adopted package consists of		
	a Communication, a new Recommendation on co-existence of GM crops with conventional and/or		
	organic crops and a draft Regulation proposing a change to the GMO legislation. The new		
	Recommendation on co-existence allows more flexibility to Member States taking into account their		
	regulation amends Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation		
	of GMOs in their territory.		
Source: adapted from Vic	ario, 2010, Davison and Bertheau, 2007 and Europa, 2008b.		

list of seed products as per regulation EC 641/2004 (EurLex, 2004). The EU maintains a zero tolerance policy for the presence of *unauthorized* (by the EU) GMOs, regardless of its status elsewhere (AP or LLP); as every unauthorized GMO is presumed to be unsafe by the EU, even minute AP or LLP of an unauthorized GMO in a product can trigger a significant reaction from EU officials including emergency measures. Should *unauthorized* GMOs be discovered via the established detection and traceability system, the EC food safety regulation (Regulation (EC) 178/2002) allows the adoption of appropriate emergency measures for imported food and feed from a third country where the risk cannot be contained satisfactorily by the affected Member State(s) (EC, n.d.a).



Figure 1: A Decision Tree for Labelling GMO Food and Feed

Source: Davison and Bertheau (2007), page 5.

178/2002 allows the enactment of emergency measures for imported food and feed should an unauthorized GMO be found in the EU and the affected Member State cannot satisfactorily contain the risk (EC, n.d.a). Emergency measures can include the assignment of special conditions, temporary or long term import suspensions, or the closing of markets.

The EU's zero tolerance for LLP of unauthorized GMOs is increasingly difficult to operationalize as the commercial production of GM crops is a global activity, with individual countries having different authorization and regulatory procedures, resulting in non-simultaneous approval of new GM crops. The EU regulatory procedure for the approval of new GM crops is very different and much lengthier than in other countries. For example, in the US, the GM authorization requires on average 15 months, while in the EU the process is longer than two and a half years (EC, 2007). This discrepancy leads to *asynchronous authorizations* where, while a GM crop is fully approved for commercial use in one country, it is not in others. The combination of *asynchronous authorizations* with the EU's *zero tolerance* policy of LLP of unauthorized GM crops can negatively affect international trade destined for the EU. The degree of economic impact depends also on the EU's trade response, which can vary from double testing at import/export points to rejection of imports and withdrawal of products that have already entered the EU market.

For example, EU imports of US-sourced maize and rice were halted in 2006 because of the trace detection of GM Herculex maize and LibertyLink rice. Herculex maize was approved in the US but not in the EU at the time, while LibertyLink rice was authorized in the US only for experimental cultivation (Stein and Rodriguez-Cerezo, 2010). Potential trade disruptions could become more severe and more frequent given the increasing rate of GM crop development and adoption in exporting countries, but not in the EU.

Currently, there are about 30 commercial GM crops cultivated worldwide, but it is forecasted that by 2015, there will be more than 120 varieties (Stein and Rodriguez-Cerezo, 2010). Given the co-mingling that occurs within international shipping, the AP and LLP of GMOs may occur in all transboundary shipments of all commodities, GM or non-GM. Testing is not necessarily a solution for managing unapproved traces as, firstly, depending on the testing performed, the outcomes can vary between the origin and destination and, secondly, destination testing results in large risks for importers and exporters. Destination testing means that already transported product can be refused entry, leading either to the cost of returning the product to the country of export or the costs of securing an alternative export market. Given the cost of demurrage and ongoing ship hiring rates, losses can mount quickly.

Some countries grant authorizations for GM crops based upon the GM crop's impact on their exports. For example, CDC Triffid flax received final food safety authorization in Canada in 1998, but was denied approval by the UK's designated authority to which EU GMO authorizations were submitted. As a result, Triffid was never released for commercial cultivation in North America. Given that the EU is the largest export market for Canadian flaxseed, any potential closure of the EU market was seen as disastrous, and segments of the Canadian flax industry lobbied for the withdrawal of Triffid from the market. CDC discontinued Triffid flax production for the sake of removing any risk of losing the EU as an export market for Canadian flax (EC, 2010e). A considerable effort was made to destroy all Triffid seed stock and no further production was authorized. However, even in these situations, unwanted mixing of GMs can result from experimental or illegal cultivation of which Triffid flaxseed is a clear case, exemplifying an unwanted mixing of GM with non-GM seed into a GM event. As reported above, in September 2009, the EC, followed by the Canadian Grain Commission (CGC) confirmed the presence of trace amounts of GM Triffid material in Canadian flaxseed shipments, which resulted in the closure of the EU market for Canadian flaxseed.

In July 2008, the WHO/FAO Codex Alimentarius Commission adopted an amendment in an annex to the GM food assessment that introduced a practical set of simplified risk assessment procedures for the temporary approval of LLP GM products, which are already approved by the exporter, but not by the importer. The guidelines temporarily allow the trace presence of GM products in the process of receiving full authorization in commodity shipments. Further, the Codex Annex encourages the exchange of information between exporter and importer regulators. As the Codex Annex satisfies both exporters and importers, it was adopted by consensus by the over 160 members of the Codex Alimentarius.

However, the Codex Annex is very flexible in terms of implementation options. Firstly, it refers to different categories of products without specifying whether the rules apply to each category in the same way and, secondly, it does not define *low level presence*, allowing countries

to decide what can be considered low level presence (Gruere, 2009). The flexibility of the standard limits its usefulness and reflects the political differences regarding the issue of GM regulation. The Codex Annex cannot, however, be applied in case of Triffid as; firstly, it was never considered for authorization by the EU and, secondly, it was never allowed for commercial cultivation in Canada.

3.2 Detection and Testing Procedures

Another important issue is the difficulty of detecting unauthorized GMs. Part of the GM authorization procedure is dependent upon the development of methods for detection, sampling and identification for specific GM traces. The detection of genetic elements relies mostly on Polymerase Chain Reaction (PCR) or quantitative real-time PCR (qPCR) approaches to testing. The testing is generally performed in two phases. During the general detection phase, screening methods targeting the most common genetic elements found in GM crops are used. In case of GM presence, event-specific methods are used, followed by the quantification of the GM presence (Morisset et al., 2009). Unauthorized but known GMs (AP) are often detected with the same methods used for authorized GMs (LLP). However, for unauthorized GM products, the available information is not sufficient for a full safety assessment in accordance with EU standards and it is unlikely that the appropriate detection methods are always readily available. Thus, the speed of the detection process depends on how fast the CRL validates event-specific methods of detection.

From a technical perspective, both the level at which GM presence, whether AP or LLP, can be detected and the level at which it can be quantified represent two important issues. The current laboratory practices allow the detection of traces of 0.1 percent presence or above, while the level of confidence is dependent on the number of samples and the number of controls (Then and Stolze, 2009). According to a report by the UK Central Science Laboratory (CSL), seed testing and detection methods vary widely among the EU Member States (MS). Sampling varies from 100 percent of all seeds to no sampling and testing, while testing usually operates in accordance to established and recognized standards. The threshold level for LLP of GMOs (i.e. a GM product that has received authorization in the EU but is found co-mingled in a conventional product) at which shipment lots are rejected or must be labelled as GM is also not consistent among MS; while most MS have zero tolerance or 0.1 percent, others have tolerance levels of 0.5 percent, 0.7 percent or 0.9 percent. MS are able to adjust the control program in terms of sampling, number of samples taken, detection limits and decisions taken regarding labelling and enforcement (CSL, 2007). Thus, by definition, 100 percent seed purity is unachievable and the zero threshold must be defined and set in practice, taking into account any technical constraints.

On February 23, 2011, the European governments agreed with the European Commission's proposal for ending the *zero tolerance* policy and allowing traces of LLP GM products up to a 0.1 percent threshold in imports of animal feed. The proposal is only applicable to animal feed and not to food for human consumption. Member States had disagreed over the coverage of the proposal; some wanted the threshold to be applied only to GMOs that have already been approved by EFSA (Inside US Trade, 2011). The conditions under which unapproved GM crops would qualify for the threshold have been strengthened such that the crops in question must have been approved in one or more non-EU producing countries and an

EU authorization application must have already been filed with EFSA for at least three months (Euractiv, 2011b; SaskFlax, 2011). The regulation for this technical solution was endorsed by SCoFCAH on February 22, 2011 and it is now subject to scrutiny by the European Parliament and Council; if these bodies do not oppose the draft, the measure will be adopted by the Commission (EC, 2011)⁶.

3.3 Case Studies - Economic Impacts Arising From AP of Unauthorized GM

A search of the NGO-managed GM Contamination Register indicates 223 cases of non-GM contamination by unauthorized GM material worldwide during the period 1997 - 2010, with 141 cases occurring in Europe. Some cases of contamination with GM material refer to Canadian rapeseed/canola (1997), US corn (EU moratorium/de facto import ban, 1998), Starlink corn (processed corn approved for animal feed but not for food in the US, 2000), Bt10 corn (AP in corn gluten for feed, 2005), Liberty Link rice 601 and 604 (AP in 2006), Herculex maize (LLP, 2006/2007), Roundup Ready II and Liberty Link (soya, 2008), BT 63 rice (AP, 2008), MON88017, MON89034 and MIR 604 (corn in soya, 2009) and FP 967 (Triffid flax, 2009/2010) (COCERAL, 2010).

3.3.1 GM Maize

In 2005, the US mission to the EU announced the accidental release of GM maize, Bt10, in the US. Bt10 is a GM maize line which was developed together with Bt11 maize in the 1990s by the Swiss-based company Syngenta. Bt10 maize is resistant to European corn borer, but its development was discontinued before it reached the stage of regulatory approval. The AP event occurred by accidental labelling of some batches of Bt11 as Bt10. As of 2001, US exports of maize to the EU were likely to be contaminated with Bt10. As a result, the European Commission together with the MS adopted Decision 2005/317/EC, which established the conditions under which US maize products could enter the EU. Firstly, each consignment of GM corn gluten feed and brewers grains originating from the US must be accompanied by a report demonstrating the absence of GM Bt10 and, secondly, the MS had to take measures to deal with products that were already on the EU market. Between April and September of 2005, 1600 analytical tests were carried out by US authorities for corn gluten feed intended for export to the EU and more than 1400 controls were carried out by the MS at point of import or on products already in the EU market. However, no positive results were recorded (EC, 2006). Even though the Commission reported that there was no evidence that the emergency measures negatively impacted the exports of maize from the US, economic costs were increased on both sides due to the additional analysis and control measures.

Another variety of Bt maize, MON88017, which was authorized for cultivation in the US in 2005, but was not yet authorized in the EU, was found as a LLP event in US shipments of soy meal in 2009 and resulted in an EU import ban of US sourced soy meal. MON88017 is resistant to European corn borer and is herbicide-tolerant. In April of 2009, EFSA issued a risk assessment of MON88017 classifying it as harmless. However, the Commission proposal to grant authorization for MON88017 did not receive support from the MS. The continued import

⁶ The status of the technical solution in feed will likely be discussed at the next upcoming meetings of the GM Food and Feed Section of SCoFCAH, provisionally scheduled for July 20, 2011 and Sept 22-23, 2011.

ban for soy products had large negative economic impacts, including a shortage of soy-based feed in the EU (GMO Compass, 2009).

The de facto ban of US maize due to MON88017 forced EU countries to import the only EU-authorized GM maize from Argentina. In 2007, when Argentina approved a new GM strain, EU importers were forced to purchase maize only from Brazil, paying a premium of roughly €50-70 per ton above the price of US maize (Gruere, 2009).

3.3.2 GM Rice

In 2006, traces of Liberty Link 601 (LL601), a GM variety of rice, were discovered in rice being sold in Europe, Africa and Asia. The EU immediately halted the imports of long grain rice from the US. Liberty Link rice varieties were engineered by Bayer Crop Science to be tolerant to Liberty Link herbicides and were not approved by the US at the time of the AP event. Even though LL601 was under development between 1997 and 2001, it was not approved for deregulation⁷ (safe for commercial use) by the USDA (Blue, 2007) until November, 2006.⁸ The EC adopted Decision 2006/578/EC, which established the conditions under which the imports of long grain rice from the US could continue. Each consignment of long grain rice from the US must be accompanied by a report demonstrating the absence of unauthorized GM material, secondly, the MS had to take necessary control measures for products already in the EU market and, thirdly, the EFSA was requested to provide scientific support on this issue. The EFSA concluded in September of 2006 that there was insufficient available information to complete a comprehensive risk assessment, and based on the available information, it was likely that the consumption of long grain rice contaminated with LL601 did not pose any imminent safety concern to humans or animals (EC, 2006).

The LL601 event resulted in a reduction of US total acres planted to rice (mostly long grain rice) by 3.37 percent in 2007 due to the lack of GM-free seed. The economic losses due to export impacts were estimated to be US\$254 million for the 2006/2007 crop year, while future export losses were estimated to be between US\$89 and \$445 million, dependent upon how long the two largest export markets, the EU and the Philippines, remain closed (Blue, 2007). The same report estimates the direct and indirect losses experienced by rice producers due to a price reduction, increased storage time, reduced seed stocks, increased testing requirements, clean up of the supply chain and lost revenue to be approximately US\$200 million. Rice processors incurred costs of approximately US\$90 million to ensure a GM-free system, while BASF, the developer of the Clearfield 131 seed line, a non-GM rice line which was contaminated with LL62 and LL604, lost between US\$1 and \$15 million. The worldwide estimated losses due to the LL601 contamination range from US\$741 to US \$1,285 million, including worldwide food

⁷ The regulation of GM products in the US is provided by three governmental agencies: USDA's Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency (EPA) and the Department of Health and Human Services' Food and Drug Administration (FDA). All three regulatory agencies have the responsibility of ensuring that GM crops allowed for release will not have negative impacts on human health or the environment. A GM crop is deregulated when the regulatory agencies have determined, based on full human health and environmental assessments, that the crop does not pose any risk to human health or environment. Once deregulated, the GM crop does not require the review of regulatory agencies for movement or release in the US (USDA, 2010).

⁸ In November 2006, the US regulatory agencies concluded that LibertyLink rice does not pose any risk to human health, food safety and the environment and, thus, APHIS extended deregulation for LLRICE601 (USDA, 2007).

recalls and the export shipping losses. The costs of the contamination event are even larger if the punitive damages against Bayer Crop Science LLP are taken into account⁹. The ban of US rice cost between 3.5 and 7.5 million Euros per rice importer (Gruere, 2009).

3.3.3 CDC Triffid

Canada is the world largest producer and exporter of flax, with an average of 746,000 metric tonnes production per year between 2000 and 2007, accounting for 40 percent of global production. The other three large producers of flax, China, the US and India, collectively account for 40 percent of world production. The largest market for Canadian flax is the EU, which normally takes over 70 percent of Canadian flax exports. Other important export markets are the US, China, Japan, Australia, Mexico and Brazil (SaskFlax, n.d.). Domestic flax production occurs mostly in the Canadian prairie provinces of Manitoba, Saskatchewan and Alberta, with Saskatchewan being the largest producer (Figure 2). Most of the flaxseed produced in Western Canada is destined for export markets.



Source: Flax Council of Canada (n.d.)

Triffid flax, or FP967, is a GM-flax developed by CDC prior to GMOs becoming a major political issue in the EU. However, given the emergence of GMOs as a major issue, the risks posed by the EU market's reaction to GM products by 2001 a prudent decision was made to deregister Triffid and it was never released for commercial distribution. In less than a year, 5,000 MT of seed were destroyed at a cost of C\$3.2 million and the CDC stock was incinerated. Thus,

⁹ In October 2010, Bayer agreed, out of court, to pay damages in the amount of US\$290,000 to eight Texas-based plaintiffs who are rice growers from three farming operations. Bayer still faces thousands of claims and is participating in mediation discussions with plaintiffs in ongoing litigation (Western Producer, 2010). As of April 15, 2010, Bayer had already lost at least four other cases against it, whose judgements were valued at nearly US\$52 million (Wolf et al, n.d).

Triffid is a unique case; though, originally *approved* for food and feed use by Canada and the US, contamination took place 8 years *after* being deregistered. In the cases of Liberty Link rice or Starlink corn, the contamination happened *before* the two GM crops received final approval, as cases of AP.

Beginning in July 2009, more than 100 reports of the presence of Triffid in different bakery, cereal and other products in a number of EU member states were received (See Appendix A, Table A.1). In November 2009, trace amounts of Triffid were found in Japan and Brazil; Brazil's government announced the mandatory testing of all flax shipments from Canada, while in January 2010, New Zealand started to develop new import protocols for Canadian flax (Smyth and Ryan, 2010). Some of Triffid's wide distribution was explained by the contamination of the breeder seed of two other GM CDC varieties: CDC Normandy and CDC Mons. According to the CDC¹⁰, CDC Normandy and CDC Mons are scheduled to be removed from the market, tested and, eventually, de-registered. Overall, 3.5 percent of farm and elevator flax samples, 10 to 15 percent of the rail shipments and 7 percent of vessel holds tested positive for CDC Triffid (Dawson, 2010). This resulted in the closure of the EU market to Canadian flaxseed.

Brazil also has a *zero tolerance* policy in place. In November 2009, after detecting traces of FP967 in Canadian shipments of flaxseed, the Brazilian government established the mandatory sampling of all flaxseed from Canada, with the rejection or destruction of lots contaminated with traces of FP967. The Canadian and Brazilian governments have negotiated a Protocol including the necessary measures for sampling and testing of Canadian flaxseed destined for Brazil to ensure a zero presence of GM traces (CGC, 2011a).

Due to traces of GMOs found in Canadian flaxseed shipments to Japan, Japan's Ministry of Agriculture, Forestry and Fisheries requested that Canada take preventative measures to avoid future contamination of flaxseed exports to Japan. The Canadian government developed a Protocol outlining the sampling, testing and detection measures to avoid the presence of GM traces greater than the allowable tolerance level of one percent. The Protocol covers the bulk shipments of flaxseed for industrial and feed use. If, after a certain period of time determined by Japan's Ministry of Agriculture, Forestry and Fisheries, compliance with the protocol is demonstrated and negative certificates are provided and validated by the Canadian government, the Japanese authorities will not conduct monitoring (CGC, 2011b).

The Protocols for Canadian flaxseed shipments, including for Brazil and Japan, are generally based on similar principles, procedures and structures, with some country-specific tailoring (CGC, 2011d). For example, the Protocol with Japan has a five rail-car limit for testing sample size not included in the Brazil Protocol. Similar to the EU Protocol, Brazil requires that the testing laboratory be ISO17025-accredited while Japan does not. The Protocols also differ in terms of information sharing and review requirements (CGC, 2011a; 2011b).

¹⁰ As stated by Dorothy Murell, Managing Director of CDC, cited in Dawson (2010).

a. Sampling and Testing Protocol for Canadian Flaxseed Exported to the European Union

Prior to the RASFF notification, in August 2009, German authorities transmitted to the EU CRL, a construct-specific method for detecting CDC Triffid Flax using Real-time PCR. The detection method was developed by Genetic ID NA, Inc., of Augsburg (Germany). The method was specific to the Triffid genetic modification as it targeted a construction found only in Triffid flax. The original method was replaced in October 2009 with a newer version developed by the same company.

Canada responded quickly to the closure of the EU flaxseed market by developing a Sample and Testing Protocol. The main goal of the Protocol is to meet the EU's strict import requirements of *zero tolerance* for unauthorized GMO traces and to assure a secure flaxseed supply. Thus, the Protocol establishes the sampling, testing and documentation measures that must be followed along the entire supply chain of Canadian flaxseed destined for the EU (CGC, 2010b).

Even though the original protocol was accepted by the EU Member States in October 2009, it imposed a large level of risk for both Canadian exporters and EU officials and importers, as the final test results were made available only after transport vessels departed from Canada. This lag time resulted in the quarantining of some flaxseed shipments in the port of Ghent, Belgium after samples tested positive for FP967 – a very costly point in the supply chain for refusals to take place. In response, the protocol was revised in March 2010, and a pre-load test at the port of export ("in-store samples") was added, allowing for the final results to be known before transport vessels were loaded (Hall, 2011). Although there could be, there is not necessarily any further testing once ships have arrived in EU ports¹¹.

In terms of sampling, the protocol specifies that three samples of flaxseeds must be collected at different levels of the supply chain: by the grain handling company from each producer delivery (sample retained for at least six months from the delivery date); before loading the railcar, with each railcar being sampled and the composition of samples comprised of not more than five railcars; and at the terminal elevators prior to loading on ships by CGC¹² personnel.

If the composite sample tests positive for the presence of FP967 at the grain handling level, all railcars that tested positive are removed from the aggregate flaxseed shipment destined for export to the EU and the list of railcars that tested negative is transmitted to CGC. The CGC samples all railcars carrying flax destined for the EU, monitors the unloading of each railcar in a designated silo, then seals and records the silo and seal number. A 2.5 kg composite sample is prepared from each silo and sent to an ISO 17025 accredited laboratory for testing. The laboratory must be from the list of *laboratories approved for testing flaxseed shipments to the European Union*¹³. These approved laboratories use a construct-specific method verified by the

¹² The CGC has published a guide on sampling methods: "Sampling systems handbook and approval guide" (CGC, 2010b).

¹³ The CGC confirms the proficiency of laboratories to test flaxseed samples using the qualitative PCR assay as per the construct-specific method approved within the Protocol for the EU. CGC maintains two separate lists of

European CRL and operate in accordance with the ISO 17025 standard on "General requirements for competence and testing and calibration laboratories" (CGC, 2010a). Any silo in a grain handling or storage facility that tested positive will be diverted from the EU flaxseed supply. The CGC also monitors the loading of negative silos onto transport vessels to ensure they are not destined for the EU and prepares an official *Letter of Analysis* which is presented to the Canadian flaxseed exporter, who, in turn, provides it to the appropriate EU authorities.

b. Economic Impact of Triffid Contamination

The most immediate impact of the Triffid contamination case was upon Canadian flaxseed exports. From a high of 321,400 tonnes of total flaxseed exports for the crop year 2008-09, the level of exports dropped by 124,800 tonnes to 196,600 tonnes for the crop year 2009-10. Exports to the EU decreased from 86,100 tonnes in December of 2008 to 54,300 tonnes in December, 2009 (CGC, 2011c). Exports of flaxseed to the EU continued to drop until May 2010 when they reversed to an increasing trend. One other interesting consequence of the Triffid case is the large increase of flaxseed exports to China. As can be seen in Figure 3, from being a negligible import market during 2008, China imported a high of 55, 200 tonnes of flaxseed in December, 2009, matching the EU's import level.



Source: Authors' calculations based on CGC (2011c).

laboratories, one of labs that have met the CGC's proficiency requirements to test samples, including producer samples, for the presence of FP967 (*Laboratories proficient in testing flaxseed samples for the presence of FP967*). These labs may not qualify to test bulk shipments of Canadian flaxseed ultimately destined for the EU. The second list is of laboratories (*Laboratories approved for testing flaxseed shipments to the European Union*) that are ISO 17025-accredited laboratories that are therefore able to test bulk shipments of Canadian flaxseed destined for the EU.

Among the three largest producers of flaxseed in Canada, Alberta (the smallest among the three) typically presents the lowest farm price level for flax. Figure 4 shows the average flaxseed farm price for the three flaxseed producing provinces as they reflect the same declining trend. The average farm price dropped from C\$490.80/tonne in December, 2008 to C\$357.40/tonne in December, 2009 and the decline continued to May, 2010. In May of 2011, the average farm price for flaxseed reached the highest level since 2008 at C\$566.38/tonne (Statistics Canada, 2011). However, the decline in flaxseed price cannot be attributed solely to the Triffid event as all crop prices suffered a severe price decline starting mid-2008. As European and Chinese prices for flaxseed are not available, the exact effect of the Triffid event on price cannot be isolated and measured. However, as can be observed in Figure 4, the flaxseed average price declined to a greater degree after September 2009 than the average prices of wheat and canola during the same period. Thus, both general market conditions and the Triffid event, likely had an influence on the sharp decline in flaxseed price.



Source: Authors' calculations based on Statistics Canada data (2011).

The gradual increase in Canadian exports to the EU, combined with the increasing average farm price for flaxseed which began in May 2010, subsequent to the adoption of the revised Protocol, shows that general market conditions have improved, but also that Canada's efforts in preserving the flax industry are producing beneficial results, given that the increase in average price for flaxseed is larger than for the other two crops chosen for comparison.

These efforts are not without costs however. The overall value of Canadian flax exports has still not recovered and the Canadian flaxseed industry must absorb substantial storing, testing and handling costs.

Testing is performed at each level of the supply chain. Initially, each producer was required to submit to an approved laboratory, a 1 kg sample for every 75 to 125 tonnes (3,000 to 5,000 bushels) of his crop. Prior to September 1, 2010, the cost of each producer test was C\$105. After September 1, 2010, the cost of testing increased to C\$240 for four subsamples from an initial 2 kg sample (SaskFlax, 2010). According to the Flax Council of Canada (2011), each 2 kg sample represents a lot size not exceeding 5,000 bushels, if the same seed source was used for the entire crop and the field's cropping history has not changed. In January 2011, the Canadian Federal Government announced a new funding initiative under the Canadian Agricultural Adaptation Program (CAAP) which provided C\$1.5 million to partially cover the testing costs incurred by Western Canadian flax producers. The first stage of the program concentrates on testing flax seeds for planting, both pedigreed and farm-saved, for the crop year 2011-12. As of January 1 2011, producers receive a 50 percent discount from the regular cost of testing up to a maximum of C\$100 per sample from the approved laboratories. Starting in August 2011, the program will be extended to the testing of all flax production (Flax Council of Canada, 2010). Thus, the costs of testing the purity of flax have partially been transferred from the industry to Canadian taxpayers.

In addition to the negative international trade impacts, co-mingling of non-GM by GM products imposes large economic losses for the EU. These include additional costs for the EU food industry, reduced profitability, disruption of processing activities, increased risk of doing business in the food sector, possible reduction of the variety of consumer products and potential for higher domestic prices (Brookes, 2008). According to the International Food and Agricultural Trade Policy Council (IPC) (2005), the global costs of segregation in European and other markets have been considerably increased given the number of samples, the type of assessment, the number of events that have to be tested and the number of crops to be evaluated. The estimates reported below were prepared for the international negotiations for the Cartagena Protocol on Biodiversity and provides costs based on two commodities from two large exporters, the US and Argentina:

If all 3,575 export cargoes of maize from the United States and Argentina were sampled and tested only once at loading, the total cost to indicate a cargo "may contain" LMOs¹⁴ would be \$1 million dollars. If, on the other hand, exporters are required to identify and quantify individual varieties, as some countries have proposed, the labelling and testing costs for maize alone, from only these two countries of origin, could quadruple to \$4.4 million annually. If more extensive sampling is required, annual testing costs for maize alone could balloon to \$18 to \$87 million.

If laboratory tests at the export origin must be confirmed at the import destination, testing costs alone could double. There would be additional costs to cover delays. Laboratory tests for LMOs generally require a five to seven day turnaround. Each day a ship waits to unload in port costs approximately \$30,000. Delays would be shorter in developed countries, with nearby laboratories that can expedite test results. But, these delays would be longer for developing countries, which do not have laboratories able to perform these tests and would need to send samples overseas for testing. These delays would add millions of dollars in demurrage costs paid by developing countries.

¹⁴ Living Modified Organism

At present, the additional annual cost to consumers in Japan and Europe of acquiring non-LMO soybeans and maize approaches \$100 million (IPC, 2005, pp. 2).

The European Commission Directorate General for Agriculture studied the economic impacts of the presence of unauthorized GMOs on feed and livestock markets in the EU. Whereas an interruption of maize imports was unlikely to have strong economic impacts on feed imports and livestock production at the EU level, a two year import interruption of soybean imports from the US, Argentina and Brazil was found to increase feeding expenditures by 23 to 600 percent with disastrous effects on the livestock and meat sector (EC, 2008b).

Regarding the additional costs that the Triffid event has imposed on the EU, they are represented, firstly, by the in-port quarantine costs incurred by EU importers, traders and processors when a shipment is found to be contaminated by GM products as shipments become the responsibility of the EU purchaser once they leave Canadian jurisdiction. Secondly, the EU can incur its own testing costs as testing can be conducted at each level of the supply chain. Thirdly, the EU livestock industry has suffered major shortages in the feed supply chain. Finally, by far the largest users of imported flaxseed, EU industrial firms that use linseed oil as a major input to linoleum and paint have suffered from disruptions in input supplies as, at least in the short-run, alternative sources of supply have simply not been available.

According to a study conducted by COCERAL¹⁵ and FEDIOL¹⁶, the total additional costs incurred by the EU flaxseed industry due to the Triffid event amount to \notin 23,530,000 (Table 2) (Dayananda, 2011).

Table 2: Total Additional Cost for EU Flaxseed Industry due to Triffid Event			
Cost Category	Cost €		
Decrease in profit	1,700,000		
Recalled products	2,100,000		
Destroyed products	1,300,000		
Storage cost (blocked products)	130,000		
Customers' claims ¹⁷	18,000,000		
Shutting down operations	300,000		
Total Additional Cost	23,530,000		
Courses Devenendo 2011			

Source: Dayananda, 2011.

According to the same study, imports of flaxseed from countries other than Canada could not replace the imports sourced from Canada and, thus, low supply together with additional management costs have resulted in a sharp increase of flaxseed price in the EU. As a large number of products have been recalled, extra costs were incurred by traders due to freight, storage, sampling, monitoring or even the destruction of some products.

¹⁵ The Committee of cereals, oilseeds, animal feed, oils and fats, olive oil and agrosupply trade of the EU.

¹⁶ The European oil and protein-meal industry federation.

¹⁷ Refunds for food delivered to customers containing flaxseed.

Thus, a *zero tolerance* policy creates an uncertain environment which imposes major risks for businesses involved in trading activities and large economic losses to both EU importers and their foreign suppliers.

4.0 Conclusions

In 2006, a WTO Panel found that the EU's moratorium on the import of products derived from the use of modern biotechnology contravened the EU's SPS obligations. The EU said it would comply with the Panel's ruling, but that it would take time. Although the EU had established the new regime to govern domestic management and imports of GM-products by 2003, an assessment of its full implications had to wait until the system could be seen in operation. Further, the EU regulatory regime for GM-products is very much a work in progress. In particular, as the Member States of the EU learn how the system operates, some Members have taken actions to prevent outcomes they don't like. The European Commission has had to acquiesce to considerable autonomy in Member State's regulatory regimes for GM-products. This latter phase of devolution of GM-products is not transparent. There are two major areas of the EU regulatory regime for GM-products where there is a need for clarification. The first is the approval process for new GM-products in the EU and is discussed in detail in the companion paper by Viju et al., (2011). The second is how imports contaminated with GM-products are dealt with in the regulatory regime.

Recently, a new GM-product has finally worked its way through the new EU approval process meaning that the regulatory regime for new products can be evaluated. Further, the case of Canadian flax exports contaminated by GM-flax has recently arisen and a new import regime put in place. Hence, its working can also be evaluated.

Does the new EU regulatory regime conform to its WTO obligations? Under the WTO, the process used to put trade barriers in place justified on sanitary and phytosanitary grounds are supposed to be science-based. In the EU, neither the regulatory regime for approval of new products, nor the mechanisms for dealing with contaminations are science-based.

The regulatory regime for contamination permits the imposition of import bans with neither a scientific justification nor a risk assessment. No scientific assessment of Triffid flax was done prior to the import ban. The import regime put in place to deal with the contamination of flax with the GM-flax CDC Triffid provides no rationale for the thresholds of safety established for the testing regime. The EU is consistently pushing for commercial, economic and social considerations to be included, along with science, in decision-making. Such considerations are often perceived as avenues for economic protection to creep into EU decision-making. Such considerations can, however, cut both ways. The Canada-EU testing regime for Triffid makes provision for, but does not necessarily require, the testing of cargoes when they reach European ports (Western Producer, 2010). The risks associated with inspection upon arrival made exports to Europe too risky. By only requiring the passing of the tests prior to product leaving Canada, flexibility to find alternative markets for contaminated cargoes has been gained. Thus, while costly, the testing regime for flax exports to the EU has allowed for the resumption of Canadian flax exports to the EU. Of course, the import Protocol negotiated between the EU and Canada for

flax was a *one off*. In a future case, economic and commercial considerations could be used to bolster economic protection. This is why science was agreed upon as the arbitrator of SPS-based trade barriers by the Member States of the WTO, including the EU. Thus, the EU regulatory regime for GM-products would seem open to a new challenge at the WTO. Of course, the political consequences of such a challenge would have to be carefully weighed.

REFERENCES

- Blue, E.N. 2007. Risky Business: Economic and Regulatory Impacts from the Unintended Release of Genetically Engineered Rice Varieties into the Rice Merchandising System of the US, Amsterdam, The Netherlands: Greenpeace International. http://www.greenpeace.org/raw/content/international/press/reports/risky-business.pdf
- Brookes, G. 2008. *Economic Impacts of Low Level Presence of Not Yet Approved GMOs on the EU Food Sector*, Briefing document. <u>www.agrodigital.com/images/estudio.pdf</u>.
- CGC. 2010a. Sampling and Testing Protocol for Canadian Flaxseed Exported to the European Union, Winnipeg: Canadian Grain Commission. <u>http://www.grainscanada.gc.ca/gmflax-lingm/stpf-peevl-eng.htm</u>.
- CGC. 2010b. Background Information on Genetically Modified Material Found in Canadian Flaxseed: Low Levels of Genetically Modified Material Found in Canadian Flaxseed, Winnipeg: Canadian Grain Commission, Feb 1. <u>http://www.grainscanada.gc.ca/gmflax-lingm/pfsb-plcc-eng.htm</u>.
- CGC. 2011a. Sampling and Testing Protocol for Flaxseed Exported in Containers to Brazil. http://www.grainscanada.gc.ca/gmflax-lingm/brazil-bresil/stpfb-peevlib-eng.htm.
- CGC. 2011b. Sampling and Testing Protocol for Bulk Shipments of Canadian Flaxseed Exported to Japan for Feed and Industrial Use. <u>http://www.grainscanada.gc.ca/gmflax-lingm/japan-japon/stpfj-peevlj-eng.htm</u>.
- CGC. 2011c. *Exports of Canadian Grain and Wheat Flour: Monthly Data*. <u>http://www.grainscanada.gc.ca/statistics-statistiques/ecgwf-egcfb/ecgm-megc-eng.htm</u>.
- CGC. 2011d. Personal communications with GGC staff, June 9, 2011.
- COCERAL. 2010. Genetically Modified Crops: Socio-economic Impacts, Co-existence with Conventional Production and Trade Issues, JRC Workshop in Seville, November 5th, 2010 <u>http://www.coceral.com/cms/dokumente/10019236_327226/41d36a2c/COCERAL_GM%2</u> <u>0Workshop%20Sevilla.pdf</u>
- CSL. 2007. Central Science Laboratory. Adventitious Traces of Genetically Modified Seeds in Conventional Seed Lots: Current Situation in Member States, Research Tender Env.B.3/ETU/2006/0106R. <u>http://www.gm-</u> inspectorate.gov.uk/reportsPublications/documents/EUseeds_final_081007.pdf
- Davison, J. and Bertheau, Y. 2007. 'EU Regulations on the Traceability and Detection of GMOs: Difficulties in Interpretation, Implementation and Compliance', CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources 2, No. 077, pp. 1-14.

- Dawson, A. 2010. 'GM-free Certified Seed Part of Plan to Regain Flax Exports to EU: Traces of CDC Triffid have been Found in Mons and Normandy Breeder Seed', *AgReader Mobile*. <u>http://www.agcanada.com/Article.aspx?ID=17377</u>.
- Dayananda, B. 2011. The European Union Policy of Zero Tolerance: Insights from the Discovery of CDC Triffid, MSc Thesis, University of Saskatchewan. <u>http://library2.usask.ca/theses/available/etd-06272011-</u> <u>111926/unrestricted/BuwaniDayanandaMScThesis.pdf.</u>
- EC. (n.d.a.) *GMOs in a Nutshell*. http://ec.europa.eu/food/biotechnology/qanda/c4_en.htm#c.
- EC. 2006. Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0626en01.pdf.
- EC. 2007. Decision 2007/157/EC: Commission Decision of 7 March 2007 repealing Decision 2005/317/EC on emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products (notified under document number C(2007) 674), Celex # 32007D0157, Brussels: Official Journal of the European Communities, 068, 08/03/2007 P. 0008–0009.
- EC. 2008a. Commission Requires Certification for Chinese Rice Products to Stop Unauthorised GMO from Entering the EU, Press Release IP/08/219, 12 February. http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/219&format=HTML.
- EC. 2008b. Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production, Report of the Directorate-General for Agriculture and Rural Development. http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf
- EC. 2010e. Final Report of a Mission Carried out in Canada From Oct 04 to 13 October 2010 in Order to Evaluate the Control Systems for Genetically Modified Organisms (GMOs) in Respect of Seed, Food and Feed Intended for Export to the EU, Health and Consumers Directorate General, 2010-8788.
- EC. 2011. 'GMOs: Harmonisation of Controls for GM Material in Feed Endorsed by Members', *MiddayExpress* of 2011-02-23', News from the Communication Directorate General's Midday Briefing, MEX/11/0223. <u>http://europa.eu/rapid/pressReleasesAction.do?reference=MEX/11/0223&format=HTML& aged=0&language=EN&guiLanguage=en</u>
- EurActiv. 2011b. EU Experts Approve Trace GM in Feed Imports: Official, February 23, 2011. http://www.euractiv.com/en/cap/eu-experts-approve-trace-gm-feed-imports-official-news-502442

- EurLex. 2004. 2004/651/EC of 6 April 2004 Celex#32004R0641 (notice of adventitious presence)
- Flax Council of Canada. 2010. Support to Industry Offsets Flax Producers' Seed Testing Costs, News release. <u>http://www.flaxcouncil.ca/files/web/NEWS%20RELEASE%20-</u> <u>%20Support%20to%20industry%20offsets%20flax%20producers%20seed%20testing%20</u> costs%2012.16.10.pdf
- Flax Council of Canada. 2011. 2010/2011 Flax Sample Testing Program; Approved Labs and Test Submission Forms. http://www.flaxcouncil.ca/files/web/2010-2011%20Testing%20Program_Sept1_R3.pdf.
- Flax Council of Canada. (n.d.). *Production Statistics: Production of Flax by Province, Canada* (000 tonnes). <u>http://www.flaxcouncil.ca/english/index.jsp?p=statistics2&mp=statistics</u>.
- GeneWatch UK and Greenpeace International. 2010. FP967 ('Triffid') Flax has been Grown Illegally in Canada and Exported Around the Globe, GM Contamination Register. <u>http://www.gmcontaminationregister.org/index.php?content=nw_detail1</u>.
- GMO Compass. 2009. Gene technology: Zero Tolerance for Non-authorised Plants Under Discussion. <u>http://www.gmo-</u> <u>compass.org/eng/news/457.zero_tolerance_non_authorised_gm_plants_under_discussion.h</u> <u>tml</u>.
- Gruere, G.P. 2009. Asynchronous Approvals of GM Products, Price Inflation, and the Codex Annex: What Low Level Presence Policy for APEC Countries?, Paper presented at IATRC, 2009, Seattle, Washington. <u>http://iatrc.software.umn.edu/activities/symposia/2009Seattle/seattle-Gruere.pdf</u>.
- Hall, B. 2011. *Triffid: A Year Later*, Flax Council of Canada, Presented at Flax Day 2011, Saskatoon, SK, January 10, 2011. <u>www.saskflax.com/PDFs/2011/2011_BarryHall.pps</u>.
- Inside US Trade. 2011. EU Member States Clash Over Unauthorized GMO Presence in Feed, Feb 10.
- IPC. 2005. 'Upcoming Decisions on Biosafety Protocol Could Sharply Increase Food and Feed Costs: IPC Urges Governments to Weigh Costs Before Taking Decisions', Agri-Trade Forum, 14(1), pp. 1-4.
- Morisset, D. et al. 2009. 'Detection of Genetically Modified Organisms Closing the Gaps', *Nature Biotechnology*, 27, pp. 700-701.
- SaskFlax. 2010. Industry Introduces Fall Testing Program for Flax. http://www.saskflax.com/newsrel_falltesting.html/.

- SaskFlax. 2011. Europe Moving Forward on 'low level presence' Policy for GM Crops, March 4, 2011. <u>http://www.saskflax.com/newsrel_europe_llpfeed.html.</u>
- SaskFlax. (n.d.) Industry Overview. http://www.saskflax.com/industryoverview.html.
- Smyth, S. and Ryan, C. 2010. Liability in the Canadian Marketplace, Presentation at Total Utilization of Flax Genomics (TUFGEN), February 23, 2010. http://www.cfgi.tufgen.ca/minutes/workshop_2010/smyth.pdf.
- Statistics Canada. 2011. Farm Product Prices, Crops and Livestock, Monthly, CANSIM @ CHASS, Tables: Manitoba (v31212177), Saskatchewan (v31212213), Alberta (v31212249).
- Stein, A. J. and Rodriguez-Cerezo, E. 2010. 'Low-level Presence of New GM Crops: an Issue on the Rise for Countries Where They Lack Approval', *AgBioForum* 13(2), Article 8.
- Stephens, D. 2010. Risk Management Studies: The European Union Perspective, presentation. Canada Grains Council 41st Annual Meeting, Fairmont Hotel Winnipeg, Winnipeg, Canada, April 19.
- Then, C. and Stolze, M. 2009. Economic Impacts of Labelling Thresholds for the Adventitious Presence of Genetically Engineered Organisms in Conventional and Organic Seed and Seed Purity: Costs, Benefits and Risk Management Strategies for Maintaining Markets Free From Genetically Engineered Plants, IFOAM EU Group. <u>www.ifoam-eu.org</u>.
- USDA. 2007. Report of Liberty Link Rice Incidents. http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf
- USDA. 2010. Laws and Regulations: Biotechnology. <u>http://www.usda.gov/wps/portal/usda/!ut/p/c5/04_SB8K8xLLM9MSSzPy8xBz9CP0os_g</u> <u>AC9-wMJ8QY0MDpxBDA09nXw9DFxcXQ-</u> <u>cAA_1wkA5kFaGuQBXeASbmnu4uBgbe5hB5AxzA0UDfzyM_N1W_IDs7zdFRUREAZ</u> <u>XAypA!!/dl3/d3/L2dJQSEvUUt3QS9ZQnZ3LzZfUDhNVIZMVDMxMEJUMTBJQ01IM</u> <u>URERDFDUDA!/?navid=LAWS_REGS&contentidonly=true&contentid=BiotechnologyF</u> <u>AQs.xml</u>
- Vakulabharanam, V. 2011. *Flax Testing Results A Positive Outcome Due to Producers' Efforts*, Government of Saskatchewan, <u>http://www.agriculture.gov.sk.ca/avg1107_pg5</u>.
- Viju, C., Yeung, M. and Kerr, W.A. 2011. Post-Moratorium European Union Regulation of Genetically Modified Products: Trade Concerns, CATPRN Commissioned Paper 2011-02.
- Western Producer. 2010. Bayer Settles Lawsuit over GM Contaminated Rice, October 28, 2010. P.18.

Wolf Haldenstein Adler Freeman & Herz LLC; Gray, Ritter & Graham, P.C. (n.d.) Bayer Rice Litigation, Recent News and Events. <u>http://www.bayerricelitigation.com/index.htm</u>.

Appen	dix	A
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Table A.1: Contamination incidents involving Triffid FP967				
Date (2009)	Country	Distributed to	Product	RASFF* number
8-Sep	Germany	Switzerland and Poland	Cereals/bakery products	2009.1171
11-Sep	Germany	Austria and Mauritius	nuts, nut products and cereals	2009.1198
15-Sep	Germany	Netherlands, Luxembourg, Italy and Switzerland.	Cereals/bakery products	2009.1208
18-Sep	Germany	Austria	Cereals/bakery products	2009.1228
21-Sep	Germany	Luxembourg	Cereals/bakery products	2009.1232
24-Sep	Germany	Austria and Mauritius	Cereals/bakery products	2009.1247
1-Oct	Germany	Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Republic of Korea, Luxembourg, Netherlands, Norway, Poland, Singapore, Spain, Sri Lanka, Sweden, Thailand, United Kingdom	baking mixture manufactured in Germany, raw materials from Canada	2009.1267
2-Oct	Germany	None	Ground brown linseed (origin unknown)	2009.127
5-Oct	Germany	None	Animal Feed	2009.1279
5-Oct	Germany	None	Animal Feed	2009.1281
5-Oct	Germany	None	Animal Feed	2009.1286
5-Oct	Austria	Austria, Croatia, France, Germany, Italy, Netherlands, Norway, Poland, Slovakia, Slovenia, Spain, Switzerland	Cereal and Bakery Products	2009.1287
6-Oct	Austria	None	Cereal and Bakery Products	2009.1295
6-Oct	Austria	None	nuts, nut products and seeds	2009.1294
6-Oct	Germany	Egypt, France, Germany, Netherlands, Spain	cereals and bakery products	2009.1289
6-Oct	Austria	None	cereals and bakery products	2009.1291

6-Oct	Austria	Bulgaria, Croatia, Czech	linseed whole grain	2009.1296
		Republic, Romania, Serbia,		
		Slovakia, Slovenia		
6-Oct	Germany	France, Germany,	brown linseed	2009.129
7.0.4	Comment	Netherlands, Switzerland		2000 1207
/-Oct	Germany	None	cereals and bakery	2009.1297
7-Oct	Germany	Mauritius	cereals and bakery	2009 1298
7-001	Germany	Waulitus	products	2007.1278
7-Oct	Romania	Austria, Belgium, Cyprus,	linseed in frozen	2009.1299
		Czech Republic, Denmark,	bakery products	
		Germany, Italy, Poland,	51	
		Romania, Switzerland		
8-Oct	Germany	None	linseed in baking	2009.1311
			mixture	
8-Oct	Germany	Austria	linseed in baking	2009.1313
			mixture	
8-Oct	Germany	Netherlands	linseed	2009.1316
8-Oct	Sweden	Italy	linseed	2009.1307
8-Oct	Germany	Macedonia, The Former	brown linseed	2009.1308
		Republic Of Yugoslav,		
		Greece,	1 11 1	2000 1200
8-Oct	Germany	Poland, Luxembourg,	brown linseed	2009.1309
		Austria, Czech Republic,		
8 Oat	Cormony	None	lingaad	2000 1214
0-001	Germany	None	linseed	2009.1314
9-000	Germany			2009.1318
9-Oct	Austria	Poland	linseed	2009.1322
9-Oct	Austria	None	linseed	2009.1323
12-Oct	Cyprus	Switzerland, Belgium,	linseed in frozen	2009.1331
		Romania, Poland, Italy,	bakery products	
		Denmark, Czech Republic,		
12 Oct	Finland	Ausula Latvia Estopia	linseed in frozen	2000 1335
12-001	Tilliand	Latvia, Estollia	hakery products	2009.1333
13-Oct	Germany	import via Poland	linseed	2009 1339
13-Oct	Germany	None	brown linseed	2009.134
13-Oct	Germany	Bulgaria Austria Czech	linseed	2009.131
15-001	Germany	Republic Germany	miseeu	2007.1341
		Croatia Romania Serbia		
		Slovenia. Slovakia		
13-Oct	Germany	Slovakia, Slovenia, Serbia.	linseed	2009.1342
		Romania, Croatia,		
		Germany, Czech Republic,		
		Bulgaria, Austria		

14-Oct	Germany	Austria	linseed	2009.1349
14-Oct	Germany	Austria	linseed	2009.1351
15-Oct	Germany	Italy, Ireland, Hungary, Croatia, Greece, United Kingdom, France, Spain, Germany, Czech Republic, Switzerland, Belgium, Austria, Slovakia, Slovenia, Portugal, Poland, Netherlands	linseed in bakery mixture	2009.1363
15-Oct	Germany	None	linseed meal (animal feed)	2009.1365
20-Oct	Greece	None	brown linseed	2009.1388
21-Oct	Germany	None	linseed in bakery mixtures	2009.1397
21-Oct	Germany	Slovenia, Hungary, Germany, Greece, Austria	brown linseed	2009.14
22-Oct	Italy	Slovenia	linseed	2009.1413
22-Oct	Germany	Italy, Portugal, Malta	brown linseed	2009.1414
26-Oct	Cyprus	None	linseed in bakery mix from Germany	2009.1444
27-Oct	Cyprus	None	brown linseed	2009.1453
28-Oct	Germany	Sweden, Poland, Netherlands, Latvia, Luxembourg, Lithuania, Italy, United Kingdom, France, Finland, Denmark, Czech Republic, Switzerland, Austria, Slovakia	linseed in bakery products	2009.1462
29-Oct	Germany	Austria	linseed	2009.1472
30-Oct	Germany	Austria	linseed	2009.1474
30-Oct	Luxembourg	None	brown linseed	2009.1476
30-Oct	Luxembourg	None	linseed	2009.1477
30-Oct	Luxembourg	None	linseed	2009.1485
3-Nov	Germany	None	brown linseed	2009.1489
4-Nov	Slovenia	None	brown linseed	2009.1497
4-Nov	France	None	linseed in wholegrain toasted bread	2009.1498
4-Nov	Germany	None	linseed in bakery mixture	2009.1501
3-Nov	Germany	None	brown linseed	2009.1506
4-Nov	Finland	imported via Israel	linseed in food	2009.BXE

			supplement	
5-Nov	Greece	None	organic brown	2009.1515
			linseed	
6-Nov	Switzerland	None	linseed in muesli	2009.1523
	(via EU			
	Commission)			
6-Nov	Switzerland	United Kingdom	brown linseed	2009.1524
	(via EU			
	Commission)			
6-Nov	Germany	None	brown linseed	2009.1531

Source: GeneWatch UK and Greenpeace International (2010).