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

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The primary reason for negotiating trade agreements – rules of trade – is to provide firms conducting international transactions with transparency regarding the ways in which governments can intervene in those transactions. Engaging in international trading activities is a risky activity. One of the major risks is that, after investing in developing a market for a product and enjoying some commercial success, a government could intervene to ban, tax or impose costly regulations on the transboundary movement of the product. If governments can intervene in international markets without constraint then the risk of investing in international trading activities rises, these investments are inhibited and the benefits of international trade foregone. This is true for both exporting firms and firms relying on imported products. While firms that wish to engage in international transactions would likely prefer that governments would agree to not intervene in international markets, they also realize that this is not realistic as there may be domestic political imperatives that politicians feel they must respond to by providing protection. As a second best alternative, firms would like rules for when and how governments can intervene. The transparency provided reduces the risk when making investments in international trading activities. Thus, at any point in time, the rules of trade represent the current compromise between firms' desire for strong constraints on the ability of governments to intervene in international transactions and governments' need to respond to domestic vested interests demanding protection.

If governments chose to ignore their international obligations, then transparency is reduced and returns to investing in international trading activities eliminated or reduced. One of the most sensitive areas of international trade relates to the rules pertaining to human, animal and plant health and threats to the natural environment – sanitary and phytosanitary issues. In the Uruguay Round of multilateral trade negotiations, an Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) was reached. It was agreed by all WTO member states, including the European Union, that scientific legitimacy would be the sole criterion upon which trade measures imposed for sanitary or phytosanitary reasons could be justified.

The central elements of the SPS are that to impose a trade barrier there must be a scientific reason for its imposition and that failing to impose the barrier would lead to an inacceptable level of risk. Thus, a country wishing to impose a barrier must provide a legitimate scientific justification and undertake a risk assessment. Either of these can be challenged by an exporting country and, ultimately, it is up to a WTO disputes panel to determine if the barrier is justified. The SPS recognizes that there may be situations when there is insufficient evidence to arrive at a scientific conclusion and in those cases a country is allowed to impose a temporary barrier until sufficient scientific information is available – a precautionary barrier. If a country imposes a precautionary barrier it is obligated to pro-actively seek the needed scientific information. Thus, firms that wish to engage in international trade in products where problems related to human, animal or plant health or risks to the natural environment could arise can expect certain processes to be followed if trade barriers are imposed. A scientific reason should be provided, a risk assessment should be undertaken, if there is no scientific consensus then, while a temporary barrier is imposed the imposing country should be actively seeking the required information.

Genetically modified (GM) organisms and products fall under SPS and have proved to be a very controversial issue in international trade. This has been particularly the case for the European Union where there has been vociferous opposition to the domestic licencing of GM organisms and products and their import among some groups in civil society – opposition that EU politicians have felt they cannot ignore. The EU Commission has chafed under its SPS obligations as the opponents of biotechnology have steadfastly insisted that the scientific evidence on the safety of GM organisms and products is insufficient, the risks are too great and/or that the technology is simply unacceptable under any circumstances.

In response to this fierce resistance to biotechnology, in 1999 the EU put in place a temporary ban on the licencing of new GM organisms and products along with a moratorium on imports. In 2003 Canada and the United States challenged the import ban at the WTO. In a 2006 judgement, the WTO Panel agreed with the complainants and asked the EU to bring its import regime into compliance with its SPS obligations. The EU said it would comply but asked for time to put a new regime in place. While the outlines of the new EU policy were announced in 2003; it has been a very difficult political process to finalize the policy and it remains a work in progress. The first new GM products under the revised policy were, however, licenced in 2010 so it seems timely to assess whether the EU is now in compliance with its SPS obligations.¹

Beyond the issue of approvals of new GM-products 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). 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 a 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, or more, GM co-mingling 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

¹ These issues are covered in considerable detail in our companion paper *Post-Moratorium EU Regulation of Genetically Modified Products: Trade Concerns*, CATPRN Commissioned Paper 2011-02.

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 CDC 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.

Oil seed flax (also known as linseed) is largely grown for industrial use, with the oil used in the manufacture of linoleum and paint. 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. 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. Thus, the closing of the EU market to Canadian flax imposed considerable costs on the Canadian industry and the costs associated with the Protocol appear to be significant. Further, EU importers of flax for industrial uses had no alternative sources of supply and also suffered considerable losses. As the operation of the Protocol has become transparent and refined, Canadian exports to the EU have begun to recover.

While Triffid had been licenced in Canada, it was never grown commercially. It was withdrawn from the market and efforts were made to destroy all existing stocks of seeds – to the best of anyone's knowledge Triffid no longer existed. Canada exported flax to the EU for a decade after Triffid was withdrawn and there were no tests available to detect its presence. Genetic science is not, however, static and new tests are being developed on an ongoing basis. In 2009 a new test detected Triffid in baked goods in the EU. This test was then used in Canada and Triffid was found throughout the supply chain. The detection of Triffid, a GM product not approved in the EU, led to the immediate import ban.

There are two major policy issues pertaining to the Triffid incident: (1) Is the import ban consistent with the EU's SPS commitments?; (2) Given that LLP incidents for non-authorized GM organisms and products are expected to increase in frequency as new GM products are approved in exporting countries, what has been learned about how the EU can be expected to

operationalize zero tolerance? In the case of Triffid flax the EU did not examine the existing scientific evidence – and evidence does exist because Triffid was approved in both Canada and the US, and it did not undertake a risk assessment prior to putting the ban in place. The EU did not formally invoke the precaution clause in the SPS – as it did not examine the scientific evidence – and has not actively sought to gather the scientific information required for a formal scientific-based decision. Thus, the EU policy on LLP for non-authorized GM organisms and products does not appear to be consistent with EU SPS commitments and it is open to a WTO challenge. While considerable attention has been given to the EU's policy for approving new GM organisms and products, as the Triffid flax incident illustrates, the EU policy on LLP can also lead to disruptions to international trade and impose considerable costs. Thus, this facet of trade policy should not be ignored by policy makers.

Until there is a successful challenge at the WTO, the EU policy on LLP is likely to remain in place. Under this policy, there is a zero tolerance level for GM material that has not received EU authorization. Zero tolerance, however, has to be operationalized – what does an exporting country have to do to prove it is in compliance with zero tolerance? The Protocol on Triffid flax was formally proposed by the Canadian flax industry, not the Canadian government, and accepted by the European Commission. It entails an extensive and costly testing regime all along the flaxseed supply chain. Canadian exports of flaxseed have resumed to the EU. The Protocol provides sufficient transparency for firms to be willing to engage in international transactions. This suggests that as long as the EU regime on LLP remains in place, firms exporting agricultural products to the EU should plan for a LLP event and develop plans as to how exports can come into compliance with the EU's zero tolerance policy. The sooner a plan is accepted, the sooner exports can resume and the disruption to trade minimised.