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Peter W. B. Phillips and William A. Kerr

University of Saskatchewan

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Author Contact Information:

Peter Phillips

Professor, NSERC/SSHRC Chair in Managing Knowledge-Based Agri-Food Development
Department of Agricultural Economics
University of Saskatchewan
51 Campus Drive
Saskatoon, Saskatchewan
Canada S7N 5A8

Phone: 306-966-4021

Fax: 306-966-8413

E-Mail: phillips@duke.usask.ca

Web page: <http://www.usask.ca/agriculture/agec/profiles/phillips.htm>

Bill Kerr

Van Vliet Chair
Department of Agricultural Economics
University of Saskatchewan
51 Campus Drive
Saskatoon, Saskatchewan
Canada S7N 5A8

Phone: 306-966-4022

Fax: 306-966-8413

E-Mail: kerrw@duke.usask.ca

The BioSafety Protocol and International Trade in Genetically Modified Organisms

The issue of appropriate rules for the regulation of trade in genetically modified organisms (GMOs) has become the focal point of an often heated debate. The wrangling over trade rules is part of the larger international debate raging over the regulation, and even the desirability of, commercial applications of genetic manipulation. Biotechnology represents a significant technological change, which along with having the potential to provide considerable benefits, also raises questions and creates uncertainties. For those investing in the development of biotechnology, trade is a crucial issue. The rate of technological advance in biotechnology is likely to be very rapid meaning that the commercial life of any new genetic modification is likely to be short. This means that access to potential markets may be a critical determinant of profitability. Environmentalists and those with strong preferences regarding the quality of their food have tended to focus on the uncertainties surrounding GMOs and have lobbied for a *go slow* approach to their release into the market. From their perspective, imports represent a potential source of undesirable products.

Governments have been caught on the horns of a dilemma – they realise the potential benefits of the new technology but also feel they must address the concerns of those who are advocating caution. The outcome of this dilemma has been that governments in different countries have taken a variety of approaches to domestic licensing depending on the relative weights given to the potential benefits and costs by policy makers. Hence, access to some markets may be delayed or denied altogether. These differences in domestic regulatory regimes for GMOs can inhibit international trade. The existing international trade institutions were not designed with the particular circumstances of the biotechnological revolution in mind. As a result, the question of appropriate rules of trade in GMOs has arisen.

In addition to the direct protagonists in the biotechnology debate, there are a large number of parties who have a considerable stake in the rules of trade, which will govern GMOs. Farmers face uncertainty regarding the advisability of planting GMOs. Food handling and processing firms may be faced with making significant investments in identity preservation systems. Governments in developing countries may have to seek technical assistance to ensure continued market access for their products. Food inspection agencies will have to budget for equipment and staff training. Consumers wishing to make informed choices will have to spend time and effort to acquire the information they need. Hence, increasing the transparency of the rules of trade should be a priority for governments. Unfortunately, the BioSafety Protocol (BSP) recently signed in Montreal only serves to further muddy the waters.

The World Trade Organisation (WTO) is the international institution that has the primary responsibility for establishing rules for trade in goods and services and the international protection of intellectual property rights. Its focus is protecting firms that wish to invest in international commercial endeavours from the capricious use of trade barriers by government. While the WTO has a Committee on Trade and the Environment, it has consistently maintained that it does not have the expertise to make policy regarding the environment, suggesting instead that the proper policy forum is Multinational Environmental

Agreements (MEAs). A number of MEAs include provisions for the imposition of trade measures. The Committee on Trade and Environment, however, has not yet been able to clarify the relationship between the WTO and MEAs and, in particular, which organisation's rules should take precedent when trade provisions of MEAs conflict with those of the WTO (Kerr, 2000). A related unresolved issue is which rules apply when the WTO and a particular MEA do not have totally overlapping memberships.

The BioSafety Protocol is a MEA that is charged with devising a comprehensive international regulatory approach to the protection of biodiversity. The Cartagena Protocol, concluded in negotiations in Montreal on January 29, 2000, establishes rules to manage the environmental risks of transboundary movements of genetically modified living organisms. Although the BSP has an environmental orientation, it also has provisions that have significant potential implications for trade in GMOs. The preamble to the protocol acknowledges this and emphasizes that it *shall not be interpreted* as changing the rights and obligations of countries under other international pacts, such as the WTO.

Traditionally, environmental protection has been a predominantly domestic policy issue. The WTO maintains the divide between domestic and trade policies through the rigid application of four principles: (1) the focus on products and not production and processing methods (PPMs); (2) the national treatment provisions (e.g., GATT 1994, Article I which states that foreign products must be treated like domestic products); (3) the most-favoured nation principle (e.g. GATT 1994, Article III which states that all contracting parties must receive the same treatment domestically as the most-favoured nation receives domestically); and (4) the common exemption of environmental and natural resource issues under GATT 1994, Article XX (general exemptions) (Phillips and Buckingham 2000). However, agricultural biotechnology, which is centred around PPMs, makes it difficult to sustain this divide. This creates a fundamental challenge for the Biosafety Protocol as it attempts to balance environmental objectives and trade objectives.

The Biosafety Protocol

The BSP was negotiated between 1996 and 2000 by 138 countries under the auspices of the 1992 Convention on BioDiversity (CBD) of the United Nations Environmental Program (UNEP). The agreement, which must be ratified by at least 50 countries before it comes into force, provides rules for transboundary movements of GM organisms intended for environmental release and for those destined for the food chain.

For living GM organisms (e.g. seeds for propagation, seedlings, fish for release), exporters will be required to obtain approval from importing countries. Within 15 days of domestic regulatory approval having been granted for a new GM variety, a country would notify a Biosafety Clearing House with information about the traits and evaluations. The first time that a new GM variety is exported as seed, the exporting country would notify the importing country. The importing country would then decide whether to approve the shipment or decline the shipment because of risks identified through a science-based risk assessment. This process is called "advanced informed agreement" (AIA). Although this seems straightforward, the Protocol includes two features that may be the source of conflicts in coming years. First, the text indicates that countries may in their reviews of GMOs consider

socio-economic factors (e.g. the impact on local farmers), provided they respect their other international obligations. Second, the protocol includes the so-called *precautionary principle*, whereby countries do not have to have complete scientific certainty to block imports of a GMO that they fear could be harmful to biological diversity. Although it is unclear how the negotiating parties expect the two exemptions to operate, it is likely, given the reference in the preamble to other international obligations, that any import bans that are not based on scientific risk assessments will be inconsistent with WTO obligations. As with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) under the WTO, temporary bans may be permitted but it is likely that countries will need to make real efforts to undertake the science to validate (or refute) the concern.

The framers of the Protocol have attempted to tightly focus it on environmental risks. To that end, transboundary movements of genetically modified organisms intended for food, feed and processing (e.g. commodities) will be exempt from the advanced informed agreement provisions. Nevertheless, exporters must label shipments with GM varieties as *may contain GMOs* and countries can decide whether to import those commodities based on a scientific risk assessment. Furthermore, GMOs intended for *contained use* (e.g. national breeding programs and research) and GMOs in transit through other countries will not require AIAs.

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 genetically modified products. Successful completion of the Protocol has the potential to positively influence international trade in three significant ways. First increased trade transparency according to the use of the AIA principle should remove friction in the market. Second the scientific risk assessment procedures should increase trade fairness by ensuring that risks to biodiversity from genetically modified products, whether domestic or foreign, are assessed consistently using credible scientific risk assessment procedures. Third, the Protocol should overcome the lack of domestic regulations in those countries with little or no experience with regulating genetically modified products (Mulongoy 1997). In this sense, the successful negotiation of the BSP can be interpreted as a potential win-win outcome. The global benefit, shared by all countries, is the overall conservation and protection of biodiversity. From an industry perspective, successful completion of the BSP has potential benefits for further research on and development, adoption and commercial use of genetically modified products because it would potentially increase predictability of market access.

It is perhaps too early to confidently evaluate the protocol. In the first weeks after the agreement, almost all participants in the talks—developed and developing country governments, agricultural producers, biotechnology companies and public interest groups—have expressed optimism that the protocol will protect the environment without unduly impeding international trade. Representatives from the *Miami Group* of countries—Canada, United States, Australia, Argentina, Chile and Uruguay—have applauded the agreement as providing sustained market access and protecting WTO rights and obligations. The EU and the Third World Network point to the *precautionary principle* as a key innovation. Producers and biotechnology companies cautiously support the narrow focus on varieties for intended

release. Public interest groups are pleased with the *precautionary principle* and provisions for socio-economic factors being taken account of in the decisions.

Nevertheless, the Protocol will not resolve all of the concerns in the marketplace. First, the US, which is the single largest producer of GM crops, has not ratified the 1992 CBD, which means that although it may abide by the Protocol, it will not be a party to it. Second, most of the developing countries in the world have little or no experience with domestic biosafety regulation and the Cartagena Protocol provides only limited protection against any adverse impact of agricultural biotechnology. The Protocol does not cover research and development, transfer, handling, testing, use and disposal of all GM products; those responsibilities will continue to fall on national governments. Third, the Protocol has not handled all of the socio-economic, ethical and consumer concerns as many hoped. Those concerns remain unanswered in any existing international agreement. Finally, there are likely to be disputes that arise from the agreement but it is not clear from the information available how the Protocol will handle them.

The economic and trade impact of the Protocol depends on how it is implemented. A recent study of the potential impact of the BSP (Isaac and Phillips, 1999) concluded that the trade impact for canola could be as small as 0.5% of total exports, equal to an estimated \$6 million annually (with the scope limited to first time shipments of GM organisms intended for deliberate release). This impact would rise if countries designate some commodity shipments as potential seed for release. As well, the impact could rise depending on how the mandatory labelling of commodity shipments influences market access. It is possible that some countries may not reject shipments based on scientific assessments but there may be delays because of the large volume of new varieties to consider. Isaac and Phillips (1999) suggest that as many as 408 new GM varieties of canola, involving 54 novel traits, could be introduced in Canada over the next seven years. Combined with the flow of new traits in other crops, many countries with limited regulatory capacity may be swamped. If segregated production and marketing systems are not possible, then all the production from a country must be considered as GM if approval for the unconfined production of even one GM variety has been granted. In the short-term, participants in the Canadian grains and oilseeds industry insist that the present Canadian distribution system makes it 100% logistically and economically impossible to segregate GM product from non-GM product (Hart, Vincent and Bubber, 1997, Phillips and Smyth, 1999), a view shared by both US and European industry participants. The few systems that were tried in Canada cost an estimated \$33-41/tonne in incremental handling costs (Manitoba Pool Elevators, 1997). More recently, a number of US grain merchants have introduced producer contracts for GM-free deliveries but it is not clear yet whether there are premiums in consumer markets to pay for the incremental costs. This could effectively impede international market access for biotechnology products.

The BSP's trade provisions and the WTO

As suggested above, four aspects of the BSP's trade provisions directly conflict with WTO principles and practices: (1) trade barriers justified on the basis of production and processing methods; (2) the inclusion of the *precautionary principle* as decision criteria for the imposition of import bans; (3) allowing socio-economic factors to be considered in the approval process for imports and; (4) mandatory labelling of commodities not destined for

agronomic production which potentially contain GMOs. The latter seems oddly placed in a protocol that is supposed to be narrowly focussed on protecting biodiversity. It can be interpreted as an attempt by those opposed to biotechnology to obtain the ability to inhibit international trade in GMOs through the back door when they have been unsuccessful in obtaining it at the WTO. The potential for conflict with WTO conventions makes it imperative that the question of which organisation take precedent over the other be decided quickly (Hobbs, 2000).

The WTO does not allow trade barriers to be put in place on the basis of PPMs. Only product characteristics can be used. It has been long recognized that allowing the use of trade barriers on the basis of PPMs would provide a wide open door for protectionist interests. If, for example, cotton cloth could be excluded from a market because it was produced on hand looms rather than modern machinery, then it would be easy for vested interests in countries using modern machinery to lobby for protection against (cheap) cotton produced on hand looms. As long as the cotton cloth from both processes is similar (does not have different product characteristics) then the WTO rules do not allow countries to impose trade barriers. When the subject of allowing trade restrictions on the basis of PPMs has been brought up in the context of GMOs at the WTO, developing countries, in particular, have objected strenuously seeing it as the *thin edge of the wedge*. Developing countries feel that they did not receive the benefits pertaining to textiles and clothing that they expected from the Uruguay Round and are pressing hard for further liberalization. Hence, they are extremely sensitive to any rule changes that could be used to thwart their attainment of increased market access in developed countries. Given the difficulties developing countries are likely to have in regulating domestic use of GMOs, they will perceive that the PPM provisions of the BSP are simply a form of disguised protectionism put in place to deny market access in developed countries for their agricultural products. They can be expected to seek recourse in WTO rules. Clearly, the WTO rules were not put in place with the unique problems associated with a technological advance such as genetic engineering in mind.

It may seem that the insertion of genetic material through biotechnology represents a product characteristic as well as a PPM and, hence, can be handled by the existing WTO rules. Unfortunately, the question is not so simple. Most of the genetically modified products in commercial production are based on improving agronomic performance such as resistance to herbicides or insects. For the consumer, there is no visible difference between a potato whose plant has been genetically altered to resist pests and one which is derived from a plant, which has not been altered. This *absence of difference* has been part of the basis for domestic approval of genetically modified foods in some countries such as Canada.

Even if one is willing to accept that agronomic enhancing modifications are additions to product characteristics, other problems remain with the BSPs inclusion of PPM as a criteria for restricting trade. The BSP makes no distinction between transgenic and non-transgenic applications of genetic engineering. Transgenic modifications (e.g. insertion of a fish gene into a tomato) do add new material from different biological organisms and, hence, could be considered a new product characteristic under the WTO. Non-transgenic modifications simply select genetic material from the same species. It allows improvements to crops such as wheat to be done accurately rather than through the trial and error methods of traditional plant

breeding. Genetic engineering is a process and, hence, falls under the BSP definition but it is hard to argue that non-transgenic use of the process adds a characteristic to the product. It was there naturally. Hence, there would appear to be a conflict between the WTO and the BSP.

Further, in the case of processed foods, the refining processes often remove all traces of the genetically modified organisms from the product (e.g. processed canola oil does not have any detectable proteins and hence does not have any transgenic materials). Thus, there would be no change in the characteristics of the product exported. No trade restrictions could be justified under the WTO but as the process was used in the initial production of the crop they could be justified under the BSP.

The *precautionary principle* is a central demand of many environmental NGOs. It has been incorporated into the European Union's (EU) environmental policy and its regulatory regime for GMOs (Perdikis, 2000). The EU has also suggested that the *precautionary principle* be incorporated into the SPS. This was, in part, a direct result of the beef hormone case and is viewed as a purely protectionist ploy by the US and Canada who had brought the case to the WTO (Roberts, 1998). The EU also wished to have it incorporated into the SPS to help it deal with consumer and environmentalist resistance to GMOs (Kerr, 1999a). As yet, they have not succeeded in having the SPS re-opened for negotiation.

The current SPS rules only allow trade barriers to be imposed for health, sanitary or phytosanitary reasons if there is a scientific justification for keeping the products out of the market and if a risk assessment has been completed. This scientific-based decision process was put in place to prevent protection being extended to domestic producers through abuse of technical regulations. There is an implicit assumption that there will be sufficient information available to make a scientific determination and to undertake a risk assessment.

Unfortunately, in the case of GMOs there is not sufficient information to do either for long term human health (Kerr, 1999a). It is a situation of uncertainty. It should be noted that the SPS does not address issues pertaining to environmental safety. The SPS does allow for situations where there is insufficient information to make a scientific determination. As suggested above, the country which justifies the imposition of a trade barrier on these grounds can only do so temporarily and must be taking active measures to secure sufficient scientific information. The entire approach to trade barriers at the SPS is *Why?* The approach under the *precautionary principle* is *Why Not?* (Perdikis, 2000). Thus, there is a fundamental difference in the WTO approach to trade restrictions and those built into the BSP.

The major problem with the *precautionary principle* is with its implementation (Kerr, 2000). It is a principle – not a decision making process. Hence, while a principle can be refined – to put some boundaries around the decision process – it cannot provide a decision making rule. The EU, having accepted the *precautionary principle* in its environmental policy at the behest of environmental NGOs and the Green Party is now wrestling with the problem of how decisions should be made in its name (see for example Commission of the European Communities, 2000). The Commission document concludes ultimately that decisions under the precautionary principle will be *political decisions*.

To see the difficulties associated with decision making under the precautionary principle, it is informative to read carefully the discussion by Streinz (1998):

Whereas this [precautionary] principle is recognized “in principle” at least in some branches, especially environmental law, it is difficult to fix the concrete emanations, the application of the principle in practice. The reason for this is that the precautionary principle should be applied explicitly in situations of recognized uncertainty, when a risk assessment has been made, but could by the limits of scientific recognition not lead to a clearly science-based decision, whereas serious risks which cannot be excluded need preventative ie “cautious” action. To determine the situations which justify the application of the precautionary principle, and, if decided to do so, to determine the extent of “caution” are political decisions, even if they may be partly based on scientific evidence. In this context it must be emphasized that the reference on “science” is not necessarily a reference to objective data and presumptions (p. 421).

There are no answers as to how much science is enough, what costs (to human health or the environment) are acceptable, when uncertainty no longer exists, etc. With an absence of transparency over these issues, the question arises as to what will be the basis of *political decisions*. Even more important, can the political decision making process be influenced by other interests. Again Streinz (1998) is instructive:

It [the precautionary principle] can be shaped to support any cause, when protagonists are arguing about the future, which does not exist except in their imaginations (p. 421).

Under these circumstances, it is not surprising that an organisation such as the WTO, which was established to protect those wishing to engage in international transactions from the capriciousness of politicians, is antipathetic to a principle that takes a *Why Not* approach to the imposition of trade barriers.

Changes in the international economy affect the relative competitiveness of firms. Competition from imports from countries whose relative competitiveness has improved will be detrimental to producers of import competing products in countries whose relative competitiveness has deteriorated. As a result, profits will be eroded and adjustment costs imposed on factors of production such as labour (Leger, et al, 1999). Those negatively impacted often ask politicians to extend them protection in the form of trade barriers. Of course, if this protection is put in place the gains expected from trade will be negated. While the WTO allows countries to retain protection extended in the past (while encouraging them to negotiate reductions), it puts strict limits on the conditions when new protectionist measures can be put in place for these reasons. Protection against competitive imports can only be extended temporarily under anti-surge measures. The BSPs provisions relating to taking account of *socio-economic factors* in the regulation of imports is in direct conflict with a central tenet of the WTO. Again it seems a strange addition to a Protocol which is concerned with ensuring biodiversity. There seems little connection between the two and one

is left wondering if this is, again, an attempt to obtain protection on this account through the back door when it could not be obtained through the WTO.

Finally, the mandatory labelling of genetically modified products not destined for agronomic production – for food, feed or processing – may be in conflict with the WTO. There are two agreements which cover labelling at the WTO – the SPS and the Agreement on Technical Barriers to Trade (TBT). The SPS takes precedent over the TBT if the product is to be labelled for health reasons. If a product is to be labelled for health reasons then the labelling must have a scientific basis and a risk assessment must be undertaken. While the BSP mandates a risk assessment, it is not clear what part the *precautionary principle* will play in the risk assessment process. Further, what should a BSP risk assessment for purposes of labelling entail? The CBD, within which the BSP falls, deals with biodiversity not human health. Hence, do the scientific justification and risk assessment associated with BSP mandated labelling of genetically modified products entail only biodiversity concerns?

If no health risk is claimed, the TBT allow labelling for the purposes of consumer information. The criteria for imposition is that the costs associated with technical barriers should not exceed the benefits received by consumers from the imposition of the barriers. The reason often given for labelling genetically modified products (although not explicitly discussed in the BSP) is presumably to provide consumers with the ability to choose not to buy genetically modified products (Hobbs, 2000).

The BSP mandates a *may contain* label. While there may be some initial loss of market as consumers exercise their preferences for non-genetically modified products, the cost of labelling for firms producing genetically modified products should be quite low. This is because consumers do not care if genetically modified products are tainted by those which are not genetically modified. On the other hand, consumers will care if a product that claims it is not genetically modified is contaminated by those which are genetically modified. This means that those wishing to sell products which do not show the *may contain genetically modified organisms* label must put mechanisms in place to make their claims (or maybe in this case their absence of a claim) credible. This involves very costly identity preservation mechanisms all along the supply chain from input suppliers and farmers to retailers. This will put those wishing to sell products which have not been genetically modified at a considerable commercial disadvantage (Kerr, 1999b). If those costs are sufficiently high, then food processors may simply label all their products *may contain genetically modified organisms* and, ironically consumer choice may no longer exist (Hobbs, 2000).

Conclusions

While it is not clear how the WTO would treat the issue of costs associated with not labelling (i.e. that not labelling a product with *may contain genetically modified organisms* will entail proving that they do not) there is a clear TBT question of costs versus benefits to consumers as a result of the BSP regulations. None of this seems to have been considered by the framers of the BSP.

While the BSP may be reasonably well designed to deal with issues related to trade in GMOs that will enter agronomic or aquaculture production, they seem poorly designed for

regulating trade in genetically modified products. While the biodiversity mandate of the BSP makes it the appropriate forum for the regulation of the former, it is not even clear that it should have jurisdiction over the latter. Regulations in these areas would appear to relate primarily to trade in goods and food safety which has traditionally been within the mandate of the WTO. The BSP is clearly inconsistent with the WTO in a number of areas. While it is a well-established principle that a country can voluntarily give up its recourse to WTO disciplines, one suspects that this will not always be the case for the issue of trade in genetically modified products. Hence, it is imperative that jurisdictional issues should be sorted out quickly because there are many interested parties that have a large stake in the outcome.

It would seem prudent for countries that have an interest in exporting agricultural products that have been genetically modified to withhold ratification of the BSP until the currently *muddied waters* are clarified. Of course, nothing precludes a country voluntarily complying with aspects of the BSP which it does accept (e.g. AIA) without having to ratify the Protocol.

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