Introduction

*Our standards on consumer protection, on the environment, on data protection and on food are not up for negotiation. There is no “give and take” on standards in TTIP.*

–EU Trade Commissioner Karel De Gucht\(^1\)

The World Trade Organization (WTO) rules applicable to agricultural biotechnology predate the commercialization of genetically modified (GM) crops; the negotiating agenda for those rules was established in 1986 in the lead-up to the negotiations called the Uruguay Round. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) is the applicable area of WTO law and dates from 1995. All members of the WTO accepted the SPS, including the European Union (EU). In the wake of commercialization, agricultural biotechnology became a contentious political issue in some countries, and the science-based SPS rules became politically unacceptable in some jurisdictions. As a result, domestic regulatory regimes and trade rules surrounding genetically modified organisms (GMOs) developed in an unharmonized fashion across the world, inhibiting international trade (Hobbs, 2007; Isaac, 2007). Nondevelopment of a global market for GMOs has led to reduced markets for those investing in the development and commercialization of new GM products and, hence, reduced expenditures on research. Multilateral trade negotiations have made no progress since 1994, and some countries wishing to break the impasse have been looking to preferential trade agreements for solutions. This paper examines the problems in the multilateral system pertaining to

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\(^1\) European Commission (2014).
trade in GMOs and assesses the likelihood that preferential trade agreements such as the Transatlantic Trade and Investment Partnership (T-TIP) or the Trans-Pacific Partnership can provide a way forward.

One of the reasons that agricultural biotechnology became such a contentious public policy question is that it is an issue where four already existing groups with strong preferences coalesced (Kerr, 2001). In this, agricultural biotechnology is unique. These civil society groups were (1) people who were already concerned about the quality of the food they were eating, 2 (2) people who were interested in protecting the natural environment, (3) people who questioned the ethics surrounding the technology, 3 (4) people disturbed by the influence of large multinational firms on the food industry. 4 Given the strength of the preferences held by these individuals, and the civil society groups they formed (or joined), biotechnology became a lightning rod for protest and political activity. In the EU it became an issue akin to gun control in the US. Over time, anti-GM vested interests arose in, for example, the organic industry 5 and some NGOs, which found “beating the anti-GMO drum” a good fundraising strategy (Marantelli, 2002). 6 The resulting divergence in domestic regulatory policies toward GM products has led to a gradual increase in trade barriers to GMOs around the world. These trade barriers have economic effects that far exceed the disruptions to trade flows because they inhibit investment in research and development in GM crops (Smyth et al., 2011).

Evolving International Trade Regimes for Agricultural Biotechnology

The WTO

In the approximately 20 years since the SPS came into force in 1995 with the conclusion of the Uruguay Round, and coincidently the first commercial planting of GM crops, there has been no change to the WTO’s rules governing trade in GM products, although there has been considerable clarification of those rules through adjudication of disputes. The major reason that no changes have occurred is that opening of the SPS for renegotiation was not included in the agenda of the Doha Round that commenced in 2001. Of course, the Doha Round was never expected to take the time it has and is currently languishing in a diplomatic limbo with no end in sight. Any changes to the current SPS will require an end to the Doha Round, followed by an agreement to have a new round along with opening the SPS for renegotiation. Given the vested interests of...

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2 Manifest in preferences for organic food, vegetarian diets, health foods, etc.
3 Concerned, for example, about transgenic transfers of genetic material that could not happen with natural selection—in essence concerned that developers of the technology are “messing with God’s work.”
4 Given that most biotechnology crops were being developed by large agribusiness firms that possessed intellectual property rights in their innovations.
5 The organic industry self-proclaimed itself GMO-free, astutely surmising that it could attract additional customers among those who did not wish to consume GM foods. Coexistence policies were then requested to protect this vested interest.
6 Examples of such fundraising efforts by NGOs can be found at http://www.cban.ca/donate and http://watchdog.org/168910/vermont-gmo-food-fight-fund/.
some countries such as the US and Canada in the current science-based SPS rules, there is little likelihood of a major initiative to alter the SPS within the WTO’s consensus-based decision-making framework.

Having agreed to having science as the basis for decision making in trade rules pertaining to sanitary and phytosanitary issues, some countries have found it very difficult to live up to their SPS commitments when putting in place their domestic policies—and biotechnology is at the heart of those difficulties. Groups in civil society have lobbied their governments strongly for both domestic production bans and import restrictions. Their basic position is that they do not want the technology used in their environment and do not want products derived from the use of the technology in their markets. The WTO has no mechanism to allow governments to respond to such demands from groups in civil society and, hence, governments under such pressure have had to seek alternative justifications for restricting market access (Kerr, 2010). Governments facing strong pressure turned to the SPS to justify trade restrictions. When they did they ran into the need for a scientific justification. The underlying premise of the SPS is that members of civil society will defer to scientific experts (Smyth et al., 2011). This has proved to be a flawed assumption in the case of those with strong anti-GM preferences. They argue that there is no consensus among scientific experts, that insufficient science has been done, and that scientific experts are in the pay of multinational companies. WTO panels have tended to defer to scientific experts when judging SPS issues, leading to SPS-based barriers being struck down.

Until 1999, EU GM policy was roughly in line with science-based regulation. In 1999, in reaction to rising concerns expressed in civil society, the existing policy was withdrawn, and a new regulatory and trade regime was to be developed. In the interim, until a new policy could be developed, a moratorium on approvals of GM crops and imports was put in place. The development of a new EU regulatory regime, however, proved to be very difficult and time consuming. Faced with the ban, the US, Canada, and others brought

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7 Of course, biotechnology has not been the sole domestic regulatory issue where conformity to SPS rules has been a challenge. The first major test of the science-based principle of the SPS was the EU ban on imports of beef produced using growth hormones. It led to a failure of the EU to comply with a ruling from a WTO panel and subsequent retaliation by the US and Canada (Kerr & Hobbs, 2005). Accepting retaliation, while part of WTO law, has seldom occurred, and the EU’s use of this escape from its commitments is unprecedented (Kerr, 2006a).

8 The entire intellectual foundation of the 1947 General Agreement on Tariffs and Trade (GATT) is a partial equilibrium neoclassical trade model in which consumers are expected to benefit from the lowering of trade barriers—and thus never ask for protection. Only producers benefit from trade barriers and are expected to ask for or fight to retain barriers. Thus, the GATT/WTO rules did not anticipate calls for protectionism from consumers (and other groups in civil society) (Kerr, 2007).

9 Though the SPS looks to a scientific consensus for decision making, the reality is that while an overwhelming majority of scientists may agree on a particular paradigm, there is never a full consensus among the scientific community. Scientific progress is premised on the idea that there will always be those who challenge the ruling orthodoxy. Thus, those looking for scientists who have differing views on, for example, climate change or biotechnology, are likely to find them (Symth et al., 2011).

10 In the case involving the EU ban on beef produced using growth hormones, the EU’s own scientific experts found no scientific reason to support the ban (Kerr & Hobbs, 2005).
a case at the WTO. The essentials of the new EU regulatory regime for biotechnology were put in place in 2003 but remain a work in progress. The WTO panel brought down its judgment in 2006 and found the EU in violation of its WTO commitments (Viju et al., 2012). In response, the EU stated that its new policy would comply with its WTO commitments but that it would take time to come into compliance (Viju et al., 2012). The new EU regulatory regime allowed for approvals of GMO cultivation and imports, but approval is a slow process. Thus, it took a considerable period to discern if the regime was compliant with the science-based principles of the SPS. It does not appear to be in compliance, primarily because science only informs the approval process, and a political process that can consider nonscientific factors in its decisions ultimately decides on GM approvals and trade measures (Viju et al., 2012). The EU’s regulatory regime, however, would require a new challenge through the WTO dispute settlement system to definitively determine if it is compliant. As yet, no such challenge has been mounted. This is the current situation with regard to biotechnology at the WTO. There is little or no prospect of renegotiating the SPS, and any change in the status quo will have to await a challenge through the dispute system.

Events in the EU, however, may precipitate new challenges to the EU regulatory regime. Disruption to trade flows arising from detection of a low-level—or adventitious—presence of GM material in shipments of non-GM crops is likely to become a growing problem as more and more GM crops are approved around the world. The EU has a zero-tolerance policy toward such commingling, meaning the refusal of shipments and ongoing import embargoes in the wake of the detection of low-level commingling (Hobbs et al., 2013). A reasonable case can be made that this facet of the EU import regime is not compliant with the SPS because the import refusals and embargoes do not conform to the requirement to examine scientific evidence and to carry out a risk assessment (Viju et al., 2014). Of course, a determination of the compliance of the EU regulatory regime pertaining to low-level presence will have to await a WTO challenge.

The second major potential area in which a challenge might be mounted is in response to the current changes in the EU governance of GM approvals. It also points out how visceral an issue GM technology has become within the EU. While the current EU regime for approvals of new GM crops may not be WTO compliant, it has approved new varieties recently. The approvals mean that the GM varieties can be grown EU-wide. Subject to the coexistence regulations of individual member states.

11 It should be remembered that a country can use any trade measures it wishes in the absence of a challenge through the dispute system.

12 The process is slow, costly, and risky. Approvals have taken up to five years (Viju et al., 2012).

13 Subject to the coexistence regulations of individual member states.
The Biosafety Protocol

While the EU and other countries facing strong anti-GM pressure have chafed under their commitments to the SPS and been frustrated by not being able to renegotiate its provisions, they have not sat idly by. They observe that a number of multilateral environmental agreements (MEAs) have trade provisions that differ from those of the WTO (Kerr & Hall, 2004). The MEA that has been negotiated to deal specifically with trade in GMOs is the Biosafety Protocol (BSP) within the Convention on Biological Diversity (CBD). The EU has been a major proponent of the BSP, and a large number of countries have ratified it. While the initial rationale for the BSP was to protect biological diversity, early on its remit was extended to deal with threats to human health (Holtby et al., 2007). The major differences between the BSP and the SPS are that the BSP (1) requires that science only need inform decisions to put trade barriers in place against GMOs and need not be the only consideration in decisions, (2) formally recognizes the precautionary principle, and (3) has no dispute settlement mechanism (Hobbs et al., 2005). The latter means that an importing country can unilaterally undertake a scientific assessment leading to trade barriers, can allow nonscientific factors to trigger the imposition of trade barriers, and can invoke the precautionary principle as a justification for import barriers without any recourse for exporters. There is no mechanism for an exporter to challenge the basis of a decision by an importer. There is no mechanism to challenge the use of other considerations when imposing trade barriers under the BSP. "There is no mechanism to challenge the "absence of sufficient scientific evidence" used to justify an importer's invocation of the precautionary principle. In essence, it gives importing countries a virtual carte blanche to impose trade barriers (Hobbs et al., 2005; Holtby et al., 2007). Thus, it removes the major constraints imposed by commitments in the SPS.

The BSP, however, does not allow the EU and other subscribing countries to fully escape the SPS. This is because the US, Canada, and Argentina—major producers and exporters of GMOs—have not agreed to sign the BSP. Under international law, the provisions of the BSP cannot be applied to them and, rather, as almost all countries belong to the WTO, it will handle disputes under the provisions of the SPS agreement. If, however, both countries in a dispute have acceded to the BSP, then, under international law, the “later in time” BSP would apply (Kerr et al., 2014b). The EU has actually been “encouraging” countries to sign up to the BSP by, for example, making the granting of reduced tariffs to developing countries under the general system of preferences (GSP) contingent upon the recipient countries’ acceding to the BSP (Khorana et al., 2012). Similar requirements to

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15 One of the main reasons for negotiating the SPS was to prevent the imposition of nefarious trade barriers justified on SPS grounds whose actual goal was to provide economic protection (Smyth et al., 2011).
16 As the US has not ratified the CBD, it is not eligible to belong to the BSP (Holtby et al., 2007).
17 There are issues with the later in time principle in international law. For example, if the Doha Round were to be successfully completed in the future, it is not clear whether the resulting WTO rules would then be considered later in time than the BSP (Kerr et al., 2014).
accede to the BSP are embedded in the regulations surrounding whether a country can supply biofuels to the EU market and receive credit toward meeting the quantity mandate for renewable fuels (Williams & Kerr, in press).

**Preferential Trade Agreements**

Given the stalemate in the Doha Round, countries have been turning to preferential trade agreements to achieve progress in trade liberalization. Three will be dealt with here: the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada, completed September 2014; T-TIP; and TPP. These agreements may provide a number of insights regarding the influence of trade agreements on policy making for GMOs.

The EU and Canada negotiated for almost six years before CETA was agreed. Canada is one of the major adopters and developers of biotechnology and has, some would argue, suffered disproportionately from EU policy on GMOs: Canadian canola’s being shut out of the EU market for oilseeds rape; the Canadian flax market’s suffering trade disruptions, loss of market, and high testing costs due to an adventitious presence incident (Viju et al., 2014); and, arguably, the failure to commercialize GM wheat. Canada definitely had an interest in gaining some concessions from the EU regarding market access for GM products. Despite assurances from Canadian negotiators that “everything was on the table,” there was speculation that the EU would prove to be intransigent on the issue (Viju et al., 2010). The negotiations were held in strict secrecy, so positions remained unclear, but there were indications that the negotiations in this area were difficult (Viju & Kerr, 2011). The secret negotiations also allowed for a diplomat’s solution to the problem—an agreement that allows difficult issues to be “kicked down the road.” What was agreed was the establishment of a mechanism for dialogue on issues related to biotechnology—a place to talk and talk but with no mechanism to bring closure to the issues discussed. The CETA text on biotechnology reads as follows:

**Article X.03: Bilateral Cooperation on Biotechnology**

1. The Parties agree that cooperation and information exchange on issues related to biotechnology products are of mutual interest. Such cooperation and exchange of information will take place in the bilateral Dialogue on Biotech Market Access Issues …. The dialogue covers any relevant issues of mutual interest to Canada and the EU, including, among others:

   (a) Biotechnology product approvals in the territory of Canada or the EU as well as, where appropriate, forthcoming applications of commercial interest to either side;
   (b) the commercial and economic outlook for future approvals of biotechnology products;
   (c) any trade impact related to asynchronous approvals of biotechnology products or the accidental release of unauthorised products, and any appropriate measures in this respect;
   (d) any biotech-related measures that may affect trade between Canada and the EU, including measures of EU Member States;
   (e) any new legislation in the field of biotechnology; and
   (f) best practices in the implementation of legislation on biotechnology.
Listed topics are largely those of interest to Canada and likely represent the only concessions Canada could obtain in the negotiations. This was a clear win for the EU.

In addition to the official text of the CETA, there was a side letter from Tonio Borg of the EU Commission addressed to the Canadian Minister of Agriculture, Gerry Ritz, dated April 24, 2014, which states:

The Commission will ensure that proposals for the authorization of genetically modified (GM) events, in particular GM canola, are processed as fast as possible within the procedures laid down in the EU approval legislation, e.g. submission of decisions to the Member States once an EFSA opinion is available. (Ref Ares, 2014)

It is not clear exactly what advantage this commitment would give Canada. GM events will still have to clear the scientific assessment of the European Food Safety Authority (EFSA). Further, EU post-EFSA procedures, which are cumbersome and time consuming, will still have to be followed. Of course, there is no guarantee that a Canadian GM event would be approved once submitted. Further, given current moves to allow individual member states to deny approval for GM events even after they receive EU-wide approval may erode even the limited benefits that may arise from the letter.

The T-TIP negotiations represent an attempt by the two largest developed economies to garner some of gains from trade liberalization that have not been forthcoming from the Doha Round. The negotiations are being conducted in strict secrecy, so it is hard to know the direction bargaining is taking. For GMOs the official position of the US is that science (often referred to as “sound science”) should form the basis of trade rules for GMOs—i.e., the rules of the SPS. Further, incidents of adventitious presence should be dealt with in ways that commercial shippers can reasonably accommodate—i.e., the EU zero-tolerance rule should be relaxed. The US also wants the time for EU approvals to be reduced. The EU, on the other hand, wants its current system, whereby science informs decisions, but the ultimate decision lies in the political sphere. In other words, there is a double hurdle: first pass the scientific test, then the political test. It will not contemplate lowering its human health and environmental protection standards. Further, it is currently a difficult time for the EU to negotiate over GMOs because its domestic regulatory regime is in considerable flux, with member states insisting that they not be bound by EU-wide decisions to approve new products. For the EU Commission negotiators, any concessions will be difficult. Thus far, outside the (secret) negotiating room, few suggestions for compromise are being floated.

There has been considerable discussion of harmonization, but largely in the realm of general principles rather than specific—or realistic—proposals. Harmonization can mean a number of things. Suppose two countries, A and B, have differing standards and regulatory procedures. Changing standards will impose costs. There are three possible outcomes: (1) country B harmonizes to the standards of country A, meaning B incurs all the costs of

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18 See Viju et al. (2012) for a description of the EU’s procedures for approving GMO events.
harmonization, (2) country A harmonizes to the standards of country B, and A incurs all the costs of harmonization, and (3) the two countries collaborate to develop a new joint set of standards, with both bearing some of the costs associated with change. Of course, A prefers the first outcome, and B the second. Either of these outcomes can arise from trade negotiations. Thus far, in the US harmonization discussions seem to revolve around the EU harmonizing to US standards, no matter how unrealistic that outcome is. In the EU there is little direct discussion of the US harmonizing to EU standards—although the hard line taken on the sanctity of EU food safety and environmental standards suggests that this is the only logical harmonization outcome.

If none of those harmonization options are likely outcomes, then new joint standards must be developed. This cannot be done in a trade agreement. These will be long and difficult negotiations. All that can be agreed in something like the T-TIP is that these discussions will take place. This is the CETA outcome. The trick is to embed something in the agreement that will force closure on the negotiations. This was not the case in the CETA so, while discussions are mandated, they can go on and on without end. The NAFTA experience is relevant. A large number of institutional arrangements were built into the NAFTA to foster regulatory harmonization (Kerr, 1992). In general, they have not worked as expected (Kerr, 2006b). This is largely because they were constituted with no closure mechanisms and became no more than discussion forums (Kerr, 1997). If there is to be harmonization regarding biotechnology in the T-TIP, it will require institutional innovation to force closure on the process of devising a mutually acceptable system.

The Trans-Pacific Partnership negotiations represent an ambitious attempt to move the trade liberalization agenda forward in response to the Doha Round stalemate. It is notable in that it involves 12 countries; both the US and Japan are part of the negotiations; it involves a mix of developed and developing countries; and it is open to additional countries joining even after negotiations have begun. Each of these features alone complicates negotiations; together they present a significant challenge, and it will represent a major diplomatic achievement if the negotiators can come up with an agreement (Kerr, 2013). The 12 countries involved are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. While the challenges are great, most of the countries involved are kept together by the singular motive of garnering better access to the US market. For the US, better access to the Japanese market is a priority, but having a major trade-liberalizing agreement success is also important.

The regulatory and trade regimes for agricultural biotechnology show little commonality across the 12 countries. Table 1 summarizes the major policy measures of the countries

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19 There was one attempt to put a mechanism for closure into the 1988 Canada-US Trade Agreement (CUSTA) that preceded the NAFTA. This clause dealt with antidumping and countervail actions and provided for a seven-year negotiation process to devise a new, mutually acceptable, dispute settlement system for such actions (Kerr, 1988). If there was no successful resolution to the negotiations, the entire CUSTA could be cancelled. There was little progress, and the deadline was quietly removed in the subsequent NAFTA negotiations in 1994 (Kerr, 2001b). No harmonized system for disputes relating to dumping and trade-distorting subsidies between the US and Canada yet exists.
currently negotiating the TPP. All of the countries are members of the WTO and, hence, the SPS. Six countries, however, have ratified the BSP, suggesting that they may be seeking an alternative to the SPS for trade GMOs. In the case of the developing country members of the TPP, for the most part, their regulatory regimes are in various stages of development. Four countries have moratoriums on cultivation of GMOs. Two countries have import bans, at least until regulations are developed. For Peru the import ban will remain in place until 2022, at the very least. Japan, Australia, and New Zealand require labeling of GM products, and some other countries are developing labeling regulations. Chile allows the cultivation of GM crops for seed purposes but does not allow domestic commercial cultivation. In short, countries taking part the TPP negotiations appear to be far apart in their approaches to the regulation of agricultural biotechnology.

Harmonization is a goal of the US. Is what is being envisioned harmonization to the US standards and processes? Given how contentious the issue of GMOs is in, for example, Japan, New Zealand, and Peru, this outcome seems unlikely. This means harmonization will require devising a new, mutually acceptable, regulatory framework for biotechnology. As suggested above in the context of the T-TIP, this cannot be done through a trade agreement. What likely can be achieved in the agreement is the institutionalization of future discussions regarding biotechnology. The efficacy of that process then depends on whether some form of closure to those discussions can be put in place—otherwise they will be places to talk and talk.

Conclusions
To gain enthusiasm and support for a potential trade agreement, a great deal is typically promised. While trade theory suggests trade liberalization is welfare enhancing, trade liberalization also produces both winners and losers. Potential losers can be expected to pursue a protectionist agenda. In the wake of the success of the GATT in reducing tariffs and other formal trade barriers over 50-plus years, trade barriers are increasingly found in domestic regulations. To achieve further liberalization means that agreements must reach deeply into domestic regulatory competencies. The international governance of GMOs represents that form of liberalization challenge. Given the strong desire of US biotechnology companies to gain improved access for their products across the world, and the equally strong anti-GM preferences of some segments of civil society (and some governments), where trade and regulatory restrictions on GMOs are onerous, there appears to be little room for compromise. Effective negotiations require room to compromise. Preferential trade agreements are currently the “only game in town” in terms of trade liberalization. In the past the US and EU may have been able to use their economic muscle to obtain

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20 The two exceptions may be Canada and Mexico, which already have preferred access to the US market under NAFTA. They certainly could be motivated by not wishing to see their preferred access eroded. Mexico is particularly sensitive to increased competition in the US market from other developing countries, and Canada has an incentive to maintain its preferred access for products such as beef, which international competitors such as Australia and New Zealand do not have. Of course, they are interested in garnering better access to the Japanese market and opening up new developing country markets.
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better terms in their regional trade agreements (Kerr & Hobbs, 2006; Kerr, 2006c). In
the case of the T-TIP, they face each other, and no significant economic advantage exits.
In the TPP, Japan acts as a considerable counterbalance to the United States.

It seems that neither the T-TIP nor the TPP can deal directly with the majority of
issues surrounding trade in the products of biotechnology. The answer lies in harmoni-
ization, but devising a new set of rules for trade in GMOs is beyond the scope of trade
negotiations and will require separate long and complex negotiations. Trade agreements
can, however, mandate future negotiations on devising new, mutually acceptable, rules
of trade for GMOs. The trick will be to find an institutional mechanism to carry such
negotiations through to a successful conclusion.

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