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Biotechnology: Can the Transatlantic Trade and Investment Partnership reconcile EU and US differences on GMOs?

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Abstract: *The US and EU have announced negotiations for a free trade agreement to be completed by end of 2014. While tariff barriers between the two entities are limited, their trade is encumbered with non-tariff barriers (NTBs), one of them being their diverging approach to genetically modified organisms (GMOs) in the agriculture and food industries. The US operates from a science-based perspective while the EU relies on the precautionary principle. This paper reviews the developments of GMOs in both the US and EU and draws on measures outlined in international organizations and recent trade agreements to explore options for the US and EU to reconcile their different perspectives within the framework of the Transatlantic Trade and Investment Partnership (TTIP).*

Keywords: Free trade agreement, Transatlantic Trade and Investment Partnership (TTIP), non-tariff barriers, biotechnology, agriculture, food, precautionary principle, genetically modified organisms, GMO, global markets.

Biotechnology: Can the Transatlantic Trade and Investment Partnership reconcile the EU and US differences on GMOs?

1. Introduction

In his State of the Union Address, President Obama announced in February 2013 that his Administration would launch negotiations on a Transatlantic Trade and Investment Partnership (TTIP), also known as TATFA (Trans-Atlantic Free Trade Agreement), with the European Union (EU) to be effective end of 2014. One month later, he signed the "Consolidated and Further Continuing Appropriation Act, 2013" (also known as H.R. 933). This law includes a rider (Section 735), commonly referred to as the "Monsanto Protection Act," which grants "a temporary permit for planting or cultivation of a genetically engineered crop, even if a federal court has ordered the planting to be halted until an Environmental Impact Statement is completed" (Baden-Mayer, 2012). Meanwhile, the EU voted to impose a 90-day period test on the toxicity of the genetically modified organisms (GMOs).

These quasi-simultaneous events indicate what bilateral trade negotiations are up against. While tariff barriers between the US and EU are limited, trade is encumbered with non-tariff barriers (NTBs), the trade of GMOs being one of them. The US and EU are on opposite sides on how to approach genetically engineered (GE) plants. On one hand, the US argues that GMOs are safe for consumption and the environment; it holds that the regulatory treatment of GMOs is to be identical to that of conventional products. On the other hand, the EU argues that the GMOs' impact on humans, wildlife, and environment are unknown; it has adopted a cautionary approval process and strict measures to trace them through the food supply chain.

The US and EU are the largest producers and exporters of agricultural products. The US is the top destination of the EU agricultural products. But while EU agricultural imports have grown since the turn of the century, the US has seen its share in these imports decline. The difference of treatment of biotechnology products has diminished the US ability to penetrate the EU market. US exports to other countries trading with the EU have also been impacted, as these countries fear their own agricultural and/or food exports to the EU might be affected. A bilateral trade agreement between the US and the EU presents an opportunity to address this imbalance.

This paper reviews the development of GMOs in both the US and EU, and draws on measures outlined in international organizations and recent free trade agreements to explore options for the US and EU to address this issue. It adds to the literature on the differing US-EU approaches to GMOs to account for the evolution of the public attitudes around the world and negotiations for a free trade agreement between the two entities. The purpose of this paper is not to assess the inherent quality of GMOs, nor does it pretend to be a legal review of their treatment.

After a brief introduction of what a free trade agreement would bring to both the US and EU in section 2, section 3 addresses the specificity of the GMO issue. Sections 4 and 5 provide a short description of the regulations and private initiatives in both entities. Finally, after a review of recent EU and US trade agreements, section 6 proposes several options for the US and EU to address the GMO question.

2. A Free Trade between the US & EU

With the stalling of the multilateral trade negotiations of the Doha Round, countries are negotiating smaller agreements among themselves. These preferential trade agreements are easier and faster to conclude. They also offer an opportunity to address specific trade issues and can strengthen a country's bargaining position vis-à-vis nonmembers (Mansfield & Reinhardt, 2003).

What can TTIP bring to the US and the EU? The US and EU are the two largest world economies; they represent 45% of the world GDP. They are each other's largest trading partner, trading about $2.7 billion of goods and services every day in 2012 and owning about $3.7 trillion in foreign direct investment in each other's economy in 2011 (USTR, n.d.). A Trans-Atlantic free-trade agreement would increase their capacity to trade with one another. Though the elimination of the remaining tariffs would boost GDP for both areas, the main benefits from a free trade agreement would result from the reduction of the existing non-tariff barriers (NTBs). NTBs result from government rules or industry regulations, and relate to "standards in the areas of health and safety, data privacy, cultural diversity, competition

policy, services regulation, genetically modified organisms (GMOs), agricultural subsidy and protection, labor and environmental rules, and geographical indications in trademarks" (Barfield, 2013).

While the US and EU have both allowed for an increasing openness in world trade, the relationship remains subject to many trade disputes and disagreements. The US claims that EU regulations on GMOs have cost US farm exporters millions of dollars. Not only direct exports have decreased but also exports to countries which are trading partners of the EU. Most of the African countries, for example, benefit from free trade access to the European market under their ACP (African, Caribbean, and Pacific) membership (CTA, 2013). These countries are reluctant to accept US crops in fear of seeing their own EU exports jeopardized. Naghshpour (2012) provides evidence that poor countries benefit amply from exports as engine of growth. The US is also home to the largest agri-biotech companies. 73% of the global commercial seed market is controlled by the top ten seed corporations, most of them having a majority stake in the US (CFS & SOS, 2013). These companies are heavily lobbying the US government for an open global market for their products.

Though attempts have been made to reduce NTBs, they have either remained insignificant or failed. Following a meeting in 2007, the US and EU created the Transatlantic Economic Council (TEC) to promote their economic integration. The Council "is headed on both sides by ministerial-level appointees with cabinet rank" (TEC, 2007). In 2011, the EU and US leaders directed the Council to identify measures which could increase bilateral trade. Those findings have been published in the High Level Working Group on Jobs and Growth Report (HLWG) early 2013. This Report sets out the framework for the negotiations of the bilateral trade agreement. It calls for ambitious "SPS-plus" and "TBT-plus," in reference to the related WTO agreements on the Application of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT), briefly described hereafter, to reconcile regulatory differences and enhance compatibility of regulation and standards (HLWG, 2013; Lester, 2012).

3. The GMO issue (WTO, UN, and Cartagena Protocol on biosafety)

3.1 What are GMOs

The terms Genetically Modified Organism (GMO), Genetically Engineered (GE), or Genetically Modified (GM) indicate that the normal gene of a plant, seed, or even animal has been modified by either "inserting a foreign gene, or by activating, inactivating or changing" its composition (Oder, 2013). These processes are different from "conventional breeding," where specific genetic traits are selected prior to the natural reproduction process to produce a superior seed. GE crops look at altering the fundamental structure of the plants, introducing a foreign element into their genotypes.

GMOs were introduced in the US in the 1990s, the first biotech crop being approved for use in 1996. The world transgenic crop surface has grown at an annual rate of 6% since then. In 2012, it reached 170 million hectares across 28 countries, with the US leading with nearly 48%. GM planting is quasi non-existing in Europe as shown in Table 1.

Table 1: GM World Planting.

Region	Countries	Hectares (millions)		
North America	USA	69.5		
	Canada	11.6		
	Mexico	0.2	81.3	47.7%
	Cuba, Costa Rica	All less than < 0.1		
South America	Brazil	36.6		
	Argentina	23.9		
	Paraguay	3.4		
	Uruguay	1.4		
	Bolivia	1.0	66.3	38.9%
	Chile, Colombia, Honduras	All less than <0.1		
Asia	India	10.8		
	China	4.0		

	Pakistan	2.8		
	Philippines	0.8		
	Myanmar	0.3	18.7	11.0%
Africa	South Africa	2.9		
	Burkina Faso	0.3	3.2	1.9%
	Sudan, Egypt	Each less than <0.1		
Oceania	Australia	0.7	0.7	0.4%
Europe	Spain	0.1	0.1	<0.1%
	Portugal, Czech Republic, Romania, Slovakia	Each less than <0.1		
	Total	170.3	170.3	

Source: ISAAA (2012)

The acreage dedicated to GE crops is concentrated around a few major crops: soybean (47%), corn (32%), cotton (14%), canola (5%), sugar beet (0.3%), and alfalfa (0.2%). As a percentage of global crops (conventional and genetically engineered), GE soybean represents 81%, GE cotton 81%, GE corn 25%, and GE canola 30%.

The development of biofuels around the world has given biotechnology companies an opportunity for new applications, these companies claiming that genetically modified plants are more resistant to crop-diseases and droughts, reduce use of toxic pesticides, improve on weed controls resulting in less tillage and soil erosion, contribute to water conservation, and improve overall yield, an important determinant of production cost. Development of genetically modified crops is at the center of biofuel research (Pollack, 2006).

3.2 GMOs and International Trade

Several international organizations address the development of biotechnology: The Codex Alimentarius (Codex), World Trade Organization (WTO), and Cartagena Protocol on Biodiversity. Their different approaches add to the complexity of the treatment of GMOs between the US and EU. While the EU and US are both signatories of the Codex Alimentarius and WTO, only the EU has signed the Cartagena Protocol on Biosafety.

The Codex Commission is an international organization which was established in 1963 under the auspices of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), both organizations of the United Nations. Its mission is to ensure "safe, good food for everyone – everywhere," and fair trade practices in international food trade (Codex, 2013). It groups 185 countries and various IGOs (inter-governmental Organizations), NGOs (non-governmental organizations), and UN groups. Codex standards are based on available science "provided by expert bodies organized by FAO/WHO" (Codex, 2013). They serve as a reference in the WTO SPS Agreement hereafter described. In 2011, Codex recognized that a significant scientific uncertainty existed in the risk analysis of GE foods, and announced that any country wishing to label GMO foods would be able to do so without violating the WTO rules (Consumer International, 2011).

The WTO (World Trade Organization) aims at opening markets around the world. In addition to the traditional reduction of tariffs and quotas, it operates from the "principle of least restrictive trade," recognizing the right that countries may have when protecting their own markets (Schaffer, Earle, & Agusti, 2005). Two agreements are of interest when it comes to the trade of GMOs: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). Both agreements came into force in 1995. The SPS Agreement recognizes the right of each member-country "to protect human, animal, and plant life from infestation, contaminants, pesticides, toxins, harmful chemicals, or disease-carrying organisms "(Schaffer et al., 2005). It specifically states that measures, beyond not being trade restrictive and/or discriminatory, are to be "based on a risk assessment made according to scientific principles and scientific evidence" (SPS, 1995). The Agreement nevertheless allows for countries to adopt restrictive measures when "relevant scientific evidence is

insufficient" (SPS, 1995). This reference to science is at the core of the diverging view between the EU and US on trade of GMOs. This is further explored in section 3.3. The TBT Agreement "governs the use of technical regulations, product, standards, testing, and certifications," and prevents countries to use these regulations and standards to limit trade (Schaffer et al., 2005); it does not define how a product should be designed or when a product is unsafe.

Finally, the UN Cartagena Protocol on Biosafety (CPB) which went into effect in 2000 looks to protect "biological diversity from potential risks posed by living modified organisms [LMOs] resulting from modern biotechnology" (CBD, n.d.). Under the Protocol, LMOs and GMOs are similar. It provides regulatory procedures for transboundary movements of those organisms; though countries are to base their decisions on a "scientifically sound and transparent manner" (CBD, n.d.), the Protocol adopts a precautionary stance towards biotechnological products. It allows for countries to restrict import of GMOs if lack of scientific evidence exists as to their safety, and to require labeling of shipments containing them.

3.3 A trade dispute between the US and EU

In 1996, the US exported its first crop of genetically modified soybeans and corn to the EU (Lynch & Vogel, 2001). Though the genetically modified crops had been approved for sale in the EU, this export drew public attention. It came at a time when the US was imposing retaliatory measures against EU agricultural products following the EU ban on the American hormone-treated beef. In addition, the EU had been dealing with regulatory failures regarding various food scares such as mad-cow, crutzfeld-jacob disease, dioxin contamination, sheep hoof-and-mouth disease. Public trust "in the opinion of European, much less American, scientists on such matters [was] low" (Gillis & Blustein, 2006). Individual member-states started enacting more stringent regulations than the EU itself. Austria, Belgium, Denmark, France, Greece, and Luxembourg were soon to block vote on any new approval of GE products (FT, 2006), leading the EU to impose an unofficial moratorium on such approval. The last approval took place in 1998. Soon thereafter, the EU published its directives regulating GMOs and/or products containing GMOs.

In 2003, the US filed a complaint (DS291) to the WTO arguing that the EU was in violation of the WTO agreements. Canada (DS292) and Argentina (DS293) were soon to side with the US in the dispute. The WTO ruled in 2006 that the EU 1998-2004 moratorium on GMO approvals and safeguard measures of Austria, France, Germany, Greece, Italy, and Luxembourg were illegal, and that procedures for authorization of GE plants were subject to unreasonable delay. Yet, while the United States "succeeded on its legal claims, domestic political constraints […] prevented the European Union from [fully] complying" (Lester, 2013). The moratorium had been lifted as early as 2004, but the individual countries have kept their safeguard measures to this date. Canada and Argentina settled their case with the EU agreeing on open communications as to the development and trade of agri-biotech products. The US and EU are still to find an agreement, the US being reluctant at taking a hard approach toward the EU.

The EU and US approach biotechnology differently. On one hand, the U.S. considers approved agricultural biotechnology products as "substantially equivalent" to their conventional counterparts and therefore hold that GMOs do not require a specific regulatory framework. On the other hand, the EU legislates around the "precautionary principle," which states that "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically" (SEHN, 1998). These different views led American exports of GE crops to the EU to decrease substantially.

The following two sections detail the trade complexity and development of GMOs in both the US and EU.

4. Development in the US

Since their approval in the 1990s for food applications, the number of GE crops has skyrocketed in the US. Today, the major crop acreages grow genetically modified crops: 95% of sugar beet, 93% of soybean, and 88% of corn (ERS, 2012). Other crops include canola, alfalfa, papaya, and squash (Oder, 2013).

The US regulation for GMOs is based on the 1984 Coordinated Framework for the Regulation of Biotechnology, which specifies that 1) the US policy is to focus on product (not process), 2) regulation is to be science-based, and 3) "GM products are on a continuum with exiting products." This framework allocates the oversight of GMOs between three federal agencies: the Environmental Protection Agency (EPA), US Department of Agriculture (USDA), and Food Drug Administration (FDA). The EPA regulates the use of pesticides and chemical substances (including "an

entire genetically engineered plant").The USDA controls transgenic plants to ensure protection to the US agriculture. The FDA is to guarantee safety of the country's food supply chain addressing issues related to "adulterated" food, "misbranded" food, and "food additives."

The FDA relies on the manufacturers' research and data to assess "the toxicity and allergenicity of the gene product and the plant itself" to authorize the marketing of an engineered crop (FAS, n.d.). From this consultative process, the FDA takes the position that the engineering process from which GMOs are derived does not grant them a special treatment (Belson, 2000). Labeling is mandated only if GE foods present significant different texture, taste, nutritional component, allergen, or toxic properties.

The US is home to the largest food biotech and related chemical companies, such as Monsanto Co., DuPont, Pioneer, Dow Agro Chemical, and Cargill. The major European biotech companies (e.g. Syngenta from Switzerland, Bayer CropScience and BASF from Germany) have all relocated part of their activities in the US to benefit from the favorable business environment surrounding the development of GMOs. These companies own the majority of the global seed market. As the result of their intense lobbying activities, the US State Department has been pursuing an aggressive commercial diplomacy to promote agricultural biotechnology around the world and US exports of biotech crops and foods (Food&Water Watch, 2013). For instance, USAID (independent agency under the State Department Authority) entices use of genetic materials in developing countries, in particular in Africa, through billions of dollars campaigns publicizing that biotechnology can improve agricultural crops and feed the world.

Meanwhile, US consumers are increasingly concerned about what is in their food. Many campaigns and initiatives are under way across the US to demand the labeling of GMOs. A GMO-free campaign has spread across 37 states (as of April 2013) to develop a national labeling requirement for GMOs. In 2013, more than 60 bills concerning GMOs have been introduced at the state levels (ANH-USA, 2013), and half of the states have introduced bills requiring their labeling (CFS, n.d.). Early June 2013, Connecticut became the first state to pass a law requiring the labeling of food containing GMOs. The application of this law is subject to two conditions: 1) four other states need to pass similar legislation, one of which being contiguous to Connecticut, and 2) those states represent 20 million inhabitants. Vermont, a nearby state -though not adjacent- of 620,000 people has passed a similar bill but remains to sign it into law in fear of legal proceedings from the biotech manufacturers claiming that such legislation would be in violation of the Federal rules as described in the previous section. At the federal level, Senator Boxer from California introduced a GMO Labeling Bill (The Genetically Engineered Food Right-to-Know Act) early 2013 for the FDA "to clearly label genetically engineered (GE) foods so that consumers can make informed choices about what they eat" (Boxer, 2013). In May 2013, Senator Sanders from Vermont introduced an amendment to the ongoing Farm Bill to give right to the states to require manufacturers of GMO food to label their products. The amendment was nevertheless shortly defeated.

The State of Washington introduced a ballot initiative in its 2013 November elections to require the labeling of foods containing GMOs. It was rejected. The state argued that it was not only a right-to-know issue but also a trade issue. Nearly 80-90% of the wheat grown in the State is for export. Yet, more than 60 countries around the world "either ban, restrict, or require labeling of genetically modified food" (Kaminsky, 2013). Those countries include all countries of the EU and others such as Japan, China, Australia, New Zealand, and Russia. This trade issue has become critical for farmers from other states. Following the discovery of an unapproved genetically engineered seed in an Oregon wheat field, Japan and South Korea temporarily suspended imports of US grains driving export prices down. Farmers from the states of Kansas, Idaho, and Washington have filed various lawsuits seeking class-action status against Monsanto, the largest US biotechnology company, for loss of competitiveness in the global markets. Meanwhile, the Supreme Court upheld patent right in a case between this company and a farmer from Indiana for use of GE seeds without paying dues. Public advocacy groups have joined forces with farmers and organic seed companies to challenge the US Supreme court on its ruling on patent infringement. This patent issue is further explored in the discussion section 6.

The Washington initiative followed the 2012 California own initiative, Proposition 37 herein referred to as Prop 37, which aimed at labeling raw or processed food if made from genetically modified organisms (Prop 37, 2012). Despite public support, Prop 37 was rejected 51.4% vs. 48.6% on the 2012 ballot, following an advertising campaign of $46 million by the major food and agricultural companies. The defeat of Prop 37 has nevertheless put the food industry into a precarious position. Consumers' boycotts spontaneously appeared against companies that funded the campaign against the ballot. In an effort to counter this growing movement, the biotechnology industry has been preparing a

national campaign to publicize the benefits of biotech crops. The main argument rests with how these crops contribute to food availability around the world when the global population is expected to reach nine billion by 2050 and at a time when droughts and floods spread around the world. The World Food prize award this past June was allocated to biotech engineers for their contribution to the genetic engineered technology. Controversy around the prize arose due to the involvement of these winners with biotech companies which are funding the World Food Prize Foundation.

Realizing that US consumers are increasingly concerned about what is in their food, the major American foods supermarket chain Whole Foods Market announced in March 2013 that it will require labeling of foods containing GMOs in all its stores throughout the US and Canada in 2018. Following this announcement, companies have increasingly required the non-GMO project, until recently the only certifying body, to certify products (Strom, 2013). Mid-April, Natural Food Certifiers announced that its kosher certification Apple K will no longer apply to foods containing GMOs. In addition to the stakeholders in the food industry, organizations in the public health, nursing, and medical sectors have been increasingly supporting the labeling of GMOs. Those organizations include -though not limited to- the American Public Health Association, the American Nurses Association, the Illinois Public Health Association, and the Catholic Healthcare West (network of 41 hospitals and 10,000 physicians). As the global grassroots movement against biotech companies has been growing around the world including the US, demand for non-GMO products for human consumption, including for products from animals which have never eaten genetically modified feeds, has increased. Non-GMO crops are now being traded at a premium.

5. Development in the EU

As shown in section 3.1, less than 0.1% of cultivated lands in the EU grow genetically modified crops. 95% of this acreage is located in Portugal and Spain, which both have authorized the planting of the Monsanto corn MON810 (Noisette, n.d.), the rest is being cultivated in the Czech Republic, Romania, and Slovakia.

Prior to1998, the EU authorized the marketing of nearly 20 GMOs. Yet, public suspicion toward GM plants led the EU to impose a moratorium on its approval of GM products in 1998 and the current supervisory framework. Three EU directives regulate GM plants: Directive 2001/18/EC, (EC) No 1829/2003, and (EC) No 1830/2003. Directive 2001/18 controls the release of GM plants in the environment, Directive 1829/2003 ("EC 1829/2003") the use of GM plants in food and feed products, and "EC 1829/2003" details the procedure under which GMOs can be introduced in the EU. In addition, "EC 1829/2003" ensures along with "EC 1830/2003" GMOs' traceability and labeling in the market place. Any food and animal feed products containing more than 1% GMO are to be labeled. This requirement was introduced to account for cross-contamination of GM into conventional plants, and give consumers right to choose between GE and conventional products.

Directive 2001/18/EC stipulates that "any company wishing to market a GMO must submit to the competent national authority of an EU Member State an application" including an evaluation of the environmental risks. Should the national authority issue a favorable report, it must inform the other Member States via the European Commission. If there is no objection, then the national authority may proceed. Authorization has a maximum duration of 10 years. Under Regulation EC 1829/2003, application submitted to the competent authority of a Member state must be made available to EFSA (European Food Safety Authority) which is the European agency responsible for assessing risks in food supply chains. Though operating out of the EU budget, it operates independently from the European Commission, European Parliament, and EU Member States. It is composed of scientific experts specialized in risk assessment. In addition to the EU directives, each country maintains a degree of autonomy regarding applications of these regulations. Austria, Belgium, France, Germany, Italy, and Luxembourg have all implemented more stringent safeguard measures than the EU as a whole. Others such as Bulgaria, Greece, Hungary, and Poland have regulations banning cultivation of GMOs. Those disparate regulations have created a highly disparate market throughout the EU.

Though European public acceptance for GMOs has slightly risen, for instance from 21% in 2001 to 27% in 2005, it varies significantly from one country to another (GMO-Compass, 2009). Use of GMO remains highly controversial across the EU. European manufacturers and grocery chains "refuse to stock products made with genetically engineered ingredients" (Gillis & Blustein, 2006). It is customary for EU end-users/marketers to require a GMO-free certificate for any product used in human applications such as beverage, food, cosmetics, or pharmaceuticals.

Facing adverse publicity in Europe, BASF, the chemical global German leader, stopped production of its GE potato Amflora in 2012, and moved its research and development to the US (Le Monde, 2012). Bayer has also decided to

relocate its global headquarters of its seed business from France to the US. Recently, Monsanto announced that it will withdraw all its applications for the growing of new genetically modified crops (five for corn, one for soy, and another one for sugar beet).These decisions highlight the difficulties that companies face when attempting to commercialize GMOs in the EU, not only from a regulatory perspective but also consumers' reluctance.

6. How to move forward

Out of the 474 trade disputes brought to the WTO to-date, 32 have been brought by the EU against the US, and 41 by the US against the EU as a whole or individual EU countries. "These cases have delved into some very sensitive domestic regulatory issues" (Lester, 2013). Their resolution has been difficult. As seen in section 3.3, while the US has succeeded on its legal claims on genetically modified organisms, "domestic political constraints have prevented the European Union from complying" (Lester, 2013), leaving the US caught between imposing retaliatory measures against the EU or cooperating to find a solution. A trade war on GMOs would defeat the whole purpose of negotiating a free trade agreement. Meanwhile, the EU settled its dispute with Canada and Argentina in 2009 and 2010 respectively, committing to open discussions on biotechnology applications to agriculture and trade-related issues to avoid any restriction of trade (IP/10/325). While the EU maintains its regulation and authorization process of GM plants, each country has put in place "coordination mechanisms to solve eventual cases of adventitious presence of non-authorised GMOs in shipments of authorised products" (Europa, 2010).

The WTO recognizes the rights of governments to set up policies for the protection of consumers' health and safety, or the environment. Those policies can nevertheless lead to higher costs for foreign producers, and to some extent inhibit innovation. Preferential trade agreements (PTAs) provide the opportunity to address these issues, in particular as they relate to intellectual property rights protection, differing standards, technical cooperation, and/or institutional mechanisms, leading to reduction of non-tariff barriers (Hayakawa & Kimura, 2014). Yet, PTAs rarely go beyond the TBT agreement of the WTO (Piermaniti & Budetta, 2006). They nevertheless promote foreign direct investment (Al-Sadig, 2011).

According to Nelson (2012), "there are two main stumbling blocks to an agreement: linkage of issues and non-tariff measures (NTMs)." Both are present in the GMO related trade. Linkage issues primarily deal with the highly protected sector of agriculture in both the EU and US, which may intensify the complexity of the negotiations. NTMs, such as technical regulation, voluntary standards, or assessment procedures can be effective trade barriers (Piermaniti & Budetta, 2006). While NTMs may be viewed as a sovereignty issue, Baldwin, Evenett, and Low (2008) argue that they are more about "obscurity." Agreeing on norms demands transparency to include institutional cooperation (including committees to discuss standards), prior notifications of change, and dispute resolution mechanism (Piermaniti & Budetta, 2006). Mutual trust of the respective approval process should lead each party to believe that the other will be capable of implementing and enforcing highly technical rules in a transparent and credible manner (Baldwin et al., 2008).

The challenge surrounding agricultural trade between the US and EU resides on a fundamentally different approach to GMOs. As seen in the previous sections, the US and EU are at opposite ends on GMO development. "There is no question that public opposition to GMOs has assumed an anti-American or anti-globalization flavor" in the 1990s (Lynch & Vogel, 2001). Monsanto symbolizes public opposition to GMOs in Europe and increasingly around the world. The European companies, such as Novartis, Rhone-Poulenc, AgreEvo/Aventis, Zeneca, BASF, or yet Bayer, have all faced similar challenges. The difficulty surrounding the development of GMOs stems from domestic consumers rather than direct trade restriction between the US and EU. European consumers strongly oppose the proliferation of GMOs. The President of the European Parliament stated that the US and EU "have differing takes on food safety, consumer protection, and environmental standards that are deeply rooted in our cultures" (Beattie & Chaffin, 2013). Both consumer and environmental interests have been influential in the Parliament, giving it more power in the EU treaties negotiations (Lynch & Vogel, 2001). France, which has already succeeded in excluding culture from the TTIP discussions, indicated that GMOs and the hormone-treated beef were two non-negotiable issues (Villechenon, 2013).

Multiple countries have been negotiating preferential trade agreements with the EU and US; few of them with both. They include Mexico, Canada ("in principle" with the EU), and South Korea. Japan is currently negotiating with both as well, on a bilateral basis with the EU, and as part of the Trans-Pacific Partnership (TPP) with the US. Meanwhile, Canada has just signed a bilateral trade agreement with South Korea (CKFTA), and talks between Mexico and South

Korea are expected to resume. A review of how the US and EU have dealt with biotechnology issues in these agreements may offer some light on how they might address them within TTIP.

Under Nafta, free trade agreement (FTA) signed between the US, Canada, and Mexico in 1994, a Free Trade Commission (FTC) was created to facilitate trade and investment, ensure effective implementation, and "avoid formal disputes through discussion and early dialogue on contentious issues" (Freshwater, 2003). Mexico remains the only country in North America to ban GMO planting. It nevertheless allows GMO imports provided they are properly labelled. Canada has allowed planting of GMOs since the late 1990s, concentrating mainly on canola, corn, soy, and sugar beets. These countries signed a memorandum of understanding in 2005 to clarify the requirements for US and/or Canada exporters to provide information about the existence or lack thereof of GMOs in their shipments to Mexico, the absence of GMOs being defined as 95% GMO-free (CBD, 2005). As party to the Cartagena Protocol on Biosafety (CBP), Mexico shares a similar precautionary approach to GMOs as the EU.

The KORUS FTA between the US and South Korea "seeks to make sure that regulations dealing with food safety or animal and plant health are based on science and do not unfairly block American exports. A permanent committee will encourage the development of science-based sanitary and phytosanitary (SPS) measures in compliance with the World Trade Organization SPS Agreement" (Korus, n.d.). The discovery of an unauthorized genetically engineered wheat in Oregon mid-2013 led Korea (and Japan) to implement testing procedures to ensure that GE wheat had not entered the commercial stream, preserving integrity of their imports.

As well, KOREU (FTA between Korea and the EU) builds on the SPS and TBT chapters of the WTO agreement to establish a framework for cooperation and exchange. In their goal of increasing food trade, both Korea and the EU are committed to increase transparency and consultation, and work "towards developing a common understanding on international standards as well as ensuring equal treatment of all EU Member States" (EU-Korea, 2011). Increased cooperation aims at improving approval process to provide greater speed and predictability to avoid the high cost of approving one company at a time. Disagreement between the two entities over GMOs is limited. As in the EU, GMOs are subject to highly negative publicity in South Korea, which makes GM food marketing "a major challenge for potential marketers who are interested in entering the South Korean market" (Kim, 2012). South Korea requires labelling of all GM food imports.

Ranking US Congress members and the Biotechnology Industry Organization (BIO) have urged the US Government to use the TPP negotiations to have the barriers to trade of agricultural products derived from biotechnology removed (Ashton, 2012; Third World Network, 2011). Among the eleven Pacific countries with which the US is negotiating, to include Australia, Brunei, Chile, Canada, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam, several of them have restrictive GMO regulations. Peru has for example just implemented a 10-year moratorium on GMO food and plants until 2023. Japan, New Zealand, and Australia all have labeling laws. Lack of transparency in those talks prevents any light at this time on how this question may be resolved.

Meanwhile, the main question for both the EU and Japan in their negotiations of the Economic and Trade Partnership focuses on the mutual recognition of existing standards and practices. Japan regulation is based on Codex guidelines; it does not however comply with Codex standards on certain issues such as related to pesticides, additives, and organic crop imports (Sunesen, Francois, & Thelle 2009). Despite a slow progress, both the EU and Japan have included elements from other agreements to acknowledge their different regulatory tradition and presence of NTMs (Nelson, 2012).

The recent agreement reached in principle between Canada and the EU, the Comprehensive Economic and Trade Agreement (CETA), this past October 2013, highlights the commitment of both entities to "establish firm science-based policies related to biotechnology" (Boscariol, Charest, Glasgow, Larroque, Potter, & Swick, 2013). Regulatory cooperation will strive at comparing data collection and analysis of practices, and conducting risk and regulatory impact assessments. Earlier access to regulatory development processes is expected to reduce approach differences in order to achieve more compatible measures and fewer trade barriers (CETA, n.d.). To add transparency to the process, interested persons in either Canada or the EU will be able to participate in public processes for the development of technical regulations. The discussion related to GMOs is nevertheless limited to the determination of a threshold which would allow imports of Canadian agricultural and food exports containing low-level of GMOs as a result of cross-contamination. Of the recent bilateral agreements negotiated by the EU, CETA is the most likely to serve as a framework for the EU negotiations with the US (Chaffin, 2013).

Lastly, it is worth noting the just signed agreement CKFTA between Canada and South Korea. Both countries have signed a separate free trade agreement with both the EU and US. They "agree to build on their shared commitments regarding the application of WTO SPS measures" (Foreign Affairs, 2014). While Canada supports voluntary labelling, it is nevertheless concerned about the accidental inclusion of GMOs in agricultural and food products reported as GMO-free. Its objective is to have trade partners accept the presence of GMOs up to 5% when making claims that " a food or food ingredient is not genetically engineered" (CFA-FCA, n.d.).

The respective US and EU preferential trade agreements and/or current negotiations offer some insights as to how the specific issues surrounding GMOs can be addressed with TIPP. Those agreements and/or negotiations all call for harmonization, cooperation, and transparency, which is very much in line with what Balwin et al. (2008) recommend for TBTs to facilitate trade: 1) harmonize norms so that only one norm applies to all members, 2) establish mutual recognition, such as all national standards are accepted by all members, and 3) making it cheaper/faster for firms to certify that their product meet the norms of the other members. These recommendations are included in the HLWG outline which calls for "regulatory coherence and transparency for the development and implementation of efficient, cost-effective, and more compatible regulations for goods and services including early consultations on significant regulations, use of impact assessments, periodic review of existing regulatory measures, and application of good regulatory practices" (HLWG, 2013). In addition, the HLWG recommends that the US and EU in their search for "more compatible regulations for goods and services" do so"with the objective of reducing costs stemming from regulatory differences in specific sectors, including consideration of approaches relating to regulatory harmonization, equivalence, or mutual recognition, where appropriate" (HLWG, 2013).

The following section explores specific provisions relating to harmonization of authorization process, harmonization of food standards, traceability (i.e. labeling), intellectual property rights, arbitration, and dispute resolution mechanism.

6.1 Harmonization of the authorization process

Differences in regulatory frameworks reduce access to market (Shweta & Swarnlata, 2008). The stakes are important for the US, not only for its direct agricultural exports to the EU but also to any other countries exporting their own products to the EU. Harmonizing legislation across the US and EU will ultimately contribute to wider market access for the American producers who currently see their access denied. This view is shared by high ranking US Congress members which have advised, as they have done so for TPP, that their congressional support, , will be subject to the liberalization of GMOs and removal of agricultural barriers.

One of the hurdles facing both negotiators is the GMO approval process. Between 1991/1998, the EU authorized the marketing of 18 GMOs. But, as seen in section 3.3, food scares in the 1990s and subsequent regulatory failure in protecting food safety throughout the EU, led to a public distrust in the regulatory process and scientist institutes (Gillis & Blustein, 2006). European consumers became leery of GM foods (Lynch & Vogel, 2001), which led to the EU moratorium on GM food approval in 1998 and the various directives currently in effect. Since the end of the moratorium in 2004, the EU has resumed approving GMOs, but process remains slow according to the US.

Differences in registration (approval) can trigger significant trade dispute (Freshwater, 2003) as seen in section 3.3. "Authorization of GMOs in the EU is only done in accordance with EU legislations" (MEMO/10/86, 2010). Yet, the EU faces the challenge of maintaining "a science-based authorisation system with the choice for Member States to decide whether or not they wish to cultivate GM crops in their territory." The core of the approval process relies on the independence of EFSA to fully assess the safety of any bio-engineered product.

In the US, as described in section 4, three governmental agencies regulate the GM production. The FDA approves the marketability of the GM plants, the EPA the "use of crops that produce their own pesticides or herbicides," and the USDA regulates the introduction of new crops during testing (Anderson & Jackson, 2003). All three agencies rely on the field-testings of the biotechnology companies, which leads to the questioning of the risk assessment. In addition, the revolving doors between the industry and the regulatory agencies raise doubts about the integrity of the assessment. Several high ranking employees of the FDA had previous employment with Monsanto. Meanwhile, EFSA saw its budget frozen in 2012 when the European parliament refused to vote in protest of the appointment of an ex-employee from Monsanto to the Board of Directors.

The lack of an "independent" authorization process in the US prevents US GE plants to meet the Codex Alimentarius guidelines. When developing standards, Codex relies on independent scientists who themselves proceed to risk assessment review. This process is similar to the EFSA's approach. A more "independent" US approval process, as within the Codex Alimentarius guidelines, would allow a speedier approval process in the EU. Regulatory agencies might need a transition period during which they would each review regulations. Strengthening regulators' cooperation on the assessment review can enable convergence on standards-related issues and increase trust and transparency. The Nafta Technical Working Group on Pesticides has demonstrated "that many of the benefits of a North American regulatory system may be achieved through co-operative work arrangements among existing agencies" (Freshwater, 2003).

6.2 Harmonization of food safety standards

Harmonization of technical standards can reduce barriers which impede trade (Sawyer, Hobbs, & Kerr, 2007). The EU itself involves substantial harmonization and recognition of product norms and testing among its 28 country-members (Baldwin et al., 2008). Yet, the trust factor resulting from differing approval process may make harmonization difficult between the US and EU. Building such trust requires significant negotiation (Nelson, 2012). The WTO recognizes as much when encouraging countries to sign Mutual Recognition Agreements (MRAs) (Baldwin, 2000). In a MRA, the EU would recognize the right of certain laboratories to certify goods in the US for use in the EU, and vice versa, lowering the cost of business across borders (Baldwin et al., 2008).

Such "recognition presents challenges since leading industry players do not, as a rule, agree on the same standards and practices, particularly if their corporate reputations are closely associated with a particular standard" (Nelson, 2012). Most of the leading biotech companies are based in the US, or have relocated to the US. As seen previously, US regulations are product-based, and hold that GE plants are no different than conventional plants, and should not be treated differently. On the other hand, EU regulations are process-based, and hold therefore that GE foods need to be identified as such. EU regulation does account for the risk of cross-contamination from GM to conventional plants. While threshold for any non-approved GMOs is 0.1% for commodities used in feed production, and zero tolerance for commodities used in food manufacturing, the EU establishes a threshold of 1% of GMOs beyond which labeling is required (Murphy, 2013). Within CETA framework, Canada aims to increase this threshold to account for contamination in its fields.

As advocated in KOREU, both entities can look at developing a common standard. The International Organization for Standardization (ISO) offers such a framework which would facilitate the global trade of GMOs. ISO standards are widely accepted around the world, allowing business around the world to access new markets.

Though no standard at this time specifically addresses GMOs, two standards are of interest: ISO 14000 (environmental management) and ISO 22000 (food safety management). The former provides procedures and tools to identify and control the environment impact, the latter addresses food safety management. ISO 22000 offers several standards, each one addressing a different aspect of the food supply chain. Due to the high degree of controversy surrounding GMOs around the world, a dedicated standard would be more appropriate, in particular to handle the specific implementation of a traceability system.

6.3 Labelling products containing GMOs

People have different attitudes to food which go beyond the mere concepts of nutritional values, foods often having societal and historical meanings. The recent move of one of the US kosher supervision agencies to exclude GMOs from its certification attests to religious dietary implications. To access foreign markets, exporters have to take into consideration the heterogeneity of those markets and meet what the foreign customers demand (Sawyer et al., 2007).

GMO labelling in the EU is compulsory while voluntary in the US. With the large majority of the crops in the US being genetically modified, the presence of GMOs in the US food supply chain in undeniable. Yet, absence of labeling requirements in the U.S. has made it difficult for US customers to identify GMOs in the US food supply chain. It has also made it challenging and costly for food producers to do so as well.

In a letter to the US Trade Representative in May 2013, the US soybean industry has suggested that it could accept labelling for foods that do not contain GMOs as opposed to foods that contain GMOs (Murphy, 2013). The USDA itself has started promoting the GM-free labelling early 2013, adopting the private "non-GMO Project's requirement, label verification, auditing process and standard" (Cleveland, 2013). This labelling allows consumers to know if the animal products they are consuming come from animals fed with GMO crops. With increased public awareness, proponents for labeling are becoming more vocal about consumers' right to full disclosure about their food.

Would the GMO-labelling replacement with a "GM-free" labelling as suggested by the US soybean industry satisfy the European precautionary stance on GM food? It is to be noted that the EU is also working on a "GM-free" label. But, for the EU, this labelling is complementary to its GMO labelling requirement to account for products from animals which have been fed GMOs, which the current legislation does not do. The EU GM-free labelling aims at remedy to this situation (Brans, 2013).

An alternative to a specific memorandum of understanding as under Nafta would be for the US and EU to achieve trade transparency using ISO standards. ISO 22000:2007 sets principles for a feed and food traceability system. Not only such a system would address safety or environmental consideration across the food supply chain, but it would also determine "history or location of a product or its relevant components," as the US itself advocates in its COOL (Country Of Origin Labeling) requirements. This regulation "requires retailers to notify their customers of the country of origin of covered commodities" to include various meats, fish, perishable commodities, or types of nuts (CFR, 2013).

ISO "uses the same definitions of traceability as the Codex Alimentarius Commission." As seen in section 3.2, both Codex and the UN Cartagena Protocol on Biosafety (CPB) recognized the right of countries to label GMO foods and/or shipments containing GMO foods. The WTO having adopted codex rules as reference, countries can do so without fearing a challenge at the WTO. Though only the EU is signatory of the UN CPB, both the EU and US are members of Codex and the WTO. This commonality offers them a framework for negotiations, at a time when increased US public pressure demand labeling. When mutual interests across national borders are identified, it is possible to move difficult negotiations forward (Schoppa, 1997).

6.4 Reconciling the intellectual property approach

Though standardization may dampen drive for innovation (Nelson, 2012), harmonization can also "bring significant benefits for innovation by increasing the size of the market for global products" (Shweta & Swarnlata, 2008). A key shared objective is to identify ways to prevent non-tariff barriers from limiting the capacity of U.S. and EU firms to innovate and compete in the markets.

One of the key issues surrounding GMOs resides in the fundamental question: can a living organism be patented?

The US recognizes that introducing a new genetic material within a cell is patentable, the resultant product not being found in nature (CFS & SOS, 2013). Consequently, corporations can obtain utility patents for their GE seeds, which forbid any use by third party to either save, use for research, or replant. This approach entrenches on the traditional practice of farmers to select and replant seeds from their crops.

On the other hand, plants are not patentable in the EU. As signatory of the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"), the EU grants an intellectual property right to producers of new varieties of plants: the breeder's right (PBR), or also referred to as plant variety rights (PVR). Contrary to the patent, this right allows re-use of the seed for a license-fee. It allows each member national legislation to grant an exemption for farm-saved seed.

Convergence of these systems are unlikely in the short term. In 2012, the European Parliament rejected the EU proposal for an Anti-Counterfeiting Trade Agreement (ACTA) which aimed at aligning regulations toward intellectual property between the signatory-countries involving the US, Australia, Canada, Japan, Mexico, Morocco, New Zealand, Singapore, South Korea, and Switzerland. The vague content of the proposal led to massive petition from the public which saw in this act open door for restriction on liberties and rights.

Though the US and EU approaches are fundamentally different, they offer some commonalities as to the protection of plant varieties. Rights under one system do not create automatic rights under the other one. The WTO's agreement on Trade-related aspects of intellectual property rights (TRIPS) require governments to provide protection for plant varieties either by patent or through a system created specifically for the purpose, or a combination of the two (WTO, n.d.). UPOV provides such a system. As signatories the "UPOV Convention," the US and EU can work together under UPOV and commit "to co-operate to promote and reinforce the protection of plant varieties." This is the approach followed by the EU and Canada in their FTA framework. CETA respects both regimes and provides certainty as to data protection for plant protection products, and recognize "the farmers' privilege" to save and replant seeds of a protected variety on their own land under the federal *Plant Breeders' Rights' Act*" (CETA, n.d.).

6.5 Reducing cost of arbitration for business

Reducing the cost of arbitration presents great benefits. In their review of the EU-US trade dispute on hormone-treated beef, Bureau, Marette, and Schiavina (1998) found that "opening the domestic market to foreign products that are perceived to be of lower quality than domestic products may lead to market inefficiencies (e.g., adverse selection)." For instance, the "European consumers place a much higher value on beef from cattle that have not been fed genetically modified corn than US consumers" (Lusk, Roosen, & Fox, 2003). The ambiguity surrounding conveyed by GMO labelling versus GM-free labelling raises concerns about information made available to consumers, and may lead to substantial disagreements.

The US Industry Trade Advisory Committee on Standards and Technical Barriers (ITAC) aims at providing "informal mechanisms for rapid resolution of disputes on TBT [technical barriers to trade] issues" (ITAC16). Outside of the trade agreement existing between them, the US, Canada, and Mexico can reconcile these issues through a regulatory cooperation council; the current TPP negotiations aim at engaging into "early consultation" for implementation of efficient and more compatible regulations for goods and services (Lester, 2013).

Yet, resolving issues from regulatory differences presents unique challenges that a free trade agreement framework may not be able to handle in terms of distinguishing what is a domestic policy from a trade restriction. It implies consideration of the different approaches relating to regulatory harmonization, equivalence, or mutual recognition.

6.6 Providing a dispute resolution mechanism

All bilateral trade agreements contain provisions as to enforcement and dispute resolution. The process tends being lengthy and "legalistic in nature rather than focusing on trade restricting measures" (Farrah, 2010).

NAFTA provides for a dispute mechanism similar to that of the WTO. It establishes a trilateral commission which can set up panels to review disputes brought by any of the member-countries. Resolution is expected to take less than a year. In its agreement with South Korea, the US negotiated a "snap-back" provision expediting disputes on the trade of cars, issue of major contention between the two countries. The provision allows each member of the agreement to implement a temporary measure against any NTB based on "reasonable evidence" (Farrah, 2010).

To facilitate application of the trade agreements, the US and EU can agree on monitoring barriers that their respective businesses face when expanding their operations, and on implementing a safeguard mechanism by which each economic entity can determine if the other one(s) has/have raised new NTBs. The US (USTR) publishes for example a yearly report *National Trade Estimate Report on Foreign Trade Barriers*.

Building on lessons from past experience and other agreements, TIPP can encourage and enable an expedited resolution of any disputes arising out the agreement. It can be instituted as proposed in CETA whereby efficient three-member panels can be set-up while at the same time include "a process for ensuring panel composition even in the absence of an agreed roster to prevent from blocking a dispute by not allowing a roster to be developed" (CETA, n.d). The ultimate goal is a much shorter process than the WTO dispute mechanism.

Conclusion

The potential of a free trade agreement between the US and EU represents an opportunity to promote an open global trade system at a time when the Doha Round multilateral negotiations are at a standstill despite the recent breakthrough at Bali. While the EU and US cooperate in many areas and have reduced their respective tariff barriers to a minimum, their trade relations are hindered by non-tariff barriers. Different regulations, standards, or rules either slow trade or prevent it. The different approach to GMOs between the two entities denies many US agricultural and food products access to the EU market as well as to some other countries when these countries export to the EU.

The complexity of the regulatory process in the EU is likely to prevent any short-term agreement on the issue, leaving the US to choose the WTO as a forum to open the European markets. Yet, this approach would present more challenges for the US than in its 2003 case, the Codex Alimentarius having held in its 2011 review that any country could apply food safety assessments of GMOs without fear of breaking its commitments with the WTO.

The US and EU are at opposing ends of the debate surrounding the proliferation of GMOs. The opening of bilateral trade negotiations presents an opportunity for the EU and US to address their diverging approach, especially at a time when increased public awareness around the world is putting pressure on governments to tackle this issue. Both the US and EU are signatories of multilateral organizations which address GMOs. A US process established by "independent" experts in line with Codex guidelines would promote an open communication between scientists from both entities which would result in a speedier approval process in the EU.

Transparency in this process would, in addition, promote acceptability, facilitate agreement on standards, traceability, and overall overcome the notion that labelling means trade restriction. The EU labeling requirement basically addresses European social mores, guaranteeing the right-to-know to consumers. In the US, states are increasingly looking to pass labeling laws, which the biotechnology, agri-business, and food industries vehemently oppose. With a large percentage of the US major crops being genetically modified, it is difficult for these industries to meet the EU threshold beyond which labelling is required. Two recent developments are of a particular importance: the current discussions between the EU and Canada on the low-level presence of GMOs beyond which the EU requires labelling, and the simultaneous US-EU development of GM-free labelling. These developments offer an opportunity for a mutual understanding on how to address GMOs. As in any negotiation, outcome will be a function of what any party is willing to give up on a specific matter.

Basic laws related to GMOs are unlikely to be changed under TTIP. But, should the EU and US not tackle harmonization of the regulations and/or standard settings, TTIP may just be a piecemeal agreement. The debate on the unbridled release of GMOs into the environment will unlikely though be resolved within the announced timeframe. Both entities can nevertheless agree on a Side-Letter agreement to further explore the issues, not holding TTIP "hostage" to strong resistance from any of the two entities. At a time when the EU is launching an ambitious initiative to streamline its numerous regulations related to food supply chains, though excluding GMOs which remain regulated under the three directives described in section 4, TTIP negotiations provide a unique opportunity to promote an harmonization of GMO regulations, standards, labeling, intellectual property rights and enforcement mechanisms around the world, the US and EU accounting for nearly half of world trade.

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