AgBioForum, 16(2): 170-176. ©2013 AgBioForum.

The Trade Dispute About Genetically Engineered Products: Argentina Against the European Communities

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From 1998 to 2003, the European Commission (EC) applied a *de facto* moratorium on the approval of new genetically engineered products. In Argentina, this situation forced regulatory changes, delaying further development and adoption of agricultural biotechnology. As this was considered a breach of international obligations, Argentina—together with Canada and the United States—engaged in a negotiation process under the Dispute Settlement Understanding mechanism of the World Trade Organization (WTO), which ended with the formation of a specific panel to rule on the case. After a complex consultation process, the panel found that the EC had acted inconsistently with its obligations under basic trade agreements, therefore ruling in favor of the complaining parties. This remarkable dispute has shown i) the increasing role of science on trade issues, ii) how the concept of precaution may lead to trade disruptions, and iii) the sound operation of the WTO dispute settlement system.

Key words: genetic engineered crops, Sanitary and Phytosanitary Agreement, trade disputes, WTO rules.

Introduction

This article aims to describe the circumstances and development of the first significant trade dispute involving the regulatory views on genetically engineered (GE, referred to as genetically modified, GM, in the European Legislation) crops. It will also show how the World Trade Organization (WTO) managed through this complex case, which—in addition to its basic long standing rules—was called to deal with emerging environmental international legislation and with food-safety issues. An additional purpose of this work is to show how social concerns over risks may impose changes on local legislation which, in turn, would impact the regulations of a trade partner. Finally, another pupose of this article is to stress the importance of keeping the highest quality standards in seeking scientific evidence on which to base regulatory decisions.

This case, which needed the help of a prominent group of experts to advise the WTO Panel, has several interesting features. It has shown i) the impact of measures supposedly addressed at the protection of the environment, on trade decisions, and regulatory policies of trade partners; ii) the limitations of an extreme concept of "precaution" when there is insufficient scientific evidence, and its relatioship with the social perception of risk; iii) that the judicial authority of the WTO was able to make legal distinctions against the biased construction of misrepresented scientific findings; and iv) the fundamental role of science in solving trade disputes related to new technologies.

Regulations and Trade Issues

The first GE seeds reached the market in 1996. The prospects of a rapid, universal adoption of the new technology (and corresponding product approvals) were soon halted by a "precuationary principle" approach adopted in the European Union (EU) for regulatory decision making.

For exporters of agriculture commodities, the lack of timely approval decisions for GE crops in prospective trade partners (the so called "asynchronous approvals") has several unpleasant consequences. In order to avoid trade disruptions, exporting countries need to watch the regulatory status of their GE products at the destination markets and also must assure that the flow of exports is kept free from products unapproved for these countries. Presence of even traces (the so called "low level presence", LLP, see box) of unapproved materials in bulk shipments of approved products can jeopardize their entry at destination and even cause their rejection.

In Argentina, field trials of GE glyphosate-tolerant soybean (GTS) started in 1991; after science-based regulatory review, its commercial release for planting, processing, and food/feed use was granted on March 25, 1996. It was assumed that the EU—consistently the most important market for the soybean meal produced in Argentina—would follow suit. As it was expected, the EU Parliament authorized the placing on the market of GTS for food and feed use a few days later on April 4, 1996. This synchrony of approvals, an issue critical for Argentina's economy, was to be expected: to the

extent that environmental and food safety assessment are science-based (as it was in the EU at the time), a high degree of consistency can be assumed in the regulatory frameworks for agricultural biotechnology in different countries, which consequently will be reflected in their regulatory decisions.

However, when non-science-based safety issues come into play, they have the potential to affect the regulatory decision-making process, eventually leading to delayed approvals; this in turn will affect trade flow if asynchronous with the approvals in the exporting countries. Argentina, a traditional agricultural commodities exporter, faced this difficulty in 1997 when non-science-based issues entered into the EU's decision-making process at the start of the harvest of the first GE crops.

By delaying the approval of the new products, the EU affected international commodity trade from 1998 to 2003. This disruption of trade, responsive to complex social and political factors in the EU, negatively impacted the Argentine economy and other agricultural commodities exporters. As negotiations to solve the hurdle ended without an agreement, Argentina, Canada, and the United States submitted a complain to the WTO that resulted in a trade case, with the dispute panel releasing its ruling by the end of 2006.

Regulations and Consumer Attitudes

At the time, more that 60% of Eurobarometer respondents (EC, Directorate General XII, Science, Research, & Development, 1997) showed a high level of concern about the supposed risks associated with food derived from GE crops, even though only 11% of them felt adequately informed about biotechnology (European Commission [EC], 2000). Public opinion quickly became skeptical of GE food (Bonny, 2003; Gaskell et al., 2000; Levidow, Carr, Wield, & von Schomberg, 1997; Torgersen & Seifert, 1997), often rooted in cultural factors (Finucane & Holup, 2005), strong campaigns by civil society activist groups, and in a decreasing degree of trust in public/private actors. In addition, a series of regulatory failures undermined the confidence of European consumers in the ability of regulatory officials to adequately protect the public's health and safety. Highly significant was the case of mad cow disease, or bovine spongiform encephalopathy (BSE). The EU's belated failure to recognize its health hazards severely eroded public trust in EU food safety regulations and the scientific expertise on which they were based. It also significantly increased public awareness of food safety issues at the very time when genetically modified foods were first being introduced in Europe, thus making people very sensitive to new technologies in the food supply industry (Lynch & Vogel, 2001).

New labeling rules were therefore approved in the EU in 1997 (European Parliament and Council, 1997), but the hostile criticism of the public towards GE foods moved the EU to delay further approvals. In 1998, the EU suspended regulatory decisions on new biotech products until revised rules governing approval, marketing, and labeling were to be implemented.

The labeling and traceability rules were later approved, set by Regulations (EC) Nos. 1829 and 1830 (European Parliament and Council, 2003a, 2003b), which covered both food and feed; these regulations required that any product with a GE material content of more than 0.9% be labeled, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product (prior to 2003, EU regulatory requirements on GE labeling were based on the detection of DNA or protein resulting from the genetic modification). This 0.9% labeling threshold only applied to GE products that have an EU authorization. As a transition measure, a temporary threshold of 0.5% was set for the presence of GE materials not yet authorized at the time, but that had a favorable assessment from an EU scientific committee. This temporary measure later expired in April 2007, meaning that after this date, no unauthorized GE material can be present at any level in non-labeled products (Food Standards Agency, 2013).

Given Argentina's export profile, the requirement of mandatory labeling at this early stage of the adoption of GE technology was considered a potential source of trade disruption; the feasibility of establishing a segregated handling system for agricultural commodities was evaluated, and it proved not to be cost effective. Consequently, Argentina was forced to change its regulations: approval of new GE products became conditioned by the previous approval by the EU (Argentina Secretariat of Agriculture, Livestock, Fisheries, and Food [SAGPyA], 1997). This departure from a strict science-based regulatory framework was informally called "mirror policy," as it established that EU approval status was the "mirror" for commercial approval in Argentina.

In 2008, the Codex Alimentarius Commission adopted an Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003), providing an international guidance for food-safety assessment of biotech events in situations of LLP (Codex Alimentarius Commission, 2009). This Annex would help importing countries to undertake a contingent, abbreviated risk assessment, not involving full domestic approval, in instances of LLP of products that have been fully authorized in the country of export in a manner consistent with Codex risk-assessment guidelines. Current efforts to develop guidelines for an expedited environmental risk assessment in LLP situations are also being conducted by the Organisation for Economic Co-operation and Development [OECD] Working Group on Harmonisation and Regulatory Oversight of Biotechnology in the last few years (OECD, 2012).

Some countries have recently drafted *ad hoc* regulations to deal with LLP situations. Tolerance for LLP of unapproved materials can be as low as 0.1%, as established in the Regulation EU No. 619/2011 for feed imports (EC, 2011a). In setting this extreme analytical level, this regulation was supposed to avoid the possibility of different conclusions regarding the compliance of a product with Regulation (EC) No. 1829/2003 (European Parliament and Council, 2003a), originated in the use of non-harmonized sampling and testing procedures. Regulation EU No. 619/2011 only applies to i) GE materials for which a valid application for commercial authorization has been submitted (with the authorization procedure pending for more than three months), provided that EFSA has not identified it as susceptible to have adverse effects on health or the environment; and ii) materials whose authorization has expired. Where results of analytical tests indicate that the presence of GE material is at or above the 0.1% threshold, the feed shall be considered as non-compliant with Regulation (EC) No. 1829/2003. Regulation EU No. 619/2011 applies only to feed, as the majority of the commodities likely to contain GE materials imported into the EU are destined to the feed sector. Discussion over the establishment of a similar threshold for food has been postponed (EC, Standing Committee on the Food Chain and Animal Health [SCFCAH], 2011, 2012), implying that currently a zero-tolerance policy continues to apply for EU unapproved GE food products.

Philippines draft regulations (Philippine Bureau of Plant Industry [BPI], 2011) requires the importer to file a petition for a "Certificate on the Safety of Recombinant-DNA Plant Material under LLP Conditions," issued after a food-safety assessment consistent with Codex Annex 3 is conducted by the Bureau of Plant Industry. A threshold is determined based on the dietary exposure to the LLP material, and the decision of the Director of BPI is posted and made available to the public.

The Dispute over GE Products and the Obligations under the WTO Rules

This trade-related regulatory requirement was clearly dependent on the "asynchrony" between the approvals in both trade partners. While this differential between the EU and Argentina was virtually non-existent with the first GE crop, it became much larger after 1998, leading to a *de facto* moratorium of approvals of new GE crops between 1998 and 2003. During that period, only two new products were approved in Argentina—and only after receiving clearance in the EU.

Interestingly, the moratorium was established by an indirect way, hence the allegation by the EC that it was not a "moratorium" but a "suspension" of approvals, as well as the denomination of *de facto* moratorium adopted later by the WTO bodies. The process started in June 1999 when Denmark, France, Greece, Italy, and Luxemburg jointly declared that they would do everything in their power to block further approvals of biotech products until measures on labeling and traceability of biotech products—at that point under discussion at the European Commission (EC)—were developed and implemented. Even though the Commission indicated that this declaration did not have legal status, it actually blocked any further approvals: the Commission realized that these Member States would act as a "blocking minority" and this belief dissuaded the EC from making use of the normal approval procedures.

As this delay was not scientifically justified, it was not in line with the WTO rules. Two international obligations in force under the WTO rules were the relevant instruments—the Agreement on Sanitary and Phytosanitary measures (SPS)[1] and the Agreement on Technical Barriers to Trade (TBT).[2] These agreements establish that restrictive measures on imports be based on scientific evidence of damage (under SPS) and prevent the use of technical regulations or standards as safeguards against imports when they constitute disguised protectionist measures (under TBT).

Considering that the *de facto* moratorium was breaching international obligations, on May 14, 2003, Argentina, together with Canada and the United States, requested the WTO to establish consultations with the

1. *http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s1p1_e.htm*
2. *http://www.wto.org/english/res_e/booksp_e/analytic_index_e/tbt_01_e.htm*

EC "concerning certain measures taken by the EC and its Member States affecting imports of agricultural and food imports from these countries," using the Dispute Settlement Understanding (DSU) mechanism.[3]

The complaining parties were challenging three categories of EC measures: i) the alleged *general EC moratorium* on approvals of biotech products; ii) various *product-specific EC measures* affecting the approval of specific biotech products; and iii) various EC Member States (Austria, France, Germany, Greece, Italy, and Luxemburg) *safeguard measures* (nine cases) prohibiting the import and/or marketing of specific biotech products.

Regarding EC-level measures, Argentina asserted that the moratorium applied by the EC since October 1998 on the approval of biotech products had restricted its imports of agricultural and food products. Regarding Member-State-level measures concerning specific biotech products, Argentina asserted that a number of EC Member States maintained national marketing and import bans on biotech products even though those products had already been approved by the EC for import and marketing in the EC. According to the complainants, the measures at issue appeared to be inconsistent with the EC's obligations under the SPS Agreement, among other WTO obligations.

The Panel—Science Enters the Dispute

Because these consultations did not result in the ending of the alleged moratorium, in August 2003 the complainants asked the WTO to establish a specific panel to address the issue. The WTO's Dispute Settlement Body (DSB) announced in March 2004 the formation of a single panel to rule on the case. The issues before the panel concerned the alleged failure of the EC to reach final decisions regarding the approval of biotech products from October 1998 to August 2003, and the WTO's consistency of prohibitions imposed by certain EC Member States with regard to specific biotech products after these products had been approved by the EC for community-wide marketing. A very active period of argumentations ensued, during which the panel asked the parties questions concerning the issues at stake, giving them the opportunity to submit arguments, scientific evidence, and rebuttals.

It is interesting to note that the central argument between the parties in this controversy was related to the concept of "precaution" and its implications when there is a gap in the information needed for decision-making. For the EC, the solution rested on the interpretation of the Preamble of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (The Secretariat of the Convention on Biological Diversity, 2000). One of the statements in this Preamble indicates that the Protocol's goal is to "[reaffirm] the precautionary approach contained in Principle 15 of the Rio Declaration." The referenced Principle 15 of the Rio Declaration reads: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (United Nations Environment Programme [UNEP], 1992). This interpretation of "precaution" would give support of the EC position, as a further recital of the Preamble of the Protocol states that the aim should be to "…[recognize] that trade and environment agreements should be mutually supportive with a view to achieving sustainable development." This implied that the Protocol and the SPS Agreement are mutually supportive and, therefore, set international standards.

For the plaintiffs, instead, the SPS is the applicable standard when it establishes (in Article 5.7) that "in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, … Members shall seek to obtain the additional information necessary for a more objective assessment of risk, and review the sanitary or phytosanitary measure accordingly within a reasonable period of time." Clearly, the EC and the plaintiffs were using contrasting interpretations of "precaution."

On August 2004, realizing the complexity of the case, the panel considered that certain aspects of the parties' submissions raised scientific and/or technical issues on which the panel might benefit from expert advice and therefore decided that it was appropriate to start a consultation process with a group of *ad hoc* experts, which were proposed and accepted by the parties. The experts were asked a set of specific questions (they ended up with 114) and their responses, as well as the parties' comments on them, were later discussed at a substantive meeting held in February 2005.

3. *http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm*

The Ruling of the Case

On September 29, 2006, after several postponements due to the difficulties of the case, the panel's 2,000-page report was circulated to parties for comments. On November 2006, the DSB adopted and published the reports (*European Communities—Measures Affecting the Approval and Marketing of Biotech Products, DS291, DS292 and DS293 European Communities—Reports of the Panel*).[4] Ruling in favor of the complaining parties, the panel found that the EC had applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003, which was when the panel was established. The panel further found that by applying this moratorium, the EC had acted inconsistently with its obligations under the SPS Agreement because it led to undue delays in the completion of its approval procedures. With regard to the product-specific EC measures, the panel found that the EC had acted inconsistently with its obligations under the same Agreement with respect to the approval procedures concerning 24 out of 27 biotech products identified by the complaining parties because there were undue delays in the completion of the approval procedures for each of these products. And with regard to the EC Member States safeguard measures, the panel found that the EC acted inconsistently with its obligations under the SPS Agreement with regard to all of the safeguard measures at issue because these measures were not based on risk assessments satisfying the definition of the SPS Agreement and hence could be presumed to be maintained without sufficient scientific evidence.

In fact, with regard to the scientific aspects of this remarkable dispute, it is interesting to note that more than 300 publications were submitted for the parties' comments. The panel has noted that both the evidence provided by the EC and the advice provided to the panel by the experts advising it that many of the concerns they identified (e.g., the transfer of antibiotic resistance from marker genes used in the production of some biotech plants to bacteria in the human gut) are highly unlikely to occur in practice. On the other hand, other concerns identified, such as those relating to the development of pesticide-resistance in target insects through exposure to pesticides (including those incorporated into biotech plants) have indeed been documented to occur but were not different from these phenomena occurring with respect to non-biotech crops.[5]

The Implementation and the End of the Case

After the publication of the panel's report, the EC informed the DSB of its intention to implement the recommendations and rulings of the DSB in a manner consistent with its WTO obligations. However, due to the complexity and sensitivity of the issues involved, the EC would need a reasonable period of time for implementation and was ready to discuss an appropriate timeframe with Argentina, Canada, and the United States. On June 2007, Argentina and the EC respectively notified the DSB that they had agreed that 12 months from the date of the adoption of the panel reports was a reasonable period of time to implement the recommendations and rulings of the DSB. This period, which was to expire on November 2007, was later modified several times, so as to expire successively on January 2008, June 2008, August 2008, December 2008, March 2009, June 2009, December 2009, January 2010, February 2010, and March 2010. A roadmap for approvals was agreed upon and updated along these activities.

In March 2010, when 10 new GE crops of interest to Argentina were approved by the EU, both parties notified the DSB of their intention to withdraw formally the settlement and to embark in a so called "mutually agreed solution" under the DSU. Under this agreement, they are to establish a bilateral dialogue on issues related to the application of biotechnology to agriculture, beyond the implementation of the WTO ruling. This dialogue is currently ongoing.

At this ending point of the dispute, it is difficult to assess Argentina's economic losses and the impact of the EU's decisions on the country's economy at large that might have occurred by delaying access to more advanced products or slowing down the development of the technology.

Concluding Remarks—Lessons to be Learned

Environment Protection and Trade Disruptions

Decisions which purport to protect the environment may have profound effects on trade: they may affect exporting partners not only at the level of product-specific trade (e.g., delaying product approval), but also by forcing systemic changes in regulatory frameworks regard-

4. *See http://docsonline.wto.org, Doc # 06-4318, File: wt/ds/293r-00.doc.*

5. *See page 1068 of http://www.wto.org/english/tratop_e/dispu_e/291r_8_e.doc.*

ing the adoption and implementation of new technologies. The economic damages resulting from this situation may be considerable, as they can affect investments on R&D and production, and therefore impact the strategies of economy development of the affected country. For instance, by making regulatory decisions dependent on trade issues as a response to the EU's *de facto* moratorium of approvals, Argentina was forced to implement a pre-market approval step for GE products.

The Prevalence of the Basic Founding Pillars of WTO Dispute Settlement System

The trade dispute over the moratorium has shown that, in spite of the strenuous efforts by the EC (UNEP, 2012), the WTO did not place the value of the Cartagena Protocol on Biosafety at the level of an international standard, compared to the SPS, the TBT, or the Codex Alimentarius-derived instruments, which are the fundamental instruments for WTO policies.

The Increasing Role of Science on Trade Disputes

The dispute at the WTO raised crucial issues with respect to the role of science in managing public risk (Shaw & Schwartz, 2005), with consequences that will extend beyond biotechnology. As new complex technologies are emerging worldwide, the social perception of risks often occurs in a context of gross information gaps that may affect the scientific basis of regulatory policies. Conflicts between society pressures and the adoption of the novel processes or products would be inevitable. Unjustified regulatory barriers—not based in scientific evidence—may not only affect trade but also restrain economic and social development, especially in developing countries, thus extending their consequences far beyond a trade dispute. It follows that scientifically sound assessment of the new potential risks will constitute a fundamental input for decision making as well as a crucial element in dealing with trade disputes. This was clearly seen in the GE crops/foods dispute discussed here, but the need to support dispute issues on hard scientific evidence is likely to occur also in other fields of technology developments, as already can be seen, for example, with nanotechnology (Li et al., 2009; OECD & Allianz Center for Technology, 2010; The Royal Society & The Royal Academy of Engineering, 2004) and the technologies for shale oil and gas exploitation (Energy Institute at the University of Texas at Austin, 2012; The Royal Society & The Royal Academy of Engineering, 2012; US Environmental Protection Agency, 2012). Recruiting dedicated, qualified advisory panels, as it was done in GE case, often would be needed to advise WTO on the decisions to solve the complex disputes. In parallel, greater efforts should be done to increase the knowledge and understanding of the new advances by society.

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Acknowledgments

I thank Dr. Drew Kershen for reviewing this manuscript and making very useful suggestions.