



**The EU-US Dispute over GMOs:
Risk Perceptions and the Quest
for Regulatory Dominance**

Since 2003 the European Union and the United States have been engaged in a fierce dispute over the safety of genetically modified organisms (GMOs) in food products. While a recent WTO ruling has found in favor of the United States, it has failed to address the underlying causes for the dispute and is therefore unlikely to bring an end to transatlantic differences. The following brief will argue that at the bottom of the current crisis are divergent regulatory approaches based on different transatlantic visions of risk management. With both actors determined to enforce their regulatory model as international standard, trade disputes between the two are likely to continue.

Background: The WTO Dispute

In May 2003, the United States, Canada and Argentina brought a case against the European Union (EU) to the World Trade Organization (WTO) alleging that the EU had imposed a de facto ban on the approval of GMO imports since 1998. The plaintiffs also challenged six EU member states that maintain a ban on several GM varieties that have in principle been approved by the European Commission¹. The US has claimed that these measures have unfairly restricted imports of agricultural and food products from the US to the measure of US\$300 million a year. In doing so, the US has been arguing that the EU's de facto moratorium has been in violation of the WTO's Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. The SPS Agreement permits countries to regulate crops and food products to protect health and the environment on the conditions that rules are *scientifically justified* and approval procedures occur without *undue delay*. The US has contended that GM food and feed crops are not substantially different from or any less safe than conventional varieties and that the EU's ban on GM imports has been in violation of WTO conditions on undue delay. Finally, the United States has argued that the EU ban has not only affected US agricultural exports to Europe, but also prevented other countries in the third world, from adopting GM crops and foods that could have improved their agricultural productivity.

The European Union approved a number of GM crops in the mid-1990s, but as the issue of GM technology became more controversial, the EU faced strong pressure from its member states to develop a more robust regulatory system. As a consequence, approval of further GM crops and foods was suspended between 1997-2004, while EU institutions and member states debated and eventually passed new legislation on the approval of GMOs and their labeling and traceability. When EU attempts to avoid a WTO dispute on the issue failed, the European Commission characterized the filing of the complaint as "legally unwarranted, economically unfounded and politically unhelpful [with regard to EC efforts to develop a regulatory system for GMOs]."² In its defense, the EU has argued

¹The European Union Center of the University of North Carolina at Chapel Hill is funded by the European Union to advance knowledge and understanding of the EU and its member countries.

that it is impossible to conclude scientifically, whether GM technology as a whole is safe or not and that GM products would have to be assessed on a case-by-case basis. It has further contended that its approval process has not shown undue delay, but resulted from a lack of responses about GMOs to EU regulators on the one hand, as well as the necessity to overcome public skepticism over GM crops on the other hand. Finally, the EU claims that some aspects of EU regulation are not covered by the SPS agreement, which “was not intended to address the prevention of risks to the environment.”³ Doing so, it emphasizes the importance of the Cartagena Protocol on Biosafety, which seeks to preserve biodiversity, but to which the US is not a signatory.

The stakes in the EU-US legal dispute over GMOs are high and a US victory would have several important impacts for the EU and the international regulatory system. First, should the US succeed with its claim, it will be eligible to seek some form of financial redress from EU member states. While damages to the US agricultural industry have been estimated at some US\$300 million annually, they are likely to rise, as other countries add to these claims. Second, a victory for the plaintiffs will enable them to seek changes to the EU regulatory system, presumably in order to bring it in line with the US’s own regulatory system. This would come at a difficult point of time for the European Commission, which is seeking to enforce its new legislation on GMOs in face of open resistance from several EU member states. The WTO ruling would, therefore, likely affect an internal struggle for power between EU institutions and member states. Finally, and most importantly, a WTO ruling would set an important precedent for future disputes on food safety, public health and environmental standards. The fall-out from this would be legion. It will affect developing countries, most of which have not yet developed a regulatory framework on GMOs. Moreover, it will likely impact the regulation of other industries, like industrial chemicals, and provide the US with the ability to challenge the EU’s recent REACH regulation.⁴ Ultimately, it would put into question the EU’s commitment to the “precautionary principle” in policy-making.

EU-US Differences in Regulatory Approaches

“Primum non nocere”⁵: Europe and the Precautionary Principle

EU legislation on GMOs has been in place since the early 1990s, but a set of new rules has been introduced in 2001 and has taken effect in 2004. Under this new legislation, the criteria for the approval of all GM crops are that they must not be dangerous to human health or the environment, mislead consumers, or be nutritionally disadvantageous compared with the conventional crop variety. Application for approval of any GM food or crop can be made in one country and, if approved, will be valid for all EU member states. An initial assessment will be given by the national authority of the member state, to which the application has been made. Following this step, all other member states as well as the European Commission are free to assess the application in turn. If no objections are raised by any of the relevant authorities, an approval will be given for a period of up to ten years. If one or more member states raise any objections the application will be taken to the EU level and sent for scientific assessment to the

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European Food Safety Authority (EFSA). The Commission will use the scientific assessment of EFSA as the basis for a proposal, which will be approved or rejected by a qualified majority of member states. If no decision for or against the proposal is reached, the Commission will be empowered to decide on the issue.

Aside from this rather arcane approval process, there are four fundamental differences that divide EU and US approaches to GMOs. First, EU approaches are based on the so-called “precautionary principle” as the most important tool for risk management. Originating in German environmental legislation of the 1960s, the precautionary principle “emphasizes a cautious approach to adopting a new technology when existing scientific understanding is incomplete or when there is not a consensus about the nature of the threat.”⁶ Accordingly, the precautionary principle shifts the burden of proof to the technology developer to demonstrate the safety of any new technology. Second, the EU approval process is not based on scientific evidence alone, but leaves considerable scope to other nonscientific factors, such as “societal, economic, traditional, ethical and environmental factors” in all risk management decisions⁷. Third, the EU grants consumers a greater right to information than is customary in the US. Accordingly, strict rules on labeling and traceability of GMOs have been enforced in the EU since the adoption of the 2001 legislation. Under these rules, labeling is mandatory for all authorized GM products. The rule applies to all products that contain a trace of more than one per cent of GMO content. Finally, EU rules on biotechnology include so-called safeguard clauses, which allow EU member states under certain circumstances to ban GM products that have previously been approved by the European Commission. The European Commission is currently involved in a dispute with several EU member states as to the applicability of these safeguard clauses⁸.

Due to the more cautious approach taken by the EU towards GMOs, there are a considerably smaller number of GM foods and crops available in Europe than the US. Nevertheless, according to the Commission, there are currently some 30 GMOs authorized for use within the EU, while a large number of other products are pending authorization. Indeed, following the adoption of new EU legislation in 2004, several new GM products have been authorized for use in the EU⁹. The problem remains that the new decision-making process has repeatedly failed to deliver decisions on the approval of new GM products. Thus, after going through the required stages, EU member states have frequently been unable to muster a qualified majority for either approving or banning a specific GM product, resulting in the European Commission making the final decision on the authorization (see above). Based on this continuing deadlock, a new discussion has ensued on how the process could be improved.

The “Sound Science” Approach: Dealing with Uncertainty in the United States

US legislation on GMOs has been in effect since 1986, as established under the Coordinated Framework for the Regulation of Biotechnology. The centerpiece of this legislation is an acknowledgment of the “substantial equivalence” of GM products and traditional products. Thus, it was decided that “genetically engineered products should

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continue to be regulated according to their characteristics and unique features, not their production method.”¹⁰ This meant that no special regulatory mechanisms for GM products have been developed in the US and the responsibility for overseeing the safety of biotechnological products has fallen to the already established agencies. These include the United States Department for Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). In their approach to regulation, these agencies have followed what has been termed as “the sound science” approach to regulation. Two features have mainly characterized this specific approach to risk management. First, administrative procedures specify that regulation must be justified by “policy rationale, scientific base, and legal authority”¹¹. Second, decisions made by US regulators are open to legal review and can therefore lead to litigation. These two features have meant that US regulations tend to be based on hard and provable scientific evidence, especially in order to withstand possible legal challenge.

The regulation of food products derived from GM crops falls to the FDA. According to a 1992 decision by the FDA, food products that contain GM crops or other materials are not inherently dangerous and, with rare exceptions, do not require additional testing or pre-market approval. GM food products are essentially treated as any other food products that do not require a special approval, unless there exists documented scientific uncertainty about their safety. Only in cases where substances introduced through genetical engineering are considered to be unsafe are additional approval procedures necessary. Similarly, labeling of GM products is only required in those cases where GM products differ significantly in nutritional value from the original product, or contain potential allergens. While public interest in GMOs has been relatively subdued there has been a discussion among regulators on revising the existing system. However, a long-awaited USDA report on Biotechnology and 21st Century Agriculture (AC21) was unable to find a consensus on “whether the current FDA regulatory system for transgenic crops is adequate to ensure safety and public acceptance.”¹²

The considerably greater ease with which GM products and crops are regarded in the US market has led to the widespread planting and processing of these products. This has made the United States the primary producer of GM food in the world, accounting for 63% of the world’s GM crops. Indeed, in 2004, about 45% of corn, 85% of soybeans and 76% of cotton planted in the US were of a genetically modified variety. Since corn and soybeans are basic ingredients for a variety of processed foods, it has been estimated that some 75% of processed foods sold in the US in fact contain ingredients derived from GM crops. Unsurprisingly, differences in handling of GM products have affected US agricultural exports to the EU. While the EU remains the fourth largest export market for US agricultural products, exports of GM products has practically ceased since 1998, causing documented losses of some US\$300 million annually.

Differences in Public Perceptions

Large differences persist in European and US public perceptions about the safety of GM foods and the competence of their food safety regulators. These differences have been

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well documented by several polls showing that while US consumers have little objections about GM food, Europeans largely reject them. Indeed, a recent Eurobarometer poll has shown that safety concerns about GM food continue in Europe, although they have somewhat fallen since the late 1990s and a considerable variance between countries can be noted. Nevertheless, overall only 45% of Europeans approve GM food in general, as compared to 61% in the US.¹³ While reactions somewhat differ from country to country, a majority in favor of GM food exists only in four out of twenty-five European member states¹⁴. These differences can largely be explained by two factors: a series of food safety crises in the mid-1990s and different cultural attitudes towards food and agriculture.

A string of well-publicized food safety scandals in Europe in the mid-1990s, at the time of the introduction of GM crops into the European market, seem to have permanently tainted European perceptions of GM food. The most important of these crises was the BSE, or “mad cow disease”, crisis in the UK. Discovered in the UK in the mid-1990s, UK food safety authorities originally argued that BSE posed no risk to consumers. In 1996, however, scientists discovered a link between BSE and the fatal Creutzfeldt-Jacob disease (CDJ). When BSE cases were subsequently discovered in other European countries, public confidence in their food safety regulators was considerably shaken. The BSE crisis soon combined with several other food scares, such as that of dioxin-tainted meat in Belgium and an outbreak of food and mouth disease in other European countries, in order to undermine public confidence in their regulators. Fortuitously, GM crops were introduced into the European market in the same year the BSE crisis began to spread. As a consequence, public opinion was extremely skeptical about governance assurances concerning the safety of GMO technology and continues to be so to the day.

In addition to the distrust that the European public at large seems to have developed with regard to their food safety authorities, it seems that certain cultural differences to agricultural production and food in general continue to influence public opinion in Europe. Thus, contrary to the US, most European countries continue to maintain a cuisine based on traditional national and regional agricultural production patterns, which have changed only slowly. Moreover, Europeans seem to have a very different public attitude towards the ethics of biotechnology and technological innovations in general that have been well documented in repeated opinion polls on these issues.¹⁵

Impact of the WTO Ruling: The End of the Precautionary Principle?

In spring 2006, after lengthy deliberations, the WTO panel charged with evaluating the EU-US dispute ruled that European countries have been in violation of international trade rules by preventing the import of GM foods and crops. The WTO ruling, however, leaves open several questions. Thus, the WTO sidestepped the issue whether EU legislation on biotechnology was illegal and did not express any opinion on whether GM foods were safe for consumption. It simply concluded that the EU had breached prior commitments under the SPS agreement by disallowing market access for some 21 products. It further ruled that bans of GM products by individual EU member states were illegal. The ruling, therefore, seems likely to challenge EU practices of granting a safety clause to individual

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EU member states. To the surprise of many, the EU did not appeal to the WTO decision, arguing that since the adoption of new EU legislation on GMOs in 2004, it was now compliant with WTO practices. The US, on the other hand, has hinted that it would continue to press for its case at the WTO and that it might challenge EU legislation on labeling and traceability of GM products.

Transatlantic differences over GMOs are, at their most basic, an expression of different approaches towards risk management. Following the “precautionary principle”, the EU has argued that responsibility for proving the safety of a product lies with the producer and that consumer demands for transparency and information should be heeded. The US, on the other hand, has argued that in the absence of scientific evidence to the contrary, every product should be treated the same way and has renounced labeling requirements. These differences have put the US and the EU at loggerheads over a series of other trade issues, from hormone-treated beef to the EU’s latest REACH Directive. Their current dispute at the WTO over GMOs, therefore, embodies only one round in an ongoing conflict over the regulation of international trade, in which both seek to enforce their own regulatory system. As the recent WTO ruling in favor of the US has not really tackled the underlying dispute over different approach to risk management, it seems likely that the EU-US row over GMOs will not remain the last of its kind.

¹ Austria, Belgium, France, Germany, Italy and Luxembourg

² European Commission, “European Commission regrets US decision to file WTO case on GMOs as misguided and unnecessary”, May 13, 2003

³ Alasdair R. Young, “Political Transfer and ‘Trading Up’? Transatlantic Trade in Genetically Modified Food and US politics”, *World Politics*, Vol. 55, July 2003

⁴ The EU’s REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Directive proposes to give greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances used.

⁵ “First, do no harm” is the well-known Hippocratic Oath of the medical profession

⁶ Alasdair R. Young, “Political Transfer and ‘Trading Up’? Transatlantic Trade in Genetically Modified Food and US politics”, *World Politics*, Vol. 55, July 2003

⁷ EU Directive

⁸ The safeguard clause was invoked on nine separate occasions, three times by Austria, twice by France, and once each by the UK, Germany, Luxembourg and Greece. The scientific evidence provided by these member states as justification of their measures was submitted to a Scientific Committee for opinion. In all of these cases, the Committees deemed that there was no sufficient evidence that could justify overturning the original authorization decision. In spite of the repeal, eight of nine bands remain in place.

⁹ See European Commission Food Authority:

http://ec.europa.eu/food/food/biotechnology/gmfood/notification_en.htm

¹⁰ Geoffrey Becker, “Agricultural Biotechnology: Background and Recent Issues”, CRS Report for Congress, September 5, 2006

¹¹ Alasdair R. Young, “Political Transfer and ‘Trading Up’? Transatlantic Trade in Genetically Modified Food and US politics”, *World Politics*, Vol. 55, July 2003

¹² USDA Advisory Committee on Biotechnology and 21st Century Agriculture, “Opportunities and Challenges in Agricultural Biotechnology: The Decade Ahead, July 13, 2006

¹³ George Gaskell, et al., *Europeans and Biotechnology in 2005: Patterns and Trends*, Eurobarometer 64.3, May 2006

¹⁴ Spain (74%), Portugal (65%), Ireland (55%), Italy (54%)

¹⁵ George Gaskell, et al., *Europeans and Biotechnology in 2005: Patterns and Trends*, Eurobarometer 64.3, May 2006