

## International Dimensions of Ethics Education in Science and Engineering Case Study Series

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### The EU-US Dispute over Regulation of Genetically Modified Organisms, Plants, Feeds, and Foods – Case Summary

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In the 1970s advances in genetics raised the possibility of adding recombinant DNA (or “gene splicing”) techniques to the array of methods used by breeders to develop new varieties of plants. Recombinant DNA technology involves isolating the fragments of DNA expressing the genes that carry a desired characteristic in one plant or variety of plant, splitting the DNA molecule of another variety or plant with other desired characteristics, combining the two partial DNA molecules into a single new DNA molecule, and then inserting that new DNA molecule into a cell and providing appropriate conditions in a lab that will enable that new recombinant DNA (rDNA) molecule to replicate. If replication is successful, the cells with the rDNA can then be used to grow a new variety of plant with tissue culture methods identical to those used by traditional hybridizers. Though the goal, development of hybrid plants or animals combining the desirable characteristics of two or more “parent” varieties, is similar to that of traditional cross-breeding through grafting of plants or artificial insemination of animals, the process was unproven. In addition, some of the prospects described by gene splicing enthusiasts inspired fears among other observers that recombinant DNA techniques could result in the breeding of very pernicious varieties. While traditional hybridizing and artificial insemination techniques can be applied only to plants or animals that will cross-breed as whole organisms, recombinant DNA techniques can by-pass that limit, and observers who believe the natural barriers to cross-breeding are part of nature’s defense against evolution of dangerous varieties looked with dismay at the prospect of jumping over that barrier.

#### General Considerations informing Policy Decisions

Policy decisions in scientific and engineering fields have a factual and a normative component. The factual component consists of the scientific or technical knowledge needed to make an effective decision; the

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normative component consists of the principles and values and principles that policy-makers or citizens believe will guide them to a good decision. The intensity of policy debate about a particular matter is related to both the level of uncertainty in scientific or technical knowledge about the matter and the level of ethical concern. The possible variation in intensity can be suggested by a nine-cell matrix:

	level of knowledge uncertainty			
		high	medium	low
level of ethical concern	high			
	medium			
	low			

Knowledge uncertainty can take any of several forms; each of them makes choosing policies difficult because uncertainty reduces ability to foresee the full consequences of any policy choice. The first, and most fundamental, form of uncertainty is lack of knowledge regarding the basic cause-effect relationships among physical phenomena. When causal knowledge is missing, people cannot anticipate how changing some aspect of a physical situation (for example, releasing chlorofluorocarbons [CFCs] into the atmosphere) will affect other aspects (the chemical composition of the atmosphere, the thickness of any particular layer of the atmosphere). When CFCs were first invented, they were regarded as environmentally superior to earlier refrigerants because the earlier ones sometimes exploded while CFCs are inert at ground level. Only in the late 1960s and early 1970s was the connection between CFC emissions and depletion of the stratospheric ozone layer understood. A milder form of uncertainty, also inhibiting good policy choices, exists when the basic causal relations are understood but the intensity of the relation between cause and effect cannot be estimated very precisely. In the 1970s and 1980s many people agreed that carbon dioxide and other gaseous emissions were altering the chemical composition of the atmosphere, but there was still considerable disagreement among experts about what amount of change in average temperature of the atmosphere would affect weather patterns around the world. A third form of uncertainty exists when both the basic causal mechanism and the intensity of cause-effect relation are understood but it is not clear how to ensure desirable changes or prevent undesirable ones. In the late 1960s, many people thought that banning use of CFCs as aerosol propellant (as in deodorants or spray paint) would prevent further damage to the stratospheric ozone layer; only in the mid 1970s was it fully understood that refrigeration uses would have to be ended as well because the small amounts of CFCs escaping from each refrigerator added up globally to significant emissions.

Ethical concern can focus on people or on nature. Traditionally, ethics focused on the impact of one person's actions on other persons, with ethicists, philosophers, and others debating questions like avoiding harm to others, ensuring fairness or justice, and how far one person may enjoy freedom from limits on choice or action. Since the late 1960s increasing attention has been devoted to the impact of human activity on nature, and considerable ethical discussion of humans' obligations to future generations of humans (intergenerational equity), to other species of life (animal welfare or animal rights) or to nature as a whole (ecological sustainability, humans as a part of a larger web of life). At any particular time, the level of

ethical concern surrounding an issue rests on a combination of its perceived importance to the well-being of humans and/or nature and on the level of consensus regarding the values that should guide policy choices and human actions on the matter.

Scientific uncertainty and ethical concern converge in the process of defining what action is “safe.” Even when the risk (the likelihood that a negative impact of a particular magnitude will occur) can be specified fairly clearly, different individuals, groups, and societies may react differently, one deciding the risk is tolerable and hence that undertaking the activity is safe (at least as long as those doing so are reasonably prudent), and another deciding that the risk is too high and hence undertaking the activity is not safe. When lack of knowledge of the likelihood and intensity of some impact is great enough that people can insist that the probability of harm is high and its intensity very strong, there will be particularly strong pressures to define the activity as unsafe.

### **Genetically Modified Organisms**

Genetic modification of organisms and plants involves identifying genes that carry desirable traits (such as pest resistance, disease resistance, or higher nutritional content), developing recombinant DNA (rDNA) containing the genes carrying the desired trait, and using that rDNA to breed a new variety of the organism or plant that will have the trait. Genetically modified (“GM”) organisms, plants, animal feeds, and human foods inspire heated debate today because they involve both high knowledge uncertainty and high ethical concern. The knowledge uncertainty is focused primarily on the impact of introducing GM organisms, plants, feeds, or foods into fields and food supplies on humans, other varieties of animal or plant life, and the natural environment more generally. Perceptions of likely impact range from minimal – GM foods, though produced by new technology, pose no greater risk to ecosystems and living beings than new varieties of plants or animals developed with traditional techniques of grafting or selective breeding whole organisms – to maximal – GM organisms are so different from varieties developed with traditional techniques that they will unbalance the natural environment. Adding to the confusion, the maximal harm scenarios come in two varieties. In the first, GM organisms either displace natural varieties or combine with them to produce destructive organisms (the “frankenfood” scenario) that crowd out others. In the second, GM organisms and plants prove so genetically identical that they can be eliminated by some disease the developers did not consider and wide adoption leaves food supplies extremely vulnerable to sudden collapse (the starvation from loss of genetic diversity scenario).

In recent years, the situation has become more fluid as gene insertion techniques have been applied to “cisgenic” as well as “transgenic” rDNA. Transgenic rDNA contains genes spliced out from different species that would not cross-breed naturally with the species being improved, and this feature of crossing natural barriers to inter-breeding inspired much of the concern about environmental effects of GM organisms and plants. “Cisgenic” rDNA is developed from organisms or plants closely enough related to one another that they would cross-breed naturally. Using cisgenic rDNA rather than traditional cross-breeding of whole organisms allows developers to select only the gene carrying a desired trait, whereas traditional cross-breeding involves taking up the entire gene sequence. Thus, for example, a conventional breeder seeking to improve resistance of potatoes to *Phytophthora infestans* (which causes potato blight)

use wild varieties that also carry genes that express toxic compounds like glyco-alkaloids. The undesired trait must then be removed by a process of back-crossing over several generations until a hybrid is developed that has the desired trait (disease-resistance) without the undesired one (glycol-alkaloids). Back crossing can be a lengthy process, whereas cisgenic rDNA produces a desired variety in a single generation.

High ethical concern about GM organisms has two sources: concerns for the integrity and sustainability of the natural environment and concern about the social consequences of allowing the supply of seeds or breeding stock to be controlled by developers (mainly thought not exclusively very large multinational corporations) having 20-year monopolies over distribution of any particular genetic material, seed, or animal breeding stock as a consequence of patent rights.

### Sources of EU-US Divergence

In debates over GM organisms, scientific uncertainty and ethical concern have played out differently in the European Union (EU) and the United States of America (USA) since the mid 1990s for institutional and ideational reasons. The US regulatory system is centralized for rule-making, with regulatory authority held by three government agencies – the Food and Drug Administration (food safety), the Department of Agriculture (planting of GM crops), and the Environmental Protection Agency (use of GM technology to create pest resistance in plants) but decentralized for rule-enforcement in that individuals, groups, firms or large sets of individuals can bring a tort suit against a developer or seller of GM seeds or plants or products made from GM plants and US law allows assessing of high financial penalties for damage. The EU regulatory system is decentralized in rule-making, with the EU Commission and EU agencies co-existing with national agencies but more centralized in rule-enforcement because the civil law systems of continental European states do not make provision for private tort suits.<sup>1</sup> While in some areas the US federal government and the governments of the 50 states of the union contend over their spheres of authority, federal authority to regulate the development and use of GM technology clearly prevails. In the EU, ongoing struggles for authority between the EU Commission (the supranational body in charge of developing draft regulations) and the EU Council and European Parliament (the representative bodies of member governments and of national populations respectively with the power to adopt regulations) as well as between EU agencies and national government agencies creates more veto points in the decision-making processes regarding GM technology than exist in the USA because neither Congress nor the courts have been involved in any sustained way with debates about use of GM technology.

These institutional differences have less practical impact when EU and US approaches to regulation are less divergent; the two have been able to develop common regulations on a wide range of technical,

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<sup>1</sup> Legal differences noted in Mark A. Pollock and Gregory C. Schaffer. 2009. *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press), p. 53. As they point out, "This difference in the operation of US and European legal systems is often forgotten in political and sociological assessments of their different approaches to the risks posed by genetically engineered varieties."

economic, and health matters.<sup>2</sup> However, in the mid 1990s European attitudes toward GM foods, animal feeds, and crops diverged significantly from US attitudes. The Reagan Administration set the basic parameters of US policy in 1986 in laying out the Coordinated Framework for the Regulation of Biotechnology. This encouraged the approach formalized in 1992 under which the US agencies treated genetic modification as another form of breeding and focused on whether a particular product of GM technology is safe. Partly because of pressures from conservatives and business interests, US regulatory approaches rely heavily quantifiable estimates of potential harms and benefits used to make cost-benefit analyses. Though initially inclined to treat GM organisms as similar, the EU and most of its member states now regard genetically modified organisms, plants, feeds, and foods as very different from “conventional” varieties developed with traditional cross-breeding and hybridization techniques because GM technology allows combining genes across species of plants or animals. This focus on the technology as fundamentally different encourages rejection of cost-benefit analysis in favor of regarding the area as one so full of uncertainty that the EU’s preference for relying on the precautionary principle in matters having environmental implications should apply. This principle mandates avoiding a new activity or technology while its long-term consequences remain unknown, and taking it up only after the best available assessment techniques show that there will be only low and reversible negative impact on the environment and particular life forms. Thus US regulatory agencies regard genetically modified organisms, plants, feeds, and foods as “substantially equivalent” to varieties produced by traditional breeding methods unless there is solid proof of a significant difference while European ones assume there is a substantial difference. Nor does the USA rely as extensively on the precautionary principle; most of its policy decisions are still guided by the traditional rule that a new activity may proceed until it is shown to cause significant harm.

These differing presuppositions result in very deep differences of regulatory approach on the two sides of the Atlantic. The basic US government decision that GM plants, animal feeds, and human foods are essentially similar to conventionally-bred plants, feeds, and foods requires regulators to demonstrate that they are notably less safe for planting or consumption before they can block cultivation or sale. In the EU, a largely opposite dynamic has prevailed since late 1998. European rules start from the proposition that GM plants, feeds, and foods are significantly different from conventionally bred ones and those who want to plant or sell them must prove to regulatory agencies that their plant, feed, or food is safe. The different orientations also affect policies towards GM organisms already in the environment: the EU requires more continued monitoring of effects than does the USA.

### Origins of the Divergence

In the late 1980s, before the regulatory differences developed, business leaders and policy-makers in the EU and the USA agreed that coordinating their policy approaches in a range regulatory policy areas would be helpful to both industry and consumers. In 1995 European and American business leaders created the Transatlantic Business Dialogue (TABD) to push for the liberalization and harmonization of laws and

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<sup>2</sup>See, for examples, George Bermann, Matthias Herdegen, and Peter Lindstreth, eds. 2001 *Transatlantic Regulatory Cooperation: Legal Problems and Political Prospects* (New York: Oxford University Press); Ernst-Ulrich Petersmann and Mark A. Pollack, eds. 2003. *Transatlantic Economic Disputes: The US, the EU, and the WTO* (New York: Oxford University Press); David Andrews, Mark A. Pollack, Gregory Schaffer, and Helen Wallace, eds. 2005. *The Future of Transatlantic Economic Relations: Continuity amidst Discord* (Florence: Robert Shuman Centre for Advanced Studies, European University Institute).

regulations regarding highly-traded goods and services on both continents. From its beginnings the TABD urged the United States and the European Union to adhere to a shared policy on genetically modified food. Its recommendations were forwarded to the Transatlantic Economic Partnership (TEP), an EU-US governmental working group charged with developing draft common policies. In 1998 the TEP created a Biotechnology Working Group that attempted to launch a project that would have created a process for simultaneous regulation of particular GMOs on both sides of the Atlantic.

The original EU rules adopted in Directive 90/220 of 1990 were very similar to the US rules, so prospects for agreeing on a common set of rules and a parallel regulatory process looked very good. Before the TEP's project got underway, however, the prospects for success were undermined by food safety scares and the rise of anti-genetically modified food protests in Europe that sent the EU policy process in a different direction. Though relating to conventionally bred plants and animals, the scare about humans contracting bovine spongiform encephalopathy (BSE or "mad cow disease") from English beef in 1996 and the discoveries of toxic materials in Belgian and French animal feedstocks in 1999,<sup>3</sup> reduced public confidence in EU and national regulators just as anti-GMO campaigns were taking off. US biotech firms were aware of the sentiments, and Monsanto sought in vain to counter them with public relations campaigns that, by suggesting critics were irrational and anti-science, only strengthened opposition by allowing environmental groups to present the GM controversy as one of embattled civil society groups up against, but ultimately overcoming, large foreign multinational corporations. All agricultural applications of GM technology were cast into doubt as environmentalists deployed a combination of worst-case scenarios about environmental damage, fears about eating foods containing ingredients with unknown health consequences, and arguments that GM technology benefits mainly those engaged in large-scale environmentally-damaging "industrial" farming so hurts poorer farmers to raise very effective technical and ethical concerns.

The government of Austria led the way to policy divergence in February 1997 by invoking the 1990 Directive's Article 16 "safeguard clause" that allowed member states to ban growing plants from particular GM seeds if they judge that growing them will threaten the country's environment even if EU regulatory authorities have accepted them as safe. Austria's decision to ban BT 176 maize (corn) developed by Novartis, inspired other governments to take similar decisions; between 1997 and 2000, six-member countries – Austria, Luxembourg, France, Greece, Italy, and Germany – had invoked the safeguard clause on 12 occasions to ban particular plants. Opponents of using GM technology claimed that Directive 90/220 was too vague and the approval process lacked sufficiently stringent risk assessment requirements, and their positions garnered substantial public support. In 1998-99 some major European food processors – Danone, Nestle, and Unilever – and some supermarket chains – including Sainsbury's in the UK and Carrefour in France – announced they would not use or sell products containing GM ingredients. Responding to the general public discontent, and hoping to ward off further member government use of safeguards, the European Commission announced on 26 November 1997 that it would amend Directive 90/220 to address the concerns of its member states and issue no further approvals of GM plants or products until the new regulations were in place. This course of action was reaffirmed in June 1999 when the EU Council outlined its thinking on a new, more restrictive regulatory scheme including tougher safety

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<sup>3</sup>Pollack and Schaffer 2009, 75.

criteria and requiring authorizations to plant or sell be renewed every 10 years. Previously issued permits remained valid, but strong consumer resistance meant that sales of GM seeds and GM-containing feeds and foods fell drastically. The value of American GM corn exports to EU countries fell from around \$211 million in 1997 to \$200,000 in 2005; similarly, GM soybean exports fell from \$2.3 billion in 1997 to \$511 million in 2005.

### **Reinforcement of the Divergence**

While developing its regulations, the EU also participated actively in the multilateral negotiations leading to conclusion of the Cartagena Protocol on Biosafety, in January 2000. Enough countries then ratified the Protocol for it to enter into force and provide binding rules for the countries accepting it. The Protocol does not affect national regulations, though it does reinforce the right of each country to make its own regulations and ensure that any seeds, plantstocks, or agricultural products imported into its territory meet its regulatory requirements through what international lawyers call a “prior informed consent regime.” The Protocol requires exporters of GM organisms to provide information about the organisms they want to send to other countries and get express approval from the importing country’s government before trade proceeds. The importing country government can require a risk assessment if none is available, and also that the exporter absorb the costs of performing the risk assessment. Any agricultural commodities (raw materials like cotton as well as animal feeds and human foods) that contain GMOs must be accompanied by documentation indicating the shipment “may contain” GMOs. Governments must also post information about their regulations, approvals they have granted, and risk assessments they have done or had others do on a central Internet site maintained by the international Biosafety Clearing-House.<sup>4</sup> This helps governments, importers, and exporters by giving them “one-stop shopping” for the information they need to operate the prior informed consent regime. The US government has not accepted the Protocol, but the 147 of the world’s 196 independent states that have – which include all members of the EU and major importers of agricultural products like China, Egypt, India, and Japan, and many African counties importing food or receiving food aid – can invoke it to require any private company or person seeking to export GMOs to comply with the rules it establishes. This follows from the traditional international law principle that each state has control over activity on its territory, and once goods shipped from one country as exports arrive reach their destination at a port or airport of another, they become imports subject to that state’s control.

Article 1 of the Biosafety Protocol contains a clear endorsement of the precautionary principle: In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 2, the General Provisions, strongly endorse the right of each country to make its own decisions.

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<sup>4</sup>The Biosafety Clearing House site is at <http://www.cbd.int/biosafety/bch.shtml> (accessed 17 June 2010).

Paragraph 2 specifies that:

The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

Paragraph 4 says that:

Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

All of these provisions reinforce the European stance that GM technology poses significant risks and so are not to be used before a very thorough prior assessment, and challenge the US stance that GM organisms are basically safe so may be used unless proven otherwise.<sup>5</sup>

Though the EU adopted its new regulations in 2001 and 2003, it did not start considering new approvals of growing GM crops or selling foods or feeds containing GM material because public opposition to GM foods remained very strong. US firms and food distributors, who believed their products were both safe and beneficial, were irritated by what they saw as an intentional move to keep the moratorium in place even though the new policies had been adopted. Many of them also thought the EU was using public opinion as a smokescreen for policies actually meant to protect European seed companies, farmers, and food wholesalers from foreign competition. Such suspicion was not entirely unreasonable; the EU has a long record of maintaining particularly high trade barriers against foreign agricultural and food products. Yet, even the George W. Bush administration, one well known for its partiality to the interests of big business and the well-organized agricultural groups, was reluctant to confront the issue head-on until May 2003. By then, the extent of anti-GMO sentiment among both the US and European public appeared stable and unlikely to be increase the publicity attending a trade dispute. More important to US decision-makers, third countries were defining their attitudes towards GMOs, with some becoming highly restrictive, and US companies and growers' associations were pressing the government to head that off.<sup>6</sup>

## **The WTO Complaint**

On 13 May 2003, the United States, Canada and Argentina filed complaints with the World Trade Organization contending that the European Union – referred to in the complaint as the European Community – moratorium on approving new genetically modified food amounted to unfair protectionist measures against their countries' GM products, actions they contended were prohibited by the General Agreement on Tariffs and Trade (GATT).<sup>7</sup> However, they carefully confined their complaint to procedural

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<sup>5</sup>Cartagena Protocol on Biosafety. Text available at <http://www.cbd.int/biosafety/protocol.shtml> (accessed 17 June 2010).

<sup>6</sup> Factors influencing the timing and form of the US complaints are discussed at length in Pollack and Schaffer 2009, pp. 179-182.

<sup>7</sup> The complaint has been analyzed by many experts, including and Pollack and Schaffer 2009, 182-198.



issues rather than challenging the EU's basic regulatory framework or the substance of its regulations. The complainants' main arguments were that neither the "de facto general moratorium" on approving any additional GM plants for growth or sale nor the Commission's failure to approve GM varieties that the European Food Safety Agency had agreed were safe were based on scientific evidence or an appropriate risk assessment as required by the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). While attempts to end the moratorium was arguably the most important single element of the complaints, the three countries also objected to six EU member states' – Austria, France, Germany, Greece, Italy and Luxembourg - use of the EU "safeguard clause" to prohibit imports of certain GMOs and/or maintain product-specific moratoriums.

The EU response emphasized two points. The EU argued, first, that it never adopted a formal moratorium on the approval of new GM crops, and cited its May 2004 approval of the *Bt-11* variety of sweet corn as evidence that a blanket ban on new GM products never existed, and that each case was decided on its own merits. Second, the EU also argued that the SPS Agreement did not adequately address the complexities of the GM food case by itself, so other international agreements, such as the 1992 Convention on Biological Diversity and its 2003 Protocol on Biosafety, that do address those complexities should also guide interpretation of obligations under GATT. It contended in particular that the 2003 Cartagena Protocol on Biosafety – to which the EU, but not the United States, Canada, or Argentina is a party – permits states to adopt a precautionary approach toward products created by application of new technologies.

After the required "consultations" between the EU and each of the complaining states failed to resolve the dispute; the matter went to a WTO Dispute Settlement Panel. While the USA, Canada, and Argentina had made separate complaints (WT/DS291, WT/DS292, and WT/DS293 respectively) all three were assigned to one Dispute Settlement Panel because of their similarity. Unlike the previous GATT Dispute Settlement Process, where the veto-power of individual member states forced panels to reach decisions all member states would accept, the WTO Dispute Settlement Process requires consensus among all parties for rejection of a Panel's report. This rule establishes a presumption in favor of accepting the Panel Report, effectively transferring decision authority from the Dispute Settlement Body composed of representatives of the member states to the Dispute Settlement Panels and, if any of the disputants is unhappy enough with the Panel's decision to seek a review, to the Appellate Board.

The three-member WTO Panel began hearing oral arguments in June 2004. Five states, Australia, Chile, China, New Zealand, and Norway, filed memoranda as third parties to the case. Australia and Chile laid out largely neutral arguments in support of third parties' and developing countries' rights to file memoranda on WTO disputes as third parties. China and Norway filed arguments supporting the EU's position, while New Zealand supported the complainants' position. The Panel also accepted briefs from three nongovernmental entities that urged it to rule that the EU's regulations were consistent with trade law, but the Panel did not mention them or use their arguments in developing its ruling.

The Dispute Settlement Panel's September 2006 final report<sup>8</sup> ruled that the EU's pre-market approval system for GM products violated the SPS Agreement provision prohibiting unnecessary delays. The Panel concluded that "the European Communities applied a general de facto moratorium on approvals of biotech products between June 1999 and 29 August 2003" and set a date of 21 November 2007 for the EU to lift its moratorium on the approval of GM products, or risk facing WTO sanctions. In addition, the Panel recommended to the Dispute Settlement Body that it request the European Commission to finish the approval process of GMOs stuck in legal limbo. The Panel requested that the Dispute Settlement Body require member states with national safeguard measures in place bring their laws into accordance with WTO regulations. The EU had contended that the GATT and the SPS Agreement, adopted in 1994, should be read in light of the later Cartagena Protocol and its institutionalization of the precautionary principle used to interpret what measures are allowed under the SPS Agreement. Argentina, Canada, and the USA contended that the SPS Agreement should be read on its own terms, not in light of a different agreement. The Panel avoided the question by declaring neither the Cartagena Protocol on Biosafety nor the Convention on Biological Diversity were pertinent to the dispute before it because some of the countries involved in the dispute were not parties to those agreements. This is consistent with the international law rule that states are bound only by rules to which they have given consent, either expressly (as by ratifying a treaty) or tacitly (as by using the rule to justify their own actions).

While the ruling could be interpreted as a victory for pro-GM interests, the Dispute Settlement Panel did not state any opinions that would prevent the EU from continuing to develop stricter regulations than prevail in the USA and other countries. The Panel focused closely on the questions before it, and consistent with good adjudication practice, did not rule on extraneous questions or make a broad statement when a narrow one would settle a point in dispute. Thus, the Final Report did not address the legality of the pre-market approval, and risk assessment procedures ultimately adopted by the EU, and in particular, avoided specifying whether the precautionary principle is (as the EU contended) or is not (as the complainant countries contended) a part of international law binding on all states. Though concluding the EU's use of this particular moratorium violated GATT rules, it did not address the legality of future product-specific measures the European Union or any other country might adopt in the future. The Panel also avoided stating any conclusions on the question of whether GM foods are substantially similar to their conventional counterparts, the position of many in the USA who support less regulation. Thus the WTO ruling went against the European Union on the technicalities of its de facto moratorium, but did not include any ruling that would force the EU into a complete revision of the EU regulatory system, though it did indicate that EU member states' maintenance of national bans on GM products the relevant EU institutions had accepted as safe were contrary to the SPS agreement.

Consistent with WTO rules, the parties then agreed that the EU should be given a 12-month "Reasonable Time Period" to come into compliance, after which complainants could seek permission to apply retaliatory measures if the EU were not making progress in bringing its policies into line with the Panel Ruling. They then agreed to extend this another year, until January 2008.

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<sup>8</sup>European Communities – Measures Affecting the Approval and Marketing of Biotech Products. WTO Document WT/DS291R (29 September 2006). Commonly known as the EC-Biotech dispute.

## Future Prospects

The EU and the US are unlikely to adopt similar regulations regarding cultivation of GM plant varieties or sale of products containing GM ingredients because public opinion remains more strongly opposed to applications of GM technology for several reasons:

1. US firms developing or hoping to develop agricultural applications of GM technologies formed an effective nationwide industry lobby despite differences in firm size and main areas of interest early in the discussions of GMOs. European firms developing or hoping to develop agricultural applications of GM technology failed to form industry lobbies, particularly at the EU-wide level, early in the process and their efforts still lag behind those of US firms. Thus the European GM debate includes fewer advocates of agricultural applications than the US debate.
2. Most GM plant varieties developed so far bred for disease resistance, herbicidal properties, or pesticidal properties, and these traits are most useful to farmers engaged in highly mechanized cultivation on large fields. There are more such farmers in the USA than in EU countries.
3. European food sellers typically purchase much of their food from local or regional suppliers rather than large transcontinental suppliers. In the USA most supermarket chains rely on large transcontinental suppliers. Genetic modifications that increase the keeping time or shipping hardiness of vegetables, fruit, and other foods are less important to European than to US food suppliers.
4. On average, European consumers place higher value on freshness and local varieties of food than do US consumers. GM organisms and plants are perceived by European consumers as highly standardized “industrial-style” products lacking character. There is a growing “buy local” movement in the USA but it still accounts for only a small part of US food consumption.
5. Though US regulatory processes in place during the 1980s actually included more opportunity for public comment than did the EU or member state processes of the time, the initial decision that GM organisms and plants are “substantially similar” to conventionally-bred organisms and plants meant that regulatory agencies did not see the need to develop new rules for making decisions about GM organisms. Thus neither Congressional debates nor the public comment process involved in agency rule-making occurred at an early stage of technology use. Because of the economic and consumer attitudes differences noted above, agricultural use of GM technology was far less widespread in Europe when opposition arose, so it was easier to interrupt approvals and press for adoption of more restrictive rules.
6. Multiparty political systems, which exist in most EU member states, make it easier for new groups, such as environmentalists, to form political parties and win seats in the national legislature than do two-party systems, as exist in the USA and the UK. The ability of small parties to win seats is increased in countries that use a proportional representation system. In such systems members of

the legislature are elected from larger multi-member districts and each party wins seats in proportion to its share of the vote in the district. It is easier to “break in” under this system than under a single-member district system. Most European countries have multiparty and proportional representation systems, which encourage European environmentalists to put a lot of energy into mobilizing ordinary voters. A two-party system, single-member districts, and greater opportunities for influencing policy through lobbying and litigation in the courts encouraged US environmentalist groups to put most of their effort into lobbying and litigation. This difference contributes to the higher level of environmental consciousness among the average European votes than the average US voter.

7. Similar ethical sentiments prevail among proponents and opponents of agricultural applications of GM technology on both sides of the Atlantic. Anti-GMO views get more traction on food issues in Europe because the greater public interest in food quality among Europeans promoted greater receptivity to arguments that GM technology modifies foods much more than traditional cross-breeding and hybridization techniques.

Differences in the way regulation proceeds in the USA and the EU also affect the results. Even if the two sets of regulators converged on a single method of risk analysis, which itself seems difficult given greater US reliance on cost-benefit modes of risk analysis and greater European reliance on the precautionary principle, the ways each implements regulations inhibits common approaches to risk management through regulations. The parallel existence of regulatory statutes and the US tort law system as well as strongly market-oriented economic beliefs encourage regulators to presume things are safe until lack of safety is demonstrated. The more hierarchical traditions of regulation in Europe combined with the relative absence of private rights to pursue matters through the courts mean that regulators are more willing to make determinations regarding individual products.<sup>9</sup>

Stalemate in Europe has also been prolonged by the work-in-progress nature of the EU regional integration project. In contrast to the USA, where federal preeminence in regulation of foods, drugs, and chemicals (including pesticides) has been established for decades, EU bodies still share authority with member state agencies on many issues, including food safety, agriculture, and environmental protection. Decision-making at the EU level can be slowed by the rules requiring that the Council adopt Directives, Regulations, and some specific regulatory decisions (including approvals of GM varieties of plants for sale or for cultivation) by a qualified majority comprising half the total number of member states and about 74% of the total votes cast under the weighted voting system. This has been the case with GM plant varieties, where the Commission was unable to get the Council to endorse any proposals to authorize marketing foods containing or growing crops of GM plant varieties in 2006-2008. Throughout that period anti-GM sentiments seemed to growing among the member states. In 2006 Hungary banned growing of many varieties approved by the European Food Safety Agency and inhibited cultivation of the few allowed by requiring that farmers leave 400-meter (1200 feet) wide isolation zones between fields planted with GM

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<sup>9</sup> Pollack and Schaffer 2009, p. 53 emphasize the tort liability implications – that FDA statements products are “safe” rather than “generally recognized as safe” would give their makers strong protection against liability suits.

varieties and fields planted with conventionally-bred varieties get all neighbors' written consent before starting cultivation of GM varieties. Poland banned sale or cultivation of all GM varieties in October 2006, a measure the EU Commission formally opposed by suing Poland for non-compliance with EU directives in the European Court of Justice.<sup>10</sup> The governments of Ireland and France also joined the government of Austria in strong opposition to allowing cultivation of GM crops and sale of GM-based products.<sup>11</sup> Meanwhile, the WTO Panel Report inspired additional interaction between the parties. Argentina and Canada let the November 2007 deadline for the EU to comply with the Dispute Settlement Panel's ruling pass without seeking permission to retaliate. The USA did ask for authorization to retaliate, the EU filed an objection, and the two moved into "technical discussions" after starting and then agreeing to a suspension of the WTO process for determining whether EU inaction merits retaliatory trade measures.<sup>12</sup> Canada formally resolved its complaint in an agreement to hold twice-yearly policy consultations with the EU in July 2009, and Argentina came to a similar agreement in March 2010.<sup>13</sup> While clearly disappointed with continuing EU stalemate, the complainants understand the contentiousness of the issue and the hazards of pressing too hard.

Signs that the stalemate might be ending appeared in early 2010. In March, after more than three years of debate triggered by strong opposition from anti-GMO groups, the Commission approved cultivation of Amflora, a starch-rich potato variety developed by the German firm BASF intended for paper manufacturing and other industrial uses. This opened the way for cultivation in Germany, Sweden, and the Czech Republic, and was seen as a significant policy development. In June news reports indicated the Commission was circulating drafts of a possible new regulation that would allow member states to ban sale of products containing any GM ingredient or cultivation of any GM variety they desire, rather than be confined to the human health, animal health, or environmental risk considerations specified in Directive 1830, in return for not blocking EU-level approval of varieties determined to be safe by the European Food Safety Agency.<sup>14</sup> In essence, members of the EU would "agree to disagree" on the issue. Biotechnology companies and farmers desiring to grow GM varieties would be able to do so under fairly strict rules regarding separation of GM from non-GM crops both in the field and in the food distribution chain if the

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<sup>10</sup> Pollack and Schaffer 2009, 247.

<sup>11</sup> "Environment Council: Ministers seek to solve impasse over GMOs." 2009. *European Report* 9 June 2009.

<sup>12</sup>See Europa Press Releases. 2009. EU and Canada settle WTO case on genetically modified organisms. <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1142&format=HTML&aged=0&language=EN&guiLanguage=en> As of May 2010 the EU and the USA had not reached a formal agreement on the dispute. See EU status notification to the WTO available at [http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc\\_146140.pdf](http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146140.pdf) (accessed 17 June 2010).

<sup>13</sup>Europa Press Releases. 2009. EU and Canada settle WTO case on genetically modified organisms. <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1142&format=HTML&aged=0&language=EN&guiLanguage=en>; joint Argentina-EU notification of settlement to the WTO available at [http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc\\_146144.pdf](http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146144.pdf) (accessed 17 June 2010).

<sup>14</sup>Joshua Chaffin 2010. Move to allow EU ban on GM crops. *Financial Times* 4 June 2010 <http://www.ft.com/cms/s/0/6654b40a-6fef-11df-8fcf-00144feabdc0.htm> (accessed 16 June 2010).

government of their country agreed. Opponents of GM foods and crops would have to continue supporting bans where they existed and campaign country-by-country to secure additional bans.

While the regulatory controversies between the US and the EU and within the EU continued, developers and growers of GM plants and food processors using GM-based ingredients both accommodated to and created pressures for reduction of the regulatory differences. US government agencies have explicitly decided against adopting labeling requirements, two methods of distinguishing foods from non-GMO sources have developed in the USA to appeal to consumers who want to avoid GMOs: a) foods labeled as “not containing” a GMO or meat and animal products as coming from animals “not treated with” a GM hormone and b) foods labeled “organic” because the USDA standards for using the organic label adopted in 2001 exclude use of GM plants, enzymes, or hormones. Export-oriented grain growers’ associations became more sensitive to problems that would arise if they continued to grow varieties allowed in the US but not in other countries in summer 2006 when trace amounts of LL601 rice developed by Bayer were found in shipments of Clearfield rice shipped abroad and both EU and Japanese authorities required all US rice shipments to be tested and certified to be LL601-free before they could be sold in their markets. Difficulties for exporters to Europe were compounded in April 2007. EU Directive 1830 specified limits on trace amounts of GM-derived ingredients in foods labeled “GMO-free.” They could contain no more than 0.9% of an ingredient derived from a GM product authorized for sale in the EU, and no more than 0.5% of an ingredient derived from a GM variety certified as safe by the EFSA but not yet approved for sale by the EU Commission for period of three years after the EFSA action. After three years a zero threshold applied to such ingredients. The zero threshold went into effect on several GM varieties in April 2007, inspiring considerable complaint from the US and other exporters to the EU because of the extreme difficulty of separating out different varieties of grain in bulk shipment and the continuing stalemate on approval of GM varieties in the EU Council.

These and other difficulties that arose when the US permitted cultivation before regulators in importing countries authorized sale of that same variety inspired the US Biotechnology Industry Organization to adopt self-regulation under which member firms will not commercialize a new GM variety until it is clear the variety will be approved for sale in key importing countries.<sup>15</sup> Biotechnology companies have also altered their development plans in response to consumer preferences. Several efforts to commercialize varieties of rice and wheat initially intended for human consumption have been abandoned. More effort has been devoted to plants used as animal feed or industrial crops (those used in manufacturing or for fuel). As Brian Hinds noted in June 2008 that:

The political battles over genetically modified organisms (GMOs) through the 1990s left the company bruised, profitless, and with scaled-back ambitions on the consumer food front. Out were promises of GMO wheat, rice, and tomatoes. In was a focus on corn, soy, and cotton – big-volume crops destined for industrial uses such as animal feed, ethanol, and textiles. The gambit worked.

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<sup>15</sup>Biotechnology Industry Organization. 2007. Project Launch Stewardship Policy available at [www.bio.org/foodag/stewardship/20070521.asp](http://www.bio.org/foodag/stewardship/20070521.asp) (accessed 16 June 2010).

Since 2003, Monsanto has transformed itself from a money-losing pariah into a \$5 billion agribusiness titan with 20% profit margins and a stock price that is up 1,200%.<sup>16</sup>

Promoters of cisgenic methods argue that cisgenic rDNA is far safer because it only uses genetic material that is already present in other varieties of the same plant or organism so would not produce strange unknown plants if varieties with rDNA were to mix in fields with natural or traditionally-bred varieties. Therefore, they argue, regulators do not need to subject it to the restrictive conditions applied to varieties developed with transgenic rDNA. Reducing the regulatory burden, in particular the requirements for lengthy field tests, isolation of fields used for GM crops from others, and traceability requirements would permit public institutions and smaller enterprises to apply the technology. This would, in their view, now only break the oligopoly of large firms that dominate the market for transgenic varieties, but also permit development of greater genetic variety in crops because the smaller firms would not need to focus on large-volume standardization of seeds as has prevailed in the transgenic field.<sup>17</sup> However, others contest claims that cisgenic methods are safer, and insist that cisgenic varieties should be regulated with the same strictness as transgenic ones.<sup>18</sup>

These pragmatic adjustments have not stilled the ethical arguments. However, there are inconsistencies of attitude on each side that leave regulators and others wondering whether policies regarding GM products and crops are based on safety concerns, ethical concerns, or economic calculations. When conservatives in the USA use calls for “sound science” as battering rams to dismantle government regulations, Europeans begin to doubt that the US government and US interest groups are really serious about science-based policy assessment. Those suspicions were fuelled by the US Bioterrorism Act of 2002, which included some trade restrictions lacking scientific rationale.<sup>19</sup> Conversely, Americans who follow GM developments closely know that European firms are the largest producers of GM enzymes in the world, many of which are used in production of cheese, beer, and other food products in European countries without controversy or special labeling. They also struggle to understand why Europeans think GM technology is so bad when they accept radioactive irradiation as a method of altering genetic material for plant breeding purposes.<sup>20</sup>

The passage of time has brought some lessening of uncertainty about the characteristics of GM organisms. Some have now been grown for 20 years or more without becoming “frankenfoods” or posing serious harm to their animal or human eaters. Many government regulators are converging on a more nuanced

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<sup>16</sup> Brian Hendo, “Monsanto on the menu,” *Business Week*, 23 June 2008 (issue no. 4089), p.

<sup>17</sup> See Cisgenesis.com 2010. “Faster and cheaper approval needed for safe, genetically modified crops without foreign genes (cisgenic crops)” available at <http://www.cisgenesis.com/content/view/4/28/lang,english/> (accessed 18 June 2010)

<sup>18</sup> See the section on Cisgenic Organisms in Institute of Science in Society (ISIS). 2007. “‘Self-cloned’ wine yeasts not necessarily safe.” ISIS Report 08/01/07. Available at <http://www.i-sis.org.uk/selfclonedwineyeast.php> (accessed 18 June 2010).

<sup>19</sup>EU Commission. 2002. “Preliminary Comments from the European Commission on the USA Bioterrorism Act, 8 August 2009.” Available at [http://ec.europa.eu/food/international/trade/us\\_bio\\_act\\_prel\\_com\\_en.pdf](http://ec.europa.eu/food/international/trade/us_bio_act_prel_com_en.pdf) (accessed June 2010).

<sup>20</sup>Noted in William J. Broad. 2007. “Useful mutant, bred with radiation,” *New York Times*, 28 August 2007, p. D1.

approach based on understanding that the environmental impacts of GM crops depend on the traits being developed and the particular ecosystems into which they will be introduced. In this view neither blanket opposition to GM technology nor blanket approval is an appropriate attitude; GM organisms must be considered case-by-case. As uncertainty about effects declines with experience, the warrant for citing uncertainty about its effects as reason to ban GM technology weakens, particularly in the eyes of actors who see successful activity elsewhere and would like to engage in it at home. However, some hold out. In April 2007 EU Environment Commissioner Stavros Dimas maintained that GMO products "raise a whole new series of possible risks to the environment, notably potential longer-term effects that could impact on biodiversity. Protected sites or areas, endangered or vulnerable species of plants and animals are of paramount importance in this respect." He dismissed Food Safety Agency (EFSA) assessments because "scientific opinions rendered by EFSA have relied exclusively on information provided by companies that look at short-term effects," meaning "EFSA cannot give a sound scientific opinion on long-term effects of GMOs."<sup>21</sup>

Since plants have been subject to human modification for millennia, the ethical arguments for opposing GM technology as interferences with nature or the divine order are far weaker and have less support than similar arguments against application of GM technology to animal or human genetic material – as suggested by the lack of a “plant rights” movement paralleling the animal rights movement. Opponents of GM as a method of plant breeding continue to maintain their other objections – the uncertainty surrounding long term effects, and the ethical objections that GM technology facilitates domination of food supplies by a small group of private companies, that it worsens gaps between wealthier and poorer farmers, and that it contributes to the further impoverishment of developing countries. The Austrian government added a new ethical claim to the European mix in April 2007 by arguing that EU rules helping consumers maintain freedom of choice by requiring GMO-containing products be labeled, should have an analog protecting a farmer’s right to avoid growing GM plants through regulations assuring good isolation of fields sown with GM crops.<sup>22</sup> In the end, there has been too little ethical consensus to maintain a bright line preventing every application of genetic modification technology even in the more skeptical Europe.

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<sup>21</sup> Quoted in EurActive Network, 2007. “Cracks start to show in EU GMO policy,” EuroActiv.com, available at <http://www.euractiv.com/en/cap/cracks-start-show-eu-gmo-policy/article-154150> (accessed 16 June 2010).

<sup>22</sup> Also noted in EurActiv Network 2007.