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

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

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Version 3; Revised July 2009

In the 1990s 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 variety, splitting the DNA molecule of another variety 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 the new (recombinant) DNA molecule to replicate. If replication is successful, the cells with the recombinant DNA 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 with 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 could by-pass that problem, and observers who believed 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 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:

This case was created by the International Dimensions of Ethics Education in Science and Engineering (IDEESE) Project at the University of Massachusetts Amherst with support from the National Science Foundation under grant number 0734887. Any opinions, findings, conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the National Science Foundation. More information about the IDEESE and copies of its modules can be found at http://www.umass.edu/sts/ethics.

	level of knowledge uncertainty			
level of ethical concern		high	medium	low
	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 older 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 is 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; 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 (in particular 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 of a negative impact of a particular magnitude) 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

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). 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).

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 because of differences in initial assumptions about the implications of genetic modification technologies. Though initially inclined to treat GM organisms as similar, the EU now regards genetically modified organisms, plants, feeds, and foods as very different from "conventional" varieties developed with traditional cross-breeding and hybridization techniques. The EU also relies very heavily on the precautionary principle in formulating policy on matters with strong environmental implications. 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. The USA regards 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. The USA does not rely as extensively on the precautionary principle as a guide to policy; most policy decisions are still guided by the older 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 coordinated policy approaches on a range of trade issues 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 trade laws 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 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 the rise of anti-genetically modified food protests in Europe that sent the EU policy process in a different direction and prevented convergence on a common position. Strong protests from consumer and environmental groups some member governments to adopt more restrictive national policies. 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 up against, but ultimately overcoming, big business. 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 "safeguard clause" included in the 1990 Directive that allowed member states to ban growing plants from particular GM seeds if they judge that growing them will threaten the country's environment. Austria's decision covered one plant: Novartis Bt 176 maize (corn). Austria's decision 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. Responding to the general public discontent, and hoping to ward off further member government use of Article 16, 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 new regulations were in place. This decision was reaffirmed in June 1999 when the EU Council outlined its thinking on a new, more restrictive regulatory scheme including tougher safety criteria and requiring that 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 a 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 exporting person or firm pay for it. Any agricultural commodities (raw materials like cotton as well as animal feeds and human foods) that contain GMOs must be accompanied by documentation indicating that 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 established bas part of the (the BCH Portal at http://bch.cbd.int). 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 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. 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.

While 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 so not be applied before a very thorough prior assessment and challenge the US stance that GM organisms are basically safe so may be used unless proven otherwise.

The EU adopted its new regulations in 2001 and 2003, but did not start considering new approvals because public opposition to GM foods remained very strong. US firms and food distributors, who believed strongly that their products were both safe and beneficial, were irritated by what they saw as an effort to keep the moratorium in place even though new policies had been adopted. Many of them also thought that 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.

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 lawsuit 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 GATT. The complainants' main arguments were that the moratorium was not 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 GATT "safeguard clause" to prohibit imports of certain GMOs and/or maintain product-specific moratoriums. The complainants also claimed that African countries were

refusing US food aid – which contained GMOs – despite famine and starvation because the African countries feared losing future access to EU markets.

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 sweetcorn 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 contended that the 2003 Cartagena Protocol on Biosafety – to which the EU, but not the United States, Canada, or Argentina – permits states to adopt a precautionary approach toward products from new technologies. 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.

Initial consultations between the EU and the US, Canada, and Argentina failed to resolving the dispute; the EU then requested that the WTO Dispute Settlement Body create a panel to settle the matter on 7 August 2003. While the USA, Canada, and Argentine 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 of the parties to the Dispute Settlement Panels and Appellate Board to which unhappy states may appeal an accepted Panel Report.

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 Dispute Settlement Panel's final report, "European Communities – Measures Affecting the Approval and Marketing of Biotech Products" issued on 29 September 2006 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 request that 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 that 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 the dispute were not parties to those agreements (none is party to the Cartagena Protocol; Canada and Argentina are, and the USA is not party to the Convention on Biological Diversity). 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 offer 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 that the EU's use of this particular moratorium violated GATT rules, it did not address the legality of future product-specific measures he 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 the complete revision of the EU regulatory system for agricultural applications of GM technology desired by pro-GM interests in the US desired.

Future Prospects

The prospects for reducing the EU-US regulatory divergence appear slim. Public opinion of GM organisms and products is far more negative in Europe than in the USA 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. European firms developing or hoping to develop agricultural applications of GM technology failed to form industry lobbies, particularly at the EU-wide level. Thus the European GM debate includes fewer advocates of agricultural applications than the US debate.

2. Most GM organism and plants are 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 the large transcontinental suppliers selling to most US supermarket chains. Thus genetic modifications that improve the keeping time or shipping hardiness of vegetables, fruit, and other foods are less important to European than to US 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 without 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 for new rules. 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 than do two-party systems, as exist in the USA and the UK. When a country also uses a proportional representation system, in which members of the legislature are elected in large multi-member districts and each party wins seats in proportion to its share of the vote in the district, it is easier for relatively small parties to win seats than in countries where each district elects only one member. These features of European national politics encouraged 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 more US environmentalist energy to flow towards those areas. For that and other reasons, it remains true that average Europeans are more conscious of environmental matters than average Americans, even though the George W. Bush administration's record has inspired a new round of popular mobilization in the USA.

7. Similar ethical sentiments prevail among proponents and opponents of agricultural applications of GM technology on both sides of the Atlantic, but the additional European concern for food quality means that arguments GM technology somehow modifies foods much more than traditional cross-breeding and hybridization techniques has more traction in EU countries.

Monsanto and other developers of GM products modified their plans after the hammering they received in the late 1990s. Brian Hindo 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.

> 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%.[1]

Monsanto may not be a pariah these days, but it certainly remains the main bogeyman to many environmentalist and consumer groups. Its ability to recover by taking advantage of the increasingly evident split between acceptance of GM varieties for industrial and feed uses and rejection of GM varieties for direct human consumption is consistent with the growing sentiment among scientists and government regulators 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.

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[1] Brian Hindo, "Monsanto on the menu," *Business Week,* 23 June 2008 (issue no. 4089). Available online http://www.businessweek.com/magazine/content/08_25/b4089032620970.htm?chan=top+news_top+news+index_news+%2B+analysis