Appendix C: Background on US regulatory process and regulations

M.J. Peterson
Version 3. Revised Dec. 2010

Appendix Contents:

1.) Background on US regulatory processes and regulations

References used in this section:

Current state of regulations: http://usbiotechreg.nbii.gov/

Links to laws and regulations: http://usbiotechreg.nbii.gov/lawsregsguidance.asp

"Five Principles of Federal Oversight for GM Foods," United States *Federal Register*, 27 February 1992, vol. 57, page 6755.

Internet links to the main regulations:

Coordinated Framework for Regulation of Biotechnology: http://usbiotechreg.nbii.gov/CoordinatedFrameworkForRegulationOfBiotechnology1986.pdf

Five Principles of Federal Oversight for GM Foods: (United States Federal Register, February 27, 1992, 57 FR 6755) [no online version]

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA): http://www.epa.gov/lawsregs/laws/fifra.html

Federal Food, Drug, and Cosmetic Act (FFDCA): http://www.epa.gov/lawsregs/laws/ffdca.html

Federal Plant Pest Act: http://ipl.unm.edu/cwl/fedbook/fedpest.html

Food Quality Protection Act (FQPA): http://www.epa.gov/opp00001/regulating/laws/fqpa/backgrnd.htm

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.

This case should be cited as: M.J. Peterson. 2010. "The EU-US Dispute over Regulation of Genetically Modified Organisms, Plants, Feeds, and Foods." International Dimensions of Ethics Education in Science and Engineering. Available www.umass.edu/sts/ethics.

Agricultural Risk Protection Act (PPA): http://www.gpo.gov/fdsys/pkg/PLAW-106publ224/html/PLAW-106publ224.htm

Toxic Substances Control Act (TSCA): http://www.epa.gov/lawsregs/laws/tsca.html

"Generally Recognized as Safe" FDA Policy Position:
http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/ucm083058.htm

Less Strenuous USDA Notification Process:
http://edocket.access.gpo.gov/cfr_2005/janqtr/pdf/7cfr340.3.pdf

Non-regulated USDA Qualification Process:
http://www.access.gpo.gov/nara/cfr/waisidx_05/7cfr340_05.html

Background on US regulatory process and regulations

M.J. Peterson with research and drafting assistance from Paul A. White
Ver.3; June 2010

Each of the 50 states of the United States has authority to regulate agriculture and activity affecting the environment, but most regulation in those areas occurs at the federal level because seeds, plants, feeds, foods, and other products sold across state lines (as most are in the USA) become part of the "interstate commerce" regulated by the national government. As in Europe, the regulatory process begins with adoption of a law that identifies the government agency or agencies to be responsible for regulations on a particular matter, sets the general goals and standards of regulation, and defines the broad elements of the regulatory process not already set out in the Administrative Practices Act. Either the President or a member of Congress can propose a new law.

Law-making requires that an identical text of a proposed law ("a bill") be adopted by a majority of the 435-member House of Representatives and a majority of the 100-member Senate. The two "houses" of Congress vote separately, and often adopt slightly different texts. When that happens, they establish a joint conference committee to develop a common text, and then each house votes again on the conference committee version. Adoption by Congress is followed by submission of the text to the President for acceptance or rejection. If the President accepts, it is signed and becomes federal law. If the President rejects (vetoes the bill), it goes back to Congress, which can override the President's veto by a 2/3 vote in both houses. Most Presidential vetoes are not overridden because of the extra-high majority required, so threat of a veto can induce Congress to modify a bill before initial adoption. This complicated process is a central part of the system of "checks and balances" between executive, legislative, and judicial power established in the US Constitution, a system very different than the parliamentary systems of Europe, which consolidate executive and legislative power in the majority party or majority coalition of parties.

Seats in the House of Representatives are divided among the 50 states in accordance with their population, with each state having a minimum of one representative; members of the House serve two-year terms and may be re-elected. Seats in the Senate are divided among the 50 states by allocating two to each state; members of the Senate serve six-year terms and may be re-elected. Senate terms are staggered so that 1/3 of the Senators are elected concurrently with all members of the House. Unlike in European countries, where the executive branch is formed by whichever party or coalition of parties wins the most legislative seats in an election, the President is elected separately. Party discipline in Congress is weaker than party discipline in the typical European national legislature, meaning that even if the President and majorities in both houses of Congress are members of the same party the President may not be able to get key elements of his program adopted.

Once the enabling law is adopted, the particular department or agency given authority to develop the specific regulations begins work. It drafts proposed regulations and publishes them in the *Federal Register* (today "publication" means posting the draft regulations on the National Archives and Records Administration's website at www.regulations.gov) for public comment. After the interval for public comment, which is 30, 60, or 90 days depending on the type of regulation involved, the agency considers any comments offered by individuals or organizations and then adopts regulations which are also published in the *Federal Register* and posted on the www.regulations.gov website.

The judicial branch is involved in regulation only when there are disputes. Any individual or corporate legal entity (which include nonprofit organizations as well as business firms) can challenge a federal law or regulation by a claim that all or some of its provisions violate the Constitution. Individuals and corporate entities can also file suits complaining that government agencies are failing to fulfill their duties to issue regulations authorized by a law, to enforce those regulations, or to follow proper procedures in issuing or enforcing regulations and seek court orders requiring the agency to act, enforce, or follow proper procedure. Some statutes, such as the Sherman Anti Trust Act, also allow individuals and corporate entities harmed by conduct defined as illegal to sue for restitution of harm even if the designated government agency does not charge the malefactor with illegal conduct. Even without an express statutory provision, individuals and corporate entities can sue others for harm under the general Tort Law.

When GM organisms and plants began to emerge in the 1970s and 1980s, there were no explicit US regulatory procedures addressing use of this new technology. The prevailing assumption was that the three federal regulatory agencies with relevant mandates – the Environmental Protection Agency (EPA), the US Department of Agriculture (USDA), and the Food and Drug Administration (FDA) would extend their existing regulatory processes to them.[1] Yet, this expectation indicated nothing about how regulation would proceed. Those skeptical of GM technology hoped that EPA would get the lead because it was expressing interest in treating GM organisms as "new" substances to be regulated strictly because of the process by which they were made.[2] Before letting the agencies start proposing regulations, the Reagan Administration undertook a general review of the potential impact of GM technology and in 1984 set up a working group within White House Office of Science & Technology Policy (OSTP) to develop federal guidelines for food biotechnology. Consistent with Reagan's conservative governing philosophy, the guidelines were intended to minimize direct federal oversight of research and development. Thus, the Coordinated Framework for Regulation of Biotechnology[3] extended the regulatory approach already used for agriculture and food safety to agricultural applications of biotechnology. Ever since, the basic postulates of US regulatory agencies' approach to GM organisms, feeds, and foods have been:

1.) focus on the finished product rather than the production process;

2.) confine restrictions on or other special regulations for use of genetic modification technology and its application to human food, animal feeds, and plants to those needed to address scientifically-demonstrated risks to health, agriculture, or the environment, and

3.) plant breeding based on GM techniques is not significantly different than plant breeding based on other techniques, so foods, feeds, and other products made with GM plant varieties are "substantially similar" to those made with conventionally-bred plant varieties and can be evaluated using the same regulatory process.

---

[1] Internet links to texts of the major statutes and to significant decisions relating to GM products are given at the end of this appendix.

[2] Adam Scheingate. 2006. "Promotion vs. precaution: The evolution of biotechnology policy in the United States," *British Journal of Political Science* 36 (2): 243-268.

[3] *United States Federal Register*, June 26, 1986, vol. 51, p. 23302; also available at http://usbiotechreg.nbii.gov/Coordinated Framework for Regulation of Biotechnology1986.pdf)

This last guideline meant that it was difficult to raise objections to biotechnology based on potential long-term environmental and health hazards, and encouraged focusing debate about GM foods on whether they have led to reduced pesticide and herbicide use, rather than environmental damage that could arise from "superweeds" or other undesirable crossbreeding of GM plants with other cultivated or wild plants.

The Reagan administration also set up an interagency Biotechnology Science Coordinating Committee (BSCC) to work with the Office of Science & Technology Policy and the three main federal regulatory agencies with jurisdictions covering some aspect of GM technology involved – EPA, USDA, and FDA – to define what would be subject to federal regulation and oversight. However, the BSCC failed to reach consensus, in part due to the varied interests represented on the committee, and ceased activity.

The immediately succeeding George H.W. Bush Administration's Council on Competitiveness, which was concerned with maintaining and enhancing US export industries, used the BSCC's materials in its efforts to become the dominant group in formulating the federal government's policies on biotechnology. However, it had competition from other government forums. While it was still developing a general framework for future policy toward the biotechnology industry, the White House Office of Science & Technology Policy issued five specific policy positions on GM food in February 1992. These specified that: [4]

1.) The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods;

2.) Information about the process used to produce a GM organism is . . . not a useful criterion for determining whether the product requires less or more oversight;

3.) No conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques;

4.) Crops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits;

5.) In many respects, molecular methods resemble the classical methods for modifying particular strains of microorganism.

Though less oriented towards business interests and taking a more "proactive" stance on the need for government regulation in many areas of the economy, the Clinton administration largely followed these directives as well. It was hesitant to make drastic changes in the regulatory system because of American firms' and growers' dominant position as producers of GM seeds and GM crops on the world market. It also used policies toward GM food to promote liberalization of US trade policies, a goal also expressed in ratification of the North American Free Trade Agreement (NAFTA) in 1994 and accession to the World Trade Organization in 1995, despite significant opposition from others in the Democratic Party.

Succeeding administrations have made incremental adjustments to policy, but each of the three main federal regulatory agencies involved has maintained its basic regulatory role and extended its activities to related aspects of GM technology.

---

[4] *United States Federal Register*, February 27, 1992, vol. 57, p. 6755.

1. Environmental Protection Agency (EPA)

The EPA's mandate covers evaluating the effects of herbicide and pesticide use on the environment as a whole. Because many GM organisms are developed for herbicide and pesticide tolerance, it also evaluates the safety of GM plants in the larger environment. The EPA's Biopesticides and Pollution Prevention Division of the Office of Pesticide Programs uses the 1972 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), to exercise oversight of GM products. FIFRA regulates the distribution, sale, use, and testing of pesticides produced in plants. Under 2002 amendments to the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA), the EPA has the authority to set acceptable limits of pesticide residue on food and animal feed. These acceptable limits are to be established on the basis of a "reasonable certainty of no harm" standard that permits presence of pesticide residues in food as long as their amounts pose no threat to human health.

The 1996 Food Quality Protection Act, an amendment of the FFDCA, authorizes the EPA to establish pesticide tolerance levels for plants and to require pre-sale registration of pesticides. Registered pesticides must be evaluated every fifteen years to ensure they still meet standards for registration. In July 2001, EPA extended its regulatory reach through a new category of "plant-incorporated protectorants" (PIPs) devised to cover all plants with genetic modifications increasing a plant's pest resistance. Under the 2001 rules, EPA had to give approval before a plant or seeds to grow a plant modified to include PIPs can be sold. EPA authority does not extend to plants a) modified to enhance nutritional content – such as rice genetically modified to contain higher levels of vitamin A, b) that naturally contain some level of a pesticide or are sexually compatible with plants naturally containing some level of a pesticide, and c) modified to alter physical features, such as plant height, if that modification does not alter the chemical composition of the plant itself.

The EPA also regulates chemicals produced or used in the USA under the 1976 Toxic Substances Control Act (TSCA). EPA authority under this Act extends to all of the roughly 75,000 industrial chemicals that are not foods, cosmetics, drugs or pesticides – subject to regulation under the TSCA.

2. The Department of Agriculture (USDA)

USDA evaluates the safety of growing a GM plant. Crops modified for drought or disease-tolerance, as well as those intended for use as animal feeds or as whole foods for human consumption (fruits, vegetables, and grains) come within its jurisdiction. USDA's GM-related activities involve four of its divisions.

The Animal Plant and Health Inspection Services (APHIS) conducts tests, issues permits to grow GM crops, and regulates importation and interstate movement. APHIS exercises jurisdiction over the actual planting of GM plants through the Plant Protection Act (PPA).

The Agriculture Research Service performs departmental tests on GM food.

The Cooperative State Research, Education and Extension Service oversees risk assessment procedures.

The Food Safety and Inspection Service (FSIS) ensure the safety of human consumable food such as eggs, meat, and poultry.

The USDA can quarantine growing regions to prevent the spread of potentially unsafe plants, restrict the import and export of potentially unsafe plants, and destroy plants grown in violation of USDA guidelines. The USDA uses the pre-GM statute, the 1957 Federal Plant Pest Act, to exercise oversight of GM plants' introduction and transportation.

Until 1992, originators of all GM plants were required to apply for permits before introducing a new GM plant into fields. In 1992, USDA established a two-track notification process for GM plants exempting some plants from the pre-introduction permit requirement. Originators of exempt plants only needed to notify the USDA 30 days prior to commencement of field testing. This easier process covers plants that meet six criteria:

1.) The plant is corn, cotton, potato, soybean, tobacco, or tomato;
2.) The introduced genetic material is stably integrated into the plant's own genome;
3.) The introduced gene's function is known and does not cause plant disease;
4.) The plant is non-toxic to non-target organisms;
5.) The introduced gene will not create new plant viruses;
6.) The plant does not contain genetic material from human or animal pathogens

The first qualification was removed in 1997; any type of plant meeting the other five would be subject only to notification requirements, not to permits.[5]

In 1992, USDA also initiated a petition process allowing the original creators of GM products to petition for exemption from both the permit and notification process. To qualify for exemption (listing as a "nonregulated" product), the original creator must demonstrate that the GM plant does not pose a greater plant pest risk than the conventional, non-GM breed from which it derived. Approval of a petition removes the GM plant from future USDA-APHIS oversight. In 1997, this was extended to allow GM plants that are "closely related" – as defined by the originator rather than USDA – to already-approved GM plants to be exempted from regulation as well.

More recently, APHIS came under pressure to justify its decisions more carefully by meeting National Environmental Protection Act requirements for undertaking an environmental impact assessment and issuing an environmental impact statement (EIS) for public comment before making a regulatory decision. In May 2007, APHIS did not appeal a US District Court ruling that it should not have removed Monsanto's Roundup-Ready alfalfa from regulated status and permitted its cultivation before issuing an EIS.[6] However, Monsanto appealed all the way to the Supreme Court, which ruled in June 2010 that the District Court was correct in disallowing complete deregulation of Roundup-Ready alfalfa but granting a nationwide injunction

[5]*United States Federal Register*, November 6, 1992, vol. 57, p. 53,036 (initial rule) and May 2, 1997, vol. 62, p. 23945 (amended rule).

[6] Geertson Seed Farms et al. v. Mike Johanns, Secretary of the United States Department of Agriculture et al., US District Court for the District of Northern California, No. C 06-01075, US Dist LEXIS 21491 (preliminary injunction, 12 March 2007) and US Dist Lexis 32701 (permanent injunction, 3 May 2007).

against selling seeds of a GM plant that had been put on the "deregulated list" until completion of the EIS was an excessive use of injunctions in the circumstances.[7] Thus, a US District Court decision in – [8] which also vacated a deregulation decision pending completion of an EIS but stopped short of an injunction by simply urging farmers to avoid the GM variety seeds until the EIS is complete – appears to be the only method of seeking interim restraint when litigants were challenging an APHIS deregulation decision that would pass scrutiny by the Supreme Court.

3. The Food and Drug Administration (FDA)

FDA evaluates the safety of eating the plant and is the most central of the agencies involved in regulation of GM food. All food additives and processed food products (e.g., a box of Cornflakes) come under its jurisdiction. The FDA takes an end-product approach and deems GM whole foods to be "substantially equivalent" to non-GM foods, unless there is reason to believe otherwise. This means that prior FDA approval of their sale is not required. The notion that GM food is "substantially equivalent" to non-GM foods is also the guideline for the USDA's approach to labeling. Retailers are not required to have labels explicitly identifying products that contain GM ingredients – a major source of contention between the Agency and consumer activist groups desiring mandatory labeling. The FDA permits voluntary labeling of GM food as long as the wording of the label does not encourage consumers to believe that a product with GM ingredients substantially differs from the conventional product. Federal court rulings on several challenges by consumer groups, most notably *Alliance for Bio-Integrity v. Shalala,* [9] have affirmed the FDA's position on this issue.

Under the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA), manufacturers are responsible for ensuring the safety of the food, and the rule applies to GM foods. There are no pre-market reviews of GM food. The FDA's position on food additives is that all ingredients already "generally recognized as safe" are exempt from the review process; GM ingredients meet this criterion as long as the equivalent non-GM ingredient meets the criteria. However, novel foods are subject to an additional layer of review. Manufacturers of the novel food must submit a petition with scientific evidence detailing the food's safety; the FDA must also ensure there is "reasonable certainty" that the use of the additive will not cause any harm.

The FDA's 1992 "Statement of Policy: Foods Derived From New Plant Varieties"[10] maintained the FDA's position that most GM products are generally recognized as safe, and hence can be marketed without prior FDA approval. This policy applies to all new plant foods, and all varieties modified through recombinant DNA technology, so-called "bioengineered foods." In the original version of the regulation, developers of GM foods could request a pre-sale consultation with the FDA. Over the years developers did so more often

[7] Monsanto Company et al. v. Geertson Seed Farms et al. US Supreme Court. No. 09-475, 21 June 2010. US 516: -- Available at http://www.supremecourt.gov/opinions/09pdf/09-475.pdf (accessed 21 June 2010).

[8]Center for Food Safety et al. v. Thomas J. Vilsack et al., US District Court for the District of Northern California. 21 Sept. 2009. No. C 08-00484 JSW. U.S. Dist. LEXIS 86343; 39 ELR 20219.

[9]116 F. Supp. 2d 166, 170 (D.D.C. 2000).

[10] *United States Federal Register*, vol. 57, no. 22984.

out of concern that consumers will avoid foods that have not been examined. In May 2000, FDA started encouraging companies to engage in consultations.

In line with the assumption that GM food is "substantially similar" to conventional food, the FDA does not require special labeling on food or foodstuffs that contain GM products. Food and suppliers wishing to inform consumers that their products do not contain GM ingredients can do so, but have to pick their way through court-supported cautions about how they convey that information, including statements that testing has not revealed any different health impact of foods containing and not containing a particular GM ingredient.

Though they have been tightened over the years, US regulations of GM plants, feeds, and foods remains less strict than EU regulations. This can be seen in Pollack and Schaffer's comparison of their key features:[11]

Phase of Commercialization	USA	EU
pre-release notification		
field tests of a new GMO	mandatory	mandatory
sale of GM plants with pest resistance	mandatory	mandatory
sale of foods with GM ingredients	voluntary if GRAS*	mandatory
approval required before planting/sale		
field tests	yes	yes
pest resistance	yes	yes
foods	not if GRAS	yes
labeling	only in specific instances; otherwise voluntary	mandatory in all instances

*Within the set of modifications generally recognized as safe

<end>

[11] Mark A. Pollack and Gregory C. Schaffer. 2009. When Cooperation Fails: *The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press), p.69 (with some clarification of wording).