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Innovative Governance Models for Emerging Technologies

9. Properly paced? Examining the past and present governance of GMOs in the United States

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9.1 INTRODUCTION

A case study of genetically modified organisms (GMOs)[1] in US agriculture and the environment illustrates the problem of policy systems to keep up or pace with advances in emerging technologies. This chapter describes the history of GMO governance in four phases, examining the oversight system's ability to pace with technological developments in each phase. In general, government decisions for oversight of GMOs, particularly GM crops, seemed to pace well with technology in a temporal sense. However, they continue to be contested and do not seem appropriate in the longer term for ensuring safety, transparency and public confidence. The GM crop oversight system exhibited temporal pacing through flexible legal frameworks, but not proper pacing. This chapter argues for a broader notion of pacing that incorporates not only elements of timeliness, but also notions of appropriateness in dynamic societal contexts. It will conclude with proposed lessons from the US GMO oversight experience for developing a new prototype model of governance for emerging technologies that properly paces with technological advancements. This model is based upon three pillars: (i) upstream oversight assessment (a subset of anticipatory governance); (ii) dynamic oversight; and (iii) strong objectivity through more extensive public and stakeholder engagement in decision making.

[1] Natural scientists prefer the term genetically engineered; however, we use genetically modified (GM), as it is more in line with international policy discussions. We use GM to indicate any organism modified by recombinant DNA or newer biotechnology methods.

9.2 THE PACING PROBLEM CONSTRUCTED

Scholars, including many of this book's authors, have pointed out the inability of legal and regulatory frameworks to keep pace with technologies.[2] These situations can cause over- or under-reach in ensuring the health and safety of new technological products, which can stall technological development or allow it to proceed unchecked with negative societal consequences. Gaps in product review or the placement of new products in old, byzantine regulatory systems create mistrust in and discontent with systems of governance. This general phenomenon has been described as the pacing problem. Governance for emerging technologies lags behind technological innovation, and innovation in governance needs to match technological innovation.

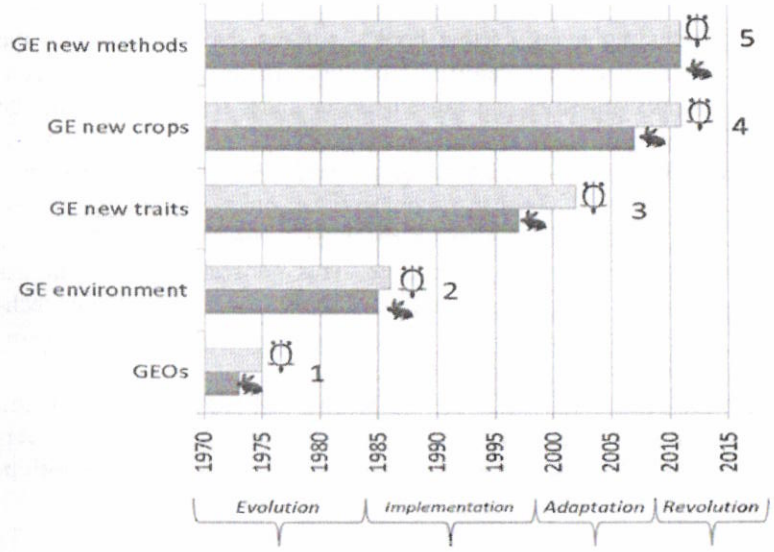
To further understand the issue of pacing and why it is a problem, historical oversight case studies can be instructive.[3] The story of oversight for GMOs in agriculture provides such a case study. The development of GMO technologies in the United States has proceeded over a 40-year period (see Figure 9.1).[4] The oversight of this developing technology has proceeded in four phases, each with different features of pacing in a temporal sense (see Figure 9.2). We have previously identified three of these phases[5] and review them here in the context of the pacing problem: evolution, implementation and adaptation. For the first time, we describe the most recent oversight phase, revolution, and discuss it in the context of pacing. Each oversight phase is distinct in its ability to keep up with GMO technologies and products and to adjust policies and procedures. Notably some of the most effective phases in rapidly changing oversight matching new GMOs present the greatest problems with regard to market and public failures. Thus, the case study suggests a need to redefine pacing to not only keep up with technology, but also to stay current with evolving public concerns, hopes and discontents about the technology. Suggestions are made for three innovations in governance to ensure not only pacing, but societally responsive and responsible pacing, which we term "proper pacing."

[2] THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT: THE PACING PROBLEM (Gary E. Marchant, Braden R. Allenby and Joseph R. Herkert, eds, 2011).

[3] Jennifer Kuzma, Joel Larson and Pouya Najmaie, "Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms," 37 J.L. MED. & ETHICS 546 (2009).

[4] Id.

[5] Id.



Note: Technological development and deployment are presented by the solid bars (rabbit icon), and key federal oversight advancements are represented by the shaded bars (turtle icon). GEOs = production of GEOs in laboratory; GE environment = release of GEOs in environment; GE new traits = release of crops with pharmaceutical or industrial traits; GE new crops = alfalfa, sugar beet, amylase corn, bluegrass; GE new methods = targeted genetic modification, etc. For example, at point 3, pharmaceuticals in crops were released in the environment in 1997, while specific guidance on isolation distances in 2003.

Figure 9.1 Key Innovation and Related Oversight Activity Over Time

The tortoise and the hare fable illustrates the pacing of the governance system (the tortoise) with various GM technological advances (the hare) in the four phases. In this fable, the hare becomes over-confident and stops to rest, while the tortoise maintains a steady pace and ultimately wins the race. However, the use of the analogy does not imply a winner of the race, but rather the stopping and starting of the hare and the slow pace of the tortoise. The tortoise stands for oversight. Traditionally the United States has governed GM crops through changes in regulations, policies and procedures, but with significant delays in their revision and execution. Comment periods and legal challenges can significantly slow government. The hare symbolizes technological development and deployment, as these will move more quickly unless the industry stops itself or is delayed by government. In other words, the normal operating mode of government oversight is slow, while the normal operating mode of the biotechnology industry is fast, even though external forces can change the pace of each (for example, 11 September 2001 made governmental action quicker, while controversy over stem cells has delayed the technology).

9.3 EVOLUTION: THE HARE RESTS FOR A WHILE

In the evolution phase (1975–1986) of GMO oversight, the hare (GMO technologies) did not get too far before she rested at two key junctures, shortly after the creation of the first GMOs and shortly before the release of the first GMOs into the environment (see points 1 and 2 in Figure 9.1). The tortoise meanwhile had a chance to catch up. The first pause in the race was prompted by the Asilomar conference, which brought together scientists and the media to discuss whether experiments with recombinant DNA (rDNA) in the laboratory warranted precaution and put some consensus restrictions on GM technology.[6] It was unique to the evolution phase of GMO oversight, as it was a voluntary pause on the part of the hare, marking the first time GM technologies stopped on their own volition (Figure 9.2a). This Asilomar meeting eventually led to the involvement of National Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC), which was then tasked with oversight of laboratory experiments involving GMOs.[7]

The second point where the hare paused during the evolution phase, she had to do so. Over time, researchers wanted to move GMOs out of the laboratory and into the environment and marketplace. The Coordinated Framework for the Regulation of Biotechnology (CFRB) was formulated in 1986[8] in response to congressional hearings and court cases over the release of the ice-minus GM bacteria into the environment. CFRB instructed three federal agencies, the US Environmental Protection Agency (EPA), the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) to use the Toxic Substances Control Act (TSCA), Federal Insecticide, Fungicide, and Rodenticide Act

[6] Paul Berg, David Baltimore, S Brenner, R. O. Roblin and Maxine F. Singer, "Summary Statement of the Asilomar Conference on Recombinant DNA Molecules," 72 PROC. NAT'L ACAD. SCI. U.S. AM. 1981 (1975).

[7] Bernard Talbot, "Introduction to Recombinant DNA Research, Development and Evolution of the NIH Guidelines, and Proposed Legislation," 12 U. TOL. L. REV. 804 (1980).

[8] Coordinated Framework for Regulation of Biotechnology; Announcement of Policy; Notice for Public Comment, 51 Fed. Reg. 23302 (June 26, 1986).

Evolution (1970--1986)

a

- (1960-70s) Scientists develop recombinant DNA techniques and eventually are able to synthesize and replicate genes resulting in the ability to produce human growth hormone.
- (1974-75) The leading genetic scientists convene at the Asilomar meeting and encourage the U.S. Govt. to develop guidelines for regulating experiment using rDNA.
- (1976) U.S. Govt. sets up the Recombinant DNA Advisory Committee (RAC) through the National Institutes of Health (NIH 1978).
- (1980) Laboratory applications (such as the development of a gene-synthesizing machine) and industrial applications (such as Exxon's oil-eating microorganism) were emerging.
- (1982) RAC reviews its 1st proposed environmental release - the introduction of ice minus during the process of field trials.
- (1984-86) Legal controversy emerges involving the "ice minus" bacterium and it's release into the environment (USC 1983).
- (1986) The Office of Science and Technology Policy (OSTP) forms a working group, called the Biotechnology Safety Coordinating Committee (BSCC), and develops a three agency jurisdictional model known as the Coordinated Framework for the Regulation of Biotechnology (CFRB)

Implementation (1986--2002)

b

- (1987-1994) USDA, FDA, and EPA interpret existing laws (such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substance Control Act (TOSCA), and the Federal Plant and Pesticide Act (FPPA)) and promulgates regulations ad policies concerning GEOs.
- (1992) FDA issues novel foods policy which states that foods derived from new plant varieties do not substantially differ from conventional counterparts.
- (1993) USDA issues regulatory guidelines for how a plant would become commercialized, or brought to the market.
- (1994) EPA develops rules for plant incorporated protectants (PIPs).
- (1994-95) The first commercial GEO products, such as the Flavr Savr tomato, emerge on the market.
- (1999) A study raises concerns about possible negative effects of Bt Corn on Monarch butterflies, however, subsequent field research has shown little possibility of harm.
- (2000) StarLink, a form of Bt Corn that is thought to cause allergic reactions in small numbers of people and therefore not allowed in the food supply, is found in food supply causing recalls of some food and controversy over biotechnology regulation.
- (2000) EPA conducts a meeting of its Scientific Advisory Panel (SAP) and considers re-registering Bt corn.
- (2000) The National Research Council (NRC) publishes a report on EPAs review of pest-protected GE plants. FDA asks for comments on a mandatory pre-market safety review of GE foods.
- (2000-01) The Office of Science and Technology Policy (OSTP) and the Council on Environmental Quality (CEQ) conducts 6 case studies on the federal regulation of agricultural biotechnology
- (2001) The FDA publishes draft labeling guidance for companies that wish to label their foods as containing, or not containing, genetically modified ingredients and for making the agency's review process mandatory (FDA 2001). The process is still not mandatory (2008).
- (2001) The EPA publishes its finalized rules for the regulation of PIPs.
- (2002) The NRC publishes a report stating that the USDA should more rigorously review the potential environmental effects that transgenic plants may cause before approval for commercial use
- (2002) Prodigene Inc. was fined for tainting soybeans in Nebraska with experimental corn used for producing human vaccines.

Adaptation (2002--2010)

c

- (2002) OSTP publishes a notice, in the federal register, proposing actions to update field test requirements for industrial plants, although it concerns mainly harvesting and extraction.
- (2002) Government Accounting Office calls for enhancement of FDA's voluntary evaluation process for GE foods.
- (2003) USDA introduces enhanced safety guidelines, including more stringent confinement measures, for field trials of pharmaceutical and industrial GE plants - creating the permitting process interim rule.
- (2004) The NRC and the Institute of Medicine (IOM) publishes a report about the unintended consequences of GE foods in which they recommend that greater scrutiny be given to foods containing new compounds (
- (2004) The FDA issues draft guidance for industry regarding the Early Food Safety Evaluation of new non-pesticidal proteins produced by new plant varieties intended for food use (2005) USDA introduces finalized safety guidelines for field trials on industrial and pharmaceutical GE plants - creating the permitting process Final rule.
- (2005) Syngenta's Bt-10 corn is found in food supply, however FDA deems it no risk and therefore not illegal (although planting Bt-10 corn in the U.S. is illegal). Field trials of Ht Creeping Bentgrass contaminate wild grass varieties in Oregon.
- (2006) FDA finalizes its guidelines to industry regarding Early Food Safety Evaluation.
- (2006) Bayer notifies FDA and USDA that trace amounts of LLRICE601 (a form of Ht rice) has been detected in commercial rice varieties and may have entered the food supply. The USDA then determines that LLRICE601 does not pose a threat based on available data (provided by Bayer) and deregulates it.
- (2007) The Animal Plant Health Inspection Service (APHIS) publishes its first Environmental Impact Statement (EIS) in compliance with the National Environmental Protection Act (NEPA) concerning its regulation of GEOs. This occurred partially in response to lawsuits challenging USDA for improperly regulating GE plants.
- (2008) Unapproved GE corn seed inadvertently sold to farmers by Dow Agrosciences affiliate Mycogen Seeds
- (2008-2009) USDA proposes revisions to its regulation under the Plant Pest Act sparking 15,000 comments and public meetings.
- (2009-2010) In separate cases filed against USDA, federal judges revoke USDA's environmental assessment (EA) and deregulation of herbicide tolerant (HT) alfalfa and HT sugar beets. The judges rule that the EAs inadequately addressed the risks posed by genetically engineered crops, specifically regarding gene flow and the possible contamination of organic crop varieties. USDA was ordered to complete the more intensive environmental impact statement (EIS) for each crop.

Figure 9.2 Initial Phases of GMOs Oversight Development

(FIFRA), Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Plant Pest Act (FPPA) to regulate the products of biotechnology and GMOs. In addition, the National Environmental Policy Act (NEPA) requires agencies to prepare detailed assessment of the impacts on the human environment.[9] Agencies can also prepare a more limited environmental assessment (EA) under NEPA if they are not sure whether the impacts are "significant." The CFRB relied on the policies that the product, not process, should be the focus of regulation and that no new laws were needed to cover GMOs and GMO products. It was set up as a science-based decision-making system, with additional focus on utilitarian accountings of costs and benefits in accordance with broader US regulatory policy.

The creation of the CFRB marks the end of the evolution phase, and GMO technologies were now poised to take off with an oversight system in place. In a temporal sense, the oversight system was well paced with the technology during this phase (Figure 9.1). Oversight systems were put in place as the technologies matured (Asilomar for laboratory work) or before they were deployed (CFRB for environmental release of GM bacteria and plants). This phase can be thought of as a pacing friendly phase, in which the tortoise and hare are aware of each other's progress and are somewhat synchronized. Because the template of the CFRB developed through existing laws, formulating new statutes did not delay governance. The framework was meant to be flexible, allowing for agency interpretation of existing laws to address health and environmental concerns. This phase can be described as pacing through coordinated interagency policy making.

However, pacing in a temporal sense did not seem to be enough to make a difference in the eyes of the public. Prominent civil society groups opposed the CFRB.[10] Many opponents believed that new and focused policies and laws were needed to fully cover the risks and societal impacts associated with GMOs and their products. They argued that biotechnology is a process that presents new risks and requires special regulation. This viewpoint runs counter to the US policy of focusing on these products being the same in kind as those that are bred by conventional means.[11] Twenty years later, this framework is still

[9] 42 U.S.C. § 4332(2)(C) (2011).

[10] George Gaskell, BIOTECHNOLOGY, 1996–2000: THE YEARS OF CONTROVERSY (2001).

[11] National Academy Of Sciences, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES (1987).

operational, although it has evolved over time (Figure 9.2). Scholars look back now on this phase as a fairly closed-door elite process for making initial decisions about GMOs. Asilomar was limited largely to scientists and the media, and the White House Office of Science and Technology Policy's formulation of the CFRB was insulated from public discussion. The CFRB's operations did not develop mechanisms to engage stakeholders and the public. The science-based premise of the CFRB left little to no room for discussion about values like preserving nature, minimal inputs to agriculture, thinking about unintended effects, and fairness of risk and benefit distributions.[12] Furthermore, the system was set up as very flexible in its loose interpretation of existing laws (for example, GM microbes as toxic chemicals),[13] which as time went on, proved to be susceptible to changing political, economic and social winds. The story begins to unfold with problems in oversight beyond temporal pacing.

9.4 IMPLEMENTATION: THE HARE TAKES OFF

General and flexible laws designated under the CFRB needed to be more concretely interpreted to regulate GMOs. The interpretation of the CFRB and the explosion of GM products in agriculture mark the second phase of oversight: implementation (Figure 9.2b). During this phase, the boundaries of various statutes significantly stretched to promulgate agency regulations for diverse products. GM plants were regulated as plant pests under FPPA, because they often contained engineered sequences from viruses and bacteria that cause plant disease or because the plants themselves can be considered plant pests.[14] The Animal Plant Health and Inspection Service (APHIS) would be the lead USDA agency for biotech crops. Under FIFRA and FFDCA, EPA regulated GM plants engineered with pesticidal-like proteins (plant incorporated protectants).[15] Inter-generic GM microorganisms were regulated as toxic chemicals

[12] Paul B. Thompson, FOOD BIOTECHNOLOGY IN ETHICAL PERSPECTIVE (2nd edn. 2007).

[13] Kuzma et al., supra note 3.

[14] Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 7 C.F.R. § 340 (1987, 1997); Genetically Engineered Organisms and Products: Notification Procedures for the Introduction of Certain Regulated Articles and Petition for Nonregulated Status, 58 Fed. Reg. 17044 (March 31, 1993).

[15] Regulations under the Federal Fungicide, Insecticide, and Rodenticide Act for Plant-Incorporated Protectants, 66 Fed. Reg. 37,855 (July 19, 2001).

under TSCA.[16] Under FFDCA, the FDA reviewed GM or bioengineered foods through a voluntary consultation mechanism.[17]

Although the CFRB was established at the beginning of implementation, the rules and guidance documents under it did not take shape until later. The technology blossomed while the roles of some agencies lagged. For example, the EPA's Plant Incorporated Protectant (PIP) rule was proposed in 1994 but not finalized until 2001, although companies complied with the draft rule in the interim. On the flip side, USDA had its field trial regulations in place in 1987, before crop field trials took place, and FDA published its guidance for novel foods produced through biotechnology in 1992, before the first GM foods entered the market. During the early part of the implementation phase, regulations kept pace with the first generation of GM products, namely genetically engineered microbes (GEMs), herbicide tolerant (Ht) and pest-resistant (primarily Bt) crops. The hare and the tortoise were moving at a similar pace (Figure 9.1, point 2). The system paced with technology through formal regulations and policies (pacing through regulation). GM crops, especially major commodity crops with insect-resistant (primarily Bt) and herbicide-tolerant (Ht) engineered genes, exploded onto the market while thousands of field trials were conducted.

Toward the end of the implementation phase – with new findings and technological developments – regulations, guidances and policies stretched in place. The CFRB and oversight system were not prepared to deal with pharmaceutical or industrial chemical production in plants, GM fish or GM insects. The hare (technology) took off ahead of the tortoise (oversight system) (Figure 9.1, point 3). Then credibility was shaken by reports of harm to Monarch butterflies from Bt pollen; comingling of Starlink Bt corn, which was not approved for human food due to concerns about allergenicity, with corn destined for human food; the detection of gene flow between Bt and non-Bt maize in Mexico; and contamination of soybeans with corn containing engineered pharmaceuticals.[18] For example, the company ProdiGene failed to eliminate volunteer GM corn plants producing pharmaceuticals from a soybean

[16] 40 C.F.R. § 725 (1997).

[17] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

[18] CONG. RESEARCH SERV., RS20732, STARLINK™ CORN CONTROVERSY: BACKGROUND (2001); J.L. Fox, Puzzling Industry Response to Prodigene Fiasco, 21 NATURE BIOTECHNOLOGY 3 (2003); D. Quist and I. Chapela, Transgenic DNA Introgressed into Traditional Maize Landraces in Oaxaca, Mexico, 414 NATURE 541 (2001).

crop planted later in the same field and destined for human food.[19] USDA imposed a fine of $250 000, and ProdiGene had to reimburse the federal government $3 million for the destruction of the contaminated soybeans. This and other controversies mark the end of the implementation phase (Figure 9.2b).

The above controversies may have taken a toll on the production and marketing of GM crops with novel traits, as well as non-commodity GM crops (minor and orphan crops), because the diversity and number of approvals for full USDA deregulation decreased in 2000 (Figure 9.3).[20] There were also media reports of large companies pulling out of certain GM crop markets (for example, pharmaceutical production in crops).[21] Toward the end of the implementation phase, the hare slowed down a bit, while regulators increased their attention to risks and their management.

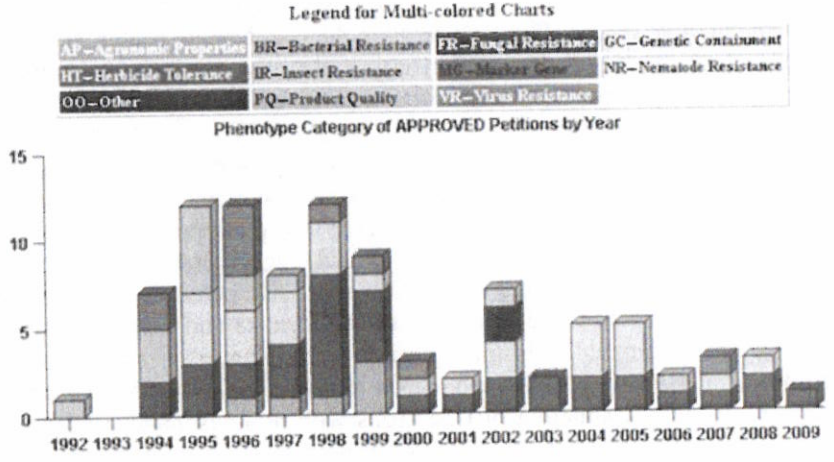


Figure 9.3 Approved Petitions for Deregulation by USDA Per Year

[19] Fox, supra note 18.

[20] Info. Sys. Biotechnology, Crops No Longer Regulated By USDA (Petitions for De-Regulation), VIRGINIA TECH (2012), available at http://www.isb.vt.edu/search-petition-data.aspx.

[21] P. Byrne, Bio-pharming, COLORADO STATE UNIVERSITY EXTENSION (April 2008), available at http://www.ext.colostate.edu/pubs/crops/00307.html.

9.5 ADAPTATION: THE TORTOISE CHUGS ALONG TO CATCH THE HARE

The adaptation phase is marked by changes to the CFRB and its operation in order to mitigate risks arising from the implementation phase and to expand the scope of the products covered by the CFRB. Federal agencies involved in US oversight did not promulgate new regulations to deal with emerging concerns, but rather chose to deal with them through regulatory guidances. Key areas of concern were health risks such as allergenicity, co-mingling of unapproved and approved GM varieties, and gene flow to wild relatives or neighboring crops. For example, the National Organic Program rule of 2000 prohibited the intentional use of GM crops in certified organic foods.[22] Troubles began with the coexistence of organic and GM crops at the end of the implementation phase. Organic farmers in the United States became increasingly concerned that GM crops would cross-pollinate with their crops, and they would no longer be able to certify their products as organic.

Although the laws and interpretations for GM crops largely remained the same during this phase, several guidance documents and regulatory policies were published to address emerging GM plant products and their impacts (Figure 9.1, points 3 and 4, and Figure 9.2c). Public and stakeholder reactions to new risk information and perceived failures of the system prompted these adaptations. The tortoise and hare took turns resting and running, with the tortoise employing a pacing through guidance. For example, FDA put out a guidance document to improve early food-safety evaluation of GM crops with non-pesticidal proteins,[23] and USDA published enhanced biosafety guidelines, including requiring more stringent confinement measures for growing GM plants containing pharmaceutical and industrial engineered proteins.[24] So far, the hare was not too far ahead of the tortoise with regard to GM crops.

[22] National Organic Program; Final Rule, 65 Fed. Reg. 80,548 (December 21, 2000).

[23] US Food & Drug Administration, GUIDANCE FOR INDUSTRY: RECOMMENDATIONS FOR THE EARLY FOOD SAFETY EVALUATION OF NEW NON-PESTICIDAL PROTEINS PRODUCED BY NEW PLANT VARIETIES INTENDED FOR FOOD USE (June 2006), available at http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf (accessed 17 July, 2013).

[24] Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11,337 (March 10, 2003).

However, for GM animals during this phase, the hare was stalled. At the time of development and during initial phases of implementation, the CFRB framework did not specifically consider the regulation of GM insects, trees, plant pharmaceuticals, fish or mammals. There is still some ambiguity about oversight for these GMOs and their products. The first GM animal for food (transgenic) use had been waiting for approval for over a decade, in part because of a lack of a regulatory guidance to interpret existing laws. Then, in 2009, the FDA proposed to oversee GM animals as "investigational new animal drugs" under FFDCA.[25] However, the first test case of growth-enhanced transgenic salmon for human consumption is still waiting approval due to controversies surrounding its use. FDA did approve a transgenic goat producing the human drug antithrombin in its milk,[26] but not for food use. GM animals seem to be resting in the tortoise's hands.

Toward the end of this phase, the hare was also stalled with regard to GM crops, allowing the tortoise to catch up. An outside racer, the NGO community, filed legal suits against the industry and USDA for lack of compliance with NEPA. These court battles distracted industry and caused great uncertainty about the future of GM crop approval processes through USDA. USDA was forced to complete its first ever Environmental Impact Statements (EISs) for GM crop deregulation (market approval) for Ht alfalfa and Ht sugar beets.[27] Plantings were delayed, and it looked as though future pre-market decisions on particular GM crops would likely be slowed with more intensive NEPA compliance requirements. The court cases are discussed further in the revolution phase, as they mark the end of adaptation and beginning of changes in US policies for governance.

The final part of this phase includes the tortoise's attempt to revise its regulations through a formal rulemaking process. In a draft rule, USDA tried to revise and clarify its authority for GM crops under the newer Plant Protection Act of 2000 (PPA) (replacing the FPPA in the CFRB) by applying its noxious weed authorities to GM crops and changing the

[25] US Food & Drug Administration, GUIDANCE FOR INDUSTRY: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RDNA CONSTRUCTS (January 15, 2009), available at http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry /ucm123631.htm (accessed 17 July 2013).

[26] Id.

[27] Congressional Research Service, R41395, DEREGULATING GENETICALLY ENGINEERED ALFALFA AND SUGAR BEETS: LEGAL AND ADMINISTRATIVE RESPONSES (September 10, 2012).

notification or permit process to a tiered permit system based on categories of risk, including a conditionally exempt category.[28] An EIS on the draft rule was also published. Because technological advances have led to the possibility of developing GM crops (or other GMOs) that do not fit within the plant pest definition but still might cause harm, the proposed regulations would also subject GMOs to oversight based on known plant-pest and noxious-weed risks of the parent organisms, or the traits of the organism, or the possibility of unknown risks as a plant pest or noxious weed when insufficient information is available. However, USDA never finalized the 2009 proposed rule. The tortoise's attempt to move with the technology was thwarted.

In summary, during the adaptation phase, pacing through guidance worked until the external stakeholder pressure and legal battles became too much for the tortoise and hare. They needed to use a different tactic.

9.6 REVOLUTION: THE HARE IS TIED UP, THEN TAKES OFF WITH TORTOISE'S HELP

The choice in changing race tactics marks the beginning of the revolution phase. During this phase, the tortoise paced through fundamental shifts in policy, including a change in the interpretation of the laws and exertion of authorities on which the CFRB was based (Figure 9.4). This change occurred following court decisions related to GM alfalfa. The GM alfalfa story is outlined below to provide background on some of the key factors that likely changed GM crop governance policies at USDA.

In 2005, USDA approved Monsanto's Roundup Ready herbicide-tolerant (RR, Ht) alfalfa for commercial planting and decided that the crop did not pose a plant pest risk. Under NEPA, instead of preparing a full EIS for this decision, the agency issued an EA-FONSI (Environmental Assessment, Finding of No Significant Impact). Organic farmers and NGOs challenged the adequacy of USDA's EA on RR alfalfa in federal district court, arguing that the agency should have prepared a full EIS. Until then, USDA had never prepared a full EIS for any GM crop approval. In 2007, the district court sided with the plaintiffs and prohibited Monsanto from planting or selling RR alfalfa seeds until a full

[28] Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms: Proposed Rule, 73 Fed. Reg. 60,008 (October 9, 2008).

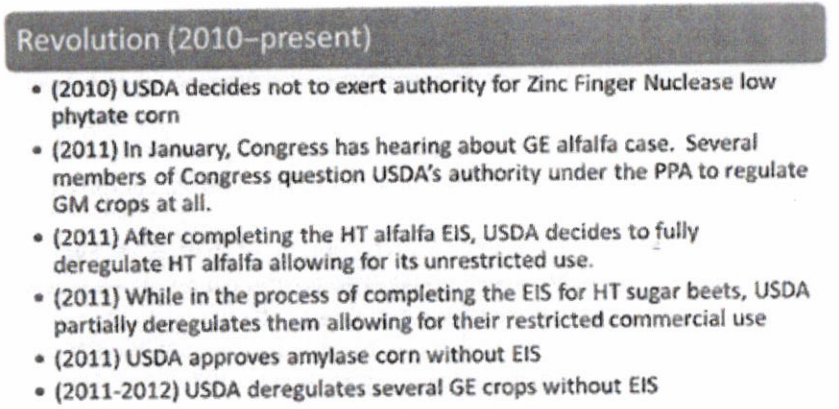


Figure 9.4 Present Phase of GM Crop Oversight

EIS was completed,[29] putting an injunction on further planting of GM alfalfa in place. It is estimated that approximately 5500 growers across 263 000 acres planted GM alfalfa before the injunction, and most of these farmers were planning on planting GM alfalfa seeds in the upcoming growing season. With all these growers in jeopardy, Monsanto appealed to the Ninth Circuit, but the court upheld the ban.[30] Monsanto then appealed to the US Supreme Court, and at that point, USDA decided not to join the case and continued to work on a final EIS for Ht alfalfa. The Supreme Court decided to take up the case, *Monsanto v. Geertson Seed Farms*,[31] and granted Monsanto's petition that the court review the scope of the permanent injunction against further planting of Ht alfalfa.

The main environmental issue in the Ht RR alfalfa case was cross-pollination with weedy relatives or organic crops. Harm could occur to the organic industry if RR alfalfa contaminated neighboring organic crops. The presence of GM alfalfa could cause organic farmers to lose their market shares. Coexistence of organic with GM crops became a focal point of the policy conversation. Scientific concerns were focused

[29] Geertson Farms, Inc. v. Johanns, No. 06-01075, 2007 WL 776146 (N.D. Cal. March 12, 2007) (preliminary injunction); Geertson Farms, Inc. v. Johanns, 2007 WL 1302981 (N.D. Cal. May 3, 2007) (permanent injunction); Geertson Farms, Inc. v. Johanns, 2007 WL 1302981, *5 (N.D. Cal. May 3, 2007).

[30] Geertson Seed Farms v. Johanns, 570 F.3d 1130 (9th Cir. 2009), rev'd sub nom. Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010).

[31] Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010).

on the possibility that wild relatives of alfalfa could be contaminated and become super weeds, resistant to Roundup or other herbicides.

In June 2010, the Supreme Court ruled that the permanent injunction against planting or selling should be removed. It noted that the district court had overreached procedurally in halting the plantings, and as a result, Ht RR alfalfa could be planted while the USDA completed the EIS. However, the Supreme Court justices did not remove the need for an EIS, and they stressed an intermediate option of partial deregulation (planting with geographic restrictions). The court's ruling also suggested that environmental harm included economic effects such as reduced agricultural yield or loss of market due to genetic contamination.[32] Thus, the ruling was interpreted as a victory by both sides. RR alfalfa could be planted in the spring, but the EIS could consider economic harm. The court suggested partial deregulation as an option, although ultimately leaving the decision to USDA.

In December 2010, USDA published the final EIS, outlining three options in the document: (1) ban the commercial planting of RR GM alfalfa (no deregulation); (2) approve it with planting restrictions such as greater isolation distances from other crops (partial deregulation); or (3) approve it with no planting restrictions (full deregulation).[33] USDA indicated that it was seriously considering the latter two options. In the document, USDA argued that "[b]ecause Congress has mandated a science-based approach in APHIS regulations and because there is no basis in science for banning the release of GT alfalfa, a blanket prohibition of the release of GT alfalfa would contravene Congressional intent and must be rejected."[34] The USDA chose in this statement to privilege the natural science over socioeconomic harms.

After the EIS was published, both sides put pressure on USDA regarding its impending decision whether to partially or fully deregulate RR alfalfa. The organic industry and NGO community were arguing for no deregulation or partial deregulation. National agricultural commodity associations lobbied against partial deregulation, arguing that it would be a significant departure from regulatory practices and could have negative

[32] Congressional Research Service, supra note 27.

[33] US Department of Agriculture, GLYPHOSPHATE-TOLERANT ALFALFA EVENTS J101 AND J163: REQUEST FOR NONREGULATED STATUS FINAL ENVIRONMENTAL IMPACT STATEMENT (December 2010), available at http://www.aphis.usda.gov/biotechnology/alfalfa_documents.shtml (accessed 17 July 2013).

[34] Id. at 14.

impacts on current trade agreements.[35] Soon thereafter, the House Committee on Agriculture hosted a forum on January 20, 2011to discuss agricultural biotechnology regulation and the GM alfalfa situation with USDA Secretary Tom Vilsack. House members intensely questioned the secretary about the partial deregulation option, and the vast majority of members indicated their support for full deregulation. The members also more broadly challenged USDA's authority for regulating GM crops under the PPA at all.[36]

On 27 January 2011, Vilsack announced that USDA was granting GM alfalfa full deregulation on the basis that it posed no greater plant pest risk than other conventional alfalfa varieties and that any option other than full deregulation was inconsistent with their regulatory authority under PPA. USDA decided that it would have no further control over the planting and distribution of GM alfalfa.

As a result of the USDA's alfalfa decision, the doors opened for other GM crops to enter the market. Responding to congressional pressure, USDA backed off its authority under the PPA and NEPA. For example, a new GM crop, Syngenta's amylase corn, was approved for market release. Amylase corn is engineered to produce a thermostable version of the enzyme alpha-amylase that breaks down starch into sugar for ethanol production. USDA deregulated it in February 2011, a month after GM alfalfa, without a full EIS. Several stakeholder groups including food producers believe that USDA failed to adequately consider the impact of GM amylase corn on human health, the environment or the livelihood of farmers.[37] In the past two years, approvals of new GM crops have spiked.

Since the alfalfa case, USDA has also, quite radically, decided that several GM crops do not fall under its plant pest authority at all, including crops produced through new targeted genetic modification methods (for example, Dow's low phytate corn)[38] and Ht Kentucky bluegrass. Initial biotechnology techniques used sequences from plant pests in the engineering process. In 2000, USDA stated that the plant pest designation was just a hook to regulate all GM crops under existing laws and that the agency would use this hook to regulate GM crops regardless

[35] Congressional Research Service supra note 27.

[36] Forum to Review the Biotechnology Product Regulatory Approval Process: A Forum Before the H. Comm. on Agric., 112th Cong. (January 20, 2011).

[37] Emily Waltz, "Amylase Corn Sparks Worries," 29 NATURE BIOTECHNOLOGY 1063 (2011).

[38] J. Kuzma and A. Kokotovich, "Renegotiating GM Crop Regulation," 12 EMBO REPORTS 883 (2011); Emily Waltz, "Tiptoeing Around Transgenics," 30 NATURE BIOTECHNOLOGY 215 (2012).

of whether crops contained plant pest sequences.[39] A decade later, with newer genetic engineering methods, these pest sequences are no longer needed for engineering, and USDA has recently decided not to use PPA for GM crops not containing plant pest sequences. USDA is now choosing to interpret its authority under the PPA strictly, even though under 7 CFR part 340 the administrator of APHIS has the ability to declare a GM organism a regulated article if:

> it has been genetically engineered from a donor organism, recipient organism, or vector or vector agent listed in 340.2 and the listed organism meets the definition of "plant pest" or is an unclassified organism and/or an organism whose classification is unknown, *or if the Administrator determines that the GM organism is a plant pest or has reason to believe it is a plant pest.*[40]

Thus, its new interpretation is a revolutionary shift. Recently Ht RR Kentucky bluegrass, which does not contain plant pest sequences (but could have been designated as a plant pest if the administrator wanted to do so) was exempted from USDA review under the PPA. Free planting of Ht bluegrass is allowed without any formal regulatory review, despite concerns about gene flow to neighboring grasses and increased weed resistance to Roundup.[41] USDA did not consider the risks through the permit or deregulation process and did not require any assessments for market release.

This period of contested legal disputes and subsequent USDA policy shifts can be interpreted as a revolution in interpretation of USDA authority. Continued legal suits would likely have pressured USDA to complete a rigorous EIS for every GM crop it considered under PPA. Each EIS would be a vast undertaking, likely taking years to complete. Congress questioned USDA authority more broadly, and most members would prefer a rapid approval of GM crops. Therefore, it has become more feasible and politically expedient for USDA not to exert authority under the PPA for GM crops that are not explicitly containing plant pest sequences or not clearly plant pests. USDA took the road that was more feasible given current resources and the political climate against tight regulation.

[39] National Research Council, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION (2000).

[40] 7 CFR part 340 (emphasis added).

[41] Paul Voosen, "In Major Shift, USDA Clears Way for Modified Bluegrass," NYTIMES.COM, July 6, 2011, available at http://www.nytimes.com/gwire/2011/07/06/06greenwire-in-major-shift-usda-clears-way-for-modified-bl-51693.html (accessed 17 July 2013).

USDA is trying to expedite its review process even for the GM plants captured under the PPA. USDA estimates that the cost of a draft EA generally ranges from $60 000 to $80 000, and the cost of a complete EIS can be over $1 million.[42] A new model proposed recently in the Federal Register would allow independent contractors to prepare EAs or EISs, funded by a cooperative agreement between the petitioner and APHIS. USDA is currently in the process of implementing the pilot program. Many groups are concerned that this model allows producers of biotech crops even more control over the NEPA process by allowing them or other private contractors to author NEPA assessment documents.[43]

In summary, this shift to pacing through policy marks the revolution phase. Initially USDA could not keep up with legal suits and the need to produce EISs, and delays resulted (Figure 9.1, point 4). Delays were likely to continue from this contested process, so USDA decided to forgo the regulation of GM crops that are not squarely plant pests. Some GM crops and products will still take a while to review, but EISs will not be the norm (for example, amylase corn), and many products will not be captured under the PPA at all (such as Ht bentgrass and low phytate GM corn). In terms of the fable, the hare caught the tailwinds of an anti-regulatory climate, and the tortoise decided to give up a leg of the race (Figure 9.1, point 5).

9.7 PROPER PACING

The US GMO oversight system formed and adjusted alongside the progress of GM crops, although it did lag behind at times (Figure 9.1). It paced in a temporal sense in different ways in the four phases: pacing through coordinated interagency policy making; pacing through regulations; pacing through guidance; and pacing through policy shift (that is, reinterpretation of authorities). In comparison to other regulatory systems – such as the one still evolving for nanotechnology – the GMO oversight

[42] Solicitation of Letters of Interest to Participate in National Environmental Policy Act Pilot Project, 76 Fed. Reg. 19,310 (April 7, 2011).

[43] E. Burkett, "Who Should Conduct Biotech Crop Assessments?" FOOD SAFETY NEWS, April 25, 2011, available at http://www.foodsafetynews.com/2011/04/look-who-is-going-to-be-doing-the-environmental-assessments/ (accessed 17 July 2013).

system for crops was arguably proactive in its beginnings.[44] For example, the NIH guidelines for laboratory use were in place shortly after rDNA techniques arose, the CFRB was in place before the technology was deployed in the field, and most agency regulations were promulgated before GM crops hit the market. The system responded to emerging conditions and external events, technological development, risk concerns and stakeholder pressure.

In general, government decisions for oversight of GM crops seemed to pace well with the technology in a temporal sense. However, many stakeholders do not see the GMO system as appropriate in the longer term for ensuring health and environmental safety.[45] We have found in previous work that stakeholders and experts familiar with the GMO oversight system rate it as highly flexible, but with weak legal grounding, few opportunities for public input, poor treatment of uncertainty, low transparency, little post-market monitoring and a lack of information for consumer choice.[46] The high flexibility has allowed the agencies to adapt with changes in technology, but it also allowed for changes in regulatory policy based on political winds instead of risk assessments (for example, Ht bluegrass).

GM crops could be considered a market success in some ways, like market penetration and industry growth, but a public failure from a science and technology policy perspective.[47] Public failures can stem from many factors, including inadequate policies that are incongruent with public values and consider only short time-horizons. The increasing number of products on the market labeled as GM-free and more widespread pressure requiring labeling of GM foods (for example, Proposition 37 in California) suggests that GM crops are a public failure.[48] NGOs and organic farming groups are not pleased with the system and continue to pursue legal challenges against the planting of

[44] Jennifer Kuzma, Pouya Najmaie and Joel Larson, "Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms," 37 J.L. MED. & ETHICS 546 (2009); Gurumurthy Ramachandran et al., "Recommendations for Oversight of Nanobiotechnology: Dynamic Oversight for Complex and Convergent Technology," 13 J. NANOPARTICLE RES. 1345 (2011).

[45] Kuzma et al., supra note 44; Thompson, supra note 122; Gaskell, supra note 10.

[46] Kuzma et al., supra note 44.

[47] B. Bozeman and D. Sarewitz, "Public Values and Public Failure in US Science Policy," 32 SCI. & PUBLIC POL'Y 119 (2005).

[48] Id.

other crops such as Ht GM canola in Oregon,[49] Ht RR Kentucky blue grass[50] and GM eucalyptus trees.[51] Controversies are being played out in the new farm bill negotiations over revising regulatory processes as well.[52]

Based on the GM crop story, a broader notion of pacing that incorporates not only elements of time but also includes responsiveness to potential ecological and social harms, as well as public desires for information, transparency and voice, is suggested. I term this "proper pacing." The oversight decisions for emerging technologies like GMOs, nanotechnology, robotics, synthetic biology, geoengineering and neurotechnology will continue to be controversial. Stakeholders and the public – with different ideas and values about the role of technology in society, assurances of safety and equal sharing of risks and benefits – are currently forced to express their views outside the oversight system, looking in only through the public comment and rulemaking process or by challenging industry and agencies in court. On the flip side, industry and government are crippled by these challenges, delaying potentially beneficial and more acceptable technologies to flourish. Fundamental change in oversight is needed to address the proper pacing problem as we enter a world changing from the confluence of multiple new technologies with uncertain impacts. Innovation in oversight is needed to match technological innovation. But most importantly, this innovation in oversight should create opportunities for dialogue and debate much earlier upstream in the technology decision making pipeline. It should be flexible in response to technologies, but the need for flexibility and the shape it takes should be decided with the input of multiple stakeholders.

Proper pacing could draw upon ideas that several scholars have proposed for new governance regimes. For example, in Marchant et al. (2011), the use of voluntary environmental programs, codes of conduct, anticipatory governance and administrative law tools are described for

[49] "Planting of GM Canola Stayed in Oregon," GM WATCH NEWS, August 18, 2012, available at http://www.gmwatch.org/latest-listing/51-2012/14131-planting-of-gm-canola-stayed-in-oregon (accessed July 17, 2013).

[50] International Center for Technology Assessment and the Center for Food Safety: Noxious Weed Status of Kentucky Bluegrass Genetically Engineered for Herbicide Tolerance, 76 Fed. Reg. 39,8100 (July 7, 2011).

[51] Emily Waltz, Cold-Tolerant Trees Win, 29 NATURE BIOTECHNOLOGY 1063 (2011).

[52] Bob Meyer, "What About that "Biotech Rider" in the Farm Bill?," BROWNFIELD: AG NEWS FOR AMERICA, November 15, 2012, available at http://brownfieldagnews.com/2012/11/15/what-about-that-biotech-rider-in-the-farm-bill/ (accessed 17 July 2013).

better pacing.[53] These methods may be feasible in the short term for pacing. However, I argue that a more fundamental paradigm shift is needed for proper pacing. Putting aside the legal and political practicalities, I briefly describe one vision for proper pacing below.

9.8 ONE POSSIBLE VISION

For this vision, I draw upon three frameworks from our previous work: dynamic oversight; upstream oversight assessment (a subset of anticipatory governance); and strong objectivity. Dynamic oversight is based on the principles of inclusivity, reflexivity, anticipation and adaptation, with the ability to move oversight from hard (regulatory) to soft approaches (codes of conduct) and back again depending on new information. Given these principles and movement, we proposed a model where three chartered groups would form the heart of decision making:[54] (1) an interagency group; (2) a diverse stakeholder group; and (3) a wider public engagement coordinating group. For example, decision making authority would still rest with the agencies, but they would be publicly accountable to the input from the stakeholder group, much like a federal advisory committee. The public engagement process could be coordinated through science museums across the country and fed into the stakeholder and interagency group process. Communication among the three groups would be routine and iterative.

The dynamic oversight model would then be used for upstream oversight assessment, a subset of anticipatory governance focusing on particular products as cases for governance.[55] Case studies of products or technologies coming down the pipeline (for example, in early development) would be presented to this three-bodied system. The technologies and their potential impacts on society would be deliberated. The three bodies would raise gaps in legal authorities, risk assessment needs, and social and ethical concerns. The system would prepare for how to govern the particular applications in the future. For example, the interagency group could examine and clarify authorities; members of the stakeholder group would put policies or codes in place, conduct safety studies or continue the dialogue to ameliorate conflict in the future; and citizens

[53] See supra note 2.

[54] Ramachadran et al., supra note 44.

[55] Jennifer Kuzma, James Romanchek and Adam Kokotovich, "Upstream Oversight Assessment for Agrifood Nanotechnology: A Case Studies Approach," 28 RISK ANALYSIS 1081 (2008).

who took part in the engagement could seek additional information about the technologies, voice their opinion to decision makers, and monitor their entry into the marketplace. Although this process would take time and resources, this upstream dialogue and deliberation is likely to be less costly than heated legal disputes and delays like in the case of GM RR alfalfa.

One important cornerstone that must be embedded in such a system is strong objectivity. With the position of strong objectivity, values shaping risk assessments and knowledge-based policy making are identified and critically evaluated, and an intermediate position between the idea that science is purely objective and the idea of relativism is taken.[56] Scientific practices and knowledge claims associated with oversight of emerging technologies would be scrutinized from diverse perspectives to increase the objectivity by maximizing to the extent possible the standpoints from which scientific and social impacts are assessed. The idea is that with dynamic oversight, upstream oversight assessment and strong objectivity, the oversight system becomes more legitimate and rigorous, properly pacing with technological advances by repeated and iterative discussions among the three groups in the system.

The GMO story tells us that change is needed. Other contemporary stories of nanotechnology, geoengineering, robotics and synthetic biology are repeating that lesson. I argue that this change should come through a paradigm shift. The model presented here may not be ideal, but it could be a starting point for discussion. The future depends on proper pacing to create a better relationship between society and emerging technologies.

[56] Sandra Harding, "'Strong Objectivity': A Response to the New Objectivity Question," 104 SYNTHESE 331 (1995).