

***Throwing Caution to the Wind:
An Examination of the Influence of Legal Culture in the GMO Debate***
MEREDITH PRICE*

Take a look at the food on your plate and picture where it came from. It is more than likely that the image you now have in your head is of a farm—vast and green with grazing cows, or saturated with fruits and vegetables slowly ripening under the sun. The idea of the happy, small family farm is one that most Americans still hold dear, but in most cases it could not be further from the truth of American food production. A more realistic image is that of a “factory farm”—a farm so large, it is tended to by groups of laborers using industrial machines. Scientists in a laboratory have inserted mutated genes into the plants, thereby changing their chemical composition to display specific traits. They have then patented and sold these seeds to the farmers who are now locked into a system that demands ownership and control of “natural” products, but flouts the risk.

Although the prospect of cheap and plentiful food is very appealing to society, its impact on health, the environment, and corporate power is far greater than we believe. Our food production systems have shifted to food developed in a laboratory. From fresh fruits and vegetables, to corn-derived additives and sweeteners present in almost all packaged goods, genetically modified organisms (GMOs) today are found in every section of the grocery store (Pollack, 2009). In 1992, the Flavr-Savr tomato—designed to prevent rotting without sacrificing taste or texture—was the first genetically modified food product introduced on the commercial market (McCabe, 2012; Pollack, 2009; Pew Initiative, 2001). Since then, the prevalence of genetically modified crops has increased dramatically. It is estimated that in 2009 approximately 93-percent of soy, 93-percent of cotton, and 86-percent of corn grown in the U.S. were genetically modified varieties. Additionally, 90-percent of canola is GMO and it is estimated that 80-percent of packaged food products in an average U.S. grocery store contains at least some GMO ingredients (Pew Initiative, 2001). It is likely all Americans have been exposed to genetically modified organisms at some point in their lives. For most Americans, that exposure occurs multiple times every day.

In popular discourse, mechanized agricultural production and genetically modified food are seen as symbols of our incredible technological progress, powerful free market, and successes in innovation. GMOs are celebrated in the biotechnology community as the panacea to food insecurity. Proponents of genetic modification note the potential for these foods to benefit both the producers and consumers. Higher yields and drought and pest resistant crops could offer substantial profit increases for farmers as well as enable them to keep up with increased demand. Consumers could benefit from increased nutritional profiles and the farmers’ savings could allow the food to be more financially accessible (Pollack, 2001).

However, these may be short-term gains only, ignoring the potential for long-term costs. Crop resistance to herbicide and pesticides could lead to resistant

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“superweeds” and “superbugs.” Cross-pollination could contaminate organic and conventional crops and risk permanently altering the genetic makeup of a crop species, thereby wreaking havoc on biodiversity and the ecosystem (McCabe, 2012). In addition to the threat posed by GMOs to human and environmental health, there is also uncertainty about the implications of allowing corporations to effectively own and control a major access point to food security, namely seeds.

The introduction of genetically modified organisms into the commercial food supply has met significant criticism regarding its ethical, environmental, and potential health related implications. Despite claims and promises by the scientific and policy communities, GMOs are a new technology that is not without risk.

It becomes necessary to ask how and why GMOs are supported in our legal culture despite their potential risks. How has the United States Supreme Court shaped the debate about GMOs in the U.S., and has it been protecting citizens’ rights? Through an examination of the U.S. Supreme Court ruling in *Monsanto v Geertson Seed Farms* (2010), my paper will highlight that, in keeping with a legal culture that values majority interests, the Court’s concern for the protection of economic interests has trumped its responsibility to protect the wellbeing of its citizens. In *Monsanto*, the Supreme Court allowed Monsanto to introduce genetically modified alfalfa to the commercial market prior to the full completion of an environmental impact assessment. This decision illustrates that the U.S. legal system favors the economic interests of corporations over the liberties of its citizens. In comparison, the European Union requires a very strict and thorough examination of environmental impact prior to its consideration of a GMO for approval and exercises significant precaution in its approval process. Where the decisions of EU lawmakers are shaped heavily by a culture of protecting minority interests and advancing precaution over innovation, the legal culture—and thus the legal system—in the United States is heavily influenced by money, power, and scientific advancement.

This paper is concerned with the influence of legal culture on the design and implementation of the regulatory system for GMOs. I will begin with a brief overview of the historical and scientific background of this technology, its commercial production and how law has attempted to regulate GM foods. Next, an examination of legal culture in America—with a long standing propensity toward furthering economic interest wherever possible—provides valuable insight into the inevitability of and political resistance to change the current regulatory system. Finally, I will contrast these ideas with the European legal approach and examine what the future implications of these ideas hold in store ethically, environmentally, and legally.

Historical context of GMOs

Attempts to modify the genetic makeup of plant and animal species have existed since Gregor Mendel’s famous experiments with pea plants in the 19th century. Mendel provided a method to selectively breed species to create hybrids that could produce offspring with desired characteristics. Hybrid plants required farmers to identify dominant and recessive genotypes and crossbreed plants until the offspring expressed the desired gene—whether size, color, or some other quality. This process was expensive and time consuming, as it often took several plant generations to produce the desired outcome (*Genetic Roulette*, 2012). Genetic modification is a next step in this scientific endeavor. In the quest to make food easier and cheaper to produce, scientists began to

explore other means of interference with plant species. Though both methods of intervention involve the natural process of cross-pollination to reproduce, hybrid plants begin naturally, progress naturally, and result naturally. By contrast, genetically modified species begin by being manually reconfigured in a laboratory, progress naturally through cross-pollination, but result in crops that display the unnaturally derived characteristic.

To better understand this approach, a brief overview of the scientific process is necessary. Biotechnology encompasses the field of using organisms to enhance or make something more useful, and most commonly applies to food and medicine. A specific form of this technology, genetic modification, is the process by which a specific gene is isolated and manipulated and then reinserted into another organism to produce a desired effect.

Currently, the most common commercially available GMOs are crops that are resistant to specific herbicides or to common pests. For example, Monsanto produces a strain of soybeans known as RoundUp Ready Soybeans. This crop is resistant to the chemical glyphosate, which is the primary ingredient in Monsanto's RoundUp herbicide. A farmer who has planted the GM soybeans can spray his entire field with the herbicide and kill only the weeds—thereby saving time and money (*Genetic Roulette*, 2012).

Some critics of genetic modification argue that the scientists creating these products are “playing God.” Indeed, the prevalence of GMOs has increased significantly and the natural boundaries of crop production have been pushed with little concern for potential limitations. As the American government continues to support powerful biotech companies and exercise weak oversight, and as these companies continue to express little concern for the potential for harm from their actions, we risk creating a system that disregards consequences until it is too late to rectify any damage done.

The introduction of genetically modified organisms has already altered the nature of food production. Unlike the earlier methods of creating hybrids, GMO production relies on technological intervention and hence, the process has allowed the corporatization of agriculture. Large agribusiness companies fund the multimillion-dollar process of research and development of GMOs. Farmers must purchase the seeds from the developer, or their authorized distributor, and are required to sign a contract that allows the corporation to sue them if they save their seeds, rather than continue to purchase from the corporation each season. It is also extremely difficult for farmers to stop planting GMOs and revert back to conventional or organic farming, both due to the contracts and due to the increased potential of cross contamination once GMOs have been planted in their fields (*Genetic Roulette*, 2012). Nonetheless, these technologies are advancing rapidly and are becoming extremely prevalent in American agricultural practices, and thus the commercial food market (Pollack and Shaffer, 2009).

Biotechnology companies such as Monsanto, DuPont, and Syngenta—who together account for nearly half of the world's proprietary seed market (ETC Group, 2008)—are using scientific technology to alter the genetic makeup of plants and animals in a process that is much faster and far more profitable than traditional agricultural science (Pollack and Shaffer, 2009). The potential benefits offered by this technology are exciting, yet the intersection of financial power with control over natural resources is of great concern.

The GMO debates

As awareness of GMOs increases, so does the debate about their safety and necessity. For some, the possibility of harm coupled with the mere fact that human life has managed for so long without this technology is enough to call for a ban on the technology. Still, others believe it offers the ability to support the growing population sustainably and effectively.

Proponents of GMOs emphasize their potential ability to address growing food concerns throughout the world. With the global population already estimated at over 7 billion people and expected to continue to increase exponentially (World POPClock), pressure is mounting on scientists and governments to come up with ways to ensure the food supply can keep up (Charles, 2013). They argue that the ability for genetically modified crops to resist pests and herbicides will enable farmers to generate higher yields at lower prices (Pollack and Shaffer, 2009). Additionally, because farmers are often unable or unwilling (when it is not cost-effective) to remove weeds with non-chemical means, herbicide resistant crops can minimize the amount of herbicides farmers must use on their fields (Whitman, 2000).

Late frosts, drought, and disease are also major threats to crops. In addition to protecting crops from loss, this technology could allow crops to be planted in geographic locations where that might not otherwise be suitable (Whitman, 2000). This could increase accessibility to a wider range of food products, especially in poor and developing nations (Charles, 2013). Disease resistance in particular is also being studied in hopes of aiding animal populations (*Genetic Roulette*, 2012).

Finally, a significant potential benefit of GMOs is increased nutrition. Scientists and GMO advocates argue that we will not only be able to feed the growing population, we will be able to provide them with more adequate nutritional profiles (Whitman, 2000). Foods that are lower in calories and saturated fat content are appealing to western consumers, and foods containing higher vitamin and mineral contents could alleviate malnutrition concerns in third-world countries (Pollack and Shaffer, 2009). One example of a nutritionally beneficial GMO that has recently been developed is “Golden Rice.” Vitamin A deficiency in several developing nations, particularly in Asia and Africa, is a major concern. Several researchers discovered the answer could lie in rice, a staple food that is both readily available and easily affordable. Using GM technology, a strain of rice has been developed—golden in color because it contains high levels of the Vitamin A precursor beta-carotene. In fact, one serving of this rice can provide 60-percent of a child’s daily Vitamin A intake (Charles, 2013).

Unfortunately, genetic modification, like any science, is not without risk. Critics point out that the process is not as simple as isolating and manipulating only one aspect of the organism (Bessin, 2004; Pollack and Shaffer, 2009). The genetically modified gene must be inserted into the organism along with a genetic sequence that promotes the expression of the modified gene (Bessin, 2004). Therefore, critics argue that the process may have unintended consequences that are not yet fully understood (McCabe, 2012).

The lack of long-term research is also a concern for GMO critics because they worry about potential effects both to the health of humans and animals, and to the environment. Studies on mice raised on genetically modified feed have noted reproductive difficulties, tumor growth, and neurological delays. Some medical professionals also warn that there is not enough conclusive evidence pointing to the

safety of GMOs for human consumption. Additionally, the fact that GMOs are a recent introduction to the food supply means the long term effects cannot yet be studied. These critics also point to a correlated increase in food allergies and diet related disease, (such as diabetes, warning that it is too soon to rule out a possible causation link (*Genetic Roulette*, 2012)). With regard to the environment, critics argue that farmers are actually increasing the chemical load on their fields in response to the development of insects and weeds that are contracting the resistant genes.

Finally, the possibility of cross-pollination threatens conventional crop integrity and could permanently alter the ecosystem by rendering non-GMO plant varieties extinct. Conventional farmers, moreover, have experienced significant profit loss due to cross contamination, particularly if they generally export their crops to countries that banned GMOs (McCabe, 2012). When rice that had been exported to Europe was found to have strains of a genetically modified organism initially developed for corn and approved only for animal feed, Europe halted all rice imports from America. Other countries, including Japan and even Iraq, called for extensive testing on all rice imports. As a result, rice prices fell dramatically and it was the farmers who bore the financial burden (Gunther, 2007).

The question that many consumers, organic food advocates, scientists, and even medical professionals have begun to ask is why. Why are consumers not being afforded the right to choose whether or not to purchase or consume GMOs due to the lack of mandatory labeling policies (Rich, 2004)? Why is the federal government so confident in the safety of these products despite potential risks (Pollack and Shaffer, 2009)? Why does it seem that the corporate interests of large biotechnology are receiving special protections and approval processes for their products (Mandel, 2004)? And why are conventional and organic farmers not formally protected from obvious negative implications of GMOs, such as cross-contamination (Grossman, 2002)? The biotechnology corporations promise their products are safe. The government seems to agree but chooses not to respond to these concerns outright.

GMOs and the law

In the legal domain, the discourse on GMOs is mostly approached from the perspective of ownership and control of the product, and regulation to ensure the safety of the products. The concern regarding ownership and control stems from the fact that large biotech companies patent their new technologies and sell them to farmers in a way that has never been done before. Prior to the advent of genetic modification, most farmers would purchase seeds, plant and harvest their crop, and save the seeds from their crop to plant again for a smaller, less profitable harvest. Additionally, if any cross-pollination might occur between farms it was generally not problematic. By patenting their genetically modified seeds, corporations are assuming ownership of what it technically still is a life form, they are selling the seeds to farmers who must sign a contract that requires, among other things, that the farmer not save any seeds (so he must buy more if he wishes to plant a second harvest). Additionally, if and when cross-pollination occurs and the genetically modified genes are discovered in a neighboring farm, that farmer can be sued for patent infringement (*Genetic Roulette*, 2012). What farmers grow and how they grow it has become property of a third, much larger and more powerful, party.

Safety regulation applies to most new technologies. The primary objective is to ensure that the environment and human health are not negatively impacted. GMOs are regulated collaboratively by the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Environmental Protection Agency (EPA). This structure is outlined in the Coordinated Framework for the Regulation of Biotechnology, which was adopted in 1986. This regulatory system relies on the assumption that genetically modified crops do not vary significantly from their conventional counterparts and are therefore generally considered safe. Additionally, it places the burden of proof regarding the safety of the products in the hands of manufacturers (McGarity, 2002; Pew Initiative, 2001; Pollack and Shaffer, 2009).

The three agencies apply over ten statutes and dozens of regulations in their oversight of biotechnology. However, all of these laws were written prior to the advent of GMOs, and struggle to keep up with the rapidly advancing technology (Pew Initiative, 2001). In 1986, it was decided that biotechnology could be adequately regulated using the existing regulatory systems in place for new commercial products. Applications for a product derived from biotechnology are typically reviewed first by the USDA. The USDA division with the principal responsibility for reviewing these articles is the Animal and Plant Health Inspection Service (APHIS). After its review by APHIS, an article is typically reviewed by the EPA and the FDA (Belson, 2000). This three-pronged system is confusing and leaves open several loopholes. It also creates a lack of responsibility and makes it difficult to find and address systemic problems.

In order for an agency to authorize the deregulation of a GMO, it must comply with the National Environmental Policy Act (NEPA), which requires an environmental impact statement when a federal decision or action will affect the quality of the human environment. NEPA was enacted in 1969 but plays a significant role in the GMO approval process as it is written. Though the act requires that assessments of environmental impact be conducted thoroughly and early in the approval process, the walk and talk of law seem to differ. An agency must first conduct an environmental assessment and if it finds potential for significant impact, a more complex environmental impact assessment is completed. Therefore, should an environmental assessment conveniently find no such impact, the more thorough analysis is not completed (Belson, 2000). Following this approach, there have been multiple instances in which the USDA has created “fast-tracks” for approval, leading to deregulation prior to ensuring full compliance with NEPA (McCabe, 2012; McGarity, 2002). In fact, after the Liberty Link rice controversy, the USDA *retroactively* approved the “contaminated” rice, stating that the “mutant” genes were no different from the ones that had already been approved for canola and corn (Gunther, 2007).

The findings of no significant environmental impact generally echo the idea that GMOs are similar enough to their conventional counterparts that additional scrutiny is unnecessary. That the current laws rely heavily on the principle that GMOs are generally regarded as safe (GRAS) poses problems regarding the legitimacy of regulation. Consultations regarding the GRAS principle are voluntary, and manufacturers are not required to disclose their test protocols (McGarity, 2002).

Recently, certain cases that did not fall under the regulation of the EPA were evaluated for environmental risk by APHIS. The National Research Council criticized APHIS’s evaluations for lacking scientific rigor, balance, and transparency. They have also been criticized for relying too greatly on existing scientific literature and data,

rather than conducting adequate testing and research regarding the specific new products under review. Additionally, once APHIS approves a plant for deregulation, it no longer has the authority to monitor and review it for unanticipated consequences (Mandel, 2004).

The regulatory problems exist throughout each agency. The EPA, for example, has authority only over the producers of pest resistant plants but not over the growers. Additionally, once a GM product has been deregulated, manufacturers are not required to notify the FDA prior to commercial introduction of the GMO to their products (Mandel, 2004).

Thus far, the law has approached GMOs with fairly open arms. By considering them “generally safe,” allowing the developing companies to conduct and report on their own tests, and by creating fast tracks to approval, the American legal system expresses little concern over the potential risks involved. A legal system is driven by its legal culture, and a look at the economically based legal culture present throughout American history provides insight into the government’s unsurprising position on GMOs.

The American legal culture

Legal culture is a dynamic term that must be further clarified to understand its relationship to the GMO debate. One school of thought argues that the law merely serves to codify appropriate behavior based on determinations already made by culture. Another approach is the concept that culture and the law develop together. Law is so embedded in culture that it has some power to manipulate society, but that same culture ensures that the law is reflective of the needs of the people. Law gives meaning and the ability to associate oneself in the social world with others, and the social world exerts certain influence over the law and the institutions that create it (Mautnet, 2011).

Throughout American history, it is evident that property and financial interests exert a heavy influence on the law and the development of the nation’s legal system. John Locke’s theory of property is one key ideological influence. In the *Second Treatise on Civil Government*, he argues that property is essential to survival and individuals enter into society for the purpose of protecting their property rights. A government that fails to uphold these rights is failing in its duty and can be overthrown.

Industrialist Andrew Carnegie published his essay *The Gospel of Wealth* in 1889. He argues that property rights are embedded in our capitalist society and are essential for progress. He writes, “One who studies this subject will soon be brought face to face with the conclusion that upon the sacredness of property civilization itself depends.” The fact that wealth and power accumulate among a few individuals and corporations is the basis of the competition that drives innovation and hard work.

The government begins to involve itself increasingly in financial and labor matters by the late 19th and early 20th century, most (in)famously in the 1905 US Supreme Court case *Lochner v. New York*. In *Lochner*, the Court clearly privileged the freedom of contract between employer and employee and economic freedom above all else (in this case, the fundamental rights of employees). Over the years, the law increasingly protected the interests of large, wealthy players—namely corporations. The government has used its power of eminent domain, for example, to further private interests, rather than the public good. Eminent domain allows the government to take private property for the “public good” and with just compensation. However, the public use requirement has been broadly interpreted, most recently in the landmark Supreme

Court decision *Kelo v. City of New London* (2005), where the Court interpreted private development as permissible public use (under the 5th Amendment). The Court is clearly willing to take on cases of corporate interest versus individual property owner, and favor corporate interests.

In *Citizens United v. Federal Election Commission* (2010), moreover, the Court went a step further and argued that since the First Amendment protects associations of individuals in addition to the individuals themselves, and a corporation is an association of individuals, its effective personhood is protected by the constitution. This model of corporate personhood is deeply problematic. The recognition of corporations as people is a flawed concept that greatly undermines the role of government. Corporations and people are fundamentally different, in that corporations can be bought, sold, and dissolved, but do not die. Moreover, a corporation has the ability to exercise far more power and influence than any individual because of its visibility, breadth of personnel, and financial resources. Granting corporations similar rights as people prevents the law from properly protecting individual interests.

The government has a unique ability, and responsibility, to interpret law to address the most pressing societal issues. The extreme likelihood of cross-contamination and the severe environmental affects that would stem from that are reality, not speculation. The financial harm that farmers face on the organic or export markets should their consumers become concerned over the possibility of GMO contamination has been documented. While the law as it is written does not fully address these problems, the law as it is interpreted has the potential to distinguish this technology as unique and worthy of special consideration. Instead, in a similar approach to the *Citizens United* case, the Court has chosen only to consider the matters before them as they appear at first glance. Considering corporations as people or GMOs as conventional crops is flawed reasoning that can be attributed to the legal culture outlined above.

Monsanto v. Geertson Seed Farms

In 2005, APHIS decided to deregulate Monsanto's genetically engineered alfalfa called RoundUp Ready Alfalfa (RRA). Concerns about the possibility of cross contamination with organic and conventional crops and the creation of "super weeds" through transfer of the herbicide resistant gene led to unrest among conventional and organic farmers. In response to this decision, two alfalfa farmers joined by food and environmental safety nonprofit organizations sought an injunction barring APHIS from executing its deregulation decision and thereby Monsanto's ability to plant the RRA (Gerendasy, 2010).

Monsanto v. Geertson was the first US Supreme Court ruling regarding genetically engineered organisms, basically allowing Monsanto to sell genetically modified alfalfa seeds to farmers prior to the full completion of an environmental impact assessment. The case had significant implications for the way in which GMOs would be regarded by the government in the future. When the decision was announced, both sides claimed victory (Leslie, 2010). However, further examination of this case reveals a missed opportunity for the Court to take a real interest in the potential for harm inherent in GMOs. The judicial passivity shown instead was likely linked at least in part to the economically driven legal culture of this country.

Monsanto is the nation's leading agricultural biotechnology company, with annual revenue over \$13 billion and a global operation that spans 66 countries, according to its website. It has also grown to be the nation's top agricultural lobbyist, with annual spending of nearly \$6 million dollars (Center for Responsive Politics, 2013). The company began in 1901 as a chemical company. In 1982, Monsanto scientists were the first to genetically modify a plant cell. Since then the company has invested considerable time and resources on the research and development of genetically engineered plants, including the alfalfa in dispute in this case.

Geertson Seed Farms, the respondent in this case, is a farm that produces and markets conventional crops. Because alfalfa is largely bee pollinated and the bees are capable of travelling long distances, their primary concern was the potential for cross-pollination of the genetically modified variety with their conventional variety. Their buyers could refuse to buy their contaminated alfalfa, and the cost of field-testing to ensure their product was free from contamination would force them to raise their prices, significantly reducing their market viability (Leslie, 2010).

When APHIS authorized the deregulation of Monsanto's Round Up Ready Alfalfa (RRA), Geertson Seed Farms sued, claiming that because the decision was rendered prior to the completion of an environmental impact assessment (EIS), it was in violation of the National Environmental Policy Act. The District Court vacated APHIS's deregulation decision, ordered them not to review the deregulation petition again, whether full or partial, until the EIS was completed, and enjoined almost all planting of the genetically modified alfalfa until the completion of the EIS. It was the injunctive relief that became the focus of appellate review, and the Court of Appeals affirmed this decision.

The issue before the US Supreme Court was two-fold. First, they looked to determine whether Geertson had standing to seek injunctive relief in the first place. Case law holds that standing to seek injunctive relief requires the plaintiff to show a "likelihood of irreparable harm" absent the relief. On this matter, the Court determined that there was, in fact, significant enough reason to believe that the potential for conventional crop contamination existed should the GM alfalfa be completely deregulated, and that this could likely lead to further harm by requiring the farmers to conduct testing, obtain certification, and take additional means to minimize contamination that would increase their operating costs substantially.

Next, the Court examined the decisions of the lower courts to prohibit APHIS from enacting a partial deregulation and enjoin future planting of the alfalfa pending the results of the EIS. The Court stated that there is a four-factor test that must be met before an injunction can be issued. The plaintiff must demonstrate "(1) that it has suffered an irreparable injury; (2) that remedies available by law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." The Court reasoned that Geertson could not prove that they would suffer irreparable injury should a partial deregulation be allowed. Without reason to block a partial deregulation the Court argued that there is no standing to issue the extraordinary remedy of injunctive relief, so the decision to prohibit future planting of RRA was misguided.

The Court's interpretation of the applicability of the four-factor test in this case is particularly interesting. The Court determined that because the harm that Geertson was

concerned with was not certain, an injunction would be an overextension of government power. Additionally, the Court stated that Geertson could not prove that they would suffer significant injury if APHIS were to proceed with a partial deregulation. The Court reasoned that injunctive relief was not needed and should not be used “to guard against any present or imminent risk of likely regulation of harm.” Choosing not to accept the potential for risk as a genuine and tangible risk in itself, the Court ignores caution and supports the regulatory assumption that GMOs are inherently safe.

The nature of the outcome reveals support for large business enterprises like Monsanto over small farms like Geertson. Wealthy corporations have the financial power and legal means to fight multiple numerous battles, whereas small farmers are at an obvious disadvantage in this area. Having to initiate new legal action each time APHIS grants partial deregulation of a genetically engineered crop is simply not feasible for those who would be most threatened by this action. This leaves the door open to Monsanto to continue its development and deregulation petitions without regard to any additional legal constraints unless farmers are able to develop and afford a strong legal case each time.

The Court argued that “a partial deregulation need not cause respondents any injury at all, much less irreparable injury; if the scope of the partial deregulation is sufficiently limited.” If APHIS were to allow planting of RRA in only remote areas, with mandatory isolation distances from other plants, and a new environmental assessment (the preliminary assessment, prior to the EIS) finds a limited risk of environmental harm, then it is likely that conventional and/or organic farmers will be unable to demonstrate a reasonable likelihood of irreparable harm. Therefore, the Court found that a complete deregulation in this case does not require the respondents to fully demonstrate the first of the four factors required for injunctive relief.

In this analysis, the Court errs in its requirement that the plaintiff bear such a heavy burden of proof. Once again, this would require means and resources that the farmers are unlikely to acquire on an ongoing basis. Additionally, the Court recognizes that the science is simply not all there; current evidence points to the significant possibility of irreparable harm from genetically modified organisms, but due to the fact that this is a relatively recent scientific process, long term definitive studies are simply unavailable. However, no definitive studies are available to demonstrate the safety of these organisms either. Clearly, the Court favors the interests of biotech companies by failing to consider the unique attributes of biotechnology.

The power of these large agribusinesses is evident in their handling of cases of contamination. In 2006, the USDA announced that traces of Bayer CropScience’s genetically modified “Liberty Link Rice,” which had not been approved for human consumption, had been found in conventional rice. Japan and many European countries banned US rice imports, leading to serious financial losses for farmers. Nearly 11,000 farmers filed more than 400 lawsuits, which were eventually combined in federal court in Missouri (Patrick, 2011).

Ultimately, a settlement was reached in which Bayer CropScience agreed to pay farmers in five states up to \$750 million dollars in damages (Patrick, 2011). The settlement included no requirements for change or additional action on the part of Bayer CropScience. With revenue reaching \$10.8 billion dollars in 2012 (Ranii, 2013), the settlement caused little concern to the company compared to the potential for increased inquiry that may have arisen from continued judicial review.

Because companies such as Monsanto and Bayer CropScience have the financial ability to protect themselves from increased scrutiny and to continue litigation for as long as necessary, the current system of judicial review once an injustice has occurred is inadequate. Additionally, requiring farmers to carry the burden of proof that a GMO is dangerous rather than requiring the manufacturer to demonstrate its safety is equally unfair. The research is simply not available to provide a concrete understanding of what these organisms will do to the environment and human health.

GMO takeover

Since *Monsanto v. Geertson*, the prevalence of GMOs in commercial food production has only increased. Without a requirement to distinguish or label their products any differently, and with the ability to produce cheaper crops to be translated into more profitable foodstuffs, corporations such as Coca-cola and Kellogs have joined Monsanto and the other agribusiness corporations to promote the use and development of GMOs despite growing public concern. As discussed above, the power of corporations is often considerably stronger than the power of individuals, and the government thus far continues to listen to the loudest, or richest, voice. The regulatory system remains the same, and the FDA, USDA, and EPA continue to champion the technological advances while mitigating the risks (*Genetic Roulette*, 2012). Nonetheless, *Monsanto v. Geertson* was a heavily publicized case, and was certainly instrumental in mobilizing food advocacy groups and the general public.

Indeed, public awareness of the controversies and concerns surrounding the government's support of big agribusiness has also expanded. In 2012, advocacy groups and organic companies spent approximately \$6.7 million dollars in support of California's Proposition 37, which would have required food products containing GMOs to be labeled as such. Major US food and biotech companies, by contrast, spent more than \$45 million on their campaign to reject this requirement. The measure was defeated by only 6 points, but the overarching debate about GMO labeling did not lose much steam (Finz, 2012).

The debate about whether or not GMOs should be labeled stems primarily from the concepts of civil liberties and market economics. On the one hand, proponents of GMO labeling argue that the protection of consumer choice depends on availability of information. Irrespective of the safe versus not safe debate, advocates of this approach argue that people should be able to make informed decisions about the food that they buy and consume. Those against mandatory GMO labeling, most notably the agribusiness and food production companies, argue that labeling GMOs lends support to the idea that they are fundamentally different from their conventional counterparts which is not in line with precedent and could threaten the marketability of their product if the public equates "different" with "bad" (Harmon, 2012).

Another recent development generating severe public outcry is the passage of the "Consolidated and Further Continuing Appropriations Act, 2013." The bill contained a section known informally as the "Monsanto Protection Act." Section 735, as it is officially known, was anonymously slipped into the bill and provides significant legal protection for biotech companies (McLendon, 2013). Specifically, the law states that once a crop has been deregulated, farmers cannot be stopped from planting the crops during disputes such as the *Monsanto v. Geertson* case. While it does not prevent biotech corporations from being sued, it does allow them to continue to profit from their

genetically modified seeds while legal action is ongoing (AgriView, 2013). Since *Monsanto* set a precedent for demonstrating harm that is difficult to prove, we now have a legal environment that allows biotech corporations to profit until potential risk turns into actual and potentially irreversible harm.

The current regulatory system does not include clear requirements for procedures and safeguards for GMO testing. This inadequacy coupled with the fact that the developers conduct their own testing leads to insufficient, and often nonexistent, oversight of field trials. Furthermore, this discovery illustrates that unapproved—and potentially dangerous—GMOs cannot be fully or reliably contained before market approval (Hubbard and Hassanein, 2013).

The mysterious reappearance of genetically modified wheat two months after passage of the MPA lends significant credibility to the concern that the implications of GMO technology may be more far-reaching and less controllable than we would like to think. Unfortunately, the ongoing dispute over GMO labeling and the fact that a law was passed protecting biotech interests at the expense of public or environmental health indicates that the GMO debate is far from over. While the U.S. is trying to apply old rules to a new and rapidly advancing technology, the uncertainty surrounding this new technology is precisely why the European Union takes a different approach to the regulation of GMOs in its member countries.

EU regulation

Lacking the same financially driven legal culture and embracing a stance that values public opinion, the European Union is more restrictive in its approach to GM crops. In 2009, while the US produced 64 million hectares of GMO crops, the EU produced only 94,750 hectares (GMO Compass). While the EU does permit some GMOs, they are based on stringent environmental harm assessments using the precautionary approach, require labeling, and a significantly more complicated approval process. In addition to approval from the EU, each member state has an opportunity to accept or reject a proposed GMO within its borders.

The EU focuses its regulation on the prevention of potential harm. In the absence of clear and sufficient evidence pointing to the safety of a product, the EU chooses to adopt a “precautionary principle,” whereby it is determined that the risks are too great to be compatible with the high regard for safety that guides its approach to GMO regulation. This principle places the burden of proof of a product’s safety on the developers, and the burden of proof that the crops are planted according to safety standards on the farmers. To gain approval, developers must demonstrate that their product is safe and outline any preventative measures to ensure that safety. Once approval has been granted, farmers are required to do everything in their power to ensure the safety of their crops (European Commission).

This precautionary principle is the guiding force behind the EU regulatory system for GMOs. In 2002, the European Commission established a new EU agency, called the European Food Safety Authority (EFSA), responsible for risk assessment, food safety information, and food safety emergency response (Pollack and Shaffer, 2009). The current regulatory framework in the EU requires strict traceability and labeling requirements for any GMOs released into the commercial market. The objective of these laws is to protect human health and safety, environmental welfare, and consumer choice. In contrast to US policies, the EU approaches GMOs as “novel” foods, rather

than equivalent ones: “Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself” (Regulation 1829/2003). This concern is also expressed in the handling procedures required by the EU.

Strict separation of conventional and genetically modified crops and labeling requirements reflect public preference and consumer interests. To ensure consumers are able to make an informed choice, any product that is genetically modified or contains genetically modified ingredients must be clearly labeled. Throughout this regulatory framework, the interaction of law and society is respected in its implications, and choice and transparency are fundamental considerations.

The EU approval process is designed to ensure an approved GMO does not pose any significant health or environmental risks (Europa). When applying for approval, a biotech company must submit, along with its application, studies showing that the GMO is not dangerous and is substantively equivalent to its conventional counterpart, methods for testing for the GM content, and suggestions for labeling of the product. The information is submitted to the EFSA who are responsible for conducting a risk assessment within 6 months. The EFSA consults the EU reference laboratory to evaluate the submitted detection methods, and a scientific evaluation of the GMO by an expert panel is conducted to confirm its safety. The EFSA issues a decision for approval or rejection, which is accompanied by their suggestion for product labeling, an environmental monitoring plan, and any restrictions or conditions of the GMO authorization such as post-market monitoring. The European Commission makes the final decision and is responsible for risk management. Once a GMO is approved, it is entered into a public database and is valid for ten years (GMO Compass). However, the EU has enacted an additional safeguard, whereby member states can ban a GMO within their boundaries should they find any additional information or studies that generate a legitimate safety concern. For example, while Monsanto’s MON810 maize is approved in the EU, it is banned in Germany, Austria, Bulgaria, France, Greece, Hungary, Luxembourg, and Poland (RT News, 2013).

Once a GMO is approved for commercial release within the EU, it is farmers who receive the next round of responsibility. Farmers are required to maintain minimum distances between their GM plants and conventional plants, even if the conventional plants are grown on a neighboring farm (GMO Compass). While the EU legal framework realistically recognizes the potential for accidental contamination, it is the farmers’ responsibility to protect against this possibility. Should cross-contamination occur, the farmer must prove that it was accidental and that all precautionary measures were followed (EU Regulation 1829/2003).

In May 2013, Monsanto announced its decision to cease lobbying for GMO approval in the EU, citing public opposition of the crops and low farmer demand (RT News). The very different approach to GMO regulation taken by the EU has clearly had very different results.

Conclusion

In contrast to the EU’s precautionary approach, America’s attitude towards GMO regulation has undoubtedly been influenced by a legal culture that favors large economic interests. The favoritism towards corporate interests has been key to genetically modified crops becoming so prevalent in the United States. Evident in developments

after *Monsanto v. Geertson* and in stark contrast to Monsanto's recent action in Europe, America's legal culture has created an environment in which GMOs are seemingly here to stay.

The current regulatory system is lagging behind the rapidly expanding and globally reaching GMO technology. Moreover, *Monsanto v. Geertson* set a precedent that allows the research and development of agricultural biotechnology to continue despite potential risk. Unless harm is clear and will certainly follow, corporations are free to continue the research and development of GMOs. As a result, neither the law as it is written nor the law as it is interpreted by the Court leaves much room to accommodate the concerns of conventional and organic farmers, food and environmental safety organizations, or the concerned public.

Whether the US should change its policies is a matter of public interest that is gaining traction as awareness of the current situation increases. A thorough appreciation for property rights and the government's role in the preservation of economic interests suggests that it is *individual* rights that should be protected, and a sustainable food policy that should be championed. How the government proceeds in that regard is yet to be seen, but the legal culture outlined in this paper will certainly continue to exert its heavy influence on attitudes, policies, and court decisions.

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