American Agribusiness & Biotechnology: A New Era of Farming

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AMERICAN AGRIBUSINESS & BIOTECHNOLOGY: A NEW ERA OF FARMING

by

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ABSTRACT

In the past fifty years there has been an incredible amount of change made to the agrarian system of the United States. New discoveries in the realm of biotechnology led to the adoption of genetically modified organisms (GMOs) in agriculture and transformed the industry. Due to regulatory policies set during the nineteen-eighties this technology was able to benefit from widespread commercialization. Today, we see the effects of this approach and are entering into a highly volatile political climate with regards to GMOs.

This paper aims to provide an analysis of the regulatory system in place and the discrepancies that exist in US policy. The factors evaluated through this thesis include the current US regulatory approach, advancements in biotechnology, and a comparative perspective on US and EU systems. In each of these reviews it is also relevant to mention consumer opinion on GMOs and the role of interest groups. It is important for every American consumer to understand the politics and technology behind their meals. Through the analysis of recent judicial decisions and the enactment of new laws this thesis explains how the use of GMOs in agriculture is causing an unprecedented change to the political structures in place.

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INTRODUCTION

The purpose of this thesis is to evaluate the current state of the American agrarian system. Within the past fifty years we have seen an unprecedented level of change in the way of crop production. Only fifty years ago a single farmer would produce enough food to feed approximately twenty-five people. Today, that same farmer can provide for up to 150 people. The development of agrarian biotechnology is relevant to political scientists due to the potential for new federal policy to take form. The current regulation of GM substances has not been updated or changed since its adoption in the nineteen-eighties. We are dealing with a system that is not only outdated, but rather questionable as well. The inefficiencies in this regulatory process have paved the way for controversy and public outcry. I believe that within the next twenty-years this topic will become obsolete. With several of the nation's more left-leaning states already taking action, we can expect to see others follow suit. Although I can ensure that this process will be gradual I do believe that federal intervention will be required. Facing a demand from consumers and environmentalists alike regulatory agencies will be forced to adopt greater levels of scrutiny. Ultimately, I foresee a nationwide GM labeling initiative to come as well.

Commonly referred to as "GMOs", genetically modified organisms have become an integral part of American farming. In this study I identify today's current state of industrial farming as the dependent variable. To explain what has allowed for this evolution of American agriculture I have chosen to focus on the role of executive policy, and advancements in technology. Accounting for these two key factors we can better understand the massive changes seen in American agribusiness. It is also important to emphasize that these developments are not exclusive to the actual production systems in place, but have impacted the global economy as

well. To provide an interesting perspective I will also compare the agrarian system of the United States with that of the European Union. By raising awareness of the difference in approach these nations take we will be able to further question the ethicality and safety of genetically-modified (GM) foods. Besides providing a comprehensive review of American agrobiotechnology I will also impart what I believe is to come in the future of agrarian biotech regulation.

The focus of this study is to establish how the transition from small family-owned farms to massive "factory farms" has taken place in a relatively short period of time. To help prove this point I will target the scientific advancements including the introduction of GMOs and policy measures that date back to the Reagan Administration. This portion of the thesis will be fact based and will serve to provide background on the topic for readers. Once these sections have been completed I will also provide insight into the very tense debate over GM foods. The controversy surrounding the food industry is quite interesting and I believe it is beneficial to understand the goals of each side of this argument. The contention over industrial farming is based on the argument of whether or not GM foods are safe and regulated well-enough. Recently, the topic of GMOs has been salient among a small portion of the activist public. Those interested in alternative health lifestyles and environmental advocates are the most vocal about GM foods. While some argue that GM foods should be eliminated completely from the American diet others simply push for labeling requirements. Overall it is safe to say that these groups wish to establish a greater level of transparency among food producers. Within the past several years activists have made substantial progress in the way of bringing attention to their cause. In some of the more liberal states, namely California and Vermont, there have even been ballot initiatives and laws passed to enact mandatory GMO labeling. Without a doubt the topic of

GMOs and food safety are current in today's political atmosphere.

The study and discussion of American agribusiness is relevant to each member of our society. Unfortunately, the vast majority of the American public is grossly uninformed about the reality of the food industry. It is likely that much of the public believes that their foods are produced in the same manner in which they were one-hundred years ago. By understanding how produce and food-goods reach the super-market consumers will be better adapt to make their choices.

Due to the sweeping changes that have occurred in the food industry one might expect to see a regulatory policy that has also seen great change. Through an evaluation of several prominent federal agencies it can be quickly concluded that this assumption is inaccurate. One may even be shocked to uncover that there have been absolutely no polices implemented that specifically regulate GM crops. The several agencies responsible for ensuring consumer food safety claim that there is no need for new regulations. Further in this study we will evaluate this claim and establish the rationale behind such executive policy.

Literature Review

In researching agency regulation and biotech trends I have found that there is truly an overwhelming amount of material on the issue. Due to the lack of new policy measures that have been implemented older sources on this topic remain surprisingly useful. Considering this information I have still made a great effort to include mainly sources published within the last fifteen years.

Over time advancements within the realm of agrobiotechnology have taken place to improve the GM crops available to producers. Through the writings of one scholar we are able to

evaluate the advantages in some of the newer GM strains. He goes on to predict that these developments are likely to result in a competitive global market. What had once began with simple pest-resistance has resulted in the ability of geneticists to improve even the nutritional qualities of certain crops. [1]The author goes on to explain the increasing level of complexity of GM strains and their commercial application. Currently the United States is the universal leader in GMO development and dedicates the greatest amount of resources to this research.

Due to a change in the political atmosphere of the food industry interest groups now have different methods of achieving their goals. Traditionally, members of these groups were forced to work through the legislature in order to push their agenda. It is now common for these groups to use the market the achieve policy change. Due to the legislative route being slow and costly it can be more practical for interest groups to seek alternative methods. The author describes the emergence of public interest in the food industry and attributes it to three specific forces. The congestion of legislative channels, increasing demand from consumers, and the domination of only a few conglomerates in the food industry are outlined under this study.[2] Within the past 50 years this industry and the work of interest groups has changed dramatically.

The topic of GM foods cannot be discussed without the inclusion of consumer opinion on the matter. Among consumers there is a much debate over whether or not GMOs are a concern. While some consumers meet GM foods with uncertainty and fear other embrace the wide-variety of goods at low prices.[3] The authors of this passage go on to quantify what factors make certain

[1] Kalaitzandonakes, Nicholas G., "Agrobiotechnology and Competitiveness" *American Journal of Agricultural Economics*- Vol 82, No. 5, Dec. 2000, pp. 1224-1233.

[2] Schweikhardt, David. & Browne, William. "Politics by Other Means: The Emergence of a New Politics of Food in the United States", *Review of Agricultural Economics*- Vol.23, No. 2, Autumn-Winter 2001, pp. 302-318.

consumers more concerned with food safety. This study serves as especially useful as it provides actual consumer experimentation through a unique analytical approach. When breaking down consumer preferences into data and analytics it is noted that many external factors may affect one's opinion on GMOs. This particular study marks the influence of certain demographic factors and lifestyle choices. The authors even suggest that both a fear of GM foods and a blatant disregard for them could be representative of the fact that consumers are simply uneducated.

During this thesis I have also chosen to analyze the characteristics of one crop. By far corn is the most widely-produced crop in the United States. Followed closely by soy and canola, corn is also the largest GM crop in the nation. In particular a stain of GM corn known as Bt corn, or *Bacillus Thuringiensis* corn has been the most popular among producers. This strain has been the topic of many scholarly articles and serves to help narrow the scope of this study. Although the implementation of Bt corn can allow for a diminished risk of pest infestation this technology comes at a cost.[4] When purchasing GM seed farmers must determine whether this greater upfront cost will pay off in the long-run. The Environmental Protection Agency (EPA) works to evaluate this premium cost and its projected benefit.

Like many other industrialized nations, Canada has a more restrictive policy on the use of biotechnology than does the United States. Policy network in Canada calls for a split in regulation between the evaluation of biotechnology and its effect on the environment, as well as the promotion of its use. Thus, in Canada the commercial influence over biotechnology has a

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[3] Baker, Gregory A. & Burnham, Thomas A. "Consumer Response to Genetically Modified Foods: Implications for Producers and Policy Makers", *Journal of Agriculture and Resource Economics*- Vol. 26, No. 2, Dec. 2001, pp. 387.

[4] Hurley, Terrance M., Mitchell, Paul D. & Rice, Marlin E. "Risk and Value of Bt Corn", *American Journal of Agricultural Economics*- Vol 86, No. 2, May 2001, pp. 345-358.

limit. In the Unites States the policy network in place has allowed for a more permissive regulation of biotechnology. This difference in regulatory approach between Canada and the United States reminds of the similar conflict that exists between the US and European Union. [5] This article aims to evaluate the reasoning behind such large policy network discrepancies and explain the potential effects it may have over time. Although our study aims to compare US and EU polices regarding GM food I believe that acknowledging Canada's approach helps to further prove the United States position as an outlier.

Working to further elaborate on global policy differences it is important to recognize how biotechnology has been addressed differently in France and the United States. The debate over the use of biotechnology is central and the transatlantic divide over this issue is reoccurring. The author uses case studies within the two nations to describe the conflict over regulation of this engineering. While France has taken deliberate measures to ensure professional regulation of genetic modification the United States resorts to an industrial method of regulation.[6]
These new biotechnical methods of production have emerged only within the last century and coincide with increased globalization. An interesting topic, the author introduces in his article the possibility of certain genes to hold a predisposition to cancers, especially breast cancer. While this article presents highly controversial ideas it makes valid points for its argument. Also worth mentioning is that over time this difference in policy between nations has grown more tense.

Although I have found value in about every article I've read on the topic of agriculture

[5] Montpetit, Eric. "A Policy Network Explanation of Biotechnology Policy Differences between the United States and Canada", *Journal of Public Policy*- Vol. 25, No. 3, Sep.-Dec.2005, pp. 339-366.

[6] Gaudilliere, Jean-Paul. "Globalization and Regulation in the Biotech World: The Transatlantic Debates over Cancer Genes and Genetically Modified Crops", *The History of Science Society*- 2nd Series, Vol. 21, 2006, pp. 251-276.

and biotechnology, John Hopkins Professor, Adam Sheingate has provided an incredible amount of insight. Not only do his writings go on to detail the evolution of biotech policy, he does well in explaining why a "bifurcated policy" exists in American government.[7] During this study several of his articles are used to elaborate on the role of executive policy in shaping today's agrarian system. In the United Stated policy surrounding biotechnology supports its use in food production but condemns that when used in stem cells and cloning. The author evaluates this discrepancy through analyzing past congressional hearings and the interest of those present. Interest group influence is a prominent theme in these decisions. The author also contrasts the policies of the U.S and Europe when it comes to GMOs. Referred to as a transatlantic divide, the author outlines the ongoing conflict over bioengineering between these nations. While the U.S. pushes their agenda on the safety and efficiency of GMO products Europe remains hesitant to adopt these farming techniques.[8] Through his articles Dr. Sheingate highlights each aspect of American agribusiness and emphasizes the significance of the Reagan Administration at a pivotal moment in GM evolution.

A prevalent conflict between farmers and seed producers, in this case Monsanto, is the issue of seed-saving. This article outlines the debate over patented seed technology and who actually own the rights to subsequent seed generations. The issue arises when a farmer uses seeds that were produced from the seeds of an initial purchase. Seed-saving, a practice commonly used by farmers for generations is now punishable when applying the first sale doctrine. Monsanto argues that this act violates their contract and it's a patent infringement as they own the rights to

[7] Sheingate, Adam. "Promotion versus Precaution: The Evolution of Biotechnology Policy in the United States", *British Journal of Political Science*- Vol. 36, No. 2, Apr. 2006, pp. 243-268.
[8] Ibid.

their genetically modified seed. They believe the farmers have not purchased the right to use these second and third generations of seed. This issue brings up economic concerns for both parties, however threatens the ability of Monsanto to invest in research and development programs. Self-replicating technologies such as seed have recently caused great upset in the realm of agriculture.[9] Opponents of GMOs have used landmark cases such as *Scruggs v. Monsanto* to win public sympathy and paint Monsanto as the ultimate evil in the GM food debate. While unfortunate for farmers, the author provides valuable insight into the reasoning behind the litigation brought by Monsanto.

During the 2012 presidential election California made history as the first state to place a GM labeling initiative on their ballot. Known as Prop 37, or the Right to Know Genetically Engineered Food Act, this would have required some degree of labeling on the packages of foods containing GM additives.[10] Although this item was not passed it did however, receive a great deal of support from voters state-wide. The proposal was rejected by only a slight margin. During the campaign multiple chemical engineering firms and consumer-good conglomerates channeled funds into resistance efforts. Donating over eight-million dollars alone, Monsanto Co. dominated the campaign. Several others including DOW Chemical Company, DuPont, Pepsi Co. and ConAgra Foods also supported the opposition to GM labeling through million dollar donations. Campaigning on the idea that unnecessary labeling would in turn cost consumers higher prices these companies were able to avoid the passage of Proposition 37. This defeat is important in the discussion of modern agriculture as we enter a new election period. It is likely

[9] Savich, Jason. "Monsanto v. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology", *Berkeley Technology Law Journal*- Vol. 22, No. 1, 2007, pp. 115-135.

[10] Adler, Jonathan. "How Not to Label Biotech Foods", *The New Atlantis*- No. 36, Summer 2012, pp. 37-43.

that similar amendments will appear of ballots nationwide during the 2016 season.

In researching this topic I have found that finding reliable and unbiased information is sometimes difficult. I strongly believe that it is important for consumers to be educated on this subject and therefore aim to present this information free of opinion. While there is ample information on this subject matter it is fragmented and near impossible to identify a source that is inclusive of each aspect previously discussed. For instance, journals which have excelled in outlining the chronology of biotechnology fail to mention the economic implications of these advancements. My intent is for this research thesis to fill the gap in material available to the public. Overall, I believe that my final research product will complement the articles and writings that I have studied.

As mentioned previously, I will also predict where American agribusiness is headed based on an analysis of recent trends. Through this forecast I will be able to differentiate my work from that of previous scholars. I believe that this component will be the most exciting and undoubtedly the most original segment of this thesis.

Research Design

The research and topics outlined in this study will be discussed in five separate chapters. In the first chapter I have introduced the variables at work and discussed the significance of studying developments in US agriculture. For the next three chapters I will provide in-depth evaluations about material I believe to be most critical. The first of these chapters will focus on the influence of executive policy during the beginning stages of developing biotechnology. Also in this chapter I will specify the duties of each agency responsible for the regulation of new GM products. Through the second chapter we will focus on the evolution of agrarian biotech

applications. In this chapter I aim to cover mainly the scientific aspects of GM foods and the way in which GM crops benefit producers. During the third explanatory chapter I will compare the approach taken on GM foods between the United States and the European Union. This comparative chapter will also allow for speculation into why such divisive policies have formed. To conclude this study the final chapter will tie together all previously mentioned ideas. I will include my prediction of where our agrarian system is headed in this final chapter as well.

THE REGULATION OF BIOTECHNOLOGY IN AMERICAN POLICY

The regulation of biotechnology has been an interesting topic due to the many discrepancies that exist in this area. By way of technological advancements in the early 1970's, scientists discovered the ability to alter the genetic makeup of species through gene transfer. These initial experiments were met with great hesitancy from government officials. Over time, however, the political atmosphere began to warm to the idea of genetic engineering. Likely this change in attitude could be explained by the realization of profit once these techniques could be commercialized. During the experimental stages of some of the first genetically modified organisms (GMOs), it became clear that the regulation of these new species would be needed. This would eventually lead to the adoption of split regulation under the guidelines known as the Coordinated Framework for Regulation of Biotechnology. Ultimately, this structure gave authority to several federal agencies. In particular; The United States Department of Agriculture (USDA), The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). When evaluating the use of GMOs in agriculture we will focus largely on the role of the FDA.

An important element to point out is the distinction between biotechnology when used in agriculture, and that which is used in the medical field. Biotechnology when used for medical sciences has largely been a source of controversy in the past. Although there has been public outcry over GMOs in agriculture as well, there has been less focus on this industry. Much of the American public is simply unaware or lacking education on the topic. When it comes to the regulation of the biotech industry we are able to see a clear split in policy. This "bifurcated

policy"[11] has been the subject of study for many scholars interested in the field. Through the next chapter we will evaluate how this policy came to be and the impact it has had on agriculture in the US.

The Coordinated Framework of Regulating Biotechnology

The Coordinated Framework, which takes a product-based approach to regulation, is what sets U.S. regulatory policy apart from the process-based approach in Europe. A product-based methodology evaluates only the end result whereas a process-based approach looks at the way in which something came to be. The outcomes of the Coordinated Framework serve to show the advantages the executive branch has over Congress when it comes to matters of policy. While many factors led to the establishment of the Coordinated Framework it was legislation under the Reagan Administration that ultimately gave way to this system that favored commercialized interests over public safety. The resulting regulation of the Coordinated Framework gave the FDA jurisdiction over matters of genetically modified food, food additives, drugs, and medical devices. The USDA oversaw genetically modified plants, animals and animal biologics. The EPA was now responsible for only plants genetically modified to have the properties of a pesticide or micro-organisms intended for non-agricultural uses.

Under the tenants of the Coordinated Framework the FDA was given authority over GM food substances. This included products intended for human consumption along with livestock feed. In order to regulate these genetically modified organisms the FDA used the previously established Federal Food, Drug & Cosmetics Act. Due to the product-based method of regulation previously discussed many of these newly created organisms were regulated no differently than

[11] Sheingate, Adam. "Promotion versus Precaution: The Evolution of Biotechnology Policy in the United States", *British Journal of Political Science*- Vol. 36, No. 2, Apr. 2006, pp. 243-268.

their non-GM counterparts. For the vast majority of these GM organisms they were able to pass through the FDA being "generally recognized as safe", or GRAS, without any substantial analysis. [12]

For as long as a GM product closely resembles an already existing product it will not undergo scrutiny. Under the FDA's FD&C Act the following is stated on the topic:

> "Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive."[13]

This disclosure has caused much concern over the years. Consumers are left to trust the judgement of an agency who ultimately determines the safety of their foods based on its general similarity to other organisms.

Another concept that has gone hand-in-hand with the GRAS method is that of substantial equivalence. The idea of substantial equivalence is much like the product-based GRAS system we have previously discussed. Under substantial equivalence new plant varieties are to be evaluated under the previously established regulations and does not provide a thorough analysis of the new organism. Although the FDA does note that it can be helpful to understand the way a species came to exist; they focus on the actual product itself.

In a 1992 FDA Federal Register entry the administration goes further into detail to explain what is meant by these various terms.

[12] Acosta, Luis, "Restrictions on Genetically Modified Organisms: United States". *Library of Congress*. March 2014.

[13] U.S. Food and Drug Administration, "Generally Recognized as Safe (GRAS)". June 2015.

> "In most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food, such as proteins, fats and oils, and carbohydrates."[14]

Thus, the FDA seeks not to analyze the engineering behind new plant species, but rather serves to prohibit those that would contain known toxins and harmful substances. Due to the near identical genetic makeup of many GM and non-GM crops the two are seen as "substantially equivalent". While the responsibility to properly regulate falls upon the FDA, producers of GM plants can be held liable for unsafe products under the agency's Public Health Service Act. This extra measure helps to ensure that the foods being put out are safe for consumption. To avoid being prosecuted for any wrongdoing, producers are able to meet with FDA representatives before releasing their foods. In theory, the two are able to work together to ensure high standards for the public.

The United States, in its Coordinated Framework, specifies three principles by which the regulation of GM foods must take place. The first of these is that the focus is on the actual product in its end state with disregard to how it was actually produced. The second of these tenants is that where there is no scientifically established risk a new technology will not be discounted or barred. Lastly, the framework states that GM foods will be addressed no differently than those of the same type which are produced through traditional methods.

Bifurcation in Biotech Policy

Due to this division in agencies the jurisdiction of biotechnologies also fell into separate congressional committees. With this separation of powers in Congress also emerged a bifurcated policy over biotechnologies, this was the distinction made between agricultural and medical uses.

[14] Kesler, David. "Statement of Policy- Foods Derived from New Plant Varieties". *U.S. Food and Drug Administration.* April 1992.

When it came to biotechnology used for medical research, legislators often had mixed feelings and took a more precautionary approach. The questionable nature of genetic modification was and still is much more pronounced in the biomedical realm.

> "Scientific breakthroughs in the late 1990s raised additional concerns about the social and ethical implications of biomedical research. In 1997, researchers in Scotland announced the successful cloning of a sheep. The following year, an American scientist derived stem cells from a human embryo for the first time."[15]

These advancements in biotechnology and their frightening likeness prompted overwhelming public concern over whether cloning was ethical in nature. In 2001, President Bush ended federal funding of research into current stem cell projects. By 2003 the House had effectively banned any and all forms of human cloning. Through Bush's presidency many attempts by Congress were made to loosen restriction on embryonic stem cell research. These efforts were largely of no prevail as each one was vetoed by Bush.[16] Much of the American public remained unsure of the ethicality surrounding stem cell research and many felt unsettled by the use of human embryos. In 2008 when Bush completed his second term in office he was replaced by Democratic Senator Barak Obama. Within only a year of assuming the presidency Obama reinstated federal funding of embryonic stem cell research by way of executive order. Since this passing almost a dozen states have passed laws restricting or prohibiting research of this nature.

One of the most interesting aspects of this conflict is the ideological split and polarization among American political parties on this subject. The Republican Party has largely promoted the commercialization of agrarian biotech uses and pushed for their approval from the initial discovery. We can see evidence of this support when the Regan Administration first removed

[15] Sheingate, Adam. "Promotion versus Precaution: The Evolution of Biotechnology Policy in the United States", *British Journal of Political Science*- Vol. 36, No. 2, Apr. 2006, pp. 243-268.
[16] Ibid.

regulatory power from the EPA to ensure that GM crops would be more loosely scrutinized.[17] It is reasonable to hold this administration responsible for the popularity of GM crops today. In hindsight, it is not likely that GM foods would have become so widespread had there been a Democrat in office. When it comes to biomedical uses of genetic engineering the Republican Party has been staunchly opposed to furthering research. Though inconsistent, the positions make sense when considering the Republican platform on free-trade and abortion. On the other hand, the Democratic Party has taken a cautious approach to the genetic modification of plant species. The concern of these individuals is that GMOs have not undergone enough testing. Democrats, who are often more likely to support environmentalism than Republicans, have also expressed concern over the FDA's lax regulation. For example, the agency does not require the producers of GM foods to complete environmental impact statements when releasing new products. However, it has been the Democrats who have brought forth proposals attempting to expand stem cell and biomedical research. Each party is guilty of upholding this double standard when it comes to regulating the use of GMOs.

Consumer Concern over GM Foods

From the very beginning stages of genetic modification many informed consumers have met this technology with hesitancy. The most promonent activists against the integration of GM products into our food system are groups promoting consumer safety and the preservation of environmenal diversity. Most consumers fear GM foods due to a widspread belief that the longterm consumption of GMOs could result in heath defects. This claim is not based entirey on science, as many credible sources have reported no concern with the technology. While many of

[17] Ibid.

those in opposition to GMOsencourage an end to their use, they have chosen to instead target alternative labeling. Inthis labeling effort activist groups have asked grocers and food conglomerates to label products accordingly when they contain GM ingredients. Due to the resistance from food producers activist groups have shifted their energy to move state governments. Through product labeling consumers would be given greater freedom when it comes to what they allow into their homes and bodies. Today's current labeling requirements provide that the attirtributes of the product be detailed but not the method of production. This measure is a step towards tansperency in an otherwise highly secretive industry. In recent years this movement has gained great momentum through legislative chanels.

During the 2012 presidential election California had an important ballot initiaive know as Proposition 37, or the Right to Know Act. If passsed, this law would have mandated the labeling of GM foods and banned any GM food products from being labeled as "natural". Opponents of this act, largely made up of aforementioned conglomerates, argue that this labeling would be costly and cause undue fear in the minds of consumers.[18] Interestingly, the largest campaign doners for those in opppostion of this act were PepsiCo, Coca-Cola, and Monsanto with each supplying over one million dollars in funding. In total those in against the passing of this act donated fourty-eight million dollars, a far cry from the acts supoprters who were able to donate around nine million.[19] When it came to vote Califonia's Propostion 37 was defeated by a margin of 2.8% of the vote. Although this act was not made into law the efforts made are not to be discounted. Those in support of Proppsition 37 were faced with overwhelming odds and managed to recive almost half the vote from constituents. As an increasing amount of consumers

[18] Adler, Jonathan. "How Not to Label Biotech Foods", *The New Atlantis*- No. 36, Summer 2012, pp. 37-43.
[19] "California Proposition 37, Mandatory Labeling of Genetically Engineered Food (2012)". *BallotPedia.*

begin to look into how their foods are produced it is reasonable to specutalte that if an act like this were to be put on the ballot again it may have more luck.

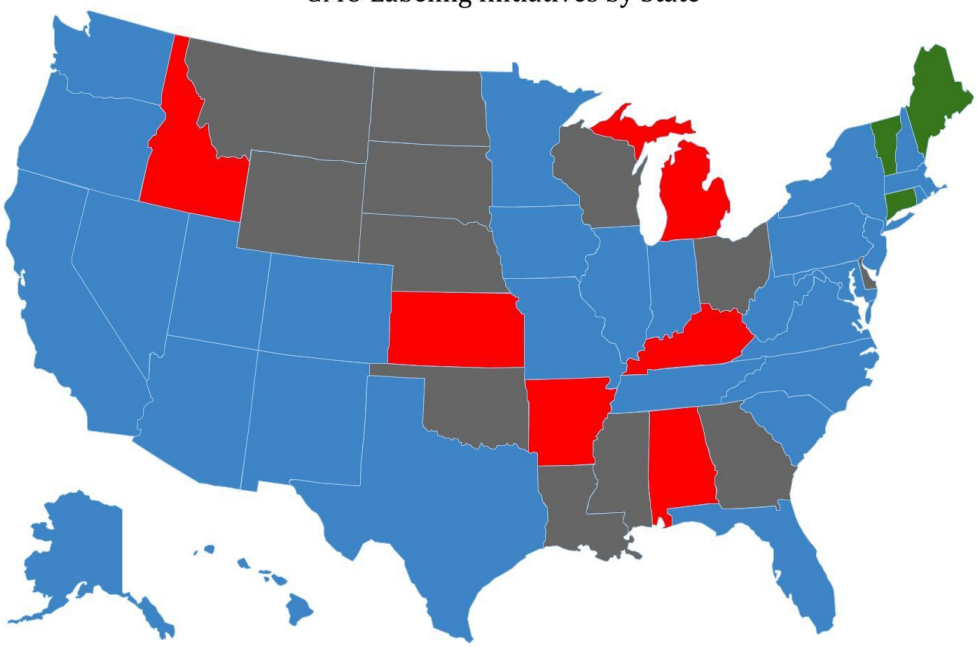
As one of the first major initivates to label GM foods for the sake of consumer empowerment, California's failed act served as a model for other states. It seems that as consumers form their own opinion's on GMOs, the science behind the safety of the technology is becoming increasinly irrelevant. Feeling pressure from constituents the majority of the U.S. has propsed labeling initives at their state level.

GMO Food Labeling Initiatives by State

Due to the inefficiencies of current federal regulatory policy, we are seeing a new trend among many American states. To date, thirty-one of the fifty states have made some effort to pass GMO labeling laws. The majority of these have used bill proposals as a means of accomplishing their objectives. While many have been rejected, these initiatives have brought even greater attention to the issue. The figure below serves to provide a visual representation of recent state actions. In order to create this chart I individually examined recent bill proposals in each of the fifty states. Due to the high prevalence of GM labeling bills, it is important to keep in mind that this data could very easily become outdated in a relatively short period of time. Each initiative has been proposed within the last four years, and it is unlikely that this rapid rate of action will slow. The majority of the states, filled in blue, have made an effort to enact a statewide GM labeling law. None of these states have been effective in their pursuit of labeling transparency, and many have continued to propose more bills of this nature. Each state that has been filled in gray has not attempted to label GMOs, nor have they sought to ban this labeling. The majority of these states lie in the Southern and Midwestern regions of the U.S. The few

states that have been filled in green are those that have effectively passed laws to label GMOs. Although these states passed their labeling bills over two years ago, only Vermont has set a plan of action. Arguably the most interesting aspect of GMO labeling efforts involves the states that have passed laws banning this labeling. Each state in red has been successful in this approach.

GMO Labeling Initiatives by State



There is no all-encompassing explanation for the distribution of these efforts, and each state has some degree of variation. It may be helpful to point out the influence of state economic factors in understanding state action. In several of these red states, namely; Kansas, Michigan, and Idaho, agricultural products make up a large portion of the state's economy. It is possible, accounting for this statistic, that we can better understand the extremely adverse reaction some states have had to GMO labeling. The opposite can also be said of the green states that have enacted GMO labeling. In Vermont, Maine, and Connecticut, the state does not heavily rely on

agriculture to supplement its economy. There is no doubt that the use of GM crops has allowed food producers and farmers to reap greater rewards. Thinking in terms of self-preservation we can assume that these red states are out to protect their own economic interests.

State Mandated Labeling Laws (2014-Present)

One of the most important developments for non-GMO activists occurred in 2014 when the state of Vermont passed the nation's first labeling law. Signed on May 8th, 2014 by the state's govenor, this initiative differed from GM labeling efforts made in other progressive states. Instead of placing the issue on ballots like Califorina and Washington had done in the years prior Vermont opted to create a bill. Although this proposal was passed in 2014 the law is not scheduled to take effect until June 1st, 2016. The tenants of this law are simalr to that of the California's Right to Know Act, as they require the proper labeling of any product containing GM ingredients and also ban these products from being labeled "natural". The Vermont law goes even further as to fine companies if their products are found to be mislabeled. Following the approval of this bill food producers across the nation began to file suit against the state.[20] These groups argue that GM labeling bills are unconsitutional and a threat to their business's success.

Last year the United States District Court for the District of Vermont heard a case that shed light into how courts may decide these controversies. On April 27th the court decided the case of *Grocery Manufactuers Association v. Sorrell*, which resulted in a verdict that largely supported Vermont's labeling efforts. The plaintiffs challenge the legality of the madate under the First Amendment, U.S. Commerce Clause and the Supremacy Clause of the Constituition.

[20] Fusaro, Dave. "Vermont Is First State to Pass a GMO Labeling Law". *Food Processing: The Information Source for Food and Beverage Producers, Industry News*. March 2014.

Under these provisions the GMA alleges that Vermont's labeling laws are a vioation of free speech, interefere with interstate commerce, and attempt to supercede federal inspection criteria.[21] Although the court dismissed these complaints, the GMA filed an injuction to delay the bill from going into effect this June.[22] At this point the court continues to deliberate on the matter and whether this law will remain. It is without a doubt that more lawsuits of this nature will continue to be brought up. Already two other states, Maine and Connecticut, have passed similar bills. These measures have received less attention because they rely on the compliance of several New England area states to also adopt GM labeling laws before they can take effect. The controversy surrounding labeling laws is especially interesting and will serve to set precedent for GM labeling across the nation.

The topic of transgenic foods and the policy affecting GM crops is especially current in today's political climate. In just about every state there are efforts being made to raise awareness of consumer food safety and bills being proposed to legislatures. Although it is not likely to become a point of interest in the next couple of presidntial elections, I see this topic becoming more mainstream within the decade. In this debate both sides have ground to stand and are able to provide valid questions about our constiutional rights. As our nation works toward becoming a more accepting and progessive body it will be interesting to see the future decisions of our judiciary.

[21] Dillard, John. "Recapping Round 1 of the Vermont GMO-Labeling Lawsuit". *AgWeb: Powered by Farm Journal.* May 2015.
[22] Kloster, Andrew. "Vermont Lawsuit a Test Case for GMO-Labeling Laws and the First Amendment". *The Heritage Foundation.* 2015.

GENETICALLY MODIFIED ORGANISMS & THEIR PURPOSE

We can trace the introduction of genetically modified organisms back to the Asilomar Conference held in 1975 in Monterey, California. It was at this assembly that scientists first introduced their findings that they were able to transfer genes from one organism to another. This process, which utilized recombinant DNA (rDNA), raised concerns over its potential impact on the environment and human health. In order to control this new technology the National Institutes of Health (NIH) created guidelines for the safe handling of organisms resulting from rDNA experimentation.[23] These guidelines, issued in 1976, mark the beginning of biotech policy in the U.S. One of the many limitations on this experimentation was the prohibition of any further release of GMOs into the environment. As the development of rDNA transfer and genetic modification evolved, scientists began to discover a commercial benefit to using their modified organisms. After the release of several genetically engineered organisms, the need for tighter regulation became apparent. . Ultimately, it was decided that the regulation of biotechnology and the introduction of these new organisms fell under the EPA's Toxic Substances Control Act of 1976 (TSCA).[24]

While the Reagan Administration was working to promote these biotechnological advancements, environmentalists and precautionary scientists were working to halt the further release of GMOs. The growing public concern over the safety of genetically modified organisms, doubled with an activist-leaning EPA posed a threat to the interests of the Reagan Administration. As a result if this conflict, the FDA and USDA were given authority to help

[23] Vogel, David & Lynch, Diahanna. "The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics". *Council on Foreign Relations.* April 2001.
[24] Ibid.

regulate biotechnology by applying their already established statutes on agriculture. Together, these agencies worked to decide the best possible method of regulation over biotechnology. This authority, referred to as the Coordinated Framework was published in the Federal Register in June of 1986.

> "The manufacture [through biotechnology] of food, the development of new drugs, medical devices, biologics for humans and animals, and pesticides will be reviewed by FDA, USDA, and EPA in essentially the same manner for safety and efficacy as products obtained by other techniques."[25]

Ultimately, once concerns over the introduction of GMOs in agriculture subsided, the legislature began to see an increase in the amount of hearings discussing the use of biotechnology in the medical industry.

Understanding the Purpose of GMOs

In recent years the use of GMOs has become prominent in consumer industries. Often when an organism is modified it is to either; alter the nutrition of a product or, in an effort to disrupt the agronomic properties. Agronomics refers to the economic balance of promoting the greatest possible crop yield while preserving high soil quality. This industry has been vastly broadened within the last fifty years as agrobiotechnology has advanced. Although GM crops are a relatively new technology the use of these strains has dramatically increased over the past couple decades. In 1996 less than 4.5 million acres of GM crops were in existence, yet in 2014, that number had grown to 448 million acres.[26] The introduction of GMOs was certainly met with great hesitancy, however this has not stopped the industry from taking off.

While genetic engineering has been used to improve the nutrition of plant species, the

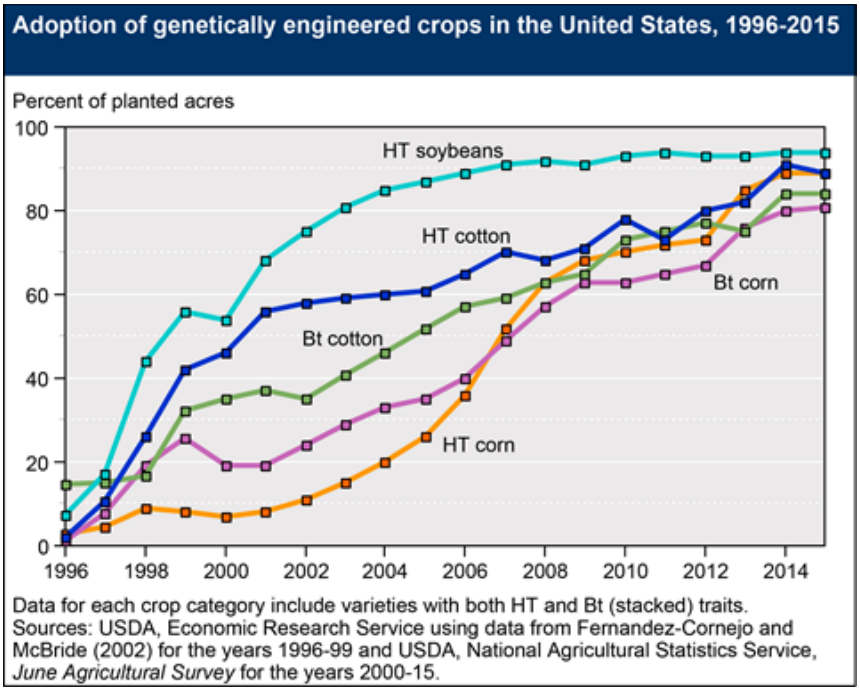
[25] Sheingate, Adam. "Promotion versus Precaution: The Evolution of Biotechnology Policy in the United States", *British Journal of Political Science*- Vol. 36, No. 2, Apr. 2006, pp. 250.
[26] James, Clive. "Global Status of Commercialized Biotech/GM Crops: 2014". *ISAAA*. Brief No. 49. 2014

most prominent use of biotechnology has been to increase crop yield. Risks such as virus, fungi, severe weather and pests can drastically affect the survival of a crop. Through various forms of genetic modification scientists have been able to increase the durability of plant species. When a crop's resistance to these threats increase many other factors change as well. Often, a crop will require less attention and the use of toxic pesticides can be greatly reduced. Other components such as the irrigation of these crops can also be affected. When a crop requires less dedication from producers to survive, the overall costs of production are reduced. This process results in a savings that consumers enjoy at their local grocer. Besides a lesser cost to consumers, GM crops serve as a more sustainable alternative to traditionally produced agriculture. In this aspect both producers and environmentalists can count a win.

Due to Europe's resistance to GM crops, which we will discuss in the following chapter, several other countries have adopted a cautionary approach to GMOs. Critics of this perverse attitude see this as being especially detrimental to the lesser developed countries (LDCs). Many African and South American nations experience starvation and epic rates of chronic hunger among their people. Allowing for nutrient enriched GM crops to be raised in these LDCs could result in a great decrease in hunger and related ailments. The United States outperforms the entire world in terms of agricultural production and this can largely be attributed to GM crops. With a growing world population it is becoming increasingly important to look for new ways to sustain human life. Within the next 30 years the global population is expected to reach nine billion people.[27] Scientists have struggled with how we will address this influx and some have suggested a more widespread use of GMOs. Because many have been lead to be fearful of

[27] Kochhar, Rakesh. "10 Projections for the Global Population in 2015". *Pew Research Center.* Feb 2014.

this technology, it will not be an easy feat to implement this system of agronomics on a world scale. In less than twenty years the use of GM crops has grown astronomically. It is becoming difficult to find American farmers who chose not to utilize this technology. Following the cultivation of some of the most prominent GM crops, the graph below shows a drastic increase in agrarian biotechnology.



A HT crop variety in this graph depicts an organism that is genetically modified to withstand herbicides. One of the most popular HT plant varieties is Monsanto's RoundUp® line. These plants are able to survive a heavy coat of pesticides that would normally kill a non-GM plant.[28] In this process any weeds surrounding the crop will be destroyed.

Although most GM crops provide a cost savings, there are cases where the genetic modification is performed to serve a mere superficial purpose. In 2015 the *Arctic Apple*, created

[28] Cornejo-Hernandez, Jorge. "Recent Trends in GE Adoption". *U.S. Food and Drug Administration.* July 2015.

by Okanagan Specialty Fruits, was approved by the FDA to be sold in the U.S. This apple differs from all others because of its ability to resist natural browning that occurs when being sliced. At this point only two varieties, Grannie Smith and Golden Delicious, have been approved for production. We can expect to see these products in grocery stores within the next couple years as it does take some time to plant and harvest an apple tree. While this particular GM food may not end world hunger, it certainly solves the issue of having undesirable apples slices on holiday fruit platters.

Selective Breeding & Transgenic Alteration

A common misconception about GMOs is that this technology has been used for hundreds, if not thousands, of years. While this statement is not entirely devoid of fact, the truth of this matter is that hybrid seed are often confused with GM seed. The intention of both methods are the same-that is, to create a unique plant strain that meets the needs of its creator. In the case of hybrid seeds farmers cross-breed similar plant species in order to combine the characteristics of the best plants. The process of hybrid selective breeding is incredibly drawn out and may take decades before the new traits can be seen. This method has been used by farmers from the dawn of agriculture and is usually performed through cross-pollination. Without hybridization and selective breeding many of the fruit and vegetable varieties we know today would not be in existence, or even suitable for human consumption. The main issue faced when using selective breeding methods is that the resulting plant species is not able to sustain its properties.[29] Offspring of a hybrid plant are not guaranteed to have the same characteristics as the parent plant and therefore seed-saving practices are less useful. To combat the dilemmas

[29] Michaelis, Kristen. "Hybrid Seeds vs. GMOs". *Food Renegade.* 2013.

faced when using hybrid seeds scientists were able to manufacture GM seeds that would keep their properties through each new generation.

GMOs, sometimes referred to as transgenic organisms, are produced through more advanced methods than selective breeding. In order to attain certain attributes engineers typically gene splice, combining rDNA from one unrelated species with another. This method has been incredibly useful in correcting the faults of traditional farming practices. Out of the few GM crops widely used today the most popular include corn, soybeans, and cotton. Currently, several types of GM tomatoes and apples have been approved by the FDA, but are produced on a much smaller scale. As transgenic organisms and the technology used to create these species advances we can expect to see more types of GM crops in the future.

A Case Study: Bt Corn

Of the various crops produced in the United States annually the largest by a great margin is corn. While corn is a seemingly innocent side dish on the plates of the American public many do not realize the multipurpose utility of the crop. From taking a daily vitamin supplement to drinking a Diet Coke consumers are unknowingly ingesting corn in almost every sitting. Because of the malleable properties of the grain corn has infiltrated almost every facet of food production. Corn, in being incredibly inexpensive, has also led to its central role in the diet of nearly every American consumer. Due to the hearty nature of the plant corn is grown all across the globe, because it is so widely available costs remain low. Interestingly, although the demand for corn is high and seemingly infinite the amount of corn being produced is able to match this demand. Much of the ability of farmers to produce corn in such massive quantities can be attributed to the growing advancements in technology. Through initial crossbreeding and then genetic

modification farmers have been able to increase crop yields and even pronounce certain traits. One of the common strains of GM corn has been named Bt corn, short for *Bacillus Thuringiensis* corn.[30] As previously explained a GM crop takes one or more traits of another organism through gene transfer. In the case of Bt corn this gene comes from a bacterium found within soils. In particular this borrowed gene works to kill the larvae of corn burrowers, which have previously posed a great threat to farmers. A great benefit among growers of the Bt corn strain is that farmers are able to use less or eliminate completely the use of pesticides in their production methods. Due to the highly selective nature of the bacterium only insects of the corn burrower family are killed. In eliminating the use of insecticides in planting Bt corn strains many other insects than pose little or no risk are spared. The photo below shows the effectiveness of the Bt crop in protecting from damage caused by the corn borer.

To the left of this image[31]are corn cobs produced in traditional, non-GMO methods. The corn show obvious signs of damage and will be counted as a loss. The right side of this image shows

[30] Hurley, Terrance. Mitchell, Paul. Rice, Marlin. "The Risk and Value of Bt Corn". *American Journal of Agricultural Economics.* Vol. 86, No. 2. May 2004. pp. 345-358.
[31] *Image Courtesy of DuPont Pioneer Optimum® Leptra® hybrid taken in Lubbock, Texas*

DuPont Pioneer's Optimum Leptra line of Bt corn. This image provides a reader who may not be familiar with corn borers, with a great visual example of their potential to destroy a landscape.

An interesting observation is made when we examine how exactly Bt corn works. Some may wonder how it is possible to pinpoint an exact order of insect. The answer is that through experimentation and extensive laboratory research scientists have been able to target an endotoxin in the Bt strain. This endotoxin takes action once the corn burrower, most often in the larvae stage ingests the corn. Once inside the larvae's stomach cavity the endotoxin begins to eat away at the stomach walls. Eventually the endotoxin eliminates the stomach walls thus allowing normal stomach bacteria to enter the larvae's bloodstream. This outbreak, causing the insect to go septic, is able to kill the larvae in just hours.[32] While quite a miserable death for corn burrowers the Bt corn strain does well in protecting the livelihood of the crop along with other innocent insects.

Cross-Contamination & Seed Saving

A very pressing issue among farmers has been the unintentional spread of GM seed between neighboring lands. This problem arises when a crop that had been grown without the use of GM seed becomes pollinated or otherwise contaminated by near-by GM crops. This is often an issue with the Bt crops strains that typically include cotton, corn and soybean. When a transfer between crops does take place it is normally harmful to the farmer who raised their crop without GM seed.[33] Organic farming requirements prohibit the use of GMOs in order for a product to be certified as organic. Cross-contamination between adjacent fields has the potential to be a financial disaster for organic farmers.

[32] Bessin, Ric. "Bt-Corn: What It Is and How It Works". *Entomology at The University of Kentucky.* Jan 2004.
[33] Belcher, Ken. Phillips, Peter. Nolan, James. "Genetically Modified Crops and Agricultural Landscapes: Spatial Patterns of Contamination". *Ecological Economics.* May 2005.

In order to ensure the integrity of their products Monsanto has developed a coalition of investigators to monitor famers using their seed. Farmers found in violation of Monsanto's terms of use can be sued for contract violations and patent infringements. Being the largest producer of GM seed, Monsanto has earned an unfavorable reputation among environmentalists. A great misconception about the company is that they persecute and sue organic farmers based on inadvertent contamination. This theory is largely unfounded and there are no cases of Monsanto suing a farmer for only trace amounts of contamination in their crops. Recently, the Organic Seed Growers and Trade Association attempted to sue the GMO giant under this premise. The case was overruled and then dismissed on appeal due to the lack of evidence against Monsanto.

While Monsanto has not sought remedies against innocent organic farmers the company has been successful in cases against users of its seed. A practice known as "seed saving" occurs when farmers use the seed product from an initial crop to plant and grow a subsequent year's crop. While this method has been popular among farmers for centuries, those in contracts with Monsanto make agreements to refrain from seed saving. Monsanto claims that this new generation of seed remains patented technology that farmers must purchase. The company serves as an industry leader in agrobiotechnology and keeps its competitive edge through research and development projects.

An instance of Monsanto bringing a case against a farmer in an effort to protect this "self-replicating" technology can be seen in *Scruggs v. Monsanto (2007)*. In this case Monsanto brought civil charges against a Mississippi cotton farmer, Mitchell Scruggs, and his brother Eddie. The pair, whom had previously purchased seed from Monsanto's Roundup Ready® line were suspected of seed saving and then reselling to third parties. Monsanto alleged that the

Scruggs brothers made a precise and very intentional decision to violate their contract when they realized the profit they could incur from resale. In making their defense the brothers attempted to apply the first-sale doctrine to justify their actions. The first-sale doctrine works to limit the scope of a copyright or trademark owner by allowing a purchaser to do as they please with a product post-purchase. The brothers argued that reselling the byproduct of their initial patented seed purchase fell within the limits of this law. In making their decision the federal court ruled that the brothers were, in fact, in violation of Monsanto's terms of use. The first-sale doctrine did not stand due to the extreme financial consequences it could have on Monsanto's future sales. By allowing the Scruggs brothers, and therefore all other farmers, to resell Monsanto seed the court would have given these farmers a chance to directly compete with the company.[34] In their final decision the court awarded Monsanto $8.9 million to account for the misconduct of the Scruggs brothers. To make matters more interesting the brother's insurance policy holder, Farmland Mutual Insurance Company was then sued by Mitchell and Eddie Scruggs following this decision. Refusing to pay the almost nine million dollar settlement, Farmland Mutual stated that the brothers voided their policy when they decided to intentionally commit wrongdoing against Monsanto. The court agreed with Farmland Mutual, however; decided not to force the brothers into paying this remedy. The judge did not see this retribution to be fitting, as the court's initial intention was not to "financially ruin" the Scruggs brothers.[35] Ultimately, *Scruggs v. Monsanto* served to prove the seriousness of infringing on a company's self-replicating technology and the measures the courts are willing to take to protect these rights.

[34] Savich, Jason. "Monsanto v. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology", *Berkeley Technology Law Journal*. Vol. 22, No. 1, 2007, pp. 115-135.
[35] Siegel, David. "Insurer Off Hook for $8.9 Million Seed Patent Verdict. *Law360.* Oct 2014.

The current events taking place in U.S. federal and state legislatures may be indicative of future policy. It will be important to watch these actions in the coming decades. With the majority of U.S. consumers already skeptical of GM foods, there is likely to be an increasing base behind labeling efforts. As many of the states begin to take on this issue we may see GMO labeling policies enacted at a federal level.

A COMPARATIVE PERSPECTIVE ON U.S. & EU AGRICULTURE

Significant differences exist between the regulatory systems governing agriculture in the United States versus those in the European Union. This distinction is extremely pronounced on the topic of GMOs but persists through all aspects of agriculture. As we have mentioned previously, the U.S. has maintained a product-based approach to regulating GM foods. Under the Coordinated Framework for the Regulation of Biotechnology newly developed GMOs were passed through the appropriate federal agency. Today's regulatory system has not seen change since it was first adopted and all agrarian biotechnology continues to be evaluated under this framework. Using methods such as GRAS and substantial equivalence new GM products are typically not thoroughly scrutinized. Typically, unless a product contains a known toxin or substance harmful to human health, the process by which it was created will not be reviewed. The risk assessments that do take place in the U.S. are submitted by the producers that create this technology. Undoubtedly, this raises question over the objectivity of these reports. Overall, the U.S. largely promotes the use of genetic engineering in agriculture, and keeps relatively relaxed guidelines in place to ensure their popularity.

The European Union, which consists of twenty-eight Western European countries, takes a much more precautionary approach on approving agricultural products. It is interesting to note that both the U.S. and EU initially met agrarian biotechnology with hesitancy. Over time however, the EU adopted policies that led to a more limited use of GMOs. In order for a GMO to be approved for cultivation the strain must first pass a thorough risk assessment. To complete this review both the producer of the crop and the European Food Safety Authority (EFSA) must publish their own assessment. It is important to note that the EFSA does not regulate GMOs, and

only makes suggestions on their safety. These assessments test the quality of the proposed organisms as well as their environmental impact.[36] The EU has received a great deal of criticism for their stricter approach to GM foods. EU leaders defend their process in claiming that a higher level of scrutiny is necessary to ensure consumer safety and economic integrity. While several of the EU's member states have placed a ban on the introduction of GMOs within their borders other countries in the EU do utilize agrarian biotechnology. The most popular GM crops in Europe include corn, cotton, and soybean. Through this chapter we will analyze the European regulatory system in its treatment of agrarian biotechnology and its interaction with US policy.

European Union Member States on GMOs

In the United States there has been some objection to the use of genetic engineering in food production. Overseas, the attitude towards GMOs is one that is much more staunchly opposed to their integration into agriculture. In recent years an increasing number of EU member states have banned the entry of GM laden foods into their borders. The countries that have approved GMOs, and allowed for the domestic production of GM crops have faced criticism from their neighbors. In total nineteen of the twenty-eight member states of the EU have decided not to grow GM crops in their state.[37] Although the EU has a much stricter regulatory system than the US many of these member states are distrusting of the EU's ability to ensure the safety of the crops. Public opposition of GMOs is extremely prominent in the EU's member states. Consumers have voiced their concern through protests and flamboyant demonstrations. It is not uncommon for GMOs to be referred to as "Frankenstein foods", and going as far as calling

[36] "Guidance on the Environmental Risk Assessment of Genetically Modified Plants". *European Food Safety Authority.* 2010.
[37] Chow, Lorraine. "It's Official: 19 European Countries Say No to GMOs" *EcoWatch.* October 2015.

agribusiness firm, Monsanto, a "biotech bully boy".[38] Still, while the majority of European consumers are opposed to GMOs the opinion from state to state does vary.

For the duration of this debate over biotech agriculture EU member state, Germany has remained one the more outspoken over its opposition towards GM foods. The country has effectively banned the cultivation of GM corn within its borders, and has adopted stricter laws against GMOs than those that the EU publishes. In 1990 Germany passed its first copy of the Genetic Engineering Act. This purpose of this act was to protect humans, animals, and the environment from any unknown risks caused by GMOs. Another important element of this act was its goal to ensure that both traditionally produced and GM crops would be able to thrive in the same areas. Lastly, The Genetic Engineering Act established the law and guidelines that researchers and producers of GMOs would have to abide by.[39] Since its publication Germany's act has undergone several revisions in order to comply with EU directives.

Although Germany does keep a very strict cap on the release of GM crops into its environment the country allows for a limited amount of GM foods and feed into its borders. The majority of these products are designed for livestock, however, the small amount that are sold to humans are labeled appropriately under EU guidelines. Germany has taken GMO labeling a step further and has allowed for a "No Genetic Engineering" label to be placed on qualifying food items. In order for a product to be approved under this label it must not contain even trace amounts of GMOs. The country has long held resentment towards GM foods, though arguably the most obvious example of their opposition comes in the form of their GMO contamination laws. Under German

[38] Vogel, David & Lynch, Diahanna. "The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics". *Council on Foreign Relations.* Apr 2001.
[39] Palmer, Edith. "Restrictions on Genetically Modified Organisms: Germany". *The Law Library of Congress.* Mar 2014

law, a party found responsible for the spread of their GM crop onto organic or traditional crops may be forced to pay hefty damages. Germany's liability regime also applies to the accidental pollution of adjacent properties.

> "The Act on Genetic Engineering contains a strict liability regime for damage caused by GMOs. Damages are capped at €85 million (about US$117,050,000), and the operators of research or production facilities must obtain liability insurance or coverage through governmental guarantees. Injunctive relief is also available."[40]

This policy should not be viewed as typical for all the EU member states as Germany has remained an outlier in its approach to GMOs. One of the most drastic differences that exists between the US and EU lies in their perspectives on cross-contamination and the coexistence of GM and non-GM crops. Issues arising over the accidental contamination of organic or traditionally produced agriculture by GM crops have been purely a civil dilemma in U.S. courts. Often, there is no outlet for producers of non-GM crops to seek retributions in the U.S. In fact, depending on the amount of contamination in an area the farmer negatively affected by this crossover could be held responsible. Environmentalists have long accused Monsanto of predatory tactics against farmers; however, stories of farmers being wrongly sued are unfounded. Tales such as those of the Scruggs brothers are often circulated and lead to misinformation and fear-mongering.

On the opposite end of the spectrum sits fellow EU member state, Spain, which is the region's largest producer of GM crops. Currently, twenty percent of the country's corn is grown from GM seed. In several regions of the country where the population of corn borers has been especially high, the use of Bt corn has been especially helpful in eliminating the majority of damage caused by these insects. Although European attitudes towards GM crops remain low in

[40] Ibid.

relation to the rest of the developed world Bt corn has helped to strengthen the Spanish economy.

Transatlantic Divide

The terminology "transatlantic divide" refers to the difference in international political economies between the U.S. and Western Europe. While this topic covers many differences between the countries involved we will be focusing only on the aspects that relate to agrarian biotechnology. There is no question that the approaches taken by the U.S. and EU member states are almost entirely adverse. For as long as the U.S. has promoted the commercialization of GMOs the EU has kept a more precautionary attitude. The EU has made efforts to help ease its members into accepting this new technology, however, many states have refused entirely. Operating under the European Commission, the European Food Safety Authority (EFSA) helps to ensure the safety and environmental impact of each newly proposed GMO. The main concerns addressed through European regulation are like those evaluated in the U.S. Each government aims to provide a safe and healthy option to both food producers and their consumers.

The root cause of the differences that exist between U.S. and EU regulation come from the use of product-based and process-based approaches. Earlier we discussed the importance that the product-based approach, which the U.S. had implemented, ensured the promotion of agrarian biotechnology. The EU, keeping in line with their precautionary values, chose to enact a process-based approach to regulating transgenic organisms. Along with this approach the EU has placed an emphasis on the traceability of GM crops. It is the responsibility of famers and food producers to ensure the accurate measure of a GMO's supply chain. Ensuring proper traceability has also allowed for better GMO labeling on consumer products. Throughout the EU products containing

more than .09% of a genetically modified substance must be labeled to notify consumers.[41] The European Commission has suggested that applying these labeling methods and traceability standards help to control any detriments that may arise from the use of GMOs

The Cartagena Protocol on Biosafety

In an effort to regulation the movement of GMO's to and from different countries, the Cartagena Protocol on Biosafety to the Convention on Biodiversity was formed. This treaty among international biotech users, aims to protect organisms natural to the environmental from being compromised by GM products. The members of the Cartagena Protocol must abide my precautionary principles, and favor consumer safety over economic gain. Within its supporting documents the Cartagena Protocol only refers to GM goods as Living Modified Organisms (LMOs).[42] At this point in time the assembly is made up of 170 parties and went into effect in 2003. This figure includes each member state of the EU, as well as developing countries around the world. The fact that the U.S. is not a party to this treaty has been pointed out and questioned in the past. It truly is odd that nation's such as Cambodia and Afghanistan have taken a stronger interest than the U.S. in investigating the safety of GMOs. However, when considering the American interest in promoting the productivity of their agrarian economy this absence becomes clear.

An issue that has arose from the U.S.'s refusal to participate in the Cartagena Protocol on Biosafety centers on trade.[43] Ultimately, the tenants of this treaty greatly affect the quality of goods that parties are able to take in. The inability of U.S. producers to ensure an accurate line of traceability in their exports has been detrimental. Many countries have decided to reject U.S.

[41] "Traceability and Labelling". *European Commission.* Feb 2016
[42] The Cartagena Protocol on Biosafety". *The Biosafety Clearing House.*
[43] Ibid,

agrarian imports because of the inability to determine the genetic makeup of the organism. With the presence of harsh cross-contamination laws in the EU, countries are now hesitant to accept GMOs from overseas.

The divide between the EU and U.S. in regard to agricultural and biotechnology continues to be a contentious debate. The relative absence of corporate interests within the European system of policy is likely to have played a part in the difference between the two bodies. The U.S. was quick to prioritize its own economic wealth, whereas the EU sought to only pass GM legislation when it felt entirely confident in the technology. U.S. politics have long included the influence of corporate interest in policy making, a trend that is not apparent in EU politics. As American consumers push for a regulatory system that models that of the EU, we may begin to see a coming together on this issue between the two.

CONCLUSION

The topic of agrarian biotechnology is an incredibly relevant topic in the life of every American consumer. In only thirty short years this technology has become so widespread that GMOs have now become an integral part of our daily diets. The utilization of GMOs in farming has undoubtedly transformed the industry and allowed for drastic increases in productivity. By adopting a product-based regulatory approach the U.S. was able to capitalize on this unharnessed technology. Ultimately, the U.S. was able to secure its place as a top agricultural producer and continues to dominate the economy today.

The influence of corporate interests the creation of U.S. policy is very prevalent when comes to regulating transgenic organisms. The ability of private interests and multinational corporations to sway policymakers is questionable in its very nature. From the early stages of its creation the Coordinated Framework had already failed its people. This attempt to provide standards for evaluating GM foods was a Band-Aid solution that should have been dissolved decades ago. To date there have been absolutely no efforts made by the USDA or the FDA to conduct independent research on the safety of GM goods. This policy is outdated and only serves to mask the inefficiencies of current federal regulation. Whether or not an individual believes GMOs to be a cause for concern is irrelevant. A greater level of care for consumer health and general transparency needs to be installed within our federal agencies.

Future Research

Through completing this research I feel that I have provided a foundation on which to launch future projects. In my efforts to be all-encompassing of this topic I feel there are many different directions that I may be able to go next. The following are several ideas that I feel

would make interesting research topics:

One future study I would enjoy completing would be to provide a more in-depth analysis of only the state actions taking place. During the time I spent creating the color map I realized the great amount of diversity in each state's proposals. For example, in both of the Carolinas the bill proposals focused exclusively on the labeling of GM dairy products. I found this to be interesting, as no other states mentioned the GM-contamination of animal products. Many of the states who did attempt to pass GMO labeling legislation were not successful. I believe it would be interesting to further examine the tenants of these state's bills and uncovered why they were rejected. I established some degree of correlation between GMO labeling actions and the economies of their state. Namely, I discussed the relation between states with a strong dependence on agriculture and the laws passed to actually ban GMO labeling. A difficulty in executing a study of this nature is the constantly changing actions of legislatures. Due to the relevance and popularity of GMO labeling work it may be a challenge to remain current.

A separate research topic could allow for a greater emphasis on the environmental impacts of industrial farming methods. Environmental law NGOs have become increasingly popular and now serve a vital role in policymaking. With an ever increasing global population it may not be possible for other nations to uphold their precautionary approach to GMOs. The destruction of animal habitats and the exploitation of natural resources are already important issues. Another aspect of this study may involve assessing the effects of consumerism on agricultural demand. This topic also relates to environmental issues associated with agriculture. While this may be less important to the study of political science, I believe this evaluation would serve to be useful. Facing the need to produce at a higher rate than ever before, our environment

could take a devastating hit. Agriculture and animal rearing are the greatest contributors to deforestation and pollution. Although many environmentalists will not admit, GM crops are more sustainable methods of farming than mass produced non-GM crops. This is especially true for the Bt and Ht strains that we have previously discussed. Their abilities to resist pests and herbicides also allow for decreases in water consumption. It will be interesting to see the outcome of policy over the next couple decades, and what the future holds for GM crops.

Lastly, a third related study could assess consumer knowledge of transgenic organisms and their regulation. Through the duration of this study I have encountered many friends and family members who hold strong feelings toward GMOs. Many of these friends are then unable to provide any knowledge of what this technology truly is. Without a doubt, the general public is even less educated on their nation's government. I believe that it would be interesting to conduct a survey that would be telling of an individual's knowledge of this topic. Due to the large role of consumers and activist groups in labeling efforts, this could provide insight into their rationale. This survey could be implemented in a variety of different ways; however, it may be best to utilize Qualtrics for better accessibility and ease. In order to properly gauge consumer awareness, this assessment could provide a variety of questions at different difficulty levels. Some of the items that could be included are as follows:

- What does the acronym GMO stand for? *Low Level*
- Which states, if any, have passed GMO labeling requirements for producers? *Mid-Level*
- What are the top three most widely-produced GM crops? *High-Level*

Once date collection had taken place, an assessment of each participant's level of knowledge could be noted. At the end of the study the average degree of consumer knowledge could be

computed. To make this study more interesting the survey could also ask the individual to estimate their own awareness, along with their level of concern for GMOs. The results of this study would allow the researcher to draw correlations, if any, between passion for GM labeling and their level of knowledge on the topic.

I strongly believe that each of these projects would help to supplement the research that I have conducted. The issues and various topics that involve agriculture and its economic influence are far-reaching. In the past, studying agriculture may have been restricted to biologists and economists. Today, we see the importance of understanding agrarian regulatory policy more than ever before. The changes that take place over the next couple decades will certainly influence the international political economy of the U.S.

Trends & Expectations

I cannot stress enough the importance of future regulatory policy over the use of GMOs. There is no doubt that structural changes will be made to the Coordinated Framework within the next twenty years. Depending of the route that U.S. policymakers seek out, the outcomes of new policy implementation could go in more than one direction.

In this first scenario we will assume that the U.S. government adopts a precautionary approach to regulating GMOs. This would involve regulating new transgenic organisms through a process-based system, and likely stalling the immediate release of new GMOs. State GMO labeling initiatives would become irrelevant once federal labeling laws were passed. This legislation would end the ongoing debate over the labeling of GM foods, and would require that the court system support the labeling laws. After the U.S. began to abide by these precautionary standards, it would be able to join the Cartagena Protocol on Biosafety. By participating in the

Cartagena treaty any trade issues that the U.S. had experienced with other nations would be resolved. This method would be favorable to consumers who wish to see a stricter level of scrutiny, and greater transparency in the industry. The possible negative implications of this method could involve the economic loss experienced by agricultural producers and food group conglomerates. These multinational corporations would suffer the greatest loss as a result of the precautionary principle. It is unlikely that this policy would cause the U.S. to sacrifice its role as a global leader in agriculture. Stripping farmers from their right to access GM crops would also result in great upset and possible lawsuits over the First Amendment. Considering these consequences I believe that this course of action would benefit the U.S. and its consumers the most.

The alternative to the previous situation would involve the refusal of executive intervention, and the failure to pass any new policies regarding GMOs. The federal government would allow for states to handle their own agriculture and the labeling of GM substances. This inaction would result in the continuation of debate over GMOs and their labeling. Keeping the Coordinated Framework in place, the U.S. would experience the same disconnect from the EU and its allies that it does presently. Over time it is likely that this difference in policy would grow more tense. Neither consumer nor producers of GMOs would ultimately benefit from this approach. Due to the controversy over GMOs it is almost necessary for the federal government to step in and end the debate. The self-regulation of agrobiotechnology firms, like Monsanto and DuPont, is no longer seen as an effective form of policy. In order to provide an unbiased evaluation of each new organism, independent research should be conducted.

No matter the outcomes of federal policy in the future, we may expect to see a change in

the popularity of GM crops. Agriculture relies on the demand of the consumers, and when large classes of people begin to avoid a product its only logical that companies adjust. Similar to the U.S. government, even private organizations exist for their people.

Closing Remarks

Entering this study I worried that my opinions may cloud my ability to provide an accurate portrayal of the industry. The issues surrounding the regulation of biotechnology are controversial and questionable. Through the duration of this research I began to see the rationale behind each side of this argument. The policy aspect of agrobiotechnology is what I have found to be most interesting, and I am excited to see the future legislation that will replace the Coordinated Framework. The state action resulting from federal inactivity is a compelling part of the case for GM labeling. It has never been more clear that a new policy approach to GMOs is necessary.

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