An Applied Research Study to Determine if GMO Food Labeling Should Be Mandatory in the U.S.

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Executive Summary

Genetic engineering (GE) involves the manipulation of genes in the lab to create new varieties of plants, animals, and organisms with desired characteristics. Most consumers in the United States are not aware of the amount of GE ingredients in the food they consume. In 2012, GE soybeans accounted for 93 percent of all soybeans planted, and GE corn accounted for 88 percent of corn planted. Most of the GE plants are used to make ingredients that are then used in other food products, such as corn starch in soups and sauces, corn syrup used as a sweetener, corn oil, canola oil and soybean oil in mayonnaise, salad dressings, breads, snack foods, and sugar from sugar beets in various foods. Consumers are concerned that they have been consuming GE foods without their knowledge, and unsure if the GE foods are safe. Consumer polls consistently show that the public would prefer that GE foods be labeled, so that they can decide for themselves whether they should consume these foods.

The FDA regulation of these foods is only a voluntary process in which the producer of the food does their own testing and provides the information to the FDA. The FDA does no testing of the foods. There is worldwide controversy about the safety of GE foods. Over 60 other countries have mandatory labeling, and more stringent risk assessments with independent testing. The purpose of this study was to determine the need for mandatory labeling. The study suggests that GE foods be disclosed to consumers by a product label that provides that information accurately. The study also determined which lawmakers are interested in the regulation. In the U.S., states have been interested in having their own mandatory labeling laws, and a few have passed their own laws. Many states have pending legislation in 2016.

It is recommended that the FDA improve upon the antiquated regulatory process regarding GE foods to suit consumer needs. Update the FDA's regulatory process from voluntary to mandatory, and require additional safety testing from the FDA or an independent source prior to approval of GE foods. Add long-term studies to give a risk management process which would add to transparency.

Chapter 1

Introduction

The health conscious public is concerned about genetically modified organisms (GMO), or genetically-engineered (GE) ingredients in the food they are consuming, and because of the media many consumers are starting to become concerned about GE ingredients that they may be consuming. The purpose of this project is to determine if GE foods should be labeled in the U.S. "Genetic engineering involves the manipulation of genes in the lab to create new varieties of plants, animals, and organisms with desired characteristics" (Senauer, 2013, p. 1). Examples of GE food products are corn, soy beans, sugar beets, aspartame, papayas, canola, cotton, dairy, zucchini, and yellow squash. Since the mid-1980s GE food crops have been grown in field trials, and they have been on the market since the mid-1990s (Kuzma & Haase, 2012, p. 1). They are also referred to as genetically-modified (GM) in certain literature.

Background of the Problem

GE foods have been on the market for over 20 years, and "continue to spark debate" (Kuzma & Haase, 2012, p. 1). The reason for the debate is that there is controversy about whether GE foods are safe. The argument made by proponents of GE foods is that we have been consuming GE foods for approximately two decades without detecting adverse health consequences, so there is no reason to warrant a more regulatory review than conventionally bred food (Kuzma & Haase, 2012, p. 1). On the other side, "opponents argue that we have not been looking hard enough for health consequences and that over long periods of time, low-level consumption may lead to chronic effects that go undetected in post-market

surveillance (Kuzma & Haase, 2012, p. 1). The GE food safety concerns fall into four categories, which are toxicity, adverse nutritional changes, allergenicity, and horizontal gene transfer (Kuzma & Haase, 2012, p. 2).

In the media, we see restaurants announcing that they will only serve non-GMO ingredients, such as Panera Bread and Chipotle. Last year the restaurant chain Chipotle announced that they would only cook with non-GMO ingredients. The Whole Foods grocery chain wants all of their products that contain GE ingredients to be labeled by their suppliers within five years (Senauer, 2013, p. 2) Currently, at most grocery stores consumers are seeing food products labeled Non-GMO, which include a wide range of processed foods to infant formulas. Recently, Campbell's Soup announced that they would label their U.S. products that contain GE ingredients, as well as several other food companies.

Most consumers in the United States are not aware of the amount of GE ingredients in the food they consume (Senauer, 2013, p. 1). In 2012, 93 % percent of all soybeans planted were GE, and 88% of corn was GE planted (U.S. Food and Drug Administration, n.d., p. 2). Most of the GE plants are used to make ingredients that are then used in other food products, such as high fructose corn syrup, corn oil, corn starch in soups and sauces, salad dressing, canola oil and soybean oil in mayonnaise, breads, snack foods, and sugar from sugar beets in many foods (U.S. Food and Drug Administration, n.d., p. 2). So, GE foods are in most of our processed foods. Potatoes, squash, apples, and papayas are other major crops that are GE (U.S. Food and Drug Administration, n.d., p. 2).

Since consumers in the U.S. are not aware of the amount of GE ingredients in food, the argument is made that "consumers have the right to know" what is in the food they

consume (Senauer, 2013, p. 1). The next argument is that "GE crops and foods are still controversial, and opponents of GE foods see risks to health, the environment, and/or the concentration of power in the food system" (Senauer, 2013, p. 1). GE foods are treated like their conventional counterparts, so some do not trust the government regulatory process (Senauer, 2013, p. 1).

Opponents of mandatory food labeling argue that a label might be seen as a warning that GE foods pose a health risk, and that the Food and Drug Administration (FDA) has already deemed them safe (Senauer, 2013, p. 2). Another argument is that consumers can choose to buy organic products if they want to avoid GE foods (Senauer, 2013, p. 2). The problem with buying organic is that it is possible for accidental contamination to occur, for example this could happen because of pollen drift from nearby fields growing a GE variety, and it is not routine to test organic products believed to contain a pesticide or GE organism (Senauer, 2013, p. 2).

Another argument is that "labeling may reduce consumer choice" because in countries with mandatory labeling the stores no longer sell GE-foods and product choice is limited (Senauer, 2013, p. 2). One major argument is that it could be costly to guarantee foods are non-GE, and the separation of GE and non-GE foods would add more cost to the foods that are tested (Senauer, 2013, p. 2). The reason that countries with mandated GE labeling have minimal food labeling costs is because the segregation is easier when the country doesn't produce GE crops (Senauer, 2013, p. 2). Currently over 60 countries require some sort of mandatory labeling of GE foods, which include the member states of the

European Union, Australia, China, India, and Japan, (Senauer, 2013, p. 1). So why is the U.S. behind in GE food labeling?

Since the early 2000's, the issue of mandatory labeling of GE foods has been debated. Many polls show that Americans are in favor of mandatory labeling. More than 25 states have had legislative proposals or ballot initiatives requiring that foods with GE ingredients be labeled (Senauer, 2013, p. 1). In 2002, Oregon was the first state to attempt to require mandatory labeling of GE foods in the U.S. with ballot measure 27 (Senauer, 2013, p. 1). In 2012 California had Proposition 37, which was narrowly defeated by six percentage points. A GE labeling law was passed in June 2013 in the state of Connecticut, but four bordering states need to enact similar regulations for it to go into effect (Senauer, 2013, p. 1). The governor of Vermont signed the first "no strings attached" GE food labeling bill in the nation into law in May 2014 (Ford & Ferrigno, 2014, p. 1). Food offered for retail sale that is GE, or contains GE ingredients must be labeled under the new law which goes into effect July 2016 (Ford & Ferrigno, 2014, p. 1).

Other considerations are that states may pass food labeling laws, but may also face the food industry in lawsuits (Senauer, 2013, p. 2). The state of Vermont is gearing up to be challenged in court (Ford & Ferrigno, 2014, p. 1). The preemption of state law by federal law would be the most likely legal basis of such lawsuits (i.e., the FDA regulations), under which state laws may not conflict with federal ones (Senauer, 2013, p. 2). The issue is complex and legal experts don't know how the courts will rule, and any decision can be appealed (Senauer, 2013, p. 2). There have been other bills in the U.S. Congress that have not passed.

Statement of the Problem

Recently, the big food companies have mounted an aggressive push to head off mandatory labeling of GE foods by states (Jalonick, 2015, p. 1). The bill in U.S. Congress, the Biotechnology Labeling Solutions Act (S2609), authored by Senator Pat Roberts, R-Kan., passed the House but did not pass the Senate. The food industry wants the GMO food labeling to continue to be voluntary. In 2011, there was a legal petition sent to the FDA from the Center for Food Safety that provided a blueprint for a federal mandatory labeling of GE foods (Sciammacco, 2014, p. 1). The FDA has never formally responded to that petition, though the agency has received more than 1.4 million comments supporting the petition and mandatory labeling (Sciammacco, 2014, p. 1). Over 200 companies and organizations have sent letters to President Obama requesting that he fulfill his 2007 campaign promise to label foods made with GE ingredients (Sciammacco, 2014, p. 1). So the issue is, should the U.S. establish legislation that requires mandatory labeling, or should the states continue to pass their own legislation?

Purpose of the Study

This study is to try to determine if mandatory GE labeling laws are needed in the U.S., or if voluntary labeling is sufficient. The criteria for assessing between these two options includes equity and efficiency. Since this is a controversial public health and public policy issue, who should regulate labeling law? This paper will analyze the current regulation, as well as other proposed regulation at the state and federal levels. I will conduct literature reviews on the debate and safety of consumption of GE foods, and research studies on public opinion polls concerning the labeling of GE foods in the U.S, as well as review

what other countries have done in regards to regulation and labeling. The literature will consist of journals, periodicals, and online references.

Importance of the Study

If consumers want to know if "food contains gluten, aspartame, high fructose corn syrup, trans-fats or MSG", they can simply read the label (Center for Food Safety, 2016, p. 1). If consumers want to know if food is from GE ingredients the information is not on the package. This study is important for consumers that are not aware that their food may be a GE product. A consumer can purchase a vegetable oil that states on the front label that it is pure and 100% natural, but when looking at the back label the one ingredient is soybean oil. A consumer may have no idea that 93% of soybean is GE produced in the U.S., which may mean that the product is in fact a GE product. The FDA regulates most of the GE food and does not do any independent safety testing, so "unsuspecting consumers by the tens of millions are being allowed to purchase and consume unlabeled GE foods" without disclosure of it. (Center for Food Safety, 2016, p. 1). The FDA only holds a confidential and voluntary meeting with a GE producer before approving commercialization of their GE food, and they only rely on the data the GE producer chooses to show them (Center for Food Safety, 2016, p. 1).

It is a public opinion that it is the "consumer's right to know (that is, autonomy) what contains GM ingredients…this policy may contradict the principle of autonomy, which in this context the ability to provide to those who want detailed information about genetic modifications made to their food products" (Dizon, et al., 2016, p. R288). Consumers who want information about their food might "believe that food labeling of GM products would

respect their autonomy", giving them the freedom to make their own informed choices (Dizon, et al., 2016, p. R288). Labeling of GM foods increase transparency for consumers who want them. Without a label, food companies continue to sell unidentifiable GM foods to consumers, "which seemingly goes against the ethical principle of autonomy" (Dizon, et al., 2016, p. R289).

Chapter two is a literature review of the history and issues regarding GM foods, which includes aspects of ethics, politics, and environments, as well as the issues regarding the debate on GM food labeling, and who should regulate labeling laws.

Chapter 2

Review of the Literature

"Genetic modification is a special set of gene technology that alters the genetic machinery of such living organisms as animals, plants or microorganisms" (Bawa & Anilakumar, 2013, p. 1035). Genes combined from different organisms is known as "recombinant DNA technology and the resulting organism is said to be genetically modified (GM), 'Genetically engineered' or 'Transgenic' " (Bawa & Anilakumar, 2013, p. 1035).

Some literature on GMOs considers whether the benefits of GMOs outweigh the risks in terms of food safety, long-term consequences to health, environmental effects, and ethical concerns (Bawa & Anilakumar, 2013; Dizon, et al., 2016; Hilbeck, et al., 2015; Khan, et al.,2012; Rajan & Letourneau, 2012; Sayre & Seidler, 2005; Wang, 2012). Other studies consider GMOs to be of no greater risk to health than conventional foods (Journal of International Affairs, 2014; Rios, n.d.; Wang, 2012; Yang & Chen, 2016). A common theme in the literature is a debate as to whether a GMO is biologically equivalent to its conventional counterpart (Andree, 2002; Chetty & Viljoen, 2007; Kling, 2014). Other research frames the debate over GMO foods and labeling as discursive (Andree, 2002; Herrick, 2005; Larrion, 2016). These are the reasons for so much controversy.

Debate

Chetty and Viljoen state that there is a continuing debate among scientists as to whether GE foods are substantially equivalent to their non-GM counterparts (Chetty & Viljoen, 2007, p. 269). Substantially equivalent means that there is no difference between the GMO and the non-GMO except for the transgene (Chetty & Viljoen, 2007, p. 269). They

state that a GM product has patent rights and a transgene, so the two products are biologically dissimilar (Chetty & Viljoen, 2007, p. 269). The reason for the debate is that certain foods, such as oils and sugars can be GE but "contain no transgene or exogenous proteins" (Kling, 2014, p. 1182). These foods are impossible to detect, because they are chemically identical to conventional ingredients (Kling, 2014, p. 1182). Some countries have exempted these foods from GM labeling, but much of the legislation in the U.S. has contained language that they need to be "labeled as [containing GM], not just derived from them" (Kling, 2014, p. 1182).

Still, there remains a scientific debate about the risks of GMO foods, and because of this debate another debate arises, which is the debate of GMO food labeling. So, while the scientific debate continues, there is a common theme in much of the literature regarding the controversy of GMO food labeling and if it should be mandatory, and if so how, which is largely a political issue in many countries including the U.S. (Bawa & Anilakumar, 2013; Chetty & Viljoen, 2007; Dizon, et al., 2016; Herrick, 2005; Kling, 2014; Rios, n.d.; Yang & Chen, 2016). Many researchers discuss the problem of a lack of transparency with GMO foods because they are not labeled (Joss, 2014; Kling, 2014; Kohl, et al., 2015; Rios, n.d.).

According to Andree, the historical background of the regulatory framing of GMOs in the U.S. is based on "manageable risk" , which was instituted because of the "strongly anti-regulatory" Reagan administration (Andree, 2002, p. 171). This manageable risk frame work is government's way of using efficiency as a criteria to determine regulation. In Wright's (1994) writing, "this made way for the 'deliberate release' policies" which were "predicated on the manageability of GMO risks, which allowed for movement of GMOs out

of the lab and into the field" (as cited in Andree, 2002). This was because politicians and scientists wanted a competitive advantage in commercialization (Andree, 2002, p. 171). The frame work for manageable risk was important because scientist "were not actually able to pinpoint where in the host's DNA an introduced genetic construct had taken hold" (Andree, 2002, p. 171). Since there were no signs of major problems, molecular biologists chose not to focus on possible unintentional effects and viewed transgenic organisms as "the sum of their parts and nothing more" (Andree, 2002, p. 172).

According to Hilbeck, et al., there has been a combined effort by GM seed developers, their scientists and journalists, to claim that the GM products are safe, that there is no risk, but other scientists and researchers in a broader community, around the world, have come together to make a statement that there is debate as to whether GMOs are safe or unsafe (Hilbeck, et al., 2015, p. 1). Hilbeck and her coauthors have examined a list of studies and have come to the conclusion that many of the studies are not toxicological animal feeding studies of the type that can provide useful information about the health effects of consuming GM foods (Hilbeck, et al., 2015, p. 3). Among the studies which were "animal feeding studies and reviews of such studies in the list, a substantial number found toxic effects and signs of toxicity in GM-fed animals compared with controls" (Hilbeck, et al., 2015, p. 3). Many studies were short term compared to an animal's life span, so long-term effects were not detected (Hilbeck, et al., 2015, p. 3). There have not been any studies done on human populations, and it has been stated that "trillions of GM meals" have been eaten in the U.S. with no harmful consequences (Hilbeck, et al., 2015, p. 2).

In 1992, the FDA declared that genetically engineered foods are not inherently dangerous by stating that ‘safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used[,]’ do not require special regulation” (Joss, 2014, p. 136). The policy is still in effect today.

Subsequently, The FDA approved the commercialization of the first GM food - the FLAVR SAVR tomato, considering it as safe as conventional tomatoes (National Human Genome Research Institute, n.d.). The literature on GM food’s history in the U.S. generally starts with the Flavr Savr tomato, which was introduced to the public in the mid-1990s, and its beneficial marketing trait was that it had delayed ripening (Bawa & Anilakumar, 2013; Dizon, et al., 2016; Joss, 2014; Khan, et al.,2012; Wang, 2012). According to the NIH website

> the FDA's decision on the FLAVR SAVR tomato - marketed by Calgene, Inc. of Davis, California - marked the first time the agency evaluated a food that was genetically engineered. FLAVR SAVR tomatoes are modified to stay firm after harvest, so they can be left on the vine longer before shipping. The FDA decided the change in the tomatoes was not great enough to warrant mandated labeling describing the alteration (National Human Genome Research Institute, n.d., p. 1).

Since the introduction of the FLAVR SAVR biotechnology has grown exponentially, both domestically and abroad (Joss, 2014, p. 138). The widespread use of this technology has been met with strong resistance from many groups worldwide, and GM technology is so controversial that some countries have called for a ban on these products (Joss, 2014, p. 139). The World Health Organization has named three risks to human health, which are

> allergenicity, the potential for the creation of new toxins or allergens; gene transfer, 'transfer from GM foods to cells of the human body or to bacteria in the gastrointestinal tract [that] adversely affects human health[;]' and outcrossing/crosspollination, the risk that GM seeds could be transferred into conventional crops or wild plants and animals which could have irreversible effects on the ecosystem by permanently changing the environment (Joss, 2014, p. 139).

According to Bawa and Anilakumar (2013) it is very important to know about the advantages and disadvantages of GM foods before we consume them, especially with regard to their safety (Bawa & Anilakumar, 2013, p. 1037). The GE foods are made by inserting genes of other species into their DNA, and this kind of genetic modification is used in plants and animals (Bawa & Anilakumar, 2013, p. 1037). Scientists are working on developing foods that have the ability to alleviate certain disorders and diseases (Bawa & Anilakumar, 2013, p. 1037). Though scientists and biotech companies make sure that there are various advantages to consuming GE foods, a sufficient amount of society is opposed to them (Bawa & Anilakumar, 2013, pp. 1037-1038).

Pros

The advantages of GE foods are that they are useful in controlling the occurrence of certain diseases of the plant (Bawa & Anilakumar, 2013, p. 1038). The Hawaiian papaya was threatened by a virus, but was saved by GE technology. GE foods grow faster than the foods that are grown traditionally (Bawa & Anilakumar, 2013, p. 1038). In addition, these foods are a benefit in places which experience frequent droughts, or where the soil is inadequate for agriculture (Bawa & Anilakumar, 2013, p. 1038). GE food crops can be

grown at places with unfavorable climatic conditions where as a normal crop can grow only in a specific season or under some favorable climatic conditions (Bawa & Anilakumar, 2013, p. 1038). Though the seeds for GE foods are pricey, it is reported that their cost of production is less than that of conventional crops due to the natural protection from pests and insects (Bawa & Anilakumar, 2013, p. 1038). This reduces the need to expose GE crops to harmful pesticides and insecticides, making GE foods free from chemicals and environment friendly as well (Bawa & Anilakumar, 2013, p. 1038). GE foods are reported to be high in nutrients and contain more minerals and vitamins than those found in traditionally grown foods, taste better, and have an increased shelf life (Bawa & Anilakumar, 2013, p. 1038).

Cons

Since GE foods are considered new inventions, not much is known about their long-term effects on human beings (Bawa & Anilakumar, 2013, p. 1038). It is believed that there is a possible risk of consuming GE foods and that they can have harmful effects on the human body, which "cause the development of diseases which are immune to antibiotics" (Bawa & Anilakumar, 2013, p. 1038). As the health effects are unknown, many people prefer to stay away from GE foods, and manufacturers do not mention on the label that foods are developed by genetic manipulation because they think that this would affect their business (Bawa & Anilakumar, 2013, p. 1038). Many religious and cultural communities are against such foods because they see it as an unnatural way of producing foods (Bawa & Anilakumar, 2013, p. 1038). Many people are also not comfortable with the idea of transferring animal genes into plants and vice versa (Bawa & Anilakumar, 2013, p. 1038).

Also, this cross-pollination method can cause damage to other organisms that thrive in the environment (Bawa & Anilakumar, 2013, p. 1038).

According to Bawa and Anilakumar (2013),

> There are controversies around GM food on several levels, including whether food produced with it is safe, whether it should be labelled and if so how, whether agricultural biotechnology and it is needed to address world hunger now or in the future, and more specifically with respect to intellectual property and market dynamics, environmental effects of GM crops and GM crops' role in industrial agricultural more generally (Bawa & Anilakumar, 2013, p. 1035).

Bawa and Anilakumar (2013) state that a health concern that consumers should be aware of with GE technology is that the plants are made to be pest-resistant and herbicide-resistant (Bawa & Anilakumar, 2013, p. 1040). This could lead to the "evolution of resistant pests and weeds termed superbugs and super weeds", which would lead to another problem (Bawa & Anilakumar, 2013, p. 1040). If spraying of herbicides becomes more frequent due to new cultivars, surrounding weeds could develop a resistance to the herbicide tolerant by the crop (Bawa & Anilakumar, 2013, p. 1040). This would cause a change in herbicide or dose, as well as an increase of herbicides on crop plants (Bawa & Anilakumar, 2013, p. 1040).

According to Landrigan and Benbrook (2015), in the United States "widespread adoption of herbicide-resistant crops has led to overreliance on herbicides and, in particular, on glyphosate, which has increased by a factor of more than 250—from 0.4 million kg in

1974 to 113 million kg in 2014" (Landrigan & Benbrook, 2015, p. 694). So, weeds resistant to glyphosate have grown and "are found today on nearly 100 million acres in 36 states", and crops must now be treated with a combination of different herbicides (Landrigan & Benbrook, 2015, p. 694). This raises a new concern about the safety of GE crops, which are that glyphosate has been determined to be a 'probable human carcinogen' (Landrigan & Benbrook, 2015, p. 694).

Another concern is that in 2014, the Environmental Protection Agency (EPA) made a decision to approve a new combination herbicide comprising glyphosate plus 2,4-D, named Enlist Duo (Landrigan & Benbrook, 2015, p. 694). "The EPA anticipates that a 3-to-7-fold increase in 2,4-D use will result" (Landrigan & Benbrook, 2015, p. 694). The 2,4-D is listed as a 'possible human carcinogen' (Landrigan & Benbrook, 2015, p. 694). The possible and probable human carcinogen "classifications were based on comprehensive assessments of the toxicologic and epidemiologic literature that linked both herbicides to dose-related increases in malignant tumors at multiple anatomical sites in animals and linked glyphosate to an increased incidence of non-Hodgkin's lymphoma in humans" (Landrigan & Benbrook, 2015, p. 694). With these developments that were not examined in previous assessments, it suggest that GM foods and the herbicides applied to them may pose risks to human health (Landrigan & Benbrook, 2015, p. 694).

Another problem with GM crops is outcrossing. In 2001, there was a lawsuit in the U.S. because of outcrossing of GM products (Joss, 2014, p. 140). "In re Star Link, a class action suit was brought on behalf of farmers and consumers, listing numerous claims premised upon products liability, negligence, fraud, and breach of express and implied

warranty when GM corn that had only been approved for animal feed use, appeared in maize products for human consumption" (Joss, 2014, p. 140). The maize was found in over 300 commercial retail foods, and consumers who ingested the maize experienced severe allergic reactions (Joss, 2014, p. 140). Public attention and growing awareness to biotechnology and the use of GM products has created a sense of warning and fear of the unknown risks that GM foods can potentially have on the environment and those individuals who unsuspectingly continue to consume such products (Joss, 2014, p. 134).

"Despite the recent history of litigation over cross-contamination of GM maize in the United States and the ongoing spread of these strains abroad, the domestic regulatory system concerning GMOs is rooted in the relaxed risk-benefit approach" (Joss, 2014, p. 145). Since the FDA is tasked with regulating food safety, questions have arisen as to whether they should act to assess the risks of GM foods separately from non GM foods while the debate continues regarding risks to human health, and in the interim, require labeling so that consumers are informed of whether GM ingredients are present and are empowered to decide for themselves (Bashshur, 2013, p. 1). "The FDA and the U.S. Department of Agriculture (USDA) have legal written standards for labeling the composition and ingredients of foods, but they do not currently have any specific requirements to specify if a product contains a GM byproduct" (Dizon, et al., 2016, p. R289).

Theory

Research findings are that the issues around GMO products, and GMO labeling are vastly debated. The research is generally done using case studies. One of the theories that is mentioned often is the theory of transparency in regards to GMO foods and mandatory

labeling of these foods. The value of transparency is that it establishes trust with the consumer, and gives the consumer a choice to make an informed decision as to whether they want to consume GMO products. This is based on the "consumers right to know" many details about the food they are consuming, and not have the fact that it is a GMO product hidden.

Other findings in prior research suggest that the GMO issues are surrounded with complexities and uncertainties, and that more long-term studies are needed. The debate is also viewed from the "theoretical standpoint of risk" (Herrick, 2005, p. 286). "The arguments for more precautionary regulation have been accompanied by demands for more openly democratic decision-making processes around risk issues, rather than simply a reversal of dominant norms" (Andree, 2002, p. 185). This gives more value to equity instead of efficiency. The public values transparency and fairness.

This study will look at public opinion polls in the U.S. to determine if GMO labeling is wanted by the public, as well as how many states have had initiatives that have passed or not passed to determine if the states would want to regulate GMO labeling themselves, since there is not a mandatory federal law. This study will also look at the current voluntary regulation in the U.S. and compare what regulation other countries have in regards to GMO labeling.

Transparency and autonomy are key theories surrounding this issue because the health conscious public are concerned about whether they may be consuming GMO products, and they do not want this fact to be hidden from them. So, those who want more information about their food "may believe that food labeling of GM products would respect their

autonomy, giving them the opportunity to make their own informed decision" (Dizon, et al., 2016, p. R288).

Another issue with transparency is that the companies that produce GM seed do not share their safety assessments of their GMO products, which makes the public distrustful of the process. Most of the literature from proponents of GMO products was not used because the journal article contained a conflict of interest, because the author may have been from the company that produced the GM seed. The FDA relies on what the GM seed producer reports to them to assess the safety risks and no outside source is consulted. GMO technology is controlled by just a very few large companies (Journal of International Affairs, 2014, p. 136). The value of risk assessment and communicating it to the public are important to gain public trust.

Chapter three will include both qualitative and quantitative data. The study will examine the current regulation in the U.S., and make a comparison to other countries. Public opinion polls on mandatory GMO labeling in the U.S., and the number of states that have had legislation will also be examined. Below is a summary of the pro and cons of GE foods.

Pros

Controls disease of plant

Grows faster, and can grow in unfavorable climatic conditions such as a drought

Grows in inadequate soil

High in nutrients

Tastes better, and increased shelf life

Cons

Long-term health effects are unknown

Leads to evolution of superbugs and super weeds due to natural pesticide in the plant

Leads to increase in herbicide

Outcrossing/crosspollination, which could change the environment

Seeds are patented

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Chapter 3

Methodology

Purpose of the Research

The purpose of this applied research for GMO labeling policy is to try to determine if mandatory GE labeling laws are needed in the U.S., or if voluntary labeling is sufficient. Since this is a controversial public health and public policy issue, if labeling is needed who should regulate labeling laws? This paper will analyze the status quo, as well as other proposed regulation at the state and federal levels. This study will review what other countries have done in regards to regulation and labeling to show that there is concern about the issue. The research will also analyze public opinion polls concerning the labeling of GE foods in the U.S to examine public concern regarding the issue.

Research Design

This research design is based on a systematic review that will consists of several different studies that have been conducted during the last several years. Some of the data will be qualitative, such as what kind of regulation is done in the U.S. compared to other countries, and examine the reasons why there is labeling in other countries. The source of this information in this study will be from journal articles and online references, which are listed in the data collection section. There will also be quantitative data on how many countries have mandatory labeling laws from an online reference. Other quantitative data will be how many states in the U.S. have had GMO labeling legislation, compared to federal legislation. The source of information that will be used regarding federal and state bills regarding GMO labeling legislation will be from a policy or research institute with online

data. Public opinion polls will also be examined, and the source will be from various studies that were conducted in the U.S.

Variables and Measurement

Since this is a policy study**, t**he dependent variable is GE labeling legislation, which is important because the study is analyzing how much interest or concern there is for legislation. The qualitative data will be a comparative narrative review of the U.S. and the European Union's (EU) regulatory process regarding GE labeling, as well as why there is labeling using content analysis. This will include two journal articles that describe the regulatory framework of the EU. Two sources that describe the U.S. voluntary consultation process, which are the University of Minnesota's Food Policy Research Center and the FDA. There will also be one journal article that is from the South African Journal of Science that describes the U.S. and compares it to the EU regulatory process.

One variable will be how many countries have mandatory GE labeling laws. This data will be collected from a policy institute that has already conducted the research. The policy institute is the Center for Food Safety (CFS) and they used a map of the world to identify which countries have mandatory labeling laws, and then divided the map into five categories. The first category is GE-free, which is described as an "official ban on GE food imports and cultivation" (Center for Food Safety, n.d.). The next category is with mandatory labeling of nearly all GE foods, as well as a threshold of 0.9-1% GE (Center for Food Safety, n.d.). Then a category with mandatory labeling of many GE foods with the threshold of higher than 1% (Center for Food Safety, n.d.). Another category with mandatory labeling of some GE food, no threshold defined, and numerous exceptions or a vague law (Center for

Food Safety, n.d.). The final category is "no GE food labeling law" (Center for Food Safety, n.d.).

Other variables are the number of bills that have been in federal and state legislation in the U.S. Another variable to include is a timeline, which will be to examine several years of data. The study will examine data from approximately 2012 to 2015, because that is what is currently and readily available. CFS compiled data in 2014 which measures the number of states with legislation, and includes categories of active legislation, ballot initiative, introduced in 2014 (not active), and passed legislation (Molla, 2014). In 2016 CFS compiled another data set of the states, but with different categories, which were enacted, pending, and pending-carryover legislation. (Center for Food Safety, n.d.).

Several public opinion polls will be examined from 2011 to 2015 to determine if the public is in favor of GMO foods being labeled. The cross-sectional data will be collected from various sources such as policy institutes and news media sources that have conducted the research, which are generally online sources. The first poll is from The Mellman Group who conducted a study in November 2015 regarding mandatory labeling of foods. The variables were a demographic of likely 2016 general election voters, favoring "foods which have been genetically engineered or containing genetically engineered ingredients be labeled to indicate that", oppose the requirement, or do not know (The Mellman Group, 2015, p. 1). They also had information on party affiliation.

The second poll is from the Associated Press-GfK poll in December 2014 and had variables of a demographic of nationally representative general population adults age 18 or older, strongly favor, somewhat favor, neither favor or oppose, somewhat oppose, strongly

oppose, not answered, for the variable "requiring food manufacturers to put labels on their products indicating if they contain any genetically modified ingredients" (GfK Public Affairs & Corporate Communications, 2014, p. 3). The third poll is from the Pew Research Center who conducted a poll in August 2014, with variables of a demographic of representative U.S. adults nationwide, with "Checking for GM Food Labeling", always, sometimes, not too often, and never (Pew Research Center, July 1, 2015, p. 127). This survey also included age, gender, race or ethnicity, education, and party or ideology. The fourth survey was conducted in April 2014 by Consumer Reports with variables of a demographic of nationally-representative U.S. adults, consumer preference for standards for GE food, with categories of should meet safety standards, should be labeled, and other (Consumer Reports National Research Center Survey Research Report, 2014). The fifth survey was conducted by the New York Times in January 2013 with a demographic of U.S. adults, and stating "that foods containing such ingredients should be identified" (Kopicki, 2013). The sixth survey was conducted by MSNBC in 2011 with a demographic of over 45,000 voters, and a yes or no to "Do you believe GM foods should be labeled?" (MSNBC, 2011).

Data Collection Procedures

The qualitative data collection procedures are collected from the journal articles that have done research on what the status quo is regarding GMO labeling in the U.S., as well as information from the FDA website. The FDA website will be used since they regulate most of the GMO food, and are the source of the process. The collection procedures are to go online to fda.gov and search for "gmo labeling", and then click on "foods derived from genetically engineered plants". The first two articles are "Consumer Info About Food from

Genetically Engineered Plants", and "How FDA Regulates Food from Genetically Engineered Plants" (U.S. Food and Drug Administration, n.d.). These articles both mention the voluntary consultation process. Another online source regarding the voluntary consultation process is the Food Policy Research Center from the University of Minnesota. This is obtained by Googling "food policy research center", then selecting "policy summaries and analysis" and finally "genetically engineered food". Other qualitative data will be collected on what other countries have done in regards to mandatory GMO labeling and why, which will also be obtained from journal articles previously reviewed in the literature review. The sources are Joss, (2014), and Kohl, et al., (2015) which discuss the European Union's regulations regarding GMO's. The final source compares the U.S. and the European Union, and that is an article by Chetty & Viljoen, (2007).

The quantitative data collection procedures for how many countries have mandatory GE food labeling laws will be obtained from the Center for Food Safety (CFS). CFS is a national public interest and non-profit organization located in Washington DC, which has already conducted this research. CFS's interactive GE food labeling laws map of the world was completed in September 2012, and posted online in March 2013. CFS will continue to update the map as new information becomes available, because the laws change and are open to revision. The data in the map also contains information regarding several categories from a ban on GE food, various mandatory GE food labeling laws, and no GE food labeling law. The various mandatory GE food labeling laws may have a threshold which refers to a percentage of GE content per ingredient in each food item. By clicking on the map and using the cursor the data from each color coded category is displayed. The data will be printed to

indicate the number of countries in each category, because when it is printed the total is shown for each color coded box. A picture of the map will be included.

Data for how many states have GE legislation will also be collected from CFS. CFS currently has data available for 2016. Their website has a state labeling legislation map that is compiled by the Tableau Desktop Public Edition. This map has information from each state and is available in an interactive online format. The information for all states will be downloaded into Microsoft excel and the relevant information will be used in a pivot table to obtain the number of the states with legislation, as well as a pivot chart. The downloaded information for the 2016 state legislation is categorized by state legislation that is enacted, pending, or pending with a carryover. Similar information is available for 2014 which was obtained from The Wall Street Journal. The categories are different than the 2016 map, but the same concept is used. The categories are for legislation that was active, ballot initiative, introduced in 2014 (not active), no legislation, and passed. This will be downloaded into a pivot table and chart as well to see how many states have had legislation.

Data for federal legislation that has been proposed will be collected from the Library of Congress website. A search for "GMO labeling" will be used, because the study is looking for bills that are regarding GMO labeling. Other variables will be used to refine the search, which will be legislation, bills, dates from 2010 to 2019. The criteria are used because those are the limits that the Library of Congress website allows for. This information will be displayed as a gallery view, so that the relevant bills are viewed side by side on one page.

Much of the public opinion polls data is listed by date on the CFS website. This website was chosen because many of the journal articles that were previously examined in the literature review used the center as a reference. Several of the polls listed also contain a link to the data, which will access the polling data. The most recent poll on CFS is from The Mellman Group, Inc., a political research firm, which was conducted in November, 2015. CFS also has a poll from Consumer Union, the policy and action division of Consumer Reports, from June, 2014. Two of the polls are media polls which can be located by google, and they were from The New York Times in 2013, and MSNBC in 2011.

Another poll from the Associated Press is the GfK Public Affairs & Corporate Communications Poll, which was done in December, 2014. There is also a recent public opinion poll that was reported by the Pew Research Center dated July 1, 2015, which examines the general public's view on science-related topics. Chapter 6 of the report is on genetically modified food. The expectation is that there will be a pattern, and public opinion polls will show that the public is concerned about GMO labeling.

Analysis

The qualitative analysis will be a comparison of the U.S. and other countries regulation policies to reach a conclusion as to how much regulation may be needed, or what the alternatives may be. The quantitative data for the number of countries will be analyzed by a comparison as well. The quantitative data for the number of states with legislation will be compared to the number of bills that have been in federal legislation to determine where the interest lies. The public opinion polls will be analyzed by comparing the numbers for and against GMO labeling. Together all of this information will give the study of this policy an

adequate over view of the past few years and current state of this growing issue. Chapter four will report the results, and discuss the implications of the findings.

Chapter 4

Results

This chapter will report the current status quo regarding the voluntary federal GMO labeling in the U.S., and compare that with what other countries have done in regards to mandatory labeling and why. Two secondary data sets of the states that have had GMO labeling legislation in 2014 and 2016 will show how much interest the states have with this issue compared to proposed federal legislation. In 2014, there were 26 states that had GMO labeling legislation. In 2016, there were 17 states with 41 bills that have GMO labeling legislation pending or enacted. Another set of secondary data regarding the number of other countries with GMO labeling laws will show that 62 countries have mandatory GMO labeling laws, and three have a ban. This chapter will also report several public opinion polls that have been taken in the U.S. that show that the public is in favor of GMO labeling laws.

Status Quo

The qualitative data to compare the status quo in the U.S. to other countries consists of a document review using content analysis and comes from journal articles and two U.S. websites. In the current regulation of GE foods, the Food and Drug Administration (FDA) decided to treat GE foods the same as they treat conventional foods, and this policy only asks producers to voluntarily submit data on GE foods to them through a consultation process (Kuzma & Haase, 2012). The FDA regulates human and animal food from GE plants like they regulate all food, and "encourage producers of new foods and food ingredients to consult" with the agency (U.S. Food and Drug Administration, n.d.). In the 1990s, the FDA instituted the Plant Biotechnology Consultation Program to conjointly work with GE plant

developers to help them make sure that foods made from their new GE plant varieties were safe and lawful (U.S. Food and Drug Administration, n.d.). The voluntary consultation program has GE plant developers routinely participate in it by completing a safety assessment of the GE plant and submitting a summary of it to the FDA (U.S. Food and Drug Administration, n.d.). The FDA evaluates the report and after it is determined that the food is safe they finish the consultation with a letter to the developer and that documentation is posted on the Biotechnology Consultations on Food from GE Plant Varieties website for public access (U.S. Food and Drug Administration, n.d.). Food companies are also allowed to voluntarily label foods as non-GE, but the labels must also point out that there is no significant difference between the non-GE and GE product (Senauer, 2013). The European Union, and the private Non-GMO Project have "set a threshold of no more than 0.9% GE content for its certification" (Senauer, 2013). Products in stores that are labeled with the Non-GMO label have been certified by the Non-GMO Project, a non-profit organization in the U.S.

The content analysis of these references consistently show that the FDA process is a voluntary process, which may mean that it is possible that some GE plants may not have gone through the process. The fact that it is voluntary and not required may raise questions for the health conscious public about the safety of the food product. The public may see this process as unsatisfactory. As mentioned earlier in chapter two, the FDA chose to treat GE foods the same as they treat conventional foods, which was a political decision to move along the biotech industry into the market for economic reasons. This is the reason for the relaxed regulation. There was more concern for the U.S. leading the industry and less concern for risk assessment.

Other Countries

Alternatives to a voluntary process are used in many countries. According to Kohl et al (2015), in many countries, GMO products have to undergo a "stringent and science-based risk assessment" before being commercialized, which is a multi-step approach (Kohl, et al., 2015). The approach is to "identify and characterize a possible hazard and to determine the likelihood of its occurrence in order to conclude about a possible risk posed by a certain GMO" (Kohl, et al., 2015). The applicant in charge of applying for the approval of the GMO must provide scientific information to "frame the risk assessment and facilitate the elaboration and clarification of testable hypotheses, and allow risk assessors to provide scientific opinions on the overall safety in order to inform risk management" (Kohl, et al., 2015).

Chetty and Villjoen (2007) state that "a sector of the biotechnology community believes that GMOs are unscientifically over-regulated, while others consider that regulations are insufficient" (Chetty & Viljoen, 2007). They mention that the FDA procedure is only a consultation process that is voluntary, and that "this involves an audit of a risk assessment based on information provided by the biotech company: 'During the consultation process, the FDA does not conduct a comprehensive scientific review of data generated by the developer' (Chetty & Viljoen, 2007). Chetty and Villjoen also state

> In contrast, the European Commission, on behalf of the European Union, requires verification of information provided and may additionally perform necessary food safety and environmental risk assessments before granting approval of a GMO. In South Africa, the Department of Agriculture, through the GMO Act of 1997, also

> performs a risk assessment audit using independent scientific expertise. While some regulatory systems are more stringent than others, it is uncertain which of these is more scientific. In reality, bureaucratic requirements are no indications of scientific content (Chetty & Viljoen, 2007).

According to research by Joss (2014), the EU is at the cutting edge of the GM food battle, they have developed the world's most intricate labeling and tracking system regarding the importation of these foods (Joss, 2014). Their regulation regarding GM technology closely supersedes the internationally suggested approach, following the Cartagena Protocol on Biosafety (Joss, 2014). They have implemented mandatory labeling and traceability rules that institute strict monitoring of GM foods before and after their original release into the market (Joss, 2014). Their regulation on labeling GM foods fall under Council Regulation 1830/2003, which covers all food groups and monitors these products at all phases of their placement in the market (Joss, 2014). The policies are covered

> by the Directive on Genetically Modified Food and Feed, and the Directive on the Traceability and Labeling of GMOs, which mandate that producers label products containing trace amounts of approved GM material by the EU. Under these directives, labels must be placed on any foodstuffs where the GM content exceeds even 0.9% of the original ingredient. Moreover, the regulation requires that food 'consisting of or containing. GMOs be labeled with the words 'this product contains genetically modified organisms' or 'this product contains genetically modified [name of organism(s).]' (Joss, 2014).

The content analysis of the references regarding other countries consistently show that "risk assessment" is the value. The EU, and other countries, use the precautionary principle to regulate GMOs. The risk assessment is based on scientific evidence instead of politics, or economics. They are placing a higher value on risk assessment for environmental and health reasons, which the public may see as a more transparent way to regulate.

Other Proposed Federal Legislation

There have been a few proposed bills in congress, and below are remarks of recent bills. A proposed Farm Bill amendment that would have allowed states to mandate GE labeling if they chose was overwhelmingly voted against by the U.S. Senate in 2013 (Senauer, 2013). In April 2013, another bill was introduced in Congress that would have mandated the labeling of GE foods by federal law (Senauer, 2013).

In 2014 the Safe and Accurate Food labeling Act (SAFLA) of 2015 was proposed in order to keep American-produced food safe, nutritious, and affordable (Dizon, et al., 2016). It would have had these requirements which were

> the SAFLA of 2015 is an amendment to the 1938 Federal Food, Drug, and Cosmetic Act (FDCA), which makes the following provisions for the FDA to regulate: (1) a more uniform labeling system for the premarketing of GM food in the U.S. to avoid labeling inconsistencies in interstate commerce, (2) all new GM crop varieties and products before being commercialized, (3) special labeling for GM products if necessary to ensure their health and safety, (4) the use of the labeling terms such as

'natural' on GM food products, and (5) label claims on products to be certified 'GMO-Free' through the USDA accredited program (Dizon, et al., 2016).

SAFLA was H.R. 1599-Safe and Accurate Food Labeling Act of 2015, and passed the House but did not pass the Senate. The bill would have amended the Federal Food, Drug, and Cosmetic Act process that is already established, and has been named the Deny Americans the Right to Know (DARK) Act by critics. In the summary of H.R. 1599, "The FDA may require a GMO food to have a label that informs consumers of a material difference between the GMO food and a comparable food if the disclosure is necessary to protect public health and safety or to prevent the label from being false or misleading" (Library of Congress, n.d.). The use of a GMO ingredient does not constitute a material difference (Library of Congress, n.d.).

There are a couple of bills regarding the labeling of GE salmon, which the FDA recently approved, that were introduced in the 114th Congress. Another bill 114 S2621 IS would have amended the Federal Food, Drug, and Cosmetic Act, but would have preempted state and law.

To date, there are no national mandatory GE labeling laws and states are starting to enact their own laws. Congress did not pass the bill to let the states require labeling if they wanted to, because that would change the status quo and may undermine the economic interest. A national labeling law would do the same, so that is why it did not pass. either. The SAFLA bill was also intended to keep the status quo and keep the states from passing labeling laws, and was lobbied for by the big food industry. This is all evidence that the federal government does not have an interest in mandatory labeling laws.

Quantitative Data on States with GMO Legislation

The quantitative data on states with GMO legislation shows that in 2016 there are currently 41 bills in 17 states. The states of Vermont and Connecticut have one bill enacted. The state of New York has 16 bills that are pending. Rhode Island has three bills pending, and Maine has three bills of which one was enacted and two are pending. Several states have two bills pending. Those states are Alaska, Minnesota, Missouri, New Jersey, and Tennessee. Seven more states have one bill pending, which are Arizona, Iowa, Illinois, Indiana, Massachusetts, Ohio, and Oklahoma. There were 33 states with no legislation. The chart is below (see fig. 1).

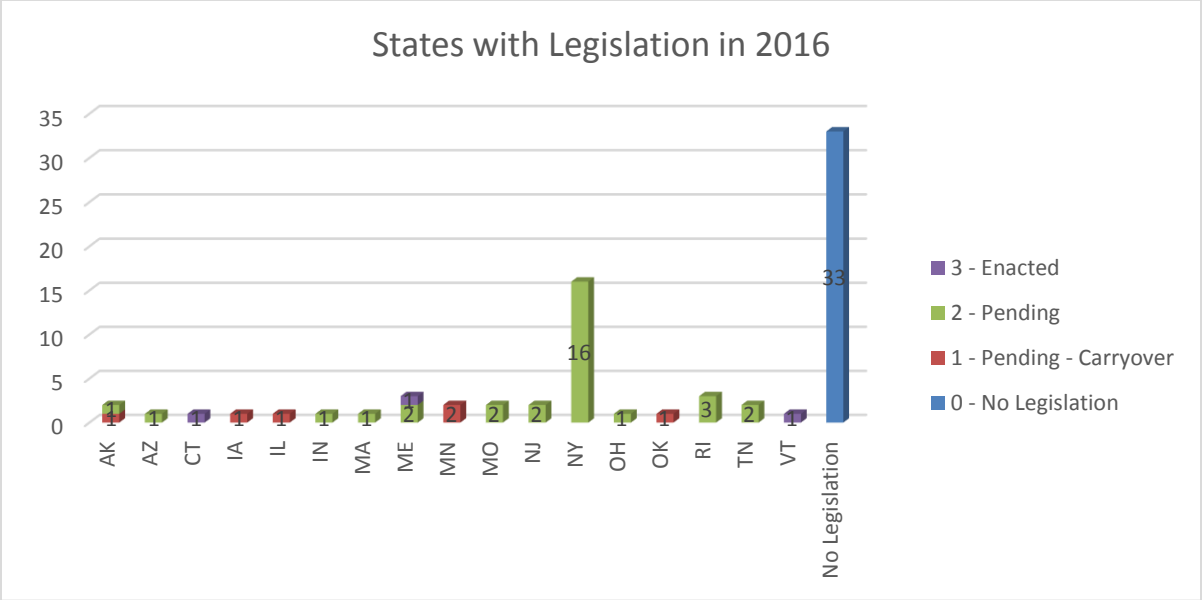

Figure 1, Source: Center for Food Safety, 2014

This means that 34% of the states had legislation regarding mandatory labeling of GM foods. Of the 41 bills, 7% were enacted, 78% where pending this year, and 14% had a pending carryover. Since Vermont and Connecticut have already passed laws, and New York had 16 bills, it is possible that the liberal states may be leading the way in this trend. It

is also possible that the farming states that grow GM foods would not support this legislation. But overall, the states seem to be more interested in mandatory labeling.

Previously in July 2014, The Wall Street Journal reported the quantitative data on states that were considering labeling for GMO foods. The limitation of this data is that it only collected which states had legislation, and did not report if the state had more than one bill, so the data is represented differently than in 2016. Of 26 states, three had passed GM labeling bills, which were Connecticut, Maine, and Vermont as previously reported. There were six states that had active legislation, which were Illinois, Massachusetts, New Hampshire, New Jersey, Pennsylvania, and Rhode Island. Colorado and Oregon had ballot initiatives. Fifteen other states had legislation introduced in 2014, but not active. The state of New York was one of them, and may have had more than one bill. So this leaves 24 states with no legislation. The chart is below (see fig. 2).

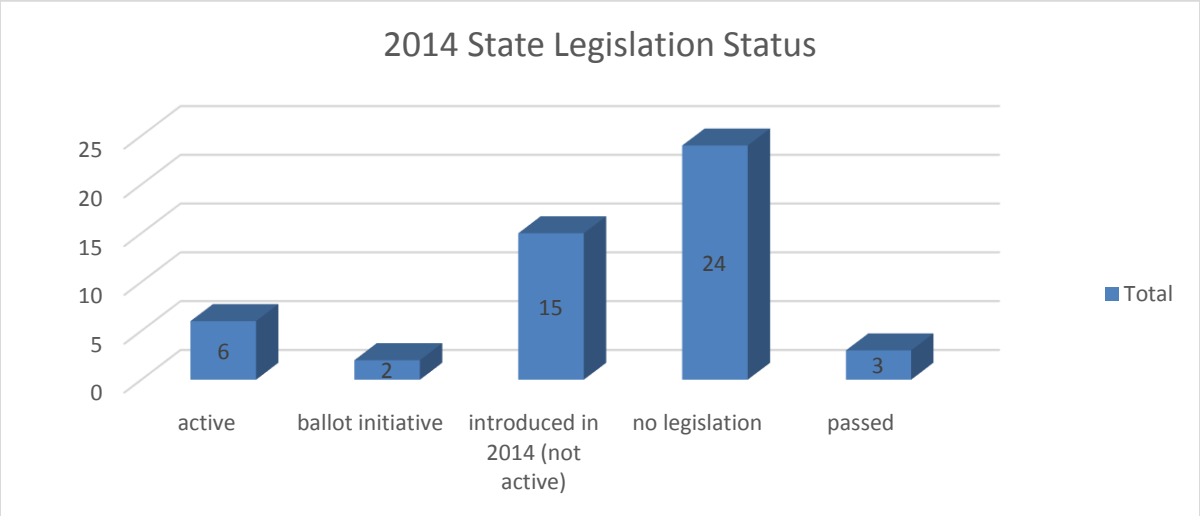

Figure 2, Source: Center for Food Safety 2014 Map (as cited by The Wall Street Journal)

This means that collectively over 50% of the states had some sort of mandatory GM labeling legislation in 2014. Of the 26 states, 7% were by ballot initiative, 11% had passed legislation, 23% had active legislation, and 57% had introduced legislation. This also means that state law makers are interested in the issue, because a smaller percentage was from ballot initiatives. Two years later the states are still concerned about the issue.

Quantitative Data on Other Countries

The quantitative data on the number of other countries that have some kind of GE labeling law from the Center for Food Safety shows that three countries have an official ban on genetically engineered (GE) food imports and cultivation (Center for Food Safety, 2016). The three were Benin, Serbin, and Zambia. The map shows that 37 countries have "mandatory labeling of nearly all GE foods and a labeling threshold of 0.9-1% GE content" (Center for Food Safety, 2016). This included the European Union, Russia, Saudi Arabia, and Australia. The next category of "mandatory labeling of many GE foods and a labeling threshold higher than 1% or undefined, and the 1% is for the entire food item" shows that 10 countries are currently using this regulation (Center for Food Safety, 2016). China, Japan, Kenya, and South Korea were included in this group. The last category with "mandatory labeling of some GE foods, but with numerous exceptions and no labeling threshold defined; or a vague mandatory GE food labeling law that lacks implementation and enforcement provisions" of which some of the included countries were India, Thailand, and Vietnam (Center for Food Safety, 2016). The map is displayed below (see fig. 3). The blue represents a ban, dark green the 0.9-1% GE content labeled, green with 1% or undefined, light green with mandatory labeling of some GE foods, and gray with no mandatory labeling laws.

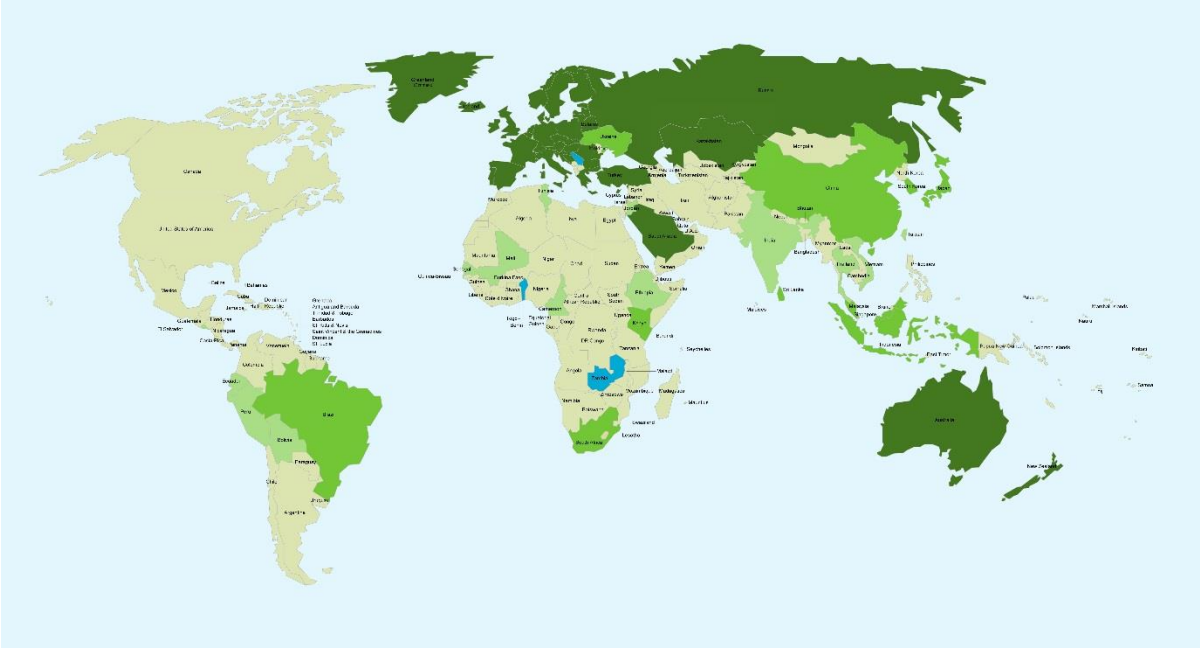

Figure 3, Source: Center for Food Safety, 2016

The limitations of this data is that it does not explain why different countries have different policies. It only shows what other countries are concerned with mandatory labeling of GM foods and the strength of the policy. It may also imply that if a U.S. company imports food products to a country that has mandatory labeling requirements the food product will be labeled.

Quantitative Data from Public Opinion Polls

A political research firm, The Mellman Group, Inc., conducted the most recent survey in 2015, and it was reported that "nearly all voters continue to want GMO foods labeled" (The Mellman Group, 2015, p. 1). The poll was taken by 800 likely 2016 voters, and 89% said they favored mandatory labels on foods which have been genetically engineered or that contain genetically engineered ingredients be labeled to indicate that, and only 6% opposed and another 6% did not know (The Mellman Group, 2015, p. 1). The views were widespread

across demographic lines, with practically all Democrats (92% favor, 2% oppose), Independents (89% favor, 7% oppose) and Republicans (84% favor, 7% oppose) supporting a mandatory label (The Mellman Group, 2015, p. 1). The survey was conducted by mobile and landline phones November 16-19 using a national registration-based sample (The Mellman Group, 2015). "The margin of error for this survey is +/-3.5% at the 95% level of confidence" (The Mellman Group, 2015, p. 1).

The Associated Press-GfK poll that was conducted in December 2014 reported that 66% of respondents strongly favored, or somewhat favored that food manufacturers label their products indicating if they contain any GM ingredients (GfK Public Affairs & Corporate Communications, 2014, p. 3). "The data were weighted to account for probabilities of selection, as well as age within sex, education, race, and phone type" (GfK Public Affairs & Corporate Communications, 2014, p. 11). The survey was conducted using a "web-enabled KnowledgePanel®, a probability-based panel designed to be representative of the U.S. population" (GfK Public Affairs & Corporate Communications, 2014, p. 11). The survey polled 1,010 general population adults, with "the margin of sampling error" being " plus or minus 3.4 percentage points at the 95% confidence level" (GfK Public Affairs & Corporate Communications, 2014, p. 11).

The Pew Research Center, which is a nonpartisan fact tank that informs the public about the trends, attitudes, and issues shaping the U.S. and the world, conducted a poll in 2014 (Pew Research Center, 2015, p. 3). The report showed that because information about GM products is voluntarily provided on some food products approximately half of U.S. adults report that they always (25%) or sometimes (25%) look to see if products are

genetically modified when they are grocery shopping (Pew Research Center, 2015, p. 127). Public attention to GM labels is approximately the same across education, science knowledge, and party or ideology (Pew Research Center, July 1, 2015, p. 132).

The Pew survey also reported that there were no statistically significant differences on the safety of eating GM foods between Republicans and those who lean toward the Republican Party as compared with Democrats and those who lean toward the Democratic Party (Pew Research Center, 2015, p. 129). It was also reported that 57% of U.S. adults thought that GM foods were unsafe to eat (Pew Research Center, 2015, p. 129). This report also included, age, gender, race and ethnicity. More women (65%) thought that GM foods were unsafe than men (49%) (Pew Research Center, July 1, 2015, p. 127). The attitudes about GM foods are roughly the same amoung both younger (ages 18 to 49) and older (50 and older) adults (Pew Research Center, July 1, 2015, p. 128). The survey reported that 68% of blacks, 65% of hispanics, and 53% of whites thought that GM foods were generally unsafe (Pew Research Center, July 1, 2015). Education and science knowledge were also factors in regards to the safety of eating GM foods. One education group had a majority that said GM foods are generally safe or unsafe by a margin of 57% to 38%, and they were the ones with a postgraduate degree (Pew Research Center, July 1, 2015, p. 128).

This survey also asked about the safety of foods grown with pesticides. It was reported that 69% of Americans thought it was unsafe to eat foods grown with pesticides (Pew Research Center, July 1, 2015, p. 137). Gender, age, race and ethnicity were also factored in, and the patterns of attitude on this issue were similar to those on the safety of eating GM foods (Pew Research Center, July 1, 2015, p. 137). This survey was conducted

by landline and cellulare telephone in August 2014, and relied on data from a representative sample of 2,002 adults nationwide (Pew Research Center, 2015, p. 2).

Consumers Union the policy and action division of Consumer Reports conducted a phone survey in April 2014. The survey was taken from a nationally representative sample of 1,004 adult U.S. residents by Opinion Research Corporation through its CARAVAN Omnibus Survey (Consumer Reports National Research Center Survey Research Report, 2014, p. 2). The survey showed that 92% of consumers thought that "before genetically engineered food can be sold, it must be labeled accordingly and meet government safety standards" (Consumer Reports National Research Center Survey Research Report, 2014, p. 2).

A media poll conducted by the New York Times regarding GMO labeling in January 2013 reported that "93 percent of respondents" said that "foods containing such ingredients should be identified" (Kopicki, 2013, p. 1). This was a national telephone poll conducted over four days, which included 1052 adults and had a margin of sampling error of plus or minus three percentage points (Kopicki, 2013, p. 2). Another media poll taken in February 2011 by MSNBC (2011) asked over 45,000 voters if they "believe genetically modified foods should be labeled" showed that 96% said yes (as cited by Center for Food Safety).

Combined these surveys show that the public is generally in favor of mandatory labels on GM foods, or foods with GM ingredients. Over half the public thinks GM foods are unsafe, and that half look to see if the product has a GM ingredient. With the exception of post graduates that thought they were generally safe, which may mean that the general

public needs to be proactively educated on the subject instead of just seeing what the media reports.

Implications and Discussion

The implications of this study are that the U.S. regulations on GM foods and labeling are relaxed compared to other countries. Many other countries take a more precautionary stance on GM foods and label them because of this. There have only been a few federal bills regarding GM labeling, but the states have had numerous bills. The state law makers have a higher interest in labeling GM foods.

The largest stakeholder is the public, which are concerned consumers, parents, and health advocates. Public polls consistently show that the public would prefer that GMO foods be labeled. This is because transparency is an important value that the public wants. The public does not want the government or large corporations to appear that they are deliberately not telling them something. The consumer would want transparency because it would establish trust and respect the "consumers right to know" what kind of food they are consuming. The public is also concerned that there is not consensus on the safety of GMO foods, and because of the potential risk they want to decide for themselves if they should consume GMO foods.

Other stake holders are the producers of GMOs, and the food companies. They are concerned that mandatory labeling may affect their business in a negative way. They have also spent millions of dollars trying to fight GMO labeling. This makes the public more distrustful, confused on the issue, and wondering what the companies are trying to hide. The

companies that were against California's Prop 37 spent over 45 million to defeat it. They most likely would have spent less money just changing their packaging, which they are starting to do anyway. Companies frequently change their packaging and update them for marketing purposes.

Chapter 5

Conclusions

Summary

This study conducted a review of the status quo in the U.S. in regards to voluntary GMO labeling, and also reviewed what other countries have done in regards to mandatory labeling. The study also reviewed how many states have had GMO labeling legislation compared to federal legislation that has not passed. Public opinion polls were also examined, which showed that the public is in favor of mandatory labeling.

Conclusions

The results of this study show that the public is wanting transparency when they go to the grocery store to purchase their food. The public opinion polls consistently showed that the public is interested in knowing about the food they consume. Recently, in 2015, 89% of the people polled said that they favored mandatory labels on foods that have been genetically engineered. The Associated Press poll in 2014 showed that 66% of the public polled strongly favored, or somewhat favored GMO labeling. The Pew Research Center poll in 2014 showed that about half of U.S. consumers look for GM labels while shopping. The poll from Consumers Union in 2014 showed that 92% of consumers wanted GM labels and government safety standards. Other polls from the New York Times and MSNBC showed that over 90% of the public thought that GM foods should be labeled.

Over 62 other countries have mandatory labeling requirements with various regulations that may have a different GM threshold for the percentage of GM content. Many

other countries had a mandatory more stringent risk assessment than the U.S. voluntary risk assessment.

Within the last few years there have been many states in the U.S. that have had mandatory GM labeling legislation. With three of the states passing legislation to require mandatory labeling. The state of Vermont was the first to pass the no strings attached law, which is set to go into effect in July 2016.

It is intuitive to think that once Vermont's labeling law goes into effect that other states will want to have the GMO labeling law as well. Maine and Connecticut need two other states to come on board to have their labeling laws go into effect. This shows that the states are willing to collaborate on the issue and should lead the way. They are not trying to make the issue complicated for food companies. This should create a domino effect with the states. There are already several large food companies that are starting to change their labeling on a nation-wide basis to comply with the new Vermont law. This is because it is more cost-effective to have one label change instead of several for each state. The evidence shows that the states are more interested in providing the regulation for mandatory labeling. The states have had more legislation than there has been in federal legislation. The federal government is not interested in passing mandatory labeling law, so the states should continue to pass their own laws if they chose to do so. This is how the public will be able to see a true and accurate food label in the grocery stores.

Recommendations

This GM food and labeling controversy is because of the lack of scientific certainty. It is recommended that the states continue to pass their own laws for mandatory GM labeling laws, since the FDA only has a voluntary consultation program that does not verify the safety of a GM food. The federal regulation is inadequate. If the states and the public wait for federal legislation to become adequate it could be a long wait. Until the public has certainty that GM foods are safe, they should have the right to a food label to help them make their own choice about which foods to consume. The public should not have to bear the burden of uncertainty. Mandatory food labeling is needed because of the fact that there is not a reliable safety system in place.

Other recommendations are that the FDA change the antiquated regulation to better fit the biotech industry. They should do some additional safety testing, or a longer term study instead of just relying on what the producer tells them. Labeling of GM foods will provide an awareness, but there should be some education provided to the public about GM foods instead of keeping the fact that a product is a GM food hidden from them. The FDA should make more information available to the public. It is recommended that the FDA improve upon the antiquated regulatory process regarding GE foods to suit consumer needs. Update the FDA's regulatory process from voluntary to mandatory, and require additional safety testing from the FDA or an independent source prior to approval of GE foods. Add long-term studies to give a risk management process which would add to transparency. Food safety is important to the public and they should have confidence that the food they are buying and consuming is safe.

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Appendix A

CSU Bakersfield
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Institutional Review Board for Human Subjects Research

Date: 6 April, 2016

To: Lisa Rey, Master of Public Administration

cc: R. Steven Daniels, Public Policy & Administration
Roseanna McCleary, IRB Chair

From: Isabel Sumaya, Research Ethics Review Coordinator

Subject: Protocol 16-42: Not Human Subjects Research

Thank you for bringing your **Protocol 16-42**, **"GMO Food Labeling Policy Research",** to the attention of the IRB /HSR. On the form, "*Is My Project Human Subjects Research?*", received on April 5th, 2016, you indicated the following:

> I want to interview, survey, systematically observe, or collect other data from human subjects, for example, students in the educational setting. **NO**
>
> I want to access data about specific persons that have already been collected by others [such as test scores or demographic information]. Those data can be linked to specific persons [regardless of whether I will link data and persons in my research or reveal anyone's identities]. **NO**

Given this, your proposed project will not constitute human subjects research. Therefore, it does not fall within the purview of the CSUB IRB/HSR. Good luck with your project.

If you have any questions, or there are any changes that might bring these activities within the purview of the IRB/HSR, please notify me immediately at 654-2381. Thank you.

Isabel Sumaya, University Research Ethics Review Coordinator