Spring 5-5-2016

What Do We Know About GMOs: A Comparison of Regulations and Labeling in the United States and Netherlands

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WHAT DO WE KNOW ABOUT GMOS: A COMPARISON OF REGULATIONS AND LABELING IN THE UNITED STATES AND NETHERLANDS

By

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Submitted in Partial Fulfillment

of the Requirements for

Graduation with Honors from the

South Carolina Honors College

May, 2016

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Table of Contents

Thesis Summary

My Maymester trip to Amsterdam inspired my study of a comparison or regulations and labeling of genetically modified foods in the United States and Netherlands. The United States has no laws specifically created for the regulation of genetically modified foods, but GMOs are overseen through a coordinated effort of three governmental agencies: the FDA, the EPA, and APHIS. On the other hand, GMOs are specifically regulated in the Netherlands under the European Commission.

The United States does not require any sort of labeling for genetically modified foods. The only government issued seal to certify a product is free of GMOs is the USDA organic symbol. However, a product must meet several other regulations to obtain this certification. In the Netherlands, labeling of genetically modified foods is required in order to ensure traceability of the product. 163 other countries throughout the world mandate the labeling of genetically modified foods as well.

The safety of genetically modified foods is one of the most hotly contested topics to date. Animal studies have shown mixed results and there have been differing interpretations of data. Many scientists who have spoken out about negative effects of GMOs have received a large negative response, especially from powerful companies with strong economic investments in GM products. The Factor GMO study is currently being

conducted in an effort to remedy this situation. It is set to be the largest long-term study on GMO safety and is being conducted by researchers with no previous bias against or for genetic modification.

Through my experience and research, I strongly believe that genetically modified foods should be labeled until there is a clear consensus in the scientific community about their safety. We do not want to put the health of people and the environment in jeopardy because we did not take the time to carefully study the effects of genetic modification before introducing these organisms into the world.

Introduction

When I was eighteen, I was diagnosed with several food sensitivities, which sparked my interest in nutrition and its impact on health. I became fascinated with research on how the food we eat can influence everything from immune functioning, to energy levels, cognitive functioning, and the incidence of chronic diseases. When I learned about a Maymester in the Netherlands, which focused on food, sustainability, and health; I immediately knew that I had to go on the trip. The idea of being able to experience another culture while learning more about topics that I am deeply passionate about captivated my attention.

My Maymester experience in the Netherlands is one that I will always treasure. I relished in the opportunity to immerse myself in another culture and also consider how it differed from my own in the United States. During the course, I was able to examine the differences in how food got from farm to table in each country. In our class lecture, we discussed the history of US Agricultural and Food Policy. One thing that struck me was seeing how the size of farms increased at about the same rate as number of farms decreased in the United States. In contrast, Amsterdam has been able to maintain smaller family farms. America has become dominated by large corporations, which may be due to the need to feed a much larger population. The average size of farms in America today is 441 acres, as compared to 64 acres in the Netherlands ("Agricultural Fact Sheet" and "Agricultural Census in the Netherlands"). However, some smaller sustainable farms are beginning to come about such as City Roots in Columbia. Our class was lucky enough to take a guided tour before we left for our trip and learn more about their sustainable agricultural

practices. While in Amsterdam, we also got to visit a biodynamic farm called City Farm.

Although the farms shared several values and practices, they also had several differences. Both farms had a strong focus on sustainability, environmental responsibility, and using traditional plant breeding techniques rather than genetic modification. At City Farm, they relied on different animals and plants in order to avoid using pesticides. They use red clover as a vitally important cover crop to add nitrogen to the soil, just like City Roots does in Columbia. They also use the red clover as feed for the cows at City Farm because it provides them with the protein and other nutrients that they need to thrive. Some of the cows are slaughtered and their meat is sold. However, the cows' main purpose at City Farm is to produce the manure that is necessary to fertilize the land where all the fruits and vegetables are grown. Bees are also an integral part of the farm for pollination. I thought it was wonderful to see how all parts of the system worked together naturally with humane treatment of animals and farming without the use of chemicals.

City Farm also had many technological innovations that were not used at City Roots. At City Farm, their tractor is equipped with a special piece that removes weeds from between the crops making use of a GPS system so that it can get incredibly close to the crops without harming them. Another innovation was the use of solar energy to power machines in which workers lay down and pick any excess weeds as it moves by slowly. I loved seeing the use of technology for sustainable purposes, rather than just for the sake of progress and efficiency. I hope that farms

across the globe can follow the example of City Farm and learn to incorporate technology in a way that works with the environment, rather than against it.

One of the most striking things that I noticed dining out in Amsterdam was that their menus were much more transparent and offered many more healthy options than those at the restaurants I have visited in the United States. The food at the restaurants in the Netherlands was free of GMOs unless otherwise specified on their menu, unlike at home in the US where no labeling is required. A café near our hotel called Bagels and Beans provided a wealth of information on their menu. There were symbols on their menu for organic, sustainable, animal friendly, and fair trade. There was also information about where they sourced their food listed in the back of the menu. One café we ate had options ranging from local grass-fed meat to organic ice cream. Another café called Greenwoods menu stated that their eggs were all organic and they even had gluten free bread. They have delicious loose-leaf tea from a company named Van Geels and Co. that only uses herbs that are 100% pure and natural in their tea. They also served fruit and vegetable juices made fresh in the restaurant. We also went to a "fast food" restaurant that was very different than in the U.S. Everything was organic and made fresh right in front of you. I got a delicious beet salad and meatballs with curry sauce, which is definitely not something you could find on the menu at McDonald's or Burger King in the United States. However, many fast food chains that began in the United States are also available in the Netherlands, but to a much lesser extent. The United States has 224.7 fast food outlets per million people, while the Netherlands has only 29.2 fast

food outlets per million people ("Fast Food Nations"). From my experience, it seemed that the majority of the restaurants we ate at in Amsterdam sourced quality ingredients and wanted their customers to be aware of this. On the other hand, I feel like a great preponderance of restaurants in the United States buy the cheapest ingredients possible in order to make a larger profit and would rather keep their customers in the dark.

In Amsterdam, we also had the opportunity to visit a fish auction and learn about a new program to promote sustainable fishing practices called Fish Tales. It is a project to get fresh fish on ice in supermarkets and also supply consumers with information about the fisherman and how the fish were caught. I think that keeping the consumer informed and educated is one of the most important factors in convincing people to buy sustainable fish. If they have the information and feel a connection with the fisherman, I believe that people will be more likely to buy sustainably caught fish, even if it does cost a little bit extra. This helps fisherman to make a fairer wage and also has advantages for the health of the consumer. I hope this program is successful and is able to spread to the U.S. and other countries across the globe.

Another experience which I greatly enjoyed was the food truck festival in Westerpark called Rollende Keukens, which means "rolling kitchens" in English. The food trucks were all so elaborately decorated. They had a much greater variety of types of food, from donuts, to barbecue, to Mexican, and Italian, than I have seen at food truck festivals at home. I got Jamaican jerk chicken with fried plantains, which were quite delicious. I also got an organic red smoothie with beets, berries, apples,

and coconut water. At Rollende Keukens, I noticed many more organic and vegetarian options than at food truck festivals I have attended in the United States. There were also some interesting food trucks ,such as one that sold crickets on a stick, which I had never seen in America.

The most startling difference between the Netherlands and the United States that I noticed in lecture and through my own observation was in food regulation, especially in regards to organic and genetically modified foods. I was intrigued and began to wonder what caused these dissimilarities and speculate about the impacts they could have on each country. This study is designed to articulate the similarities and differences in food regulations related to organic and GMO foods in the United States versus the Netherlands and to identify factors that contribute to these differences. The main goal of this study is to explain, through research and my own observations, the need for more comprehensive research and labeling of GM foods.

What do GMO and Organic mean?

The official definition of genetically modified organisms (GMOs) given by the World Health Organization (WHO) states that GMOs are "organisms (i.e. plants, animals, or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination" ("Frequently Asked Questions," 2016). The Netherlands, which is a member state of the European Union (EU), and United States agree upon this definition, however, the Food and Drug Administration (FDA) in the US Prefers the term "genetic

engineering" to "refer to genetic modification practices that utilize modern biotechnology" ("How FDA Regulates Food," 2015).

The two main methods for production of genetically modified foods are recombinant DNA technology and reproductive cloning. Recombinant DNA technology involves splicing a particular gene or gene segment and removing it from one species, so that it can be inserted into the DNA of another organism. The goal is to isolate a particular gene from the donor and introduce it into the genome of the host. Therefore, the favorable trait from the donor will then be expressed in the host. Reproductive cloning involves removing the nucleus of a donor organism and implanting it into the cytoplasm of the host cell (from which the original nucleus has been removed). The result is an organism that contains the exact same genetic material as the donor organism (Diaz, 2015).

The EU and US are in close agreement about organic food standards. Organic farming focuses on sustainability, the preservation of biological diversity, and respect for the environment. The use of synthetic pesticides, herbicides, and fertilizers are prohibited. Any food classified as organic is prohibited from any form of genetic modification, however any GMO is not necessarily considered organic ("Producing Organic," n.d. and "What is Organic?," 2011).

How Are GMOs regulated in the United States and Netherlands?

GMOs regulated in both the United States and in the Netherlands, however their approaches are radically different. For a GMO to be approved for sale as food and

feed in the EU, an application must be submitted to a competent national authority. The application must include information such as toxicological reports, all relevant studies, and plans for post-market monitoring. The national authority has two weeks to make a decision and if the application is approved, it is then sent to the European Food Safety Authority (EFSA). The EFSA performs a risk assessment and makes a summary of the application available for the public to view. The EFSA assigns the environmental risk assessment (ERA) to an EU member state if the application covers cultivation. The ERA report is then sent to the EFSA for review. Risk of the GMO is assessed by the Panel on Genetically Modified Organisms in three major categories: effect on human health, the environment, and safety of animals ("GMO Authorizations", 2016). The Panel on Genetically Modified Organisms is an independent group of scientists who are experts in their respective fields ("Panel on GMOs," n.d.). This process typically takes six months and the consensus is published in the EFSA journal. The EFSA then presents their conclusion to the EC and the Member States. Their determination is also made accessible to the public, who has 30 days to post their thoughts on a website. The Commission has three months after receiving the EFSA's decision to present it to the member states for approval or denial. A majority of national representatives of the member state in the Standing Committee on Plants, Animals, Food, and Feed must approve the final decision. The authorization is valid for a maximum of 10 years and can be renewed ("GMO Authorizations," 2016).

The United States does not have any legislation that specifically addresses GMOs. The regulation of GMOs is a coordinated effort of several government

agencies. The Plant Protection Act (PPA) stipulates that the Animal and Plant Health Inspection Service (APHIS) has the power to regulate the movement of any organism in order to prevent " introduction into the United States or the dissemination of a plant pest or noxious weed within the United States ("United States Code," 2014). GMOs generally fall under the category of "plant pests or potential plant pests and as regulated articles." A plant pest is defined as any organism that "can directly or indirectly injure or cause disease or damage in or to any plants" ("United States Code," 2014). A regulated article is defined as "any organism which has been altered or produced through genetic engineering… and meets the classification of plant pest" ("Code of Federal Regulations," 2013). APHIS approves the introduction of genetically modified plants by a notification procedure, permit procedure, or determination of non-regulated status.

If a plant meets certain guidelines, the applicant may follow the notification procedure. These requirements include the plant is not categorized as a noxious weed, the donor DNA has been "stably integrated" into the host, the expression of the gene that has been introduced is well understood and does not cause plant disease, does not produce an "infectious entity," or encode substances that are toxic to other organisms, the introduction of the gene is not likely to generate a new virus, and the genetically engineered plant does not contain any animal or human pathogens ("Code of Federal Regulations," 2013). APHIS can accept the notification or if it is rejected; the applicant must follow the permit procedure. The permit procedure is much more in-depth and must also include detailed information on the host and donor organisms, the genetic information which was isolated, the engineering techniques and process, date and location of release into the

environment, and field test reports ("Code of Federal Regulations," 2013). If the permit is accepted, the permitee must follow the agreed upon conditions and the GM plant is still subject to inspections by APHIS. In order to gain non-regulated status, the person must provide APHIS with evidence including information on the donor and host organisms, scientific literature, experimental data, field test results, and any known potential risk in order to support why the plant should be exempt from regulation.

In the United States the Food and Drug Administration (FDA) is the agency that regulates food, animals, drugs, and biological products. In the Federal Food, Drug, and Cosmetic Act (FFDCA) GM food falls under the umbrella of "food additives." However if a substance is "generally recognized as safe" by experts, it does not fall under this classification. The FFDCA defines a food additive as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" ("United States Code," 2010). A person must petition to the FDA for a food additive to be allowed for retail to consumers. The petition must include all exploratory and supporting data on the additive, chemical identity and composition, suggestions for use, intended effects, methods for determining the amount used in food, and reports of the investigations of the safety of the additive. The Secretary can then decide the appropriate conditions for use, maximum allowed quantity for use in food, methods for addition, directions for labeling and packaging and accept the additive; or the Secretary can deny the use of the additive altogether.

If a food is "generally recognized as safe" however, it does not have to go through this stringent petition process ("United States Code," 2010).

Most GMO's are considered by the FDA to fall under the category of "generally recognized as safe." This means that GM foods are allowed for sale without being scrutinized by the FDA in the same manner as "food additives." The FDA's Statement of Policy on foods derived from New Plant Varieties in 1992 states that "the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used" ("Statement of Policy," 1992). This statement sets the precedent that the FDA's focus in evaluation of GM foods is focused mainly on the product, rather than the process by which the food is engineered. The document states that the portions of food that result from genetic engineering are "substantially similar to substances commonly found in food, such as proteins, fats and oils, and carbohydrates" ("Statement of Policy," 1992). Only if a GM ingredient "differs significantly in structure, function, or composition from substances found currently in food" is it not considered to be GRAS ("Statement of Policy," 1992). Congress implemented the GRAS category of food additives because "subjecting every intentional additive to FDA premarket review was not necessary to protect public health and would impose an insurmountable burden on FDA and the food industry ("Statement of Policy," 1992). It is left up to the company creating new food additives discretion to decide whether premarket approval is necessary.

The Environmental Protection Agency is the authority in the US that monitors pesticides and microorganisms created through the process of genetic

modification. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) gives the EPA the power to regulate the sale, distribution, and use of pesticides. For a pesticide to be used and sold, it must first go through a registration process. The applicant is required to disclose the formula of the pesticide, whether it will be classified for general or restricted use, statement of claims (and a description of experiments and results to verify these claims), directions for use, and labeling information. If the Administrator believes that the information supplied is valid, labeling complies with the EPA's requirements, and believes that the pesticide will "perform its intended function without unreasonable adverse effects on the environment," it is approved ("United States Code," 2013).

How is Organic Food Regulated in The United States and Netherlands?

Unlike the regulation of GMO's, the EU and United States are much more closely aligned in their regulation of organic foods. The EU Organic Program is the regulatory agency for organic products and the regulating body in the US is the National Organic Program (NOP) under the United States Department of Agriculture (USDA). In 2012 the EU-U.S. Equivalence Agreement was adopted allowing for organic labeling reciprocity between the United States and member states in the EU in order to prevent having to obtain two separate organic certifications to meet both program's standards. This agreement states that organic certifications given by the USDA National Organic Program and the EU Organic Program are equivalent to one another. The two stipulations to this agreement are that for US exports "Tetracycline and streptomycin were not used to control fire blight in apples and pears" and for EU

exports “antibiotics were not administered to animals” (“The EU-U.S. Organic Equivalence Cooperation,” 2012).

Although this agreement has been established, there are subtle differences between EU and US policy. The NOP covers personal care products, while the EU Organic Program only regulates food and feed. Also, in the EU individual member states are given the authority to set up their own government agencies to regulate organic certifications. However, in the United States the NOP is the sole body responsible for monitoring the organic certification agencies in the United States. The regulation of the methods of production in the EU and US are also slightly different. In the US, forbidden methods of organic production are stated, while in the EU only those production methods that have been permitted are listed. With respect to antibiotic administration for organic animals, there is also a discrepancy between the US and EU. In the US an animal given any antibiotics cannot be classified as organic. On the other hand, in the EU it is mandated by the government that farmers must give antibiotics to sick animals. The animal can be given antibiotics up to three times in one year and still be considered organic by the EU Organic Program. The requirements for organic labeling in the EU and US are the same, but with slight variation. For a product to be labeled organic in both the EU and US, it must contain at least 95% organic ingredients. The US also has an additional label stating a product is “made with organic” ingredients, and only requires that the product contain 70-95% organic substances (“The EU-U.S. Organic Equivalence Cooperation,” 2012). Overall, the EU and US agree on the main tenets of organic production and regulation, with slight nuances between the two.

Labeling of GMOs in the United States and Netherlands

Labeling of GMO's is also addressed differently in the United States and Netherlands. In the EU traceability of products is required which "enables tracking GMOs and GM food/feed products at all stages of the supply chain." The farmers and producers are required to label the product in such a way to notify the consumer that it has been genetically modified. If the food contains less than 0.9% of genetically modified ingredients, there is no label required. Companies can also elect to apply for a GM-free labels to further ensure consumers that particular standards have been met to ensure the purity of their food or feed ("Traceability and labeling," n.d.).

In the United States there is no requirement for the labeling of GM foods. The Genetically Engineered Food Right-to-Know Act has been proposed as an amendment to the FFDCA. The bill calls for the "prohibit[ion] [of] the sale of food that has been genetically engineered or contains genetically engineered ingredients, unless that information is clearly disclosed ("H.R.913 - Genetically Engineered Food Right-to-Know Act," 2015). The Bill was introduced to the House in February of 2015 and referred to the Subcommittee of Health, however no further actions have been taken. The only label given by a government agency that assures a food is not genetically engineered is the USDA organic seal. However, in order to gain this status a product must meet many additional requirements besides solely being free of any genetic modifications.

The non-GMO project is an independent non-profit organization in North America to which companies can voluntarily submit their product for screening for

GMOs. The screening process takes four to six months to complete. The non-GMO project requires that any human food, supplements, or personal care products must contain less than 0.9% of genetically modified ingredients in order to gain their seal of approval. If the appropriate standards are met, a non-GMO verified symbol can be placed on the product in order to inform consumers ("Non-GMO Project," n.d.).

Are GMOs safe to eat?

There is a glaring lack of independent, peer-reviewed published literature on the long-term health effects of GM foods. The following studies are included to illustrate this point and demonstrate why the subject of GMOs has been so hotly contested. Currently, bias and inherent flaws in research design have made it nearly impossible to examine the effects of GM foods on health. The entanglement of politics, economic interests, and science has created a catastrophic mess that has left everyone perplexed.

Dr. Arpad Pusztai was regarded as an expert on plant lectins and funded $1.6 million pounds by the British government to carry out research on the effects of consumption of potatoes, which were genetically modified to express the lectin *Galanthus nivalis* agglutinin (GNA) ("Why I Cannot Remain Silent"). In his experiments, rats were divided into three groups and either fed a diet containing: GM potatoes, non-GM potatoes, or non-GM potatoes with a GNA supplement. The rats fed the GM potatoes demonstrated a significant increase in mucosal thickness in the stomach after only 10 days that was due to the "expression of the GNA transgene in the potato" (Ewen and Pusztai, 1999). Pusztai also found a significant decrease in the organ weights of the mice fed with GM potatoes over a longer period of time. Before

publication, Pusztai spoke out about these results on TV's World in action. Pusztai felt it was his civic duty to let the public know now, rather than waiting a few years until his results were published that the foods they were eating could have potential negative impacts on their health. His study was funded by British taxpayer dollars and he felt the people had a right to know. He was not prepared for the unprecedented level of backlash that his 150-second segment would receive. Pusztai was banned from speaking publicly, his research was halted, and his contract was not renewed. Several unfounded criticisms including accusations that he never even conducted the studies were made and The Royal Society, a major scientific academy in the UK, condemned his work. However, despite this scrutiny some of these results were published in the highly distinguished journal the Lancet in 1999. Pusztai's data passed six reviewers, which is four more than is typically required. In 2005 the Federation of German scientist presented Pusztai with the Whistleblower award for his courage to speak out, even when it was unpopular ("Why I Cannot Remain Silent," 1999).

Monsanto, an enormous agrochemical and agricultural biotechnology corporation, conducted a 13 week study on the effects of feeding Sprague-Dawley rats with grain from Roundup Ready® corn which is tolerant to the herbicide glyphosate. This study was conducted in order to provide evidence to food safety authorities that the GM corn was " as safe as food produced from conventionally bred crops." The researchers concluded that their were no "biologically meaningful" differences in health between rats fed the grain from GM corn and the control group that was fed the grain from non-GM corn (Hammond, 2004).

However, independent researchers reviewed the results of this study and found

that there were actually "statistically significant differences in multiple organ function parameters, especially pertaining to the liver and kidneys, between the GM and non-GM maize-fed group" (Seralini, 2012). In response, Seralini and his colleagues conducted a similar experiment to that of Monsanto, but over the course of two years, instead of just 13 weeks. This allowed for the examination of the long-term effects of GM feed on Sprague-Dawley rats. They also included four conditions, including one control: non-GM maize cultivated without Round-up and three treatment conditions: non-GM maize with a Roundup supplement, GM maize cultivated with Roundup, and GM maize cultivated without Roundup. This allowed the researchers to determine whether any effects were due to the genetic modification, Roundup, or both (Seralini 2012).

Liver abnormalities were 2.5-5.5 times more likely in the treatment conditions than in the control condition. Significant chronic kidney deficiencies were found in all of the treatment conditions. Mice in the treatment condition had an earlier onset and greater size of tumors when compared to mice in the control condition. Many endocrine glands were also affected in the treatment conditions, which led to severe disruption of hormone levels. Mortality rate was also significantly greater in female rats in all treatment conditions and in the groups of male rats fed with GM maize than in the control condition (Seralini, 2012). However, the study was critiqued for using too few mice and an absence of proper statistical analysis ("The Seralini GMO Study," n.d.). A year after its publication

and coincidentally after a former Monsanto scientist was appointed to the journal's board, *Food and Chemical Toxicology* retracted the study ("The Goodman Affair," 2013).

Because of the backlash towards scientists studying GMOs, such as Seralini and Pusztai, many scientists have been reluctant to study the effects of GMOs directly. However, an indirect way of studying GMOs has emerged through the study of herbicide toxicity. One large problem with herbicide-tolerant GM crops, such as the Roundup ready corn studied by Seralini, is that they have been linked to increased herbicide use (Hilbeck, 2015). Glyphosate is one of the most common herbicides used throughout the world. It is an active ingredient in Roundup weed killer produced by Monsanto (Cressey, 2015). The World Health Organization (WHO) classified glyphosate as a "probable carcinogen" in 2011 ("JMPR," 2015). Increased use of glyphosate on GM crops may lead to increased rates of cancer and could potentially cause a myriad of other negative health effects.

Recommendations for future Research

The results of these studies, although not perfect, are shocking and shed light on several flaws in the regulatory process of GM food. I believe that it should be required for an independent research team to verify the safety of all GM foods. Large corporations such as Monsanto and Calgene have put money, time, energy, and resources into their products and their main goal is to make a profit. Therefore, it is far too likely for these companies to be biased in their interpretation of the results.

Also, standards for the length of these studies need to be established as well. As demonstrated in the previous studies, GM foods may not cause severe health problems in a short period of time, but their consumption significantly increases the risk of cancer in the long run. Most GM food studies on rats are 90 days, which corresponds to only about 7 years in a human's life. Before introducing a product into the food supply, it should be rigorously tested for an appropriate length of time. Our government needs to be the agency that ensures companies care about the long-term health of their consumers, not just making a quick profit.

A new study, The Factor GMO experiment, has been developed in an effort to put an end to the years of controversy and confusion. It is set to be the world's largest study on GMO safety and will last from 2-3 years. A Russian non-governmental agency, the National Association for Genetic Safety (NAGS), has spearheaded the coordination of the project. NAGS has selected a board of expert scientists that are considered neutral in that they "have no connection to the biotech industry or the anti-GMO movement" ("Factor GMO," n.d.). The study is currently working to raise $25 million, however they are refusing to take donations from GM manufacturers in order to avoid any potential bias. The full list of donors will be available after the start of the study. In an effort to provide complete transparency, all data and results will be available to the general public. The rats in the study will be fed "doses of the GMO's {GM maize] and their associated pesticides [glyphosate herbicides] that reflect real-life exposures that humans and livestock animals could be exposed to" ("Factor GMO," n.d.). The study will examine multiple generations of rats in order to discover whether GMOs have an impact on reproductive capabilities and the incidence of birth defects. The study will include

multiple interim testing points in order to gain a better picture of if/when any abnormalities begin to develop in the rats ("Factor GMO," n.d.). Hopefully, Factor GMO will shed light onto the health effects of consumption of GM foods and inspire other independent well-designed studies.

Recommendations for Labeling

In a study conducted by Rutgers University in 2013, researchers found a great lack of public knowledge on the topic of GMOs. 54% of respondents said they know "very little or nothing at all about genetically modified foods" while 25% reported never having heard of GMOs. Only 26% of the respondents were aware that the US has no policy requiring GM labeling (Hallman, n.d.). This is especially alarming considering it has been roughly estimated that 70-80% of foods consumed in the United States have been genetically modified in some form ("Grocery Manufacturers Association Position on GMOs," n.d.). Currently buying USDA certified organic produce or looking for the non-GMO verified symbol are the only ways for American consumers to ensure that their food is GMO-free. Organic food is often more costly and not feasible for many American families. With the inherent lack of credible research to prove that GMOs are safe for consumption, the labeling of GMOs in the United States is imperative for consumers to be able to make their own informed decisions.

In a phone study conducted in 2015 by the Mellman Group of 800 Americans, 89% preferred that "foods which have been genetically engineered or containing genetically engineered ingredients be labeled to indicate that." 6% were in

opposition and the remaining participants were indifferent. 88% of participants also preferred a printed GM label, while 8% would rather scan a barcode on their phone to obtain the information about the product ("Just Label It," n.d.). These results demonstrate clearly that there is a public demand for more knowledge about genetic modifications in their food supply.

Although the federal government has failed to listen to the peoples' requests, some state governments are beginning to take action. Many states have proposed their own versions of the Right to Know Act, which was introduced at the federal level, but was referred to a subcommittee after its presentation in the house. There are slight variations in each states proposition, however the basic premise behind each is that any food that is a product of genetic engineering must be labeled to inform consumers. These labels must be present on the package of the food or a sign must be clearly visible next to the product if the food is unpackaged. Many states also include a clause that prohibits the use of any form of the word natural on the product label of GM foods so that consumers are not misguided (Almendrala, n.d.)

In California, Proposition 37 stirred up quite a large debate. Large companies, including Monsanto and Hershey, spent $44 million in their campaign against the bill. They created ads stating that proposition 37 would be expensive for consumers and disrupt the economy. Those who were in favor of Proposition 37 were only able to raise $7.3 million. In the end, Proposition 37 was defeated by a narrow margin (Almendrala, n.d.). However, it was not a total loss because the bill set the precedent of pushing for regulation of GMOs at the state level.

Connecticut and Maine have passed similar GMO labeling laws, however they include a "trigger clause." This means that the law will not go into effect until the following conditions are met: four other states must pass similar legislation, one of these must be a bordering state, the total population of states that enact similar legislature must be at least 20 million. The main reasoning for this clause is for ease of trade between states and to lessen any possible detrimental economic impacts. Act 150 in Vermont is the first to be passed into a law without any stipulations. This act is set to go into effect in July 2016, however many complaints have been filed stating that Act 150 is in violation of the First Amendment, the Fifth Amendment, and the Commerce Clause of the United States Constitution. If Congress agrees with these claims, they could potentially prevent the implementation of Act 150 ("Vermont Lawsuit," n.d.).

Although these propositions at a state level do not seem as if they are a victory, their importance is far greater than the legislation itself. These laws are raising public awareness about GMOs and starting the dialogue as to how they should be addressed. Most people blindly put their faith in the government to keep them safe from potential harms. The more educated that people are that the government has no conclusive evidence to support the safety of GM foods, the more likely they are to push for labeling legislation in the future.

These state level efforts are encouraging, however, in the end for GM labeling to be successful in the United States federal regulations need to be implemented. The United States needs to swallow their ego, push aside pride, and look at the cold hard facts. As of

now the research is too ambiguous to say that GM foods will have no negative impact on human health. They need to look to the example of 64 other countries that label their GM products so that customers have a right to make their own decisions. A consumer should be able to decide by looking at a package if they want to buy a GM food just like they can look at the calories or allergen information. The government needs to stop being influenced by the money of large corporations and do what is best for the health of the American people. Besides giving Americans an informed choice, labeling would also help to ensure the traceability of GM foods. If a certain illness becomes liked to a particular food, it would be much easier to trace whether the food was a product of genetic modification. This could provide valuable information for means of treatment and even potentially save lives.

Conclusion

In an effort to explain the need for labeling of GM foods, this study has looks at the stark contrast of the regulation of GMOs in the United States and in the Netherlands. The dichotomy between these two countries portrays that the current US system of GM regulation and labeling is inadequate and does not provide the public with sufficient information to make knowledgeable decisions. This study also illustrates the scarcity of independent, peer-reviewed published literature on the long-term health effects of GM foods. Without knowing the long-term consequences of consumption of GM foods, I believe it is much better to be safe than sorry. We do not want to look back in 20 years and say that we would have, could have, and should have done things differently if we had known the consequences. Although labeling

in itself cannot protect everyone from any potential side effects genetic modification may have, it would give Americans the chance to make an informed choice about their food, which is a right that all people should have.

References

Agricultural census in the Netherlands. (2015, August). Retrieved April 24, 2016, from http://ec.europa.eu/eurostat/statistics-explained/index.php/Agricultural_census_in_the_Netherlands

Agriculture Fact Sheet. (2016). Retrieved April 24, 2016, from http://www.agday.org/media/factsheet.php

Almendrala, A. (n.d.). Prop 37 Defeated: California Voters Reject Mandatory GMO-Labeling. Retrieved February 23, 2016, from http://www.huffingtonpost.com/2012/11/07/prop-37-defeated-californ_n_2088402.html

Cressey, D. (2015, March 25). Widely Used Herbicide Linked to Cancer. Retrieved April 24, 2016, from http://www.scientificamerican.com/article/widely-used-herbicide-linked-to-cancer/

DeFazio, P. A. (2015, February 12). H.R.913 - Genetically Engineered Food Right-to-Know Act. Washington, DC: U.S. Government Printing Office. Retrieved January 3, 2016 from the World Wide Web: https://www.congress.gov/bill/114th-congress/house-bill/913.

De Vendômois, J. S., Roullier, F., Cellier, D., & Séralini, G. E. (2009). A comparison of the effects of three GM corn varieties on mammalian health.*Int J Biol Sci*, *5*(7), 706-726.

Diaz, J. M. (2015, August 24). Genetically modified organism (GMO). Retrieved January 15, 2016, from http://www.britannica.com/science/genetically-modified-organism

Ewen, S. W., & Pusztai, A. (1999). Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine.The Lancet, 354(9187), 1353-1354.

Factor GMO. (n.d.). Retrieved February 23, 2016, from http://factorgmo.com/en/

Fast-food nations. (2015). Retrieved April 24, 2016, from http://www.economist.com/fastfood

Frequently asked questions on genetically modified foods. (2016). Retrieved January 15, 2016, from http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/

GMO Authorisations for Food and Feed. (2016, February 17). Retrieved February 20, 2016, from http://ec.europa.eu/food/plant/gmo/authorisation/food_feed/index_en.htm

GMO-Labeling Laws: Why the Trigger Clause? (n.d.). Retrieved February 23, 2016, from http://www.nutritionaloutlook.com/articles/gmo-labeling-laws-why-trigger-clause

Grocery Manufacturers Association Position on GMOs. (n.d.). Retrieved February 23, 2016, from http://factsaboutgmos.org/disclosure-statement

Hallman, W. K. (n.d.). Public Perceptions of Labeling Genetically Modified Foods. http://humeco.rutgers.edu/documents_pdf/news/gmlabelingperceptions.pdf

Hammond, B., Dudek, R., Lemen, J., & Nemeth, M. (2004). Results of a 13 week safety assurance study with rats fed grain from glyphosate tolerant corn. *Food and Chemical Toxicology*, *42*(6), 1003-1014.

Hilbeck, A., Binimelis, R., Defarge, N., Steinbrecher, R., Székács, A., Wickson, F., ... & Novotny, E. (2015). No scientific consensus on GMO safety.Environmental Sciences Europe, 27(4), 1-6.

Joint FAO/WHO Meeting on Pesticide Residues (JMPR). (2015). Retrieved April 24, 2016, from http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/

Just Label It. (n.d.). Retrieved February 23, 2016, from http://www.justlabelit.org/wp-content/uploads/2012/01/Mellman-Survey-Results.pdf

Non-GMO Project. (n.d.). Retrieved February 23, 2016, from http://www.nongmoproject.org/about/

Panel on Genetically Modified Organisms. (n.d.). Retrieved January 15, 2016, from http://www.efsa.europa.eu/en/panels/gmo

Producing Organic. (n.d.). Retrieved January 15, 2015, from http://ec.europa.eu/agriculture/organic/organic-farming/what-is-organic-farming/producing-organic/index_en.htm

Séralini, G. E., Clair, E., Mesnage, R., Gress, S., Defarge, N., Malatesta, M., ... & De Vendômois, J. S. (2012). RETRACTED: Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Food and chemical toxicology*, *50*(11), 4221-4231.

The Goodman affair: Monsanto targets the heart of science - Earth Open Source. (2013). Retrieved February 23, 2016, from http://earthopensource.org/2013/05/19/the-goodman-affair-monsanto-targets-the-heart-of-science/

The Seralini GMO Study – Retraction and Response to Critics « Science-Based Medicine. (n.d.). Retrieved February 23, 2016, from https://www.sciencebasedmedicine.org/the-seralini-gmo-study-retraction-and-response-to-critics/

Traceability and labelling. (n.d.). Retrieved February 23, 2016, from http://ec.europa.eu/food/plant/gmo/traceability_labelling/index_en.htm

U.S. Animal and Plant Health Inspection Service, USDA (2013). Code of Federal Regulations (Vol. 5). Washington, DC: U.S. Government Printing Office. Retrieved January 3, 2016 from the World Wide Web: https://www.gpo.gov/fdsys/pkg/CFR-2013-title7-vol5/pdf/CFR-2013-title7-vol5-sec340-1.pdf.

USDA Foriegn Agricultural Service. (2012, February 15). The EU-U.S. Organic Equivalence Cooperation. Agricultural Information Network: Author. Retrieved January 3, 2016 from the World Wide Web: http://gain.fas.usda.gov/recent%20GAIN%20Publications/The%20EU-U.S.%20Organic%20Equivalence%20Cooperation_The%20Hague_Netherlands%20EU-27_2-15-2012.pdf.

US Department of Health and Human Services: Food and Drug Administration (1992). Statement of Policy: Foods Derived From New Plant Varieties (Vol. 57 No. 104 e). Washington, DC: U.S. Government Printing Office. Retrieved January 3, 2016 from the World Wide Web: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm.

U.S. Food and Drug Administration. "How FDA Regulates Food from Genetically Engineered Organisms" (2015, October 13). Retrieved January 15, 2016, from http://www.fda.gov/Food/FoodScienceResearch/GEPlants/ucm461831.htm

U.S. Office of Law Division of the U.S. House of Representatives. (2010). United States Code (Title 21- Food and Drugs). Washington, DC: U.S. Government Printing Office. Retrieved January 3, 2016 from the World Wide Web: https://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIV-sec348.pdf.

U.S. Office of Law Division of the U.S. House of Representatives. (2013). United States Code (Title 7). Washington, DC: U.S. Government Printing Office. Retrieved January 3, 2016 from the World Wide Web: http://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter6/subchapter2&edition=prelim.

U.S. Office of Law Division of the U.S. House of Representatives. (2013). United States Code (Title 7 Agriculture, Chapter 104). Washington, DC: U.S. Government Printing Office. Retrieved January 3, 2016 from the World Wide Web: https://www.gpo.gov/fdsys/pkg/USCODE-2014-title7/pdf/USCODE-2014-title7-chap104-subchapI-sec7712.pdf.

Vermont Lawsuit a Test Case for GMO-Labeling Laws and the First Amendment. (n.d.). Retrieved February 23, 2016, from http://www.heritage.org/research/reports/2015/11/vermont-lawsuit-a-test-case-for-gmo-labeling-laws-and-the-first-amendment#_ftn3

"What is Organic?" (2011, September). Retrieved February 23, 2016, from https://www.ams.usda.gov/publications/content/what-organic

Why I cannot remain silent: Interview with Dr Arpad Pusztai. (1999, September). Retrieved February 23, 2016, from http://gmwatch.org/index.php?option=com_content