Genetically Engineered Food Right-to-Know: Recommendations for Specific, Unthreatening, and Accurate GE Food Labels

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ENGL 390 – 1101

16 December 2014

Executive Summary

Market share of genetically engineered (GE) foods have reached record highs (U.S. Food and Drug Administration [FDA], 2013). GE producers benefit from increased product revenue, and consumers benefit from more nutrient dense foods. Additionally, GE foods might address food shortages for future generations (UN, 2004). However, because the public is mostly either misinformed or uninformed about GE foods and since these foods are not regulated adequately under the Federal Food, Drug, and Cosmetic Act, the public continually raises concerns about their safe consumption. With new research showing these foods to be increasingly safe, the public's concerns can be appeased by new legislation ensuring their safety.

Modern second-generation GE foods are the result of a decade of improvements on first-gen GE foods and centuries of advancements in selective breeding and genetics. Second-gen GE foods do not involve selective breeding techniques, as these are primitive, less specific ways of enhancing observable traits (European Food Safety Authority GMO Panel Working Group on Animal Feeding Trials [EFSA], 2008). Many popular accounts erroneously link the hazards of selectively bred foods to GE. Second-gen GE foods are specifically enhanced products produced by advanced genetic methods, allowing only desirable traits to be transferred from species to species. (Rojas-Méndez, Ahmed, Claro-Riethmüller, & Spiller, 2012). As such, concerns about GE food safety do not reflect recent advancements.

Additionally, the safety of GE foods can be guaranteed on many levels: chemically, to detect hazardous mutations; individually, to study their effects in living systems; and collectively via governmental regulation. Safety on the chemical level can be assured through protein and DNA-based techniques (Western blot, ELISA, and PCR to name a few), each with their own unique advantages and disadvantages when applied to initial GE food safety screening

(Nakajima, Koyano, Akiyama, Sawada, & Teshima, 2010; Yamaguchi, Sasaki, Umetsu, & Kamada, 2003). Safety on the individual level can be assured through studies in humans and in model systems, such as mice. Results are then compared to tests of conventional foods along parameters such as body weight, food consumption, blood chemistry, organ weights, and clinical history (EFSA, 2008). Safety on the collective level can be achieved through governmental supervision by regulatory agencies (FDA, 2014). As demonstrated, the framework is set for assuring safe GE foods, however, legislation has not yet caught up with technology.

The public's misconceptions of GE foods further complicate the issue. Perceptions of GE foods are shaped by past reports of dangerous selectively bred and first-gen GE foods, ethical reservations, cultural beliefs, and false impressions about the GE industry. The media and the organic food industry exacerbate the problem when they present lopsided evidence against GE, promoting their agendas (Loureiro & Bugbee, 2005; Saher, Lindeman, & Hursti, 2006). Combining the technical aspects of GE food production and current research on safety, while mindful of the public's perceptions, we set forth best practices in ensuring awareness of food safety for the American public. As such, we propose an improved amendment to the Federal Food, Drug, and Cosmetic Act requiring all GE foods to be labeled. Our recommendations for these labels achieve (1) greater public appeal in rebranding genetic engineering as genetic enhancements, (2) improved disclosure by listing technical information for all enhancements, and (3) a sense of safety and credibility by reporting regulatory approval on all GE labels. In sum, policy makers should not implement legislation that impedes GE foods from entering the marketplace, but instead ensure that all GE foods in the marketplace are safe.

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Genetically engineered (GE) foods have gained substantial market share over their conventional counterparts during the past decade; in some food categories their share has climbed as high as 93% (U. S. Food and Drug Administration [FDA], 2013). The reason behind GE foods' increasing ubiquity is their utility. On one hand, GE food producers benefit from increased product yields, which translate into increased revenue. On the other hand, consumers benefit from increased food availability and more nutrient dense foods. With world population projected to reach almost 9 billion by 2050, GE foods are a promising approach to increase food availability for a growing human population (United Nations Department of Economic and Social Affairs, 2004). Critics of GE foods claim that any benefits that these foods might convey are coupled with some potentially harmful effects. While this may have been true a decade ago, the literature shows that the majority of GE foods on market today are safe to consume (European Food Safety Authority GMO Panel Working Group on Animal Feeding Trials [EFSA], 2008). As genetic engineering is a rapidly advancing field, legislation ensuring the public's safe consumption of GE foods needs to be updated to reflect these advancements.

The Food and Drug Administration (FDA) has ensured the safety of our foods since the Federal Food, Drug, and Cosmetic Act was enacted in 1938. As food markets have changed throughout the decades, amendments to this law have ensured continued safety for our citizens. Additional amendments are now being proposed to include safety regulations on GE foods to meet this same end. One such amendment is H.R. 1699, the Genetically Engineered Food Right-to-Know Act (2013). Although commendable in merit, the bill falls short in practice. It only

requires simple labels stating whether a food has GE ingredients or is GE free. Additionally, proposed label verbiage marking GE as "materially different" neither assuages the public's fears, nor educates them on GE food safety (Genetically Engineered Food Right-to-Know Act, 2013).

As such, my report outlines pertinent research needed to make informed policy decisions on mandatory GE labeling practices. I open with a condensed historical summary of the field to provide a context for our later assertions. I continue with a detailed analysis of the standing of the safety of GE foods today through a synthesis of research, field reviews, and regulatory standards. Since labeling is a practice that has direct impact on the public, I continue with a section on current public perception of GE foods to serve as a framework for labeling recommendation. Combining the technical aspects of GE food creation with current research on safety in the framework of the public perception allows me to set forth best practices in GE food labeling for the American economy. The labels I propose are more detailed, and they achieve the goal of food safety that the Federal Food, Drug, and Cosmetic Act sets forth better than H.R. 1699. My recommendations, outlined in greater detail in subsequent sections, achieve:

1. Greater public appeal by rebranding genetic modifications as genetic enhancements,
2. Improved disclosure by listing technical information as to all enhancements (ex. enhanced for 10g more iron content per serving), and
3. A sense of safety and credibility by reporting regulatory standings (ex. scientifically tested and FDA approved).

While I will correct several misconceptions about GE foods throughout the report and address counter-arguments to our assertions in a later section, it is necessary to first clarify several pertinent terms for clear understanding of our report. I emphasize that while often

perceived as different processes, genetic engineering and genetic modification (GM) are the same: GE is simply the approved scientific term for GM (EFSA, 2008). Additionally, genetic engineering does not involve selective breeding techniques (EFSA, 2008). Selective breeding is a primitive, less specific way of manipulating observable traits in foods and non-foods. Many popular accounts on the hazards of GE foods inaccurately report on selectively bred foods. Conversely, my report focuses on GE foods, as should new legislation. I mention selective bred foods only briefly for complete disclosure and comparability with GE foods.

Historical Background

Policy makers cannot make informed decisions on an issue without first knowing the surrounding context. GE foods are no exception. GE foods are the result of almost two centuries worth of scientific advancements in the fields of selective breeding and genetics. Selective breeding techniques originated thousands of years ago in Europe, where breeders selectively mated donkeys and horses to produce sterile transport animals called mules (GM Education, 2014). While the roots of selective breeding are centuries old, genetic research only began to gain prominence in the 19th century due to strong social, political, and technological constraints against human intervention on life. Even after years of gathering conclusive research on plant and animal domestication, Charles Darwin hesitated in publishing his book, *The Origin of Species*, because of such strong social and political pressures. In his book, he asserts that it is possible to selectively breed species based on desired characteristics, reporting with shocking accuracy by today's standards (Darwin, 1859). Although Darwin was unaware of the underlying principles, a few years later, Gregor Mendel built off of Darwin's theory. Working with pea plants, he ascertained the basic principles of genetic inheritance, giving empirical rationale to selective breeding techniques (Mendel, 1866). Then, after nearly a century, Watson and Crick

(1953) elucidated the structure of the DNA, revealing the genetic code. With the code revealed and models of inheritance in hand, the foundation was set for a genetic engineering revolution.

Research stemming from the work of these pioneers has made modern genetic engineering possible in the 20th century. The Human Genome Project gave rise to modern genome sequencing technologies and identified regions of interest for manipulation (GM Education, 2014). Additional research revealing that all species operate under the same genetic code paved the way for recombinant DNA techniques, which allow scientists to extract DNA sequences coding for a desirable trait and transfer them to new species (Kuiper, Kleter, Noteborn, & Kok, 2003). These techniques, coupled with previously ascertained selective breeding techniques were introduced to the food industry at the end of the 20th century. These so-called "first generation" GE foods consisted of rudimentary modifications contrived for the sole benefit of the food producer (Konig et al., 2004). These modifications are considered rudimentary, as selective breeding techniques act on observable (scientifically termed "phenotypic") variation with a genetic basis, and as a result, undefined regions of physically linked traits may "go along for the ride" during this broad selection process. For example, first-gen herbicide-resistant maize thrives when sprayed with large doses of pesticide allowing it to grow in weed-free environments; however, consumption of such maize has been linked to tumor growth in lab studies (Gianessi & Carpenter, 2001; Loureiro & Bugbee, 2005).

For health and safety reasons, producers have moved away from selective breeding toward more precise recombinant DNA techniques in the development of "second generation" GE foods. Recombinant DNA techniques at the beginning of the 21st century are more precise than selective breeding, however, they could still only transfer broad sections of DNA. Thankfully, as with any new technology, methods are improving at a rapid pace and regions for

manipulation are becoming increasingly smaller. Benefits of today's precise modifications are multifold: for food producers, they offer traits such as improved pesticide resistance and longer shelf life (Saher et al. 2006), for consumers, they offer traits such as increased omega-3 fatty acid content in bread and increased protein content in yogurt and eggs (Rojas-Méndez, Ahmed, Claro-Riethmüller, & Spiller, 2012).

While technological barriers have been surpassed, the social and political issues that early scientists faced are still present. Although producers know the many possible benefits of GE foods, only the increasing market presence of GE foods has raised consumer awareness and concerns about their ethics and safety. As such, it is the duty of public officials to ensure that the public is properly informed about modern GE foods, they are aware of their possible benefits, and are protected against their potential dangers. Laws should move past social and political biases; they should be made for the present, knowing the past, and preparing for the future.

Current Safety Status of Genetically Engineered Foods

As GE food legislation must fit within the historical framework, it must also reflect the current safety status. Research shows that GE foods are improving: second-gen GE foods are mostly all safe to consume. However, the public is hesitant. Thus, it is the duty of public officials to ensure that all products, natural and engineered, are properly regulated for safe consumption. At present, GE foods have the potential to be monitored chemically, to detect hazardous mutations; individually, to study their effects in living systems; and collectively via governmental regulation. Legislation must be harmonious on all levels in order to effectively serve the people.

Ensuring complete safety of GE foods is difficult, as the ways to genetically modify foods continue to grow and diversify. Thankfully, the most widely used and most modern

approach, genetic engineering, is safer overall than conventional mutation and selective breeding techniques. This is because GE has high specificity and is performed under strictly controlled conditions, only transferring advantageous genes (Kuiper et al., 2003). While this process is not foolproof, as some studies show (Garza & Stover, 2003; Nicolia, Manzo, Veronesi, & Rosellini, 2014), cases of harmful GE foods are less frequent than cases of harmful selectively bred foods. As such, policy makers should not implement legislation impeding GE foods from entering the marketplace, but implement legislation that ensures all GE foods in the marketplace are safe.

Detection

To ensure their safety, researchers have adopted a variety of protein-based and DNA-based techniques to detect harmful modifications found chemically among GE foods. One such protein-based method, the Western blot, is highly specific and effective in insoluble protein detection (Nakajima et al., 2010). It involves antibodies binding to specific proteins, producing a stained product, which then qualitatively determines whether a protein is above a certain threshold concentration (Ahmed, 2002). As the results are strictly qualitative, this procedure is more suited for research applications than GE food screening. Another protein-based method, ELISA (short for enzyme-linked immunosorbent assay), involves target proteins binding to immobilized antibodies coupled to a colored reactant on a test strip (Nakajima et al., 2010). In contrast to Western blot, ELISA produces quantitative results in a short time frame, making it suitable for initial GE food screening (Yamaguchi et al., 2003). Overall, ELISA testing is fast and relatively inexpensive compared to other methods; however, target proteins can be easily denatured in testing and thus slip detection (Spiegelhalter, Lauter, & Russell, 2001). Even more specific in harmful mutation detection is the DNA-based test of PCR, short for the polymerase chain reaction, which by amplifying specific DNA segments and separating them based on

molecular weight, allows researchers to identify and quantify segments of interest as small as 200 base pairs (Yamaguchi et al., 2003). This high level of specificity makes PCR a good candidate for GE food screening, as many specific protein products can be amplified and compared to known detrimental sequences. In practice, PCR can detect hazardous sequences at concentrations of 0.01% or greater, (Spiegelhalter et al., 2001), making PCR one of the most precise methods to test GE foods for safety on the chemical level. Testing conditions must be strictly monitored, however, as even stray dust particles can adversely affect results (Spiegelhalter et al., 2001).

Testing of GE foods is not limited to just chemical studies. Typically, after GE foods pass chemical inspection, researchers test them in living systems before marketing them. Humans are the ideal test subjects, but ethics limit human trials until researchers obtain nearly conclusive evidence of safety. Since mice share over 85% of our genome, with many sequences 99% identical, they serve as a suitable and more ethical model system (National Human Genome Research Institute, 2010). Studies in mice are performed under strict conditions that involve mice being fed GE foods such as maize, potatoes, rice or soybeans over prolonged periods, while having their body weight, food consumption, blood chemistry, organ weights, and clinical history monitored (EFSA, 2008). The results of such experiments are reviewed comprehensively in reputable scientific publications such as the *Journal of Food and Chemical Toxicology*. These reviews find the majority of GE foods to be clinically safe exhibiting little to no clinical abnormalities (EFSA, 2008). In fact, several cases noting adverse effects have been retracted due to mis-interpretation of results or study limitations (EFSA, 2008; Nicolia et al., 2014). After GE foods pass mice studies, they often move onto human trials, which operate under similar parameters. As humans cannot ethically be confined to a lab for long-term studies, comparative

methods are employed. These tests involve comparing the effects of consuming GE foods to consuming conventional foods. Results of these tests collectively show the majority of GE foods to be clinically safe, exhibiting little to no clinical abnormalities (EFSA, 2008; Nicolia et al., 2014). A schematic representation of how these tests may be incorporated into real-world applications for the United States, adapted from the European Food Safety Authority, is reported in the appendix, table 1.

Regulation

The variety and scope of tests available to identify harmful GE foods allows federal regulators to set quality standards. While decades of GE food safety research have revealed best practices for governmental regulation, few pieces of legislation reflect this body of knowledge. The Food and Drug Administration (FDA) currently maintains that all food, genetically engineered or conventionally grown, must adhere to strict safety requirements under the Federal Food, Drug, and Cosmetic Act. Additionally, the FDA is supported in monitoring the safety of GE foods by the U. S. Department of Agriculture (USDA) in monitoring the chemical safety of GE foods, and by the Environmental Protection Agency (EPA) in assuring growing of GE foods is environmentally sustainable (FDA, 2013). While regulations by these governmental bodies have taken great strides in ensuring safe consumption of GE foods, regulations must be modernized to reflect their current safety status.

Public Perception of Genetically Engineered Foods

Current scientific research shows that most second-generation GE foods are as safe as conventional foods, with measurable improvements over selectively bred and first generation GE foods. Despite this, the public remains largely uninformed or misinformed about the relation between biotechnology and foods and is therefore hesitant to consume GE foods. This is because

many factors influence the public's perception of GE foods, including: demographics, such as gender or education; preexisting personal values and beliefs; confusion as to who benefits from GE foods; food-related attitudes, such as health-risks or nutrition; and media portrayal of GE foods (Dreezens, Martijn, Tenbült, Kok, & de Vries, 2005; Knight, Mather, & Holdsworth, 2005). In order for legislation involving GE foods to be effective, policy makers must ensure that the values held by consumers are taken into account and that any recommendations for labeling are respectful of and tailored to these specific needs.

Current GE consumers fill a narrow demographic. Across gender, age, education, geographic location, and income, current studies show that GE foods currently do not have broad consumer appeal in spite of increasing market penetration (Ling and Santos, 2013). Currently, men are more accepting of GE foods as they more often choose foods based on attractive texture, color, extended shelf life, and perceived taste rather than sourcing methods (Ling and Santos, 2013; Arvanitoyannis and Krystallis, 2005). Recent studies also show younger age groups to be more positive towards GE foods; strongly associated with this demographic is the value of accepting rather than being skeptical of new technologies (Magnusson and Hursti, 2002). Additionally, those with higher levels of education in any field, especially those educated in the natural sciences are more likely to consume GE foods, viewing them as healthier and more sustainable (Magnusson and Hursti, 2002; Saher et al., 2006). The issue is complicated for policy makers as proper labeling and GE food education would make these foods appealing to a much broader demographic. This would likely reach consumers such as: women who choose foods based on sourcing method and currently view GE foods as immoral or unethical; older consumers who purchase tried-and-true foods and require evidence showing how GE improves upon conventional foods in order to try them; and previously uneducated consumers who cannot

presently perceive the benefits to consuming an engineered product over a conventional one. While the current GE food consumer belongs to a narrow demographic, increasing market share and benefits of GE foods necessitate that GE policy appeal to all demographics across all regions.

Consumers are more than just a subset of demographics. As individuals, their overall attitudes toward food are shaped by a variety of preexisting values, morals, and beliefs. Across the nation, several of these stand out and should be addressed in GE legislation. In the U.S. many value tried-and-true methods: these consumers require time and evidence to support the new technology involved with GE (Arvanitoyannis and Krystallis, 2005). Additionally, there are those who value consistency: these consumers, described as having food neophobia, are not only against trying GE foods, but are against trying all new foods (Arvanitoyannis and Krystallis, 2005). Some wonder how GE foods impact the environment, such as how increasing pesticide resistance can potentially cause GE crops to become weeds (Loureiro & Bugbee, 2005). Others question the ethics of GE foods. Many are morally against altering animals for GE meats, while most are okay with altering plants for GE fruits, vegetables, and grains (Magnusson and Hursti, 2002). Finally, consumers across the U.S. have diverse religious beliefs, which help shape their attitudes towards what they consume (Arvanitoyannis and Krystallis, 2005). These varied and complex values, morals, and beliefs make it hard to compose legislation for a broad audience, but they must be respected in order for such legislation to be effective.

The media also heavily influences consumers in the U.S. In order to captivate audiences, the media often presents GE foods as “frankenfoods.” As a result, consumers are left with the impression that GE foods are unnatural and pose health risks like cancer, antibiotic resistance, and increased allergenicity (Loureiro and Bugbee, 2005; Arvanitoyannis and Krystallis, 2005).

The organic food industry, which actively campaigns against GE foods, also uses the media to misinform consumers. They air ads that promote conventional foods, which selectively exclude details of the enhancements of GE foods that would appeal to the public's senses, and instead include vivid imagery of fresh foods that appeal to the public's emotions (Saher et al., 2006). For this reason, many consumers believe that GE foods have not progressed from their first-gen iterations. On average, they avoid GE foods, as they believe that GE crops only benefit producers and large corporations by increasing their profit margins and expose consumers to health risks and offer no tangible benefits (Magnusson & Hursti, 2002; Frewer et al., 2004; Rowe, 2004; Knight et al., 2005). For policy makers, legislation allowing increased consumer education would not only widen the demographics of GE consumers as mentioned previously, but would also serve in correcting these misconceptions.

While demographics, personal values, and external influences all play a role in the public's perception of GE foods, the most relevant determinants of consumer willingness to buy GE foods are their specific attitudes toward food. Americans are becoming increasingly choosy of their foods, with a USDA study finding up to 57% of American adults using the nutrition facts panel on foods most or all of the time to make food purchase decisions (USDA, 2014). With all of the hesitation towards GE expressed in previous sections, it should be surprising that 71% of American consumers said they are ready to try GE foods, according to another recent study (Loureiro and Bugbee, 2005). The caveat is that these foods must be tangibly beneficial to them, with properties such as improved nutritional value, grown using less pesticides, out of season fruit availability, and better taste (Loureiro and Bugbee, 2005; Boccaletti and Moro, 2000; Magnusson and Hursti, 2002; Arvanitoyannis and Krystallis, 2005). Currently, consumers feel most ready to try GE plant derived foods, with most believing them to be environmentally

sustainable as compared to conventionally grown foods (Magnusson and Hursti, 2002; Arvanitoyannis and Krystallis, 2005). Conversely, consumers are least likely to try GE meat products as genetically altering animals violates many consumers' values and beliefs (Magnusson and Hursti, 2002). Food attitudes are malleable, however, as shown by a positive response to pork with significantly lower fat content, from respondents to the same survey. This case highlights that an appreciable health benefit can outweigh ethical concerns and lead to a purchase (Magnusson and Hursti, 2002). All in all, the public is ready to try GE foods; policy makers need to ensure that these foods are indeed beneficial to consumers and that they are properly informed about any possible health benefits and detriments.

Recommendations for Labeling

The evidence presented above shows that while once experimental and largely hazardous, GE foods have since improved, and therefore a legislative framework should be developed to certify them as safe for consumption. Unfortunately, as highlighted throughout my report, the American public is either uninformed or misinformed about GE foods. While educating American consumers will be a large-scale, costly, and time consuming undertaking, I believe that policy makers have the greatest power to make a change and shape the future landscape of foods in the United States. As American consumers are becoming increasingly health conscious, seeking out nutritional information to make product purchase decisions (USDA, 2014), policy makers stand to educate American consumers and regulate GE foods by implementing mandatory GE food labeling legislation. These labels would take advantage of the fact that consumers are already reading food labels, in order to educate the public about GE and appease their concerns. In order to best achieve these goals, the mandatory labels should:

1. Refer to genetic modifications as genetic enhancements to achieve greater public appeal,
2. Disclose technical information as to all enhancements (e.g. enhanced for 10g more iron content per serving), and
3. Report regulatory standings (e.g. scientifically tested and FDA approved) for a sense of safety and credibility.

Earlier, I clarified the misconception between genetic modifications and genetic engineering, stating that they are effectively the same. When implementing new policy, the problem with both of these terms is that the public is equally aware of both of these and has strong negative connotations associated with them. The term "modification" invokes a feeling that nature's process has been disturbed, making the foods unnatural. "Engineering" might even be worse for it invoking an image of something that isn't food at all, but rather something created artificially. For this reason, I have recommended rebranding the terms genetic engineering and genetic modification as "genetic enhancement" for GE food labeling applications. First, referring to the process with a new term allows the public to form new opinions on genetic engineering, which is necessary given the advancements in safety assurance and greater consumer application options. Second, the term enhancement better reflects what GE is doing for the consumer. While scientists are physically engineering the product, consumers benefit from the enhancements to that product. Utilizing a term that directly relates to consumer application narrows the learning curve necessary for GE acceptance.

In addition, as the American consumer is becoming increasingly health conscious and actively reads food nutrition labels, my second recommendation of disclosing the technical information as to all enhancements not only educates the consumer about what they are eating,

but helps to make GE products more appealing and understandable to consumers. Much of the hesitation towards trying GE foods comes from a lack of understanding of what is specifically involved with the genetic engineering process and how that makes a difference to the consumer. By detailing GE enhancements on product labels, the consumer will understand what makes each specific GE products different from their conventional counterparts. This practice would be applicable to all foods, offering essential information including: additional nutritional content, reduced fat, cholesterol, or calorie content, prolonged shelf life, out-of-season availability, more flavor, reduced pesticide in growth, etc. Comparatively to H.R. 1699 in its current standing, which advocates for phrases such as "materially-different" or "non-modified" (Genetically Engineered Food Right-to-Know Act, 2013), this detailed labeling practice informs the consumer specifically about the product and allows them to make informed decisions about their food purchases. With the aid of a detailed label, consumers will understand what has been enhanced and apply this to their individual dietary needs to decide if this makes a difference to them.

Above all, consumers need to know that the foods that they and their families are eating are safe to consume. Numerous studies reveal a high willingness to pay for food enhancements, but equally as many report that the foods must be as safe as conventional foods in order for consumers to purchase them (Loureiro & Bugbee, 2005; Knight et al., 2005). At present, the FDA and the Federal Food, Drug, and Cosmetic Act regulate foods to assure their safety. While this has been acceptable for conventional foods, regulations need to be modernized, taking advantage of the technology presented above to assure that all GE foods on the market are safe. With enhanced FDA regulation of GE foods, consumers would have reason to feel more secure about consuming GE foods as they would be monitored and assured by the FDA, USDA, and EPA, a standard that is not mandatory of conventional foods (FDA, 2013). In terms of labeling,

consumers should be made aware of any assurances of safety on the product label. Information that the FDA, USDA, EPA or any other government body inspected and certified the food is vital to the consumer and will directly aid in placating fears of past GE foods.

Overall these detailed labels will serve to inform the consumer about any enhancements made to the food. Studies show that GE foods are largely safe to consume and consumers are ready to try GE foods. By implementing these recommendations, policy makers can help educate the public about modern GE foods, correct misconceptions left by the past, and move forward to help create foods specifically tailored for our societies' dietary needs.

Counter Arguments Addressed

No argument is complete without acknowledging its limitations and addressing opposing viewpoints. The recommendations given above are best practices suggested based on the literature available on GE foods, their safety, and their public's perception in the United States. As real world events are unpredictable, these recommendations may require slight alterations over time to work in a real world setting. Additional concerns covering a range of topics are addressed separate subsections below.

How are these recommendations specific to the United States?

The above report was carefully curated to include only research, American or otherwise, that represents American demographics. As such, the elucidated recommendations are a direct result of the trends outlined by the literature on American perceptions of GE foods and market readiness of GE foods. While the recommendations reflect the attitudes of the United States as a whole, modifications may be necessary for local markets inside the U.S. For an additional comparison, I have reviewed the literature on the current status of GE food safety and the public's perceptions of GE foods in Europe. On one hand, a report by the European Commission

and another by the World Health Organization conclude that consuming GE foods does not pose a higher health risk than consuming conventional foods (European Commission, 2010; World Health Organization, 2005). On the other hand, several studies show that, overall, European consumers are against all types of GM foods, with 70.9% of European study participants seeing GE foods as unnatural (Knight et al., 2005). This research shows that while GE foods in Europe are as safe as GE foods in the U.S., consumers are not ready to try them. With such strong public opposition to GE foods, recommendations of labeling GE products would not be nearly as effective in Europe as they would be in the U.S.

How will these recommendations alleviate ethical, environmental, and safety concerns?

While the proposed labeling recommendations focus mainly on educating consumers on GE foods, they also include subtleties that alleviate several ethical, environmental, and safety concerns. In terms of ethics, consumers are most apprehensive towards GE meat products, currently choosing organic for perceived better treatment of the animals (Dreezens et al, 2005). Conversely to what most believe, organic status does not ensure ethical treatment of animals, with many organic farms cramming animals together to increase profits just as factory farms (People for the Ethical Treatment of Animals, 2014). At present, having a USDA certification is the only assurance of ethical treatment of animals, as monitored by the USDA's Food Safety and Inspection Service (USDA, 2008). With mandated USDA approval for all GE meat products and open disclosure of this on all GE meat product labels, consumers concerns of the ethical treatment of animals should be alleviated.

Some consumers are concerned about GE crops posing long-term negative impact on the environment. Much of this concern stems from GE crops with pesticide resistant properties, as these populations when grown in a natural setting could exert selective pressures on natural

populations and become weeds endangering other natural populations (Nicolia, 2014). While this is possible, there have been no documented cases of such occurrences to date (Nicolia, 2014). In fact, the same outcome is possible with natural plant populations with natural mutations, or when non-native populations invade a new territory with the help of a transportation vector. To ensure full environmental safety, future precautions should be taken to isolate GE crops from natural populations. For now, EPA seals on GE product labels will help alleviate consumer concerns.

Other consumers feel that that there is still much to be learned about GE foods and feel that they should not be treated as safe until more research is conducted. To illustrate the disconnect between public perception of GE foods and their safety, consider the following: on one hand, a 2013 Gallup study shows that 48% of respondents believe that GE foods are a serious health hazard (Gallup, 2013). On the other hand, the U.S. National Academy of Sciences found that consuming GE foods is no riskier than consuming conventional foods (National Research Council & Institute of Medicine, 2004). In spite of this, consumers in the United States still think that the risks of GE foods outweigh their benefits (Costa-Font, Gil, & Traill, 2008). Some consumers go as far as to link the recent increase in food allergy diagnoses to the rising market presence of GE foods (Key, Ma, & Drake, 2008). This causation is unlikely, since although 20% of the U.S. population believes they have food allergies, only 2% can in fact be diagnosed with them (as cited in Buchanan, 2001). Instead, consumers should feel more comfortable consuming GE foods, as they require additional allergenicity and safety testing, while conventional foods can enter the market without such testing (Key et al., 2008). Additionally, many studies showing GE foods be toxic have been retracted for false allegations (Séralini et al., 2012; Nicolia et al., 2014). In this respect, GE foods should be seen as a safer alternative to conventional foods, with assurance of their safety right on the label.

How can organic foods be less safe than genetically engineered foods?

There are as many misconceptions about organic foods as there are about GE foods. Most of the misconceptions stem from misleading terminology. For example, the term "free-range" evokes images of animals on an open farm. However, in reality the only stipulation for "free-range" animals is that the door to their enclosure has to be opened once daily, not limiting the size of their cage or the number of animals per cage (PETA, 2014). The organic food industry uses these misleading terms such as "free-range" to appeal to consumers' emotions in order to increase their financial gains (Saher et al., 2006). A cursory scan of the literature reveals a multitude of studies on the benefits of consuming GE foods and relatively few that can accurately claim health benefits to eating organic foods. While organic foods have their merits, as they are grown in more environmentally friendly ways, and they possess less food additives (Saher et al., 2006), these properties are not unique to organic foods. Any food, conventional, genetically engineered, or organic has the potential to be environmentally friendly and healthy. The difference is that only GE foods can claim that they are specifically enhanced for better nutritional and health content, with examples such as rice with added iron and beta-carotene, low calorie foods for diabetics, bananas that produce human vaccines against Hepatitis B, and rice expressing Human Serum Albumin to treat blood loss (Magnusson & Hursti, 2003; Ling and Santos 2013; Loureiro & Bugbee, 2005; Sheng et al. 2014).

Conclusion

The debate surrounding GE foods has come to the forefront as a result of the increased market presence of GE foods and related safety concerns. The possibilities for genetic modification of foods are abundant, each with promising benefits to offer the American public. Thankfully, detecting harmful modifications is possible in many ways: chemically, to detect

hazardous mutations; individually, to study their effects in living systems; and collectively, via governmental regulation. Currently, the United States lacks adequate legislation ensuring the safety of these foods for its consumers. The issue is further complicated by a variety of personal values on the subject. The public remains largely uniformed about GM foods or misinformed by the media, hindering their spread and preventing the public from benefitting from these foods.

As such, I recommend that policy makers amend H.R. 1699, in order to better help the American public. My recommendations for an improved GE labeling program achieve greater consumer appeal by rebranding genetic engineering as genetic enhancements, increased consumer awareness with technical information on each GE label, and increased customer safety satisfaction with seals of governmental assurance on each GE label, too.

These recommendations are only the first steps on the road towards the American public accepting GE foods. We have come far, but difficulties still lie ahead. I intend this report to be a catalyst for further discussion and for further research. It is only Congress and the scientific community, working alongside each other, who can change the way the American public perceives and how to American public reacts to GE foods. Genetically engineered foods offer potentially endless possibilities. They stand to solve growing food insecurity borne by a growing human population. They stand to eradicate and treat diseases that have ailed humanity for centuries. It is time for Congress and the scientific community to take the lead in educating an uniformed and misinformed public about the multifold benefits of these foods. In the words of Norman Borlaug, the father of the green revolution who saved a billion lives, “food is the moral right of all who are born into this world.” Genetically engineered food offers the possibility of yet another green revolution and the saving of yet another billion lives.

References

Ahmed, F. E. (2002). Detection of genetically modified organisms in foods. *Trends in Biotechnology, 20*(5), 215-223. doi:10.1016/S0167-7799(01)01920-5

Arvanitoyannis, I. S., & Krystallis, A. (2005). Consumers' beliefs, attitudes and intentions towards genetically modified foods, based on the 'perceived safety vs. benefits' perspective. *International Journal of Food Science & Technology, 40*(4), 343-360. doi:10.1111/j.1365-2621.2004.00916.x

Boccaletti, S., & Moro, D. (2000). Consumer willingness-to-pay for GM food products in Italy. J Agrobiat Manag Econ, 3(4), 259-267.

Buchanan, B. B. (2001). Genetic Engineering and the Allergy Issue. *Plant Physiology, 126*(1), 507. doi:http://dx.doi.org/10.1104/pp.126.1.5

Costa-Font, M., Gil, J. M., & Traill, W. B. (2008). Consumer acceptance, valuation of and attitudes towards genetically modified food: Review and implications for food policy. *Food Policy, 33*(2), 99-111. doi:10.1016/j.foodpol.2007.07.002

Darwin, C. R. (1859). *The Origin of Species*. London, UK: John Murray.

Dreezens, E., Martijn, A., Tenbült, P., Kok, G., & de Vries, N. K. (2005). Food and values: an examination of values underlying attitudes toward genetically modified- and organically grown food products. *Appetite 44*(1), 115-122. doi:10.1016/j.appet.2004.07.003

European Commission. (2010). *A decade of EU-funded GMO research (2001-2010).* Brussels, Belgium: Directorate-General for Research and Innovation, Directorate E for Biotechnologies, Agriculture, Food, Unit E2 for Biotechnologies. Retrieved from: ftp://ftp.cordis.europa.eu/pub/fp7/kbbe/docs/a-decade-of-eu-funded-gmo-research_en.pdf

European Food Safety Authority GMO Panel Working Group on Animal Feeding Trials. (2008). Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials. *Food and Chemical Toxicology*, *2008*(46), s2-s70. doi:10.1016/j.fct.2008.02.008

Frewer, L., Lassen, J., Kettlitz, B., Scholderer, J., Beekman, V., & Berdal, K. G. (2004). Societal aspects of genetically modified foods. *Food and Chemical Toxicology, 42*(7), 1181-1193. doi:10.1016/j.fct.2004.02.002

Gallup. (2013). *Nutrition and Food*. Retrieved from: http://www.gallup.com/poll/6424/nutrition-food.aspx

Garza, C., & Stover, P. J. (2003). General introduction: the role of science in identifying common ground in the debate on genetic modification of foods. *Trends in Food Science & Technology, 14*(5-8), 182-190. doi:10.1016/S0924-2244(03)00062-1

Genetically Engineered Food Right-to-Know Act, H.R. 1699, 113th Cong. (2013).

Gianessi, L. P., & Carpenter, J. E. (2001). *Agricultural Biotechnology: Updated Benefit Estimates*. Washington, DC: National Center for Food and Agricultural Policy Retrieved from: http://archives.foodsafety.ksu.edu/articles/39/ag_biotech_benefits.pdf

GM Education. (2014). *A brief history of genetic modification*. Retrieved from http://www.gmeducation.org/faqs/p149248-20brief%20history%20of%20genetic%20modification.html

Key, S., Ma, J. K-C., & Drake, P. M. W. (2008). Genetically modified plants and human health. *Journal of the Royal Society of Medicine, 101*(6), 290-298. doi:10.1258/jrsm.2008.070372

Knight, J. G., Mather, D. W., & Holdsworth, D. K. (2005). Consumer benefits and acceptance of genetically modified food. *Journal of Public Affairs, 5*(3-4), 226-235. doi:10.1002/pa.24

Konig, A., Cockburn, A., Crevel, R. W. R., Debruyne, E., Grafstroem, R., Hammerling, U., et al. (2004). Assessment of the safety of foods derived from genetically modified (GM) crops. *Food and Chemical Toxicology, 42*(7), 1047-1088. doi:10.1016/j.fct.2004.02.019

Kuiper, H. A., Kleter, G. A., Noteborn, H. P., & Kok, E. J. (2002). Substantial equivalence—an appropriate paradigm for the safety assessment of genetically modified foods? *Toxicology, 2002*(181-182), 427-431. doi:10.1016/S0300-483X(02)00488-2

Loureiro, M. L. & Bugbee, M. (2005). Enhanced GM foods: Are consumers ready to pay for the potential benefits of biotechnology? *Journal of Consumer Affairs, 39*(1), 52-70. doi:10.1111/j.1745-6606.2005.00003.x

Magnusson, M. K., & Koivisto Hursti, U-K. (2002). Consumer attitudes towards genetically modified foods. *Appetite, 39*(1), 9-24. doi:10.1006/appe.2002.0486

Mendel, G.J. (1866). *Experiments on Plant Hybridization*. Presented at the Nature Research Society of Brünn.

Nakajima, O., Koyano, S., Akiyama, H., Sawada, J., & Teshima, R. (2010). Confirmation of a predicted lack of IgE binding to Cry3Bb1 from genetically modified (GM) crops. *Regulatory Toxicology and Pharmacology, 56*(3), 306-311. doi:10.1016/j.yrtph.2009.09.020

National Human Genome Research Institute. (2010). Importance of Mouse Genome. Retrieved http://www.genome.gov/10001345

National Research Council, & Institute of Medicine. (2004). *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*. Washington, DC: The National Academies Press.

Nicolia, A., Manzo, A., Veronesi, F., & Rosellini, D. (2014). An overview of the last 10 years of genetically engineered crop safety research. *Critical Reviews in Biotechnology, 34*(1), 77-88. doi:10.3109/07388551.2013.823595

People for the Ethical Treatment of Animals (PETA). (2014). *The Organic and Free Range Myth*. Norfolk, VA. People for the Ethical Treatment of Animals. Retrieved from: http://www.peta.org/issues/animals-used-for-food/free-range-organic-meat-myth/

Rojas-Méndez, J. I., Ahmed, S. A., Claro-Riethmüller, R., & Spiller, A. (2012). Acceptance of Genetically Modified Foods with Health Benefits: A Study in Germany. *Journal of Food Products Marketing, 18*(3), 200-221. doi:10.1080/10454446.2012.666453

Rowe, G. (2004). How can genetically modified foods be made publicly acceptable? *Trends in Biotechnology, 22*(3), 107-109. doi:10.1016/j.tibtech.2004.01.007

Saher, M., Lindeman, M., & Koivisto Hursti, U. K. (2006). Attitudes towards genetically modified and organic foods. *Appetite, 46*(3), 324-331. doi:10.1016/j.appet.2006.01.015

Séralini, G-E., Clair, E., Mesnage, R., Gress, S., Defarge, N., & Malatesta, M. (2012). Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Food and Chemical Toxicology, 50*(11), 4221-42231. doi:10.1016/j.fct.2012.08.005.

Sheng Y, Qi X, Liu Y, Guo M, Chen S, He X, Xu W. (2014). Subchronic toxicity study in vivo and allergenicity study in vitro for genetically modified rice that expresses pharmaceutical protein (human serum albumin). *Food and Chemical Toxicology*, *72*(7), 242-246. Doi:10.1016/j.fct.2014.07.030.

Spiegelhalter, F., Lauter, F. R., & Russell, J. M. (2001). Detection of Chemically Modified Food Products in a Commercial Laboratory. *Journal of Food Science: Concise Reviews in Food Science, 66*(5), 634-640. doi:10.1111/j.1365-2621.2001.tb04613.x

United Nations Department of Economic and Social Affairs, Population Division. (2004). *World Population to 2300*. New York, NY: United Nations. Retrieved from: http://www.un.org/esa/population/publications/longrange2/WorldPop2300final.pdf

U. S. Food and Drug Administration (FDA). (2013). *FDA's Role in Regulating Safety of GE Foods*. Silver Spring, MD: U. S. Food and Drug Administration. Retrieved from: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm352067.htm

United States Department of Agriculture (UDSA). (2014). *American Adults are Choosing Healthier Foods, Consuming Healthier Diets - USDA research shows improvements in diet quality between 2005 and 2010*. Washington, DC: U. S. Department of Agriculture. Retrieved from: http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2014/01/0008.xml

United States Department of Agriculture (UDSA). (2008). *Fact Sheet: USDA's Food Safety Inspection Service, Inspection for Food Safety: The Basics.* Washington, DC: U. S. Department of Agriculture. Retrieved from: http://www.usda.gov/wps/portal/usda/usdamediafb?contentid=2008/02/0055.xml&printable=true&contentidonly=true

Watson, J. D., & Crick, F. H. (1953). Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid. *Nature, 171*(4356), 737-738.

World Health Organization. (2005). *Modern food biotechnology, human health and development: an evidence-based study*. Geneva, Switzerland: Department of Food Safety, Zoonoses and Foodborne Diseases. Retrieved from: http://apps.who.int/iris/bitstream/10665/43195/1/9241593059_eng.pdf?ua=1

Yamaguchi, H., Sasaki, K., Umetsu, H., & Kamada, H. (2003). Two detection methods of genetically modified maize and the state of its import into Japan. *Food Control, 14(*3), 201-206. doi:10.1016/S0956-7135(02)00062-2

Appendix

Table 1: EFSA proposed strategic scheme for pre-market safety and nutritional testing of GM plant derived feed and foods for 2008 onwards. Adapted from: (EFSA, 2008)

DRUM note:
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Cover Letter

December 16, 2014

Congressman DeFazio
2134 Rayburn Office Building
Washington, DC 20515

Dear Congressman DeFazio and staff,

H.R. 1699, also knows as the Genetically Engineered Food Right-to-Know Act, although commendable in merit, falls short in practice. As a senior Biology major at the University of Maryland with a background in research and public policy, I agree that the Federal Food, Drug, and Cosmetic Act should be amended to require that genetically engineered foods be properly labeled, as this information is highly valuable to the public. I, however, take contention with the proposed method of doing so and agree with many of your colleagues' reservations on the House Subcommittee on Health. As such, I urge you to amend this bill to make labeling practices both fair and accurate.

The attached report provides a detailed synthesis of the current research in the field of GE foods, which can serve as a background for amending this bill. I open with a condensed historical summary of the field to provide context. I continue with a detailed analysis of the current standing of the safety of GE foods through a synthesis of the current research, field reviews, and current regulatory standards. Since labeling is a practice that has direct impact on the public, I continue with a section on current public perception of GE foods to serve as a framework for labeling recommendations. Presenting technical aspects of GE food creation and current research on safety, while being cognizant of public perception, allows me to set forth best practices in GM food labeling for the American economy.

I commend you for taking great strides to ensure GE food safety for the modern generation by creating H.R. 1699. However, given its unlikely status of amending the Federal Food, Drug, and Cosmetic Act, I believe that our report, when used to amend H.R. 1699, can not only be instrumental in helping improve its chances of passing Congress to become law, but also help the American public by providing more specific, unintimidating, and accurate labels for GM foods.

Sincerely,

Robert J. Tully

Audience Analysis

The attached report proposes enhanced labeling for genetically engineered (GE) foods, expanding and furthering those outlined in H.R. 1699, a proposed amendment to the Federal Food, Drug, and Cosmetic Act. The primary target audience of this report is Congressman DeFazio of Oregon, the main sponsor of H.R. 1699. The secondary target audience is the American public, since the Congressman's legislation aims to represent the attitudes of his constituents and the American public on GE foods. The public is concerned about the rising market presence of GE foods, their possible health, environmental, and ethical issues, and what harms and benefits these foods might convey for them and their family. Because of these concerns, the public desires clear and concise GE food labels to assure them of the safety of consuming such foods.

The Congressman is not an expert in the field of genetic engineering. However, he must ensure that his legislation fits within the historical framework of the field and also make certain that all recommendations reflect the safety status of GE foods. The attached report addresses these individually in detailed sections. The Congressman and the American public know that consuming altered foods can be dangerous to their health, while unaware of the reasons why. Their limited knowledge of GE foods comes from biased sources, such as the media and the organic food industry. This report contrasts these various perspectives with unbiased scientific research so that its recommendations are based on scientific facts that benefit the public, rather than corporate agendas that profit certain industries.

The report is specifically tailored to address the differing values of the primary and secondary audiences. Additionally, this report focuses on American research to make tailored

recommendations for the American economy, since the American public has different attitudes toward GE foods as compared to the European public and others across the globe.

The demographics of the secondary audience are varied. On the one hand, the majority of food shoppers are women, who are discerning about the perceived nutritional benefits of the foods they choose. On the other hand, men tend to choose foods based on perceived taste, color, texture, and packaging, often regardless of perceived nutritional benefits. As such, most U.S. consumers are experienced shoppers with preconceived notions about the foods they consume. The attached report synthesizes the varied demographics of American food shoppers and their perceptions about food, in order to make tailored recommendations about GE labels that would best meet consumer needs.

The report aims to educate the primary and secondary audiences about the complexity of the GE food industry and GE foods in general. The report highlights that GE foods can be as safe as conventional foods. Moreover, improved GE food regulations may make many of these foods even safer than their conventional counterparts. It also tries to convey that biased organizations have shaped the popular opinion about GE foods, which stand financial gain from spreading misconceptions about the GE food industry. Finally, the report aims to persuade that GE food labels are not meant to deter consumers from these foods, but instead inform them about the benefits of their consumption and assure them of their safety.