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Labeling Genetically Engineered Food: Biotech's Best Bet

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EXECUTIVE SUMMARY

The labeling debate over genetically engineered (GE) food encompasses many emotions, fears, and personal beliefs over the use of biotechnology in food production. The complexity of the biotechnology, combined with the high political and economic stakes associated with the U.S. agriculture industry, has resulted in a polarized response to GE seed. Supporters of mandatory labeling believe that there are health and safety risks that regulators are overlooking. Proponents of GE technology believe it is safe and requires no special labeling requirements. We sought to identify for our client DuPont, a member of the biotech seed industry:

- What is good public policy regarding the GE food labeling debate?
- How can the biotech seed industry support the creation of good public policy?

The Food and Drug Administration's (FDA) mandate precludes it from mandating a label on GE food since genetic engineering is a production process and does not create a materially different end product (compared to a product produced without genetic engineering). Per the mandate, a mandatory label on GE food is unnecessary because there is no scientific evidence GE products negatively affect consumer's health or safety, nor is the final food product materially different from non-GE food. This regulatory position has failed to silence the debate.

Our team analyzed the GE food labeling debate, using a framework developed through case study research, to determine how the biotech seed industry can address concerns embedded in the debate. Our final recommendations are:

Recommendation 1: Instill confidence in regulatory agencies

Although no credible studies have linked the consumption of GE products to any negative health effects, beliefs that GE products are harmful persist. The FDA, USDA, and EPA have all found GE products to be safe, but consumers are concerned these agencies are infiltrated by corporate personnel and interests. Explaining to consumers the comprehensive review and required approval process of the three separate federal agencies can help reduce their anxiety related to a complex technology few consumers understand. Additionally, connecting consumers with the scientists at these regulatory agencies can re-establish the independence of the agencies and decrease consumers' concerns.

Recommendation 2: Educate consumers

The biotech seed industry's food safety message does not resonate with consumers primarily because of a lack of trust in corporations. This is the result of the past actions of some members of the food value chain that destroyed public trust in corporations. It is, therefore, incumbent upon every member of the food system to rebuild that trust. The biotech seed industry should promote the benefits of GE crops and explain the costs of mandatory labeling in a multi-pronged information campaign. Biotechnology benefits abound, but unless the industry proactively markets them, the positive aspects are drowned out by half-truths and misinformation. The rise of social media has only accelerated this trend.

Recommendation 3: Promote a national labeling standard and definition

Rather than opposing mandatory labeling, or individual state ballot initiatives, the biotech seed industry should proactively advance a plan to create a voluntary, nationwide labeling standard and definition. Similar to educating consumers, promoting a national labeling standard provides the industry with an opportunity to explain why a patchwork of state regulations is detrimental to the public interest. It also gives the industry a platform to advance a solution to a problem, which concerns many consumers. Defining which products would require labels narrows the debate and ensures producers and consumers are operating according to the same standard.

Recommendation 4: Deliberately increase industry transparency

Finally, the biotech seed industry must increase the transparency of the GE process and the development of their products. Identifying and addressing common consumer fears is a great place to start. The biotech seed industry should honestly communicate the risks associated with GE crops, as well as the negative side effects, both real and potential, associated with GE technology. Pesticide resistance is a substantial concern that has arisen largely from the widespread cultivation of GE crops. Instead of ignoring this negative aspect of GE crops, the industry should acknowledge these risks and then discuss ways to address them. Inviting critics or adversaries of the biotech seed industry to take tours of operations or attend presentations is another way to increase transparency.

One potential way to implement all of the recommendations above is through a voluntary, federally regulated Quick Response Code (QR code). The code, when scanned, would launch a web information page, regulated by the FDA. This type of regulated label ensures product information is presented accurately and free of industry influence. The label itself would be "truthful and not misleading" per FDA guidelines since it is a digital bar code. Furthermore, the label's presence would not create an implicit bias toward the product, unlike other voluntary labels. As uncovered in research interviews, the current opposition from the food industry to a mandatory label, explicitly stating the presence or absence of GE material in the food product, is rooted in the implicit value judgment of GE food that such a label would create. A digital QR code eliminates the possibility of such a bias. Perhaps most importantly, the QR code would support individual consumers' right to know what is in their food and how it is produced.

The research team formed our conclusions after analyzing the following five food labeling case studies to determine the key factors of general food labeling and thereby understand the likely outcome of the GE food labeling debate:

- Case Study 1: Labeling of Organic Foods
- Case Study 2: Labeling of Trans Fats
- Case Study 3: Labeling of rBST Milk Hormone
- Case Study 4: Labeling of Calorie Counts at Restaurants
- Case Study 5: Labeling of AquAdvantage Salmon

Two types of outcomes were identified: "labeling-related outcomes" and non-labeling-related, or "other outcomes." Labeling-related outcomes were dependent primarily on regulatory policy; whereas, other outcomes were predominantly market based.

Factors relevant to the labeling decision were analyzed to understand how regulators function within their mandates. Factors leading to other outcomes were used to understand how the market responded when laws or federal guidelines failed to adequately address consumer concerns. The following is a summary of the outcomes and the factors that led to them:

	ORGANICS		TRANS FATS		rBST MILK HORMONE		CALORIE COUNTS		AA SALMON	
OUTCOMES / FACTORS	*Labeling* Voluntary labeling (USDA)	*Other* Increased demand/sales	*Labeling* Mandatory labeling (FDA)	*Other* Ingredient switch	*Labeling* Voluntary labeling (FDA)	*Other* Increased demand/sales	*Labeling* Mandatory labeling (FDA)	*Other* Ingredient switch	*Labeling* No final determination	*Other* No final determination
Lack of material difference	◆				◆				◆	
Prevention of false/ misleading labels	◆				◆				◆	
Negative health effects			◆	◆			◆			
National-level legislation	◆		◆				◆			
State-/local-level regulation				◆			◆	◆		
Consumer demand/advocacy	◆	◆		◆	◆	◆		◆		

The team analyzed the GE food labeling debate through the lens of these factors to predict possible labeling outcomes. These became the basis for three potential policy alternatives: status quo, mandatory labeling, and voluntary labeling.

To determine how the biotech seed industry could address significant factors driving the labeling debate, especially in light of the three policy alternatives, we aligned client concerns with the factors to find areas of overlap that required action.

	GE FOOD LABELING	ALIGNMENT		CLIENT CONCERNS	
Factors	Lack of material difference	◆	◆	Food labels should be "truthful and not misleading"	Concerns
	Prevention of false/ misleading labels	◆			
	Negative health effects		◆	Health and safety is the #1 priority	
	National-level legislation	**Possible**	◆	National standard should be instituted	
	State-/local-level regulation	◆			
	Consumer demand/advocacy	◆	◆	Consumer driven product demand Consumer access to information (transparency)	

Our recommendations address each of these areas of alignment, which are potential opportunities for the biotech seed industry to reshape the GE food labeling debate because they combine regulatory guidelines, food value chain needs, and consumer concerns.

OVERVIEW OF THE PROJECT

2.1 Brief History of the Labeling Debate

The commercial sale of GE crops began in 1994.[1] There is broad science-based consensus, from organizations such as the American Medical Association (AMA) and National Academy of Sciences, that foods brought to market derived from GE crops pose no greater risk to human health than conventional food.[2] Other regulatory and intergovernmental bodies that support the inclusion of GE foods for human consumption include the World Health Organization (WHO), U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), the European Commission, and several other national academies of science.[3] However, opponents have objected to GE food on several grounds including: Precautionary Principle, health and safety issues, a consumer's "right to know" how their food is produced, environmental concerns, intellectual property rights, and the role of small business in the economy.

Labeling of GE products in the marketplace is required in 36 countries and the European Union;[4] however, the U.S. has no labeling requirement for GE foods. The FDA, which is primarily responsible for the health and safety of food sold in the U.S., stands by its current policy that requires a food label if there is a significant difference in composition or difference that is material to health. The FDA has not found any such difference in GE foods.[5]

In the absence of a national labeling requirement, pro-labeling advocates have pushed forward ballot initiatives in several states to require state-level GE food labeling. "In 2013, Connecticut and Maine passed GE food labeling laws with contingency clauses for implementation, and Vermont passed the first GE food labeling bill without a trigger clause. Vermont's law is scheduled to go into effect in 2016, but is currently being challenged in court."[6] This has begun to create a patchwork of varying regulations and requirements across the country, eliciting strong pushback from members of the food value chain (defined in Appendix B).

2.2 Problem Statement

The biotech seed industry possesses powerful technology to alter the genetic make-up of crops used in the food supply. The complexity of the technology, combined with the high political and economic stakes associated with the U.S. agriculture industry, has resulted in a polarized response to GE seed. We sought to identify:

» What is good public policy regarding the GE food labeling debate?

» How can the biotech seed industry support the creation of good public policy?

2.3 Client Concerns and Priorities

This report was written for a biotech seed company and incorporates not only our client's concerns and priorities, but also those of the general biotech seed industry. We identified these concerns through multiple interviews, conversations, and emails with the client.

1. **Health and safety is the number one priority**

   Only healthy and safe food should be created for consumers. The FDA, Environmental Protection Agency (EPA), and USDA should remain responsible for approving genetically engineered food products.

2. **A national standard and definition should be instituted**

   Food labeling regulations should be consistent across the nation. A national regime should designate which specific types of products require labels, consistent with a science–based safety assessment system. This means a state-by-state system of labeling requirements and guidelines is not acceptable. A national standard would also include adventitious presence thresholds. A threshold of 0.0% is unrealistic and cost prohibitive.

3. **Labeling costs should be borne by those who value the label**

   If a segment of the consumer market demands a label, the cost of the label should be allocable to those individuals. A labeling regime will raise costs to consumers, as well as other members of the food value chain. Outside of the FDA and USDA requirements, the market should drive consumer information and product availability.

4. **Consumers drive product demand and therefore dictate company strategy and decisions**

   Seed development is driven by the needs of farmers and other members of the food value chain. Seed production occurs over a three year planning horizon, while seed research and development takes many more years. Considerations of this timeline are necessary before large changes are made. Consumer demand has driven innovative and creative GE seed development as a means to meet the global goals of food production, environmental stewardship, and health and safety concerns.

5. **Consumers deserve access to information, or transparency, in support of knowledgeable consumer choices**

   The costs and benefits of biotechnology should be available to consumers in order to fully educate the public on agriculture, food, and biotechnology. This includes information about the FDA, USDA, and EPA requirements that must be met before a company introduces a new product to the market. The information should be accessible to the general public in an accurate, non-misleading, and understandable format.

6. **Decision on GE food label should follow the "truthful and not misleading" FDA guidelines**

   If a labeling change is instituted, the labels should be verifiable, non-discriminatory, and not misleading. Since safety standards set by the EPA, FDA, and USDA must be met prior to product release, labeling requirements should adhere to the safety standard required by regulators.

7. **Global food security is ensured through the food value chain**

   The biotech seed industry is an integral part of the food value chain that ensures all people have access to food. Crop yields must increase to meet the demand, which is projected to reach 9 billion people by the year 2050.

2.4 Other Food Value Chain Members Concerns and Priorities

Throughout our interviews with various members of the food value chain, we uncovered additional concerns that influenced company positioning in the GE food labeling debate.

Food and Beverage Manufacturers:

1. **Price increases:** The cost of switching to non-commodity, or specialized, ingredients will raise prices since such ingredients are difficult to find in large quantities and require additional expense to verify their origin.

2. **Consumer demand for non-GE food:** Consumer demand and marketing determine market share, and ultimately the business's success. If consumers want a specific product, a food manufacturer will provide it, but

there is little evidence that consumers want non-GE foods since sales of those products have not increased once labeled as non-GE or "non-GMO."

3. **Regulatory clarity:** Ambiguity on package label language has been frustrating.
4. **Marketing vs. health and safety:** Labeling the absence of an ingredient is viewed as a marketing tool, rather than an important piece of information for the consumer. Labeling the presence of an ingredient is viewed as a safety or health issue.

Non-profits/Advocacy Organizations:

1. **Measurability of GE material:** The inability to measure the presence or absence of GE material can be manipulated by unscrupulous producers, resulting in consumer harm or misinformation.
2. **Mandatory pre-approval:** Some of the organization support mandatory pre-approval (i.e., not the current voluntary pre-approval system even though the current system has virtually 100% industry compliance).

Food Retailers:

1. **Supply what consumers demand:** Several simply want to provide consumers with the products they desire.
2. **Regressive taxation of poor:** The typical customer is not demanding GE labels. Anything that raises prices functions as a regressive tax on the poor who spend a higher percentage of their income on food than those in the middle and upper class.
3. **Creation of new industry:** Mandatory or voluntary labeling would lead to the creation of a new industry for GE credentialing.
4. **Tracking system:** It is difficult to keep track of which products contain GE materials. If a product cannot be tested for the absence of GE material, then it must be tracked from its origin. Labeling a food product that cannot be tested is risky since it provides opportunity for fraud.
5. **Simplicity:** Any label should be simple and clear.

Commodity Processors:

1. **Identity preservation supply chain:** In the current commodity based food system, most products are easily swapped between other processors, which helps the industry manage risk. Labeling specific attributes creates an identity preservation supply chain, which could have significant impacts on producers and consumers.
2. **Supply constraints:** Typically processors contract with farmers more than a year in advance, which makes large, near-term changes in production difficult.
3. **Decrease in customer choice:** If the goal of mandatory labeling is to provide the customer choice, it is a failed policy. The general reaction in countries with mandatory labeling laws has been to either reformulate ingredients or exempt the product from labeling.
4. **Demand driven system:** A voluntary label is more effective in providing choice as it allows consumers to "pull" those products through the food supply chain.
5. **Fact-based consumer preferences:** Processors want to meet consumer demand but desire consumer's preferences to be based upon factual basis, not the whims of a minority.

Similarities to Client Concerns:

1. **Increase transparency:** Every food value chain member supports increased transparency and the consumer's right to know.
2. **National standard and definition:** There is near unanimous support for a uniform, national standard and definition.
3. **QR code support:** Many members embrace the idea of a QR code.
4. **Global food security:** There is a shared concern for global food security.
5. **Regulatory guidance:** The value chain has a strong desire for definitive guidance from regulators with regard to GE labeling.
6. **Educate consumers:** All members of the food value chain and regulators share the responsibility to educate consumers.
7. **Health and safety:** Each company we interviewed kept the health and safety of the consumer in the forefront of their minds. As one professor, who has spent his entire career in agriculture and agribusiness, said during an interview, "We're all vulnerable. We all make mistakes. We keep testing food all the way up to the consumer to make sure it's safe. [...] We have plenty of problems with our food system. Do you think anyone who runs a food company wants to risk the future of their company by their products killing one person?"

2.5 About the Team

This policy analysis exercise was completed by a two-member graduate student team at the Harvard Kennedy School as a Master in Public Policy graduation requirement. The purpose of this exercise was to understand the intersection of business and government in creating good public policy.

PROJECT SCOPE & METHODOLOGY

This report is limited in scope to a recommended approach for the biotech seed industry to pursue in the GE food labeling debate. Given the indirect repercussions of a labeling requirement, the recommendations are broad suggestions for engagement. The biotech seed industry is not directly affected by GE food labeling, but as an integral member of the food value chain, labeling requirements affect its business planning and strategy considerations. The report focuses on the regulatory mandates and guidelines of the FDA to understand the likely outcome of the labeling issue. It also includes the USDA's mandate and guidelines where appropriate.

Given the enormity of the GE food labeling debate, this report does not include the following: an analysis of the EPA and its regulations concerning GE seed or the actual costs of any labeling regime that may be implemented. Some cost estimates are referenced, but these estimates are from specifically cited cost analysis reports performed by others. Additionally, the testing methodology, capabilities, and verification of determining adventitious presence are a significant part of this discussion, which this report does not address.

In order to identify appropriate public policy recommendations, the research team utilized a case study approach. Analyzing and understanding the historical, economic, and regulatory context of a variety of food-related cases allowed the team to create a framework to understand the GE food labeling issue and provide recommendations. We reviewed each case study with FDA and USDA officials to gain insight where appropriate.

3.1 Creating the Framework

The team examined the following case studies: organics, trans fats, rBST milk hormone, calorie counts, and AquAdvantage salmon.

» Organics: Organic labeling is closely linked to GE food labeling through overlapping stakeholders and ideologies. Organic foods are identified through their production process, but similar to GE foods, the final products are materially the same. The two categories are linked by the fact organic produce cannot originate from GE seed. Organic foods are subject to voluntary labeling,

regulated by the USDA, instead of the FDA.

» Trans fats: Mandatory labels identifying trans fats is one of the more recent food labeling controversies. Trans fats received a large amount of attention from the medical and public health communities, especially in the context of a wider national debate on obesity. Anti-GE proponents cite it as an example of regulatory failure due to delayed action.[7]

» rBST milk hormone: The synthetic milk hormone rBST is closely related to GE food given the role of biotechnology in both. The FDA ruled a voluntary label was acceptable and did not require a mandatory label because the use of rBST related to a production process rather than a material difference in food products.

» Calorie counts: Similar to trans fats, caloric intake has come under scrutiny as more and more Americans are identified as obese. Corporations balked at the requirement to label caloric levels of individual dishes at restaurants, claiming the labels increased costs, fell short of the public health goal, and could even increase caloric intake. Consumers' right to know the calorie content of their food at restaurants is similar to the consumers' desire to know if GE was used to create their food products.

» AquAdvantage salmon: AquAdvantage (AA) salmon is not yet on the market. AA salmon is GE salmon, which the FDA has deemed safe, but has not given final approval. The fish is the first GE animal to be raised primarily for human consumption. The labeling conversation surrounding AA salmon focuses on many of the same issues as GE plants.

The research team considered, but ultimately excluded the following case studies:

» Kosher: Kosher labels are permitted since it represents a religious exemption.[8] The GE food labeling debate is not religious based, although some individuals pursue it zealously.

» Cigarettes: Cigarette labeling went through a lengthy public debate, but the products are not considered food. Furthermore, cigarettes have largely fallen out of favor with consumers through various initiatives, making it difficult to isolate the labeling effect.

» Dolphin-safe tuna: The voluntary label is part of the Dolphin Protection Consumer Act, and almost entirely related to a production method. The team felt the organic case study was a closer comparison for GE food labeling.

» Alcohol: Health and safety concerns are the primary reason for labeling alcohol. We did not find any credible science indicating a similar level of health concern for GE food.

After reviewing each case, we:

1. Identified significant outcomes of the case
2. Divided the outcomes between labeling-related and non-labeling-related ("other") outcomes
3. Identified labeling-related outcomes as either mandatory or voluntary
4. Identified the regulatory agency responsible for implementing and executing the identified regulation
5. Determined the primary factors responsible for each outcome.

Since this project focuses on GE food labeling, our report predominantly examines labeling-related outcomes and factors. To determine the most important factors to regulators and to the labeling outcome, we extracted all the main factors from the case studies and compared them. We then created a framework to identify the most important factors in the GE food labeling debate and likely regulatory responses.

3.2 Applying the Framework

The team then analyzed the GE food labeling debate for key factors. We filtered the factors through the predictive framework developed from our case study analysis to evaluate labeling-related outcomes. Based on which factors were present, we determined the likelihood of an outcome. Next, we relabeled the predicted outcomes as the set of potential GE food labeling policy outcomes or alternatives. The most likely policy alternative was later used to design specific recommendations. We then aligned the GE labeling factors, potential outcomes, and the client's concerns to construct recommendations. Client concerns that did not align with relevant factors in the debate were eliminated from further analysis. The remaining factors were then analyzed and a key recommendation developed for each factor, based on the most likely outcome. The final recommendations represent actions the biotech seed industry should take in order to best satisfy numerous stakeholders interests.

The diagram in Figure 1 (p. 9) maps the identification of factors to the final recommendations made in this report.

The team also identified non labeling-related "other" outcomes such as changes in social or business norms as a

result of the labeling movement. For example, consumers may no longer purchase a certain product discussed in the labeling debate (social norm) or a business may no longer sell an item (business norm) being debated. Since effective public policy encompasses more than just rules and regulations, the main factors that led to "other outcomes" provide insight into consumer demand, the need for transparency, and creating trust in the national food supply.

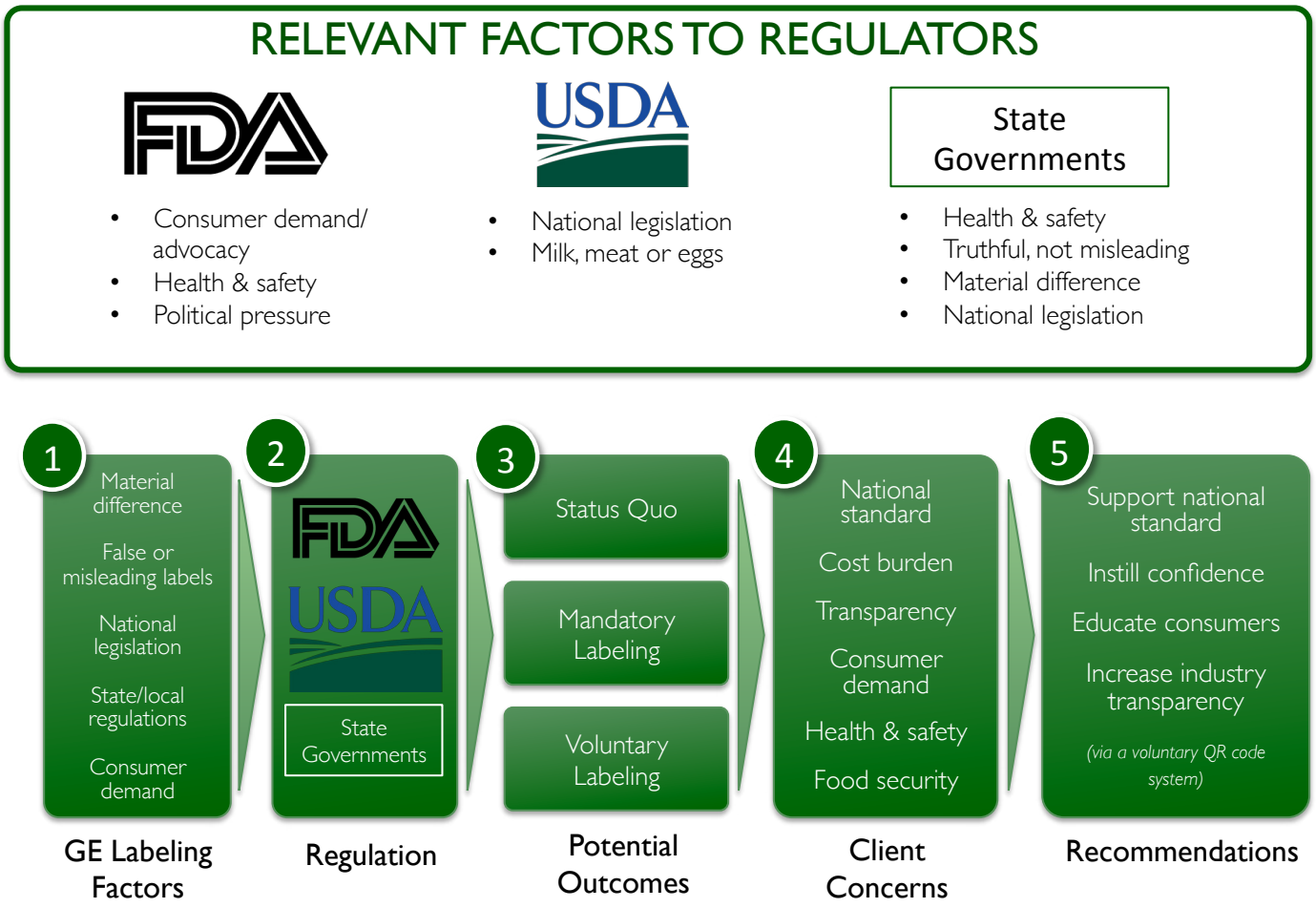
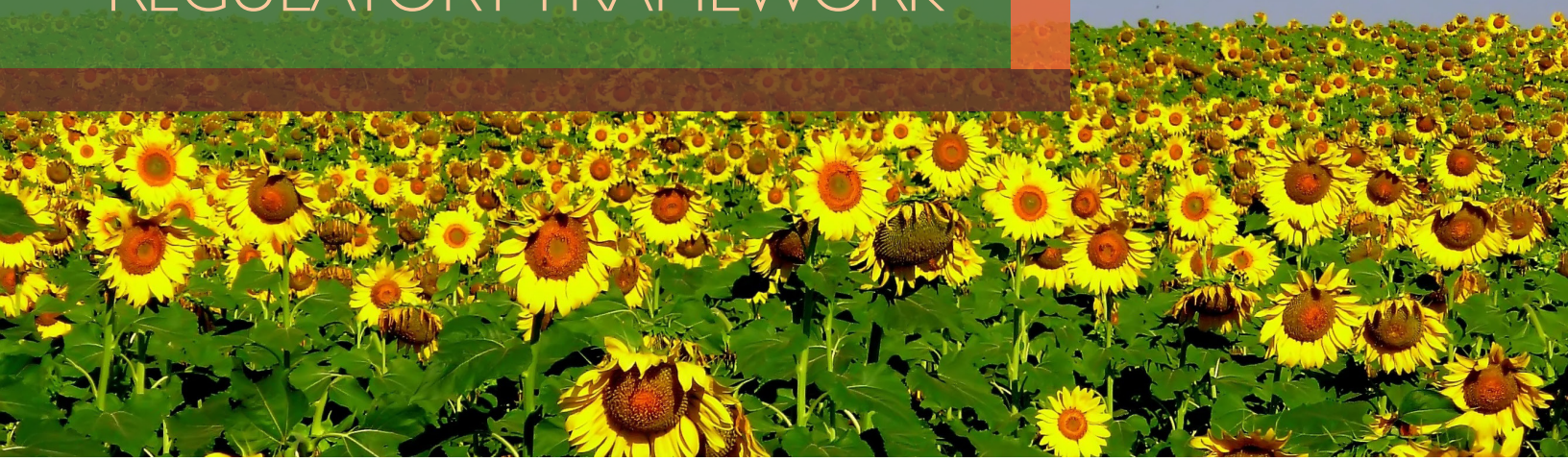


Figure 1: Mapping the identification of factors to the final recommendations.

REGULATORY FRAMEWORK



Biotechnology regulation falls under the purview of three federal agencies: the FDA, USDA, and EPA. The **Coordinated Framework for Regulation of Biotechnology was finalized in 1986;** it has three tenets:

- U.S. approach would focus on the end product of genetic modification technology, not the process itself,
- Verifiable scientific risks would be required to bar use of the technology, and
- Genetically modified products are on a continuum with existing products, and therefore, existing regulatory oversight is sufficient to protect the public.[9]

4.1 FDA Regulations[10]

The FDA provides regulatory oversight under the **Federal Food, Drug, and Cosmetics Act of 1938**[11] (FFD&C Act). The agency is charged with the safety of all marketed food and places the onus on producers, developers, and manufacturers to ensure food produced and sold for market consumption complies with safety standards. The FFD&C Act identifies a distinction in "food adulteration," between adding substances and those that are naturally present. Added substances are held to a stricter standard. Some additives require certification, while others are Generally Recognized As Safe (GRAS) by the FDA and do not require certification. If a food additive is not GRAS, the producer must demonstrate to a reasonable certainty that no harm will result from the intended use of the additive. Any product made of GRAS ingredients can go directly to market; the FDA, however, retains the right to challenge this assertion.

The FDA considers GE foods GRAS.[12] This is because the genetic changes to the plant do not affect any "characteristic of the food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food…)" as defined in section 201(s) of the FFD&C Act. Section 403 of the FFD&C Act governs the labeling of foods. Labels are generally required to be truthful, informative, and not misleading. Labeling is discussed further below.

The FDA's biotechnology policy was released in **1992** as its **Statement of Policy: Foods Derived from New Plant Varieties.**[13] The document clarifies the agency's interpretation of the FFD&C Act with respect to human foods and animal feeds derived from new plant varieties and provides guidance to industry on scientific and regulatory issues related to these foods. The 1992 policy does not establish special labeling requirements for GE foods as a food class. The policy states the FDA has no basis for concluding that GE foods differ from other foods in any meaningful or uniform way or that the new technique presents any different or greater safety concern than foods developed by classic breeding.

In **1999**, the **FDA requested comments on its policies related to GE products**[14] in the food supply. The feedback contained strongly held but divergent views on whether GE foods should be required to bear a special label. There was general agreement that providing more information to

consumers would be useful. Commenters supported a need for guidance from the FDA regarding appropriate ways the industry could voluntarily provide information on a food label regarding GE ingredients. However, the FDA notes that comments requesting mandatory disclosure of GE ingredients did not provide data or other information regarding consequences to consumers from eating GE foods or any other basis for the FDA to find under section 201(n) of the FFD&C Act that such a disclosure was a material fact. The agency is still not aware of any data or other information that would lead to a conclusion that GE foods are materially different and must be disclosed under sections 403(a) or 201(n) of the FFD&C Act.

Due to the FDA's position that GE foods are GRAS, it does not require the labeling of GE ingredients. However it did issue **DRAFT Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering**[15] in **2001**, which contains nonbinding recommendations. Under section 201(n), the presence or absence of information is relevant in determining whether a label is misleading. The key points of the guidance are as follows:

- FDA is generally supportive of voluntarily identifying the use of GE to create food products.
- FDA is generally unsupportive of requiring the identification of the use of GE since such labeling may be misleading for the following reasons:
    1. Use of "genetically modified" or "GMO" is inaccurate since genetic modification includes modifications achieved through classic breeding and is not specific to genetically engineered food products. Use of "genetically engineered" or "biotechnology" is more accurate.
    2. "GMO free" may be misleading on most foods, since most foods do not contain organisms.
    3. Use of the term "free" may be inaccurate since there is the potential for adventitious presence of GE materials. "Free" can only be used if there is an identified threshold and method for testing this in a wide variety of foods. Such test methods and defined threshold do not currently exist.
    4. A statement that a food does not contain GE ingredients may be misleading since it implies that the labeled food is superior to foods that are not so labeled.
    5. A statement that a single ingredient was not GE may imply the absence of other GE material in the food product.
    6. A statement that a food or ingredient is not GE when there is no marketed GE variety in that category of food is misleading.
- It is difficult to substantiate that a food or ingredient is non-GE because the testing methods to confirm the claim do not exist. Instead, special handling and segregation of the ingredients would be required. This should fall under a production process.

In **2001**, the FDA issued a **proposed rule** that would require developers to submit a scientific and regulatory assessment of the bioengineered food 120 days before the bioengineered food is marketed. In the **premarket notification** proposal, FDA recommends developers continue the practice of consulting with the agency before submitting the required premarket notice. The proposed rule was not finalized.[16]

The FDA also regulates GE animals under the new animal drug provision of the FFD&C Act. Genetically engineering an animal affects the structure or function of the animal, and meets the FFD&C Act's drug definition. Generally, a new animal drug is "deemed unsafe" unless the FDA has approved a new drug application for that particular use. Under the FFD&C Act, sponsors are required to demonstrate the safety and effectiveness of the new animal drug for the proposed conditions of its use prior to marketing. For new animal drugs that are intended for use in food-producing animals, FDA's evaluation of safety also includes an evaluation of food safety.[17]

In 2009, the agency released its finalized **Guidance for Industry 187: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs**. The guidance explains the regulation process and provides recommendations to producers of GE animals to help them meet their obligations and responsibilities under the law.[18]

4.2 USDA Regulations[19]

Under the **Plant Protection Act**, the Animal and Plant Health Inspection Service (APHIS) of the USDA has the authority to regulate, prohibit, and restrict the importation, exportation, and the interstate movement of plants, plant products, certain biological control organisms, noxious weeds, and plant pests.[20] The Biotechnology Regulatory Services is an APHIS operational program unit, which protects agricultural and natural resources by ensuring safe development of GE organisms using a science-based regulatory framework. GE plants, "regulated articles," are reviewed to ensure that, under the proposed conditions of use, they do not present a plant pest risk through ensuring appropriate handling, confinement, and disposal.[21]

"APHIS regulations provide a petition process for the determination of non-regulated status. If a petition is granted, the organism will no longer be considered a "regulated article" and will no longer be subject to oversight by APHIS. The petitioner must supply information such as the biology of the recipient plant, experimental data and publications, genotypic and phenotypic descriptions of the genetically engineered organism, and field test reports. The agency evaluates a variety of issues including the potential for plant pest risk; disease and pest susceptibilities; the expression of gene products, new enzymes, or changes to plant metabolism; weediness and impact on sexually compatible plants; agricultural or cultivation practices; effects on non-target organisms; and the potential for gene transfer to other types of organisms. A notice is filed in the Federal Register and public comments are considered on the environmental assessment and determination written for the decision on granting the petition. Copies of the APHIS documents are available to the public."[22]

4.3 EPA Regulations[23]

The EPA derives its regulatory mandate and authority regarding GE technology from the **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**[24] and the **Food Quality Protection Act (FQPA)**.[25] The agency institutes a registration process, which "regulates the sale, distribution, and use of pesticides in order to protect health and the environment, regardless of how the pesticide was made or its mode of action."[26] This includes pesticides produced by an organism through GE technology, such as Bt corn or Bt cotton. FIFRA specifically regulates the distribution, sale, use, and testing of pesticidal substances produced in plants (i.e., plant incorporated protectants or PIPs) and microbes. Under the FQPA, applicants must register pesticidal products prior to their sale and distribution, and the EPA may establish conditions for use as part of the registration. The EPA also sets consumption safety levels for pesticide residues on and in food and animal feed or establishes an exemption from the requirement.[27]

4.4 State Regulations

States maintain the freedom to regulate food products sold within their jurisdiction. However, the FDA retains the authority to overrule state regulation affecting food products if interstate commerce is affected.[28] Furthermore, state legislation may be challenged in federal court and overturned by judicial ruling. According to the Center for Food Safety, as of October 2014, over 30 states have put forth bills to create GE legislation. The following states have successfully passed labeling requirements: Vermont, Connecticut, and Maine. The Connecticut and Maine legislation will only be enacted if five neighboring states (for Maine) or a combination of states that add up to 20 million residents (for Connecticut) also pass similar labeling laws.[29]

4.5 European Union Regulations vs. U.S. Regulations

The U.S. and the European Union have two fundamentally different positions when determining acceptable health, environmental, or safety standards for GE products. The U.S. is currently more willing to accept biotechnology related risk, while the EU is more risk averse. The different approaches to biotechnology regulation are highlighted when discussing GE food labeling and helps explain how the two entities regulate the exact same technology in such different ways.

The U.S. and European countries have switched positions with regard to their regulation stringency. From the 1960s to mid-1980s, health, safety, and environmental regulations were more restrictive in the U.S. than in Europe. However, since the 1980s, the opposite has been true, and Europe's regulations are viewed as more restrictive than the U.S.[30] Europe's regulations are often characterized by a suspicion of science and a reluctance to trust either government or industry.[31] By providing customers with information regarding the presence of GE material in food products, the European Union's goal was the offer customer's informed choice. However, the result has been a decrease in available choices because of the stigmatization of GE products with the label. In July 2010 the European Commission adopted a new flexible approach to GE cultivation, which takes into consideration Member States desires, but ensures scientific evidence remains the basis for any GE authorization.[32] The U.S. regulators, in contrast, have seemingly cooperated with industry and demonstrated a willingness to embrace technological innovation.[33]

The Precautionary Principle lies at the heart of both regions' regulatory process, and is defined as, "the precept that an action should not be taken if the consequences are uncertain and potentially dangerous".[34] European scientists criticized the U.S. for strict environmental standards in the late 70's; one such scientist suggested the U.S. sought to "reduce 'reasonable risk' practically to 'zero risk.'"[35] A British journalist went further, "We saw the Americans thrashing around from one pollution scare to the next, and we were mildly amused. One moment it was cyclamates, mercury the next, then ozone, lead, cadmium – over there they seemed set on working their way in a random manner through the whole periodic table."[36] Ironically, Americans today could say a very similar thing about European regulator's insistence on evaluating different GE traits.

CASE STUDIES

5.1 Organics

BACKGROUND

The industrialization of agriculture in the 1940s created a demand for food grown without chemical inputs.[37] As the desire for organic crops increased, Congress authorized the USDA to establish a National Organic Program (NOP) in 1990.[38] NOP is part of the USDA's Agricultural Marketing Service and has grown rapidly over the last decade. There are now approximately 30,000 USDA-certified organic farms or processing facilities worldwide.[39] Organic food sales account for just over 4% of total U.S. food sales, but organic food demand continues to grow by double-digit percentage growth.[40]

OUTCOMES

1. **Voluntary labeling under the USDA.** Unlike most food products, the USDA, rather than the FDA, governs organic goods. The voluntary label refers to a production method, rather than a material difference in the product. Not all organic products carry the same wording or label. The USDA has established three levels of organic labeling (See Figure 2, p. 14).[41]

2. **Increased consumer demand for and sales of Organics.** Organic products command a price premium,[42] and while there is an ongoing debate related to the nutritional value between organic and conventionally grown products, demand has continued to increase.[43] The chart below depicts the rise in organic demand, with fruit and vegetables comprising the majority of the increased sales. Consumers tend to cite health or environmental reasons to explain their preference for organically produced food.[44]

ORGANICS		OUTCOMES	
		Labeling related	Other
		Voluntary labeling (USDA)	Increased demand/sales
FACTORS	Lack of material difference	◆	
	Prevention of false/ misleading labels	◆	
	Negative health effects		
	National-level legislation	◆	
	State-/local-level regulation		
	Consumer demand/advocacy	◆	◆

FACTORS THAT DETERMINED OUTCOMES

1. **Consumer demand/advocacy and National-level legislation.** Consumer demand was the primary reason USDA offered the label instead of the FDA, because consumer demand alone is not a sufficient reason for the FDA to label a product.[45] Yet, many consumers were not satisfied with this result and helped facilitate the passage of the Organic Foods Production Act, which created the NOP. USDA's Agricultural Marketing

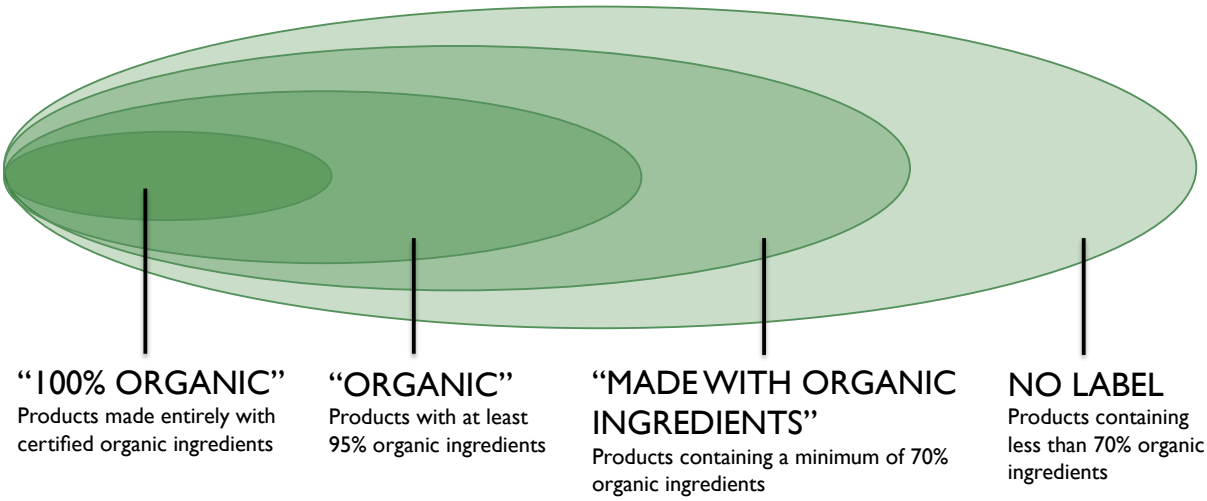
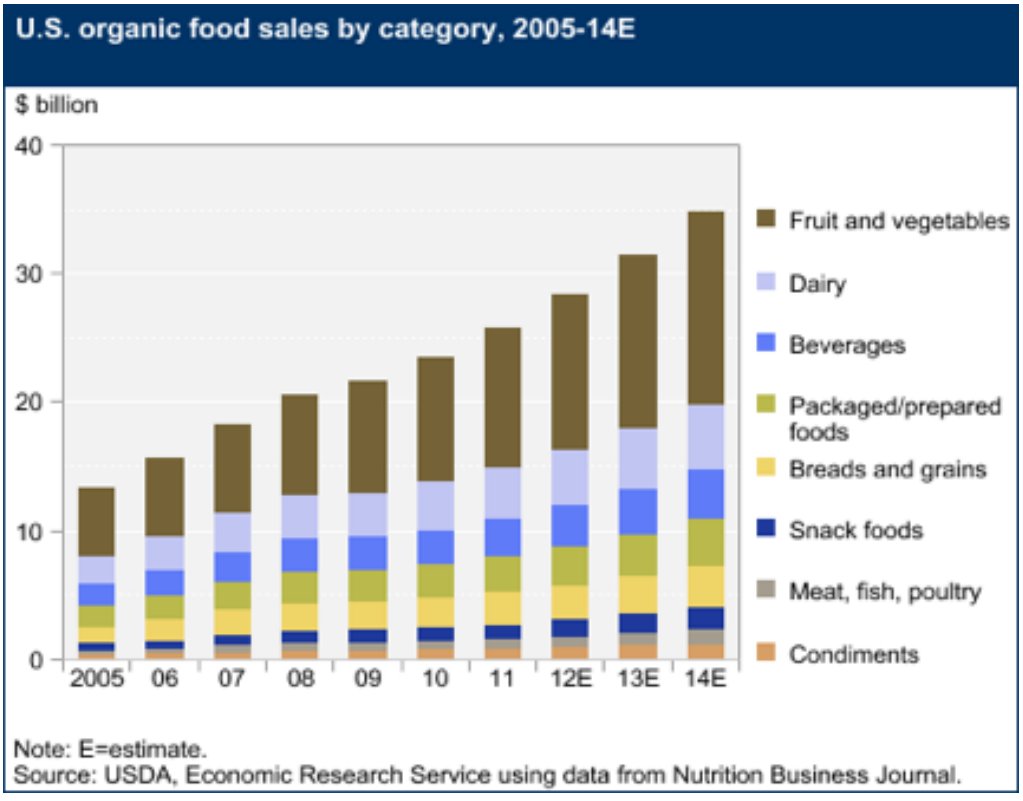


Figure 2: The three USDA certification levels of organic products. Note: Only products with more than 95% organic ingredients may display the USDA Organic seal.

Services oversees the NOP because it was created through national legislation in response to marketing demands.

2. **Lack of material difference from similar products.** The FDA decided not to label organic products because it represented a difference in production methods, rather than a material difference between organic and conventional food products. For instance an organic tomato looks, tastes, and has the same characteristics as a tomato grown in a conventional manner. Requiring a label for products without a material difference violates the FDA's mandate to provide truthful, non-misleading guidance.
3. **Prevention of false or misleading labeling.** The legislation creating the NOP was also crafted in response to concerns about food producers providing false, misleading information regarding organic products. Producers, given the opportunity to make a claim about their products without an official standard or qualification, may state untruthful information, which confuses the consumer. USDA recognized a problem with the organic term and, as a result, set standards organic producers must follow in order to label their products with USDA's certified organic seal.[46] It is important to note many people now, incorrectly, believe organic food is nutritionally superior to conventionally grown produce,[47] which may mean the label is misleading consumers.



5.2 Trans Fats

TRANS FATS		OUTCOMES	
		Labeling related	Other
		Mandatory labeling (FDA)	Ingredient switch
FACTORS	Lack of material difference		
	Prevention of false/ misleading labels		
	Negative health effects	◆	◆
	National-level legislation	◆	
	State-/local-level regulation		◆
	Consumer demand/advocacy		◆

BACKGROUND

Trans fats are a type of unsaturated fats, which can be artificially created, and are used in food production. By the 1980s, animal fats were a great concern of dieticians. Activists took out full-page newspaper advertisements attacking the use of beef tallow in McDonald's french fries and urging fast-food companies to switch to vegetable-based oils, including partially hydrogenated versions which contained trans fats. The result was an industry-wide switch to trans fats.[48]

OUTCOMES

1. **Mandatory labeling under the FDA.** Before 2006, American consumers could not directly determine the presence or quantity of trans fats in food products. On July 11, 2003, the FDA issued a regulation requiring manufacturers to list trans fat on Nutrition Facts panels.[49] The negative health effects were the primary catalyst behind the FDA's decision to mandate labeling.
2. **Ingredient switch.** On November 7, 2013, the FDA issued a preliminary determination that trans fats are not GRAS. This meant trans fats could not be used in foods without specific regulatory authorization, virtually eliminating trans fat from the U.S. food supply.[50,51] However, the elimination of trans fats was already happening on a large scale. Between June 2006 to October 2007, Wendy's, Taco Bell, McDonald's, and Chick-fil-A announced plans to eliminate trans fats from restaurants.[52,53,54,55] They were later joined by the Walt Disney Company and the Girls Scouts.[56,57]

FACTORS THAT DETERMINED OUTCOMES

1. **Negative health effects.** In 2006, the New England Journal of Medicine published a comprehensive review of studies on trans fats and reported a strong and reliable connection between trans fat consumption and coronary heart disease.[58] The scientific evidence has led the National Academy of Sciences' to conclude there is no safe level of trans fat consumption.[59]
2. **Consumer demand/advocacy.** Advocacy groups targeted food vendors through legal action. In May 2003, BanTransFats.com, Inc. filed a lawsuit against Kraft Foods to force Kraft to remove trans fats from the Oreo cookie. The lawsuit was withdrawn when Kraft agreed to work to find a substitute for trans fat in the Oreo.[60] Similarly in 2006, the Center for Science in the Public Interest (CSPI) sued KFC over its use of trans fats. As a result, KFC announced it would replace partially hydrogenated soybean oil.[61] The larger result of these lawsuits was the switch to trans fat-free oils by other major fast-food purveyors.
3. **State- and local-level regulation: quantity limitations.** Many cities, counties, and states have joined the march against trans fats. On December 5, 2006, New York was the first large U.S. city to strictly limit trans fats in restaurants. Other areas with similar bans include Philadelphia (PA), Boston (MA), Nassau County (NY), King County (WA), and the State of California.[62]

5.3 rBST Milk Hormone

BACKGROUND

Bovine somatotropin (BST) is a naturally occurring hormone in dairy cattle. Researchers discovered that dairy cows given additional amounts of BST produced more milk. In the 1970s, biotech company Genentech used recombinant DNA to create a synthetic hormone called recombinant bovine somatotropin (rBST),[63] which had the same effect as naturally occurring BST. The FDA ruled rBST safe for use in 1993, finding no significant difference between milk produced from

rBST MILK HORMONE		OUTCOMES	
		Labeling related	Other
		Voluntary labeling (FDA)	Increased demand/sales
FACTORS	Lack of material difference	◆	
	Prevention of false/ misleading labels	◆	
	Negative health effects		
	National-level legislation		
	State-/local-level regulation		
	Consumer demand/advocacy	◆	◆

rBST treated cows and non-rBST treated cows.[64] The WHO, AMA, National Institutes of Health, and regulatory agencies in 50 countries all concluded that milk from rBST treated cows is as safe for human consumption as milk from non-rBST treated cows.[65] The concern for animal welfare, not negative human health effects, led the European Union to ban the use of rBST.

OUTCOMES

1. **Voluntary labeling under the FDA.** The FDA allowed producers to use voluntary labels to inform customers of their non-rBST production practices, provided the labels were truthful and not misleading.[66] The agency stressed their guidance was not binding on states, and states would bear the primary responsibility to ensure rBST labeling claims were accurate[67]. The FDA also expressed concern the term "rBST-free," may "imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced."[68] The FDA suggested an accompanying statement to place the claim in context to ensure consumers understood no significant differences existed in milk between the two production methods.[69]

Photo source: "Hormones in Milk," website accessed February 12, 2015, http://thechart.blogs.cnn.com/2008/04/09/hormones-in-milk/

It is important to note the FDA issued labeling guidance in response to consumer, industry, and states' requests even after it found no material difference in milk produced through either of the production methods. The FDA delegated responsibility for enforcement of labeling requirements to the states, but noted if the product was involved in interstate commerce, the FDA retained jurisdiction to ensure the label was true and not misleading.[70] Specifically, the agency noted that under section 201(n) of the FFD&C Act both the presence and the absence of information are relevant to whether a label is misleading.[71] While the FDA allowed voluntary labeling, the agency kept open the possibility of further guidance to help resolve future disputes.

The judicial system also limited FDA's labeling authority. A federal court found under current law, the FDA does not have authority to require labeling based on consumer interest alone. In Stauber v. Shalala, the court explained that absent evidence of a material difference, the use of consumer demand as a rationale for mandatory labeling would violate the law:

> *"If there is a difference, and consumers would likely want to know about the difference, then labeling is appropriate. If, however, the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different. In the absence of evidence of a material difference between rBST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act."* [72]

2. **Increased consumer demand for and sales of non-rBST treated milk.** Even with the disclaimer, many companies believe consumers want milk from non-rBST treated cows. Kroger, Starbucks, and Safeway are just a few companies who have agreed to purchase milk only from dairies that do not use rBST.[73]

FACTORS THAT DETERMINED OUTCOMES

1. **Consumer demand/advocacy.** Despite the FDA verifying the safety of rBST milk, many consumers felt the milk was different than milk produced from cows without rBST.
2. **Lack of material difference from similar products.** The agency cannot differentiate milk produced by rBST treated cows from those not given the rBST hormone.[74] Therefore, under the FFD&C Act, the FDA concluded it cannot require labeling based solely on differences in the production process.[75]
3. **Prevention of false or misleading labeling.** The FDA expressed concern a voluntary label could mislead consumers without proper context.[76] The Oakhurst Dairy case validated the FDA's concern. Oakhurst Diary, a family owned dairy in Maine, labeled its milk with the slogan, "Our farmers' pledge: no artificial growth hormones."[77] Monsanto sued Oakhurst on July 3, 2003, seeking an injunction to keep the dairy from using the label.[78] A compromise was reached when Oakhurst agreed to add a qualifying statement to its label saying, "FDA states: No significant difference in milk from cows treated with artificial growth hormones."[79]

5.4 Calorie Counts

CALORIE COUNTS		OUTCOMES	
		Labeling related	Other
		Mandatory labeling (FDA)	Ingredient switch
FACTORS	Lack of material difference		
	Prevention of false/ misleading labels		
	Negative health effects	◆	
	National-level legislation	◆	
	State-/local-level regulation	◆	◆
	Consumer demand/advocacy		◆

BACKGROUND

Approximately one-third of Americans spend 50 cents of every food dollar on food prepared outside the home.[80] The average American eats out six meals a week, and children consume almost twice as many calories when they eat a meal at a restaurant compared to a meal at home.[81] The 1990 Nutrition Labeling and Education Act did not cover nutrition labeling for restaurants and other ready-to-eat foods.[82] Obesity costs the U.S. over $190 billion each year because of higher health care costs associated with conditions such as heart disease, stroke, and diabetes.[83] With the advent of the Patient Protection and Affordable Care Act (ACA), systemic health concerns such as obesity have become issues of national concern in an effort to drive down costs for the entire health system.

OUTCOMES

1. **Mandatory labeling under the FDA.** The ACA was passed in March 2010, and led to the requirement for restaurant chains with 20 or more locations to publically post calories. Evidence of the effects of disclosing calorie content is mixed. "New York City commissioned a broad survey…Au Bon Pain, KFC, and McDonald's showed proof of calorie reduction after the law. At seven restaurant groups, there was no evidence of reduction, and at Subway, there was an increase of calorie consumption per visit."[84] Another study looked at Starbucks stores in New York City and noted a 6% decrease in customer calories after the calorie counts were posted.[85]
2. **Ingredient switch.** In a study published in 2013, a Johns Hopkins University public health researcher found restaurant chains' new menu items contained about 60 fewer calories than items already on the menu. The cuts are not coming from signature items but from newer items, such as salads and drinks.[86] Many other popular chains introduced smaller portions on their menu to highlight their lower calorie menu options."[87]

FACTORS THAT DETERMINED OUTCOMES

1. **State- and local-level regulation: mandatory labeling.** In 2006, New York City began requiring chain restaurants to post calorie counts on menus. Many other cities, counties, and states followed suit. This prompted the National Restaurant Association to side with consumer health advocates in an attempt to get a federal standard instead of dealing with a patchwork of varying local regulations. By November 2014, approximately 18 localities had menu-labeling regulations in effect.[88]
2. **Negative health effects.** Approximately 30% of Americans are identified as obese.[89] Studies link eating out with obesity and higher caloric intake.[90] Restaurant food is generally higher in calories and saturated fats and lower in nutrients, such as calcium and fiber, than meals prepared at home. It is difficult for people to limit their intake of calories at food service establishments without nutrition information.[91]
3. **National-level legislation.** The passage of national legislation is perhaps the most significant reason companies are required to disclose calorie counts. The National Labeling and Education Act in 1990, coupled with the Patient Protection and Affordable Care Act in 2010, played a significant role in the development and implementation of calorie count labels.

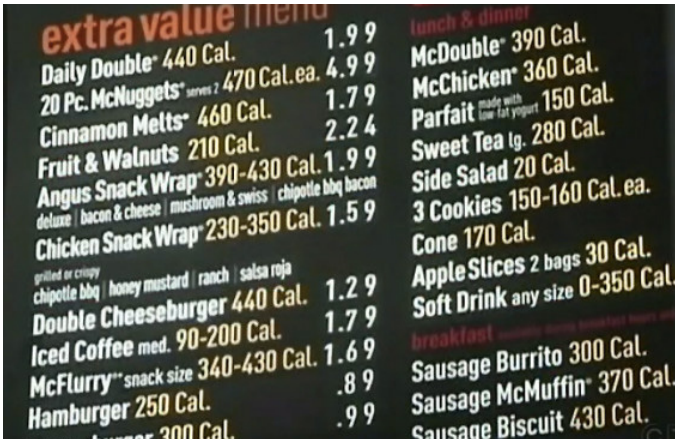


Photo source: "Whiley Nutrition Bytes," website accessed May 10, 2015, http://wileynutritionbytes.com/.

5.5 AquAdvantage Salmon

AA SALMON		OUTCOMES	
		Labeling related	Other
		No final determination	Unknown
FACTORS	Lack of material difference	◆	
	Prevention of false/ misleading labels	◆	
	Negative health effects		
	National-level legislation		
	State-/local-level regulation		
	Consumer demand/advocacy		

BACKGROUND

In 1989, Canadian researchers developed a transgene for wild Atlantic salmon, which became known as AA salmon.[92] A Pacific Chinook salmon's growth hormone-regulating gene and a promoter from an ocean pout were added to the Atlantic salmon's genes to allow the fish to grow faster.[93] The FDA is responsible for approving AA salmon because the genetic adaptation, called an "rDNA construct," meets the definition of a "drug" under the FFD&C Act.[94] In 2010, the FDA said AA salmon appeared safe to eat.[95] AquaBounty also received a letter stating all seven parts of the evaluation of a GE animal were complete.[96] The company then received a favorable environmental assessment from the FDA in December 2012.[97] As of May 2015, no final decision has been reached.

OUTCOMES

Meat from AA salmon is not yet approved to enter the U.S. food system, but the case raises interesting questions related to the process of regulatory approval and the labeling of GE food. If the FDA approves AA salmon's New Animal Drug Application (NADA), a label will accompany AA salmon fish eggs, the fry, and fish sold to growers before they are sold for food.[98] This is different than the label required for food products made from AA salmon.[99]

1. **No final determination made by FDA.** AA salmon is first GE animal designed for human consumption.[100] Consumers' concerns over the approval and introduction of a GE fish into the food chain have yet to fully mature but could play a key role in the labeling decision. Even though consumer demand is not a sufficient reason to label a product,[101] consumers could petition elected officials to change labeling laws through legislation. Political pressure seems to play a significant role in the approval process. The FDA has taken nearly 20 years to issue a final ruling on AA salmon. Furthermore, over 21 months have passed since all requirements have been met, yet there is still no FDA approval. Regardless of FDA's ruling, few biotech companies can wait two decades for approval of their products.

FACTORS THAT DETERMINED OUTCOMES

1. **Lack of material difference from similar products.** Food derived from AA salmon must be materially different from food derived from Atlantic salmon to require a label. Without a material difference, the FDA relies on a presumption that GE food ingredients are Generally Regarded As Safe (GRAS). Furthermore, the FDA does not consider GE food to be materially different.[102] This determination has been reviewed and upheld by courts.[103]
2. **Prevention of false or misleading labeling.** A label must describe the difference between the products in a truthful, non-misleading manner.[104] If the food derived from AA salmon is the same as food derived from Atlantic salmon, there is no justification to label. In fact, a label could even mislead consumers to believe one type of fish is superior to the other.

FACTORS & OUTCOMES

6.1 Summary Matrix of Case Studies, Outcomes, and Factors

We organized the case study factors to create a framework to analyze the GE food labeling debate. The matrix below lists the key factors identified in the previous section that related to labeling. The outcomes across the top row are either labeling-related or other outcomes.

	ORGANICS		TRANS FATS		rBST MILK HORMONE		CALORIE COUNTS		AA SALMON	
OUTCOMES / FACTORS	*Labeling* Voluntary labeling (USDA)	*Other* Increased demand/sales	*Labeling* Mandatory labeling (FDA)	*Other* Ingredient switch	*Labeling* Voluntary labeling (FDA)	*Other* Increased demand/sales	*Labeling* Mandatory labeling (FDA)	*Other* Ingredient switch	*Labeling* No final determination	*Other* No final determination
Lack of material difference	◆				◆				◆	
Prevention of false/ misleading labels	◆				◆				◆	
Negative health effects			◆	◆			◆			
National-level legislation	◆		◆				◆			
State-/local-level regulation				◆			◆	◆		
Consumer demand/advocacy	◆	◆		◆	◆	◆		◆		

6.2 Labeling-related Outcomes

We identified two main labeling-related outcomes based on the case studies.

VOLUNTARY LABELING – Under either the FDA or USDA, a voluntary labeling regime was established under which members of the food value chain could apply specific labels. Because labeling is strictly regulated under federal guidelines, voluntary labels were controlled by the FDA and USDA to ensure the labels were true and not misleading. The FDA and USDA, therefore, can set up guidelines to ensure consistency and uphold national standards, which helps consumers make informed choices.

MANDATORY LABELING – Any mandatory label under the FDA or USDA imposed specific guidelines for the food value chain. Mandatory labeling typically reflects vital information for consumer health choices. The labels are often the result of national legislation requiring the FDA or USDA to take action by providing guidance and regulating the label.

6.3 Labeling-related Factors

Normally, if the labeling issue in question focuses on a material difference, a false or misleading label, or a negative health effect, the FDA provides mandatory labeling guidance. If there is a lack of material difference, the label does not result

in false or misleading information, and there are no negative health or safety concerns, the FDA does not issue mandatory labeling guidelines.

However, national legislation, driven by different factors, can force mandatory or voluntary labeling action by the regulatory bodies. When states and localities enacted legislation on an issue, national legislation was used to create consistency and to promote trade and commerce between states. The FDA also retains the authority to issue mandatory guidelines for this same reason – to safeguard consistency and trade between states. National legislation can also be considered a response to consumer demand, unlike FDA mandatory guidelines, which cannot be created in response to consumer demand.[105] When national legislation is created in response to consumer demand, the FDA may provide guidelines for voluntary labeling or the legislation may place the labeling authority under another regulatory agency, such as the USDA.

Additional Labeling-related Outcome:

When studying the case studies above, we recognized state or local regulation was a significant factor in several cases. While none of our case studies produced an outcome with states implementing specific labeling guidance, it is a possible outcome we should consider. The team therefore created a third outcome, which is called "status quo."

STATUS QUO – The status quo is the absence of mandatory or voluntary labeling guidelines. This leaves space for states to enact their own initiatives or legislation to regulate labels for products sold in their states. Understandably, this results in a fragmented system with varying standards across the country.

The FDA does respond to consumer demand and advocacy that results in manufacturer-initiated voluntary labeling. The response is to ensure voluntary labels are not false or misleading. Because consumers may misinterpret the labels, the FDA can choose to provide guidance on what can and cannot be stated on the label to protect the consumer.

SUMMARY		LABELING-RELATED OUTCOMES			
		Voluntary labeling (USDA)	Voluntary labeling (FDA)	Mandatory labeling (FDA)	Status quo (States)
FACTORS	Lack of material difference	◆	◆		
	Prevention of false/misleading labels	◆	◆		
	Negative health effects			◆	◆
	National-level legislation	◆		◆	
	State-/local-level regulation			◆	
	Consumer demand/advocacy	◆	◆		◆

The following matrix summarizes the labeling-related factors and outcomes discussed above:

SUMMARY		OTHER OUTCOMES	
		Increased demand/sales	Ingredient switch
FACTORS	Lack of material difference		
	Prevention of false/ misleading labels		
	Negative health effects		◆
	National-level legislation		
	State-/local-level regulation		◆
	Consumer demand/advocacy	◆	◆

6.4 Other Outcomes

Two non-labeling-related outcomes were identified based on the case studies.

INGREDIENT SWITCH – Members of the food value chain switched ingredients in response to the market. Consumers shifted preferences based on the labeling changes and marketing campaigns. It is important to note the labeling changes did not mandate ingredient switches.

INCREASED DEMAND AND SALES – Consumers demand products for many reasons. Some of the rationale is based on evidence-based conclusions and others can be the result of fads, advocacy, misinformation, advertising, etc. We did not examine in detail the cause of increased demand or sales but merely note its influence on corporate strategy and lobbying efforts.

6.5 Other Factors

Debates over food products never remain a single-issue conversation focused solely on labeling. This is evident in the non-labeling outcomes, or the "other" outcomes – increased demand or sales, and ingredient switches. Increased demand of the products discussed in the debate is closely tied to consumer demand and advocacy. This is also true for ingredient switches. However, increased demand is solely linked to consumer demand or advocacy. Ingredient switches are additionally linked to state or local regulations that shift the market for the products in question. In response, manufacturers switch ingredients to maintain or gain market share. Many times, the state or local regulations are a function of consumer advocacy. Finally, if there are negative health effects, manufacturers switch ingredients to ensure the health and safety of their products.

ANALYSIS OF GENETICALLY ENGINEERED FOODS

7.1 GE Food Labeling-related Factors

Having identified factors relevant to the labeling outcomes of other products and the factors most important to regulatory agencies, we examined the GE food labeling controversy in order to predict the labeling outcome. The table to the right lists the factors that drove the labeling decision in the case studies with an "◆" beside the factors present in the GE food labeling discussion.

GENETICALLY ENGINEERED FOODS		OUTCOMES	
		Labeling-related	Other
FACTORS	Lack of material difference	◆	
	Prevention of false/ misleading labels	◆	
	Negative health effects		
	National-level legislation		
	State-/local-level regulation	◆	◆
	Consumer demand/advocacy	◆	◆

Based on numerous scientific studies, the FDA has determined there is no material difference between a product produced through GE and one produced in the traditional manner. Without a material difference, the FDA cannot require a mandatory label based upon a production method, therefore a label is unnecessary. Preventing false or misleading labels is also a mandate for the FDA. Since there are no material differences between the products, requiring a label for one product while not labeling another can mislead consumers because it implies a difference.

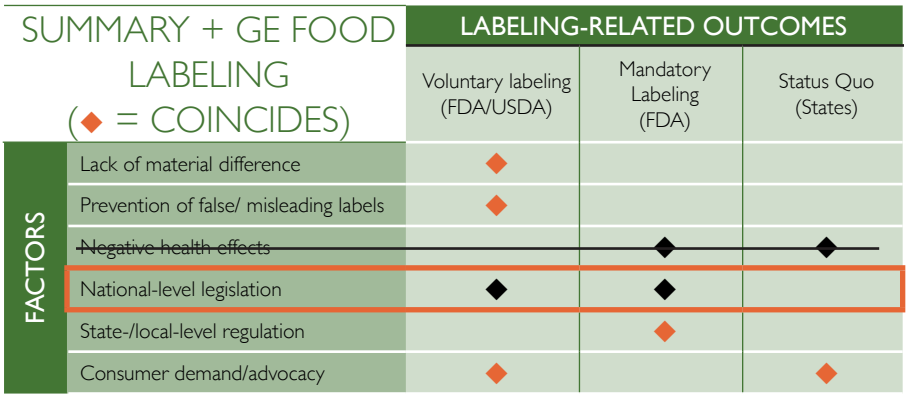
The FDA has also concluded that there are no negative health effects from consuming GE products; the agency is not alone in its conclusion. The National Academy of Sciences, which holds a congressional charter and serves as advisers to the nation on science, engineering, and medicine, states, "To date, no adverse health effects attributed to genetic engineering have been documented in the human population."[106] Over 2,000 studies document that GE foods are as safe as or safer than conventional or organic foods. A team of Italian scientists examined 1,783 studies related to the safety and environmental impact of GE food and could not find a single credible situation in which GE foods posed harm to humans or animals.[107] Given this absence of scientifically proven negative health effects, the FDA mandate prevents it from requiring a mandatory label of GE products.

National level legislation, however, could alter the FDA's mandate to require labeling for products with different production methods or, in fact, any other characteristic. The team views this possibility as unlikely and is not aware of any proposed national legislation to require GE food labeling with a legitimate chance of becoming law.

Three states have passed laws related to GE food labeling, but only Vermont's law is scheduled to go into effect in 2016. Many other states have placed GE food labeling initiatives on ballots, but they have mostly been defeated. If several states pass laws, this could create a showdown between the FDA and states because industries would argue the patchwork of state specific laws impedes interstate commerce. Based upon the FDA's past position and our interviews with the agency, we believe the FDA would stand firm on its position to not label GE products and a court battle would likely follow. GE food labeling proponents are unlikely to prevail in court, given past precedent.

Consumer demand has the power to force national legislation or state and local regulation. Consumer demand can therefore indirectly evoke a response from regulators through the electoral process, which is the most likely avenue for consumer demand to result in a labeling requirement. This is the current status quo. In some states such as Hawaii, city or county ordinances may force the state to regulate or seek judicial recourse over labeling or cultivation of GE crops. Similar to how calorie count laws increased momentum

when New York City mandated them, if large cities or counties start requiring GE labels, it could drive states to adopt similar laws. This possibility seems rather remote at the current time, as few cities in the country have the market power or political desire to pass such an impactful ordinance.



7.2 Predicted Labeling Outcome

A comparison of the factors present in the GE food labeling debate and the factors analyzed in the five case studies provides us with potential labeling-related outcomes in the table below. The lack of material difference, prevention of false/misleading labels, and absence of negative health effects indicate the FDA is unlikely to require mandatory labeling of GE foods. The FDA also has a requirement to prevent false, misleading labels. This is the justification the FDA would likely rely upon if the agency decided to require a label for GE products. The FDA would probably set levels of adventitious presence or clarify specific language for voluntary labels seeking to express the absence of GE content, to ensure consumers were not deceived by misleading statements. The FDA has mentioned on numerous occasions that consumer demand alone is not sufficient to warrant a labeling requirement.

The possibility of mandatory labeling seems remote at this time; however, national-level legislation remains a possibility and could force the FDA to mandate labeling. Another possibility is through state and local regulations. If enough states pass labeling laws that interstate commerce is affected, the FDA may be forced to act or the Supreme Court could eventually rule on a case. Although, if several states enacted GE food labeling laws, we think national-level legislation would precede these scenarios.

National legislation, in our opinion, is much more likely to implement a voluntary labeling system as seen in the chart above. This can be done through either the USDA or FDA. For example, the USDA responded to consumer demand with organic labeling, although it took Congressional legislation. In our opinion, it is more likely that the voluntary labeling precedent established by the FDA's response to the rBST-free milk case will be followed.

7.3 Other Factors

Even if consumer demand does not result in a labeling requirement, the changes in demand or ingredient switches by companies may cause significant disruptions to the commodity supply chain. Furthermore, consumer pressure already plays a significant role in GE crop development. Two different biotech seed companies told us that the length of time to acquire regulatory approval for new GE seed has increased from four years to seven. While the slowing of approval is not labeling related, it is dramatic and could be due to political considerations within regulatory agencies.

State or local regulations are also a response to consumer demand or advocacy primarily through the electoral process. This argument is explained in section 8.1, where we discuss the role of state and local regulations on a national labeling requirement.

7.4 Predicted Other Outcomes

Currently, U.S. retailers market on behalf of food producers who label products according to the latest social trends in hopes of winning market share. Producers have started to switch small numbers of ingredients to non-GE versions, which are easier to source in small quantities. This behavior represents a small portion of the food chain, but if it were to reach higher levels, it would have large impacts upon the supply chain.

Our current supply chain is commodity based, with the majority of food grown in bulk and handled accordingly. If the system were forced to switch to a specialized, or segregated GE vs. non-GE system, the economies of scale would disappear. As one food manufacturer explained to us, sourcing non-commodity ingredients is expensive, and the consumer will ultimately bear the added cost. Ultimately, the strength of demand for non-GE food will determine the level of ingredient switching. If there is no increase in demand to compensate for the additional cost, food manufacturers have stated that they will switch back to GE varieties. Calculating the costs and secondary effects of switching from a commodity-based system to a specialized supply chain is outside the scope of this paper.

A second possible outcome is a change in demand for non-GE products. In one instance, General Mill's decision to switch to non-GE ingredients for Original Cheerios was followed by a declaration that the company would not change other cereal compositions, presumably because the change did not induce higher sales. On the other hand, Whole Foods has grown dramatically over the last decade, reflecting an increased demand for organic and non-GE foods. As a result, it is difficult to predict whether a labeling policy will result in an increase or decrease in demand for non-GE products.

7.5 Policy Alternatives

After determining and comparing the relevant factors in GE food labeling to each of the cases described above, we believe three possible outcomes exist for GE food labeling and have noted our position on the likelihood of each, which informs our later recommendations:

1. **Status Quo** – The Non-GMO Project and other similar organizations continue to offer third party verification services. No specific government standard related to language or level of adventitious presence is set, although there are recommended guidelines. Products without a GE equivalent may receive a label from manufacturers seeking to capitalize on the public's lack of understanding. States continue attempts to legislate either the production or labeling of GE products.

   The status quo of states passing or attempting to pass different labeling requirements is unlikely to persist much longer. The Vermont law is currently being challenged in court. Interstate commerce would be hindered with the implementation of many of these laws, which makes the intervention of the FDA a likely scenario in this outcome.

   Mandatory Labeling – The FDA's labeling mandate would expand via congressional legislation to incorporate differences in production methods with regard to genetic manipulation of plants or animals. The agency would set a standard for adventitious presence and regulate which products are required to carry a GE ingredient label.

   Mandatory labeling is the least likely outcome. The FDA has made it clear it has no intention of labeling GE products. One benefit of a mandatory label would be a clear, unambiguous standard for adventitious presence as well as labeling language requirements. The most significant downside to this alternative is the increased costs associated with the label. Cornell University estimates the cost of a mandatory label in New York to be $500 per year for a family of four.[108] Unless national legislation forces it to act, FDA mandatory labeling will not occur.

2. **Voluntary Labeling** – Congress directs the USDA or FDA to implement a labeling initiative similar to the National Organic Program. There are standards for adventitious presence, as well as a list of which products are allowed to carry the label so consumers are not misled. Third party verification groups must follow a standard protocol.

   We view voluntary labeling as the most likely course of action. Consumers are learning more about the benefits of genetic engineering, and mandatory labeling ballot initiatives are rarely successful. Additionally, voluntary labeling seems to be a compromise most parties in the GE labeling controversy can accept.

The table below conveys assumptions we made in our predictions of how each outcome could materialize and provides a summary comparison of the three possible outcomes.

POTENTIAL LABELING OUTCOMES

Status Quo	Mandatory	Voluntary
1. No standard for adventitious presence	1. All products would be labeled, possibly at a 0.5%, 0.7%, or 0.9% adventitious presence level	1. Standard for adventitious presence
2. Multiple 3rd party verifiers	2. FDA would oversee program and labeling requirements	2. Clear language guidelines
3. State ballot initiatives	3. Increased costs for all consumers	3. Federal regulations
4. No clear labeling language	4. Challenge to design a value-neutral label	4. Places cost burden on appropriate party
		5. Challenge to design a value-neutral label

RECOMMENDATIONS

8.1 Client Concerns Relevant to GE Food Labeling

Our recommendations were formed as a response to client concerns (section 2.3) that align with key factors in the GE food labeling debate.

	GE FOOD LABELING	ALIGNMENT		CLIENT CONCERNS	
Factors	Lack of material difference	◆	◆	Food labels should be "truthful and not misleading"	Concerns
	Prevention of false/ misleading labels	◆			
	Negative health effects		◆	Health and safety is the #1 priority	
	National-level legislation	**Possible**	◆	National standard should be instituted	
	State-/local-level regulation	◆			
	Consumer demand/advocacy	◆	◆	Consumer driven product demand Consumer access to information (transparency)	

Of the seven client concerns, five aligned with factors at play in the GE food labeling debate. The two client concerns that did not align and were not included in our recommendations were:

1. Labeling costs should be borne by those who value the label, and
2. Global food security is ensured through the food value chain.

Although health and safety are a client priority, since there are no proven negative health effects, it is not a GE food labeling factor. Ironically, it seems to be the most common argument opponents use to argue against including GE foods in the food system.

We tailored our recommendations to the biotech seed industry as a whole under the assumption that voluntary labeling would be the most likely labeling outcome because of the current regulatory framework. Specifically, we attempted to address industry concerns related to transparency; truthful, not misleading food labels; consumer demands; and a national standard.

8.2 Recommendations

The biotech seed industry must engage in multiple information and marketing campaigns to reframe the debate over the health and safety of GE products. Science has repeatedly demonstrated the safety of GE products, but social media perpetuates a false yet compelling argument for the uninformed. An urgent and important first step in the process of reframing the debate is to **increase consumer confidence in the three regulatory agencies** that review GE products. A second and concurrent step is to **educate consumers.** Next, the biotech seed industry should unite to **promote a national labeling standard and definition**. Finally, companies within the industry must intentionally **increase transparency**

of the GE process. Regardless of how the labeling debate ends, the biotech seed industry will benefit from these four recommendations.

RECOMMENDATION 1: Instill Confidence in Regulatory Agencies

One of the primary considerations consumers voice about GE products is the health and safety of the food. Despite the lack of studies substantiating harmful outcomes, these feelings and beliefs persist. The FDA, USDA, and EPA have all found GE products to be safe, but consumers are concerned these agencies are infiltrated by corporate personnel and interests.

The Center for Food Integrity's (CFI) latest research focuses on how best to communicate complicated information to consumers and illuminates the consumer confidence challenge regulatory agencies face. CFI created three different messengers to identify which one influenced consumers the most. The messengers were "Mom Scientist," "Government Scientist," and "Peer." CFI found consumers trusted the "Mom Scientist" most, followed by a "Peer", and least of all the "Government Scientist."[109]

Since consumers start from such a cynical position, the regulators cannot merely reiterate their neutrality because no one believes them. Corporations cannot advocate for the agencies because the distrust of corporations would undermine their efforts. Therefore, the industry needs to hire a spokesperson that consumers trust to promote the neutrality and competency of government regulatory agencies. Possible candidates are a former FDA scientist who is also a mother, or a small farmer who can discuss the stringent requirements of GE product approval.

This spokesperson can build consumer trust by explaining the GE approval process. Providing an overview of the coordinated framework between the FDA, USDA, and EPA would cultivate confidence by increasing consumer's familiarity with regulator's work. Explaining that three separate federal agencies review and approve any new GE product can help reduce consumer anxiety related to a complex technology most people find difficult to comprehend. A trusted spokesperson can also hold an open and honest discussion of GE products that failed the regulatory review. Highlighting the failures can reassure consumers that the regulatory agencies are protecting their interests. Additionally, the FDA could publicly release feedback it has given to companies before final approval.

Biotech seed industry members should also take one other important step – communicate that the industry will not sell or market any seed without FDA, USDA, and EPA approval. While the companies already abide by this process, most of the general public is unaware of it. If the industry wanted to go further, it could ask retailers to communicate the same message to consumers. Taking this simple step assures consumers that government agencies and industry participants are concerned about their health and safety.

RECOMMENDATION 2: Educate Consumers

Members at every point along the food value chain, from seed companies to food manufacturers to food retailers, informed us that everyone in the food value chain, including regulators, bore a responsibility to educate consumers about the safety of GE products. The biotech seed industry's message does not resonate with consumers primarily because of a lack of trust in corporations. This is the result of actions that some members of the food value chain made in the past that destroyed public trust in corporations. It is, therefore, incumbent upon every member of the food system to rebuild that trust. Fortunately, the advantages of GE crops are compelling on many levels.

Many consumers do not know the benefits of biotechnology in crop production. One academic professor told us, "People have made food a political weapon rather than improving the nutrition of the food for people who desperately need it." For instance, most are unaware of the potential of Golden Rice, a type of GE rice, to save millions of lives. Few consumers are aware of the environmental benefits of GE crops, such as less soil erosion due to reduced tillage, diminished insecticide use, and lower carbon emissions from fewer trips across a field. Furthermore, GE crops represent an opportunity for farmers in developing countries to increase profits and help alleviate poverty. Biotechnology benefits abound, but unless the industry proactively markets them, the positive aspects are drowned out by half-truths and misinformation.

Consumers are also unaware of the costs of nationwide mandatory labeling. Groups such as Just Label It make it sound very simple, leaving consumers to wonder, "If it's so easy, why isn't my food labeled?" The thoughts naturally turn to "companies must be hiding something." Biotech seed industry members should use this opportunity to point out the often overlooked expenses of labeling by referring to independent academic research, such as a recent Cornell study which estimates labeling costs at approximately $500 per year for a family of four.[110] The industry can also explain how mandatory labeling functions as a regressive tax on the poor who spend a greater proportion of their income on food than the middle class or the wealthy.

Initiating a marketing campaign to educate consumers on the benefits of GE crops, while simultaneously refuting false

information about the health and safety of GE products is the most important and beneficial recommendation we can make. Once consumers learn the truth about genetic engineering, the majority of labeling concerns will disappear.

RECOMMENDATION 3: Promote a National Labeling Standard and Definition

Rather than oppose mandatory labeling, or individual state ballot initiatives, the biotech seed industry should proactively advance a plan to create a voluntary, nationwide labeling standard and definition. Similar to educating consumers, promoting a national labeling standard provides the industry with an opportunity to explain why a patchwork of state regulations is detrimental to everyone's interest. It also gives the industry a platform to advance a solution to a problem, which many consumers are concerned about but lack knowledge in.

Many anti-GE proponents advocate for a national labeling standard and are trying to use individual state ballot initiatives to reach their goal. Instead of fighting the costly state-by-state ballot initiatives, advocating for a national standard saves time and effort, while favorably advancing the industry's public perception. A unified definition adds clarity for producers and consumers to engage in conversations about specific products, which could benefit both parties. Furthermore, opponents of GE will no longer have the ability to criticize the industry as attempting to hide damaging information. This stance allows the biotech seed industry to lead the food value chain on the issue of GE food labeling, and would likely result in favorable publicity.

RECOMMENDATION 4: Deliberately Increase Industry Transparency

Finally, the biotech seed industry must increase the transparency of the GE process and the development of their products. Much of this transparency will be accomplished by educating the consumer, but the industry can do more. Identifying and addressing common consumer fears is a great place to start. The industry could also reach out to adversaries and universities to establish trust and convey common values. These actions represent a few steps of a continuous cycle of increasing trust and transparency.

CFI's research in 2013 focused on the issue of building trust between consumers and large food companies and provides a framework to deliberately increase industry transparency. The research suggested the seven-step process depicted in Figure 3.[111]

Steps 2 and 7 are specific areas of focus in the effort to increase transparency and build trust. The biotech seed industry should honestly communicate the risks associated with GE crops, and the negative side effects, both real and potential, associated with GE technology. Bt and glyphosate resistance are two substantial concerns that have arisen largely from the widespread cultivation of GE crops. Instead of ignoring this negative aspect of GE crops, the industry should acknowledge these risks and then discuss how the industry plans to address them.

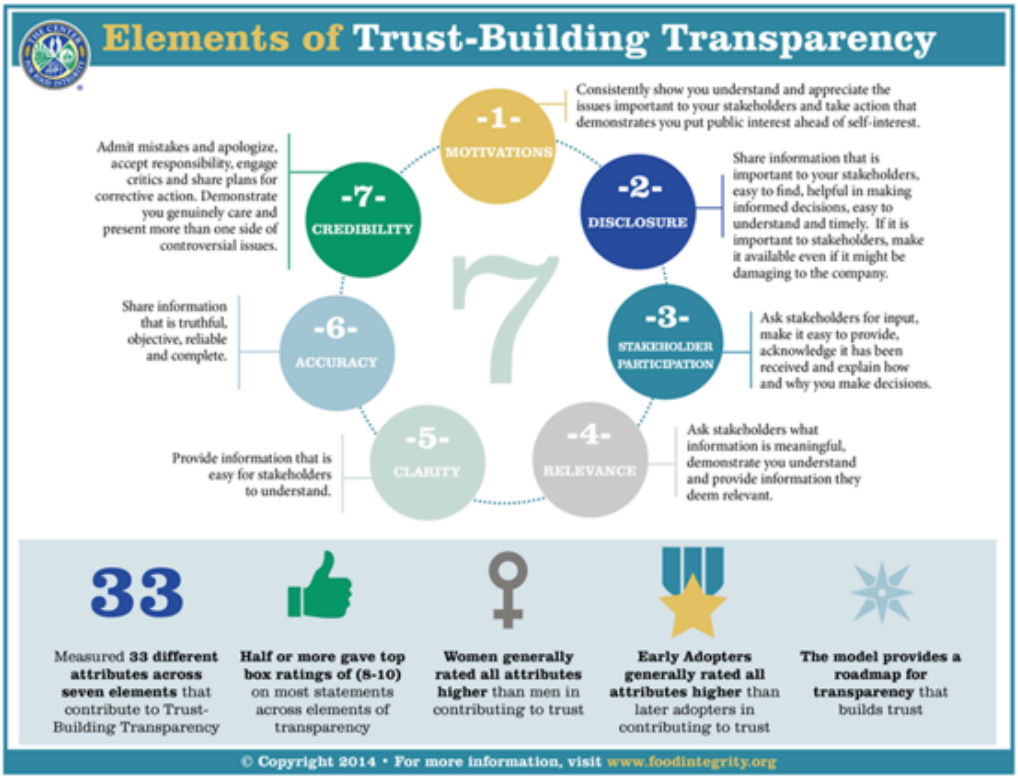


Figure 3: CFI's seven-step framework to increase industry transparency.

Quantifying risk may also help consumers accept the use of the technology in their lives. The fact there has never been an illness, allergy, or medical issue related to GE products is powerful. The industry could use this information and contrast it to risks consumers take every day, such as driving their children to school. A MasterCard®-style commercial listing several common activities and their associated risks

could be developed, followed by a question asking what the increased risk of damaged health from consuming GE products is; a big zero could fill the screen, similar to the "Priceless" commercials. Quantifying the risks people face and placing them in proper context help people avoid overemphasizing the improbable.

Inviting critics or adversaries of the biotech seed industry to take tours of operations or attend presentations is another way to increase transparency. Individuals can see for themselves the hard work and effort that goes into producing quality seed for American farmers. If a health blogger changes his or her opinion on GE crops after seeing the laboratory and understanding the science, his or her voice may reach far more people and change more minds than the industry could. Similarly, partnering with universities outside of the normal agricultural states through field trips or tours can help increase transparency. Agreeing to participate in independent research studies is another way the industry can demonstrate its commitment to open and honest communication.

8.3 Implementation of Recommendations: QR Code

The GE labeling debate is complex and warrants a comprehensive approach to addressing consumer's concerns about the GE process while simultaneously satisfying consumers' desire to know what is in their food. We believe a federally regulated, voluntary Quick Response Code (QR code) on product labels is the best way to implement our recommendations.

- **Recommendation 1: Increase confidence in regulatory agencies** – By allowing the FDA to standardize and control the information displayed when a consumer scans the QR code, the consumer instantly learns the regulatory agency's responsibility over the product. The FDA, EPA, and USDA may also want to include a link to describe the process of GE product approval.
- **Recommendation 2: Educate consumers** – Once a consumer has landed on the initial FDA-controlled page, industry members can provide links to additional research or information about GE technology.
- **Recommendation 3: Promote a national labeling standard and definition** – The voluntary QR code helps address the issue of which products would need to have a label. Because it is voluntary, the decision of whether or not to label a product is left to the producer, who is incentivized to participate in the voluntary labeling regime.
- **Recommendation 4: Increase transparency** – Providing a lot of information about the process and science behind genetic engineering through the QR code is a great way to increase transparency by providing detailed information directly to consumers.

For further details and analysis of implementing the QR code, please see the associated appendix, which includes political and operational feasibility analyses.

8.4 Recommendations for Alternate Outcomes

The recommendations listed above were created under the assumption that voluntary labeling would be the most likely labeling outcome because of the current regulatory framework. Should the labeling outcome remain unchanged, that is, the status quo of a state-by-state patchwork continue, we believe our current recommendations will continue to be the best course of action for the biotech seed industry.

However, if a mandatory labeling law is enacted, our recommendations change. The incentive to instill confidence in regulatory agencies and the rationale for promoting a national standard disappear with mandatory labeling. Instead, educating consumers would increase in importance, and our recommendation to increase transparency would remain the same.

QR CODE

Advocating for the implementation of a national, voluntary QR code, is the best way for the biotech seed industry to approach the GE food labeling controversy. Federal regulations would ensure the information is presented accurately and free of industry influence. The label itself is truthful and not misleading. Furthermore, the label's presence will not create an implicit bias toward the product, unlike the voluntary organic label. Perhaps most importantly, the label supports individual consumer's right to know what is in their food. The QR code label represents a feasible implementation scheme, which can be executed quickly and without significant cost to retailers or consumers.

Figure 4: The use of QR codes can promote national labeling standards and increase transparency.

CONCLUSION

Before Norman Borlaug died in 2009, he spent many years campaigning against those who for political and ideological reasons oppose modern innovation in agriculture. He said, "If the naysayers do manage to stop agricultural biotechnology, they might actually precipitate the famines and the crisis of global biodiversity they have been predicting for nearly 40 years."[112] It is our opinion that many of the proponents for GE food labeling desire not just a label but rather the destruction of what they perceive to be the harmful evolution of American agriculture. Fortunately, science supports the benefits and potential usefulness of GE crops, but supporters of biotechnology cannot rely on science alone.

The biotech seed industry should not worry about the FDA requiring a mandatory label for GE derived products based on the agency's current mandate. Industry members should unite behind a proposal for a national QR code and start proactively engaging the public with a positive GE message. Increasing the public's trust of regulatory agencies and educating the consumer about the benefits of biotechnology are two excellent places to start. Building trust with the consumer through openness and transparency will also facilitate acceptance of complicated technological advances the average consumer may not entirely understand. Once the industry starts implementing this strategy, the labeling controversy will fade from view and companies can once again focus on meeting the challenge of feeding an additional two billion people in the next 35 years.

APPENDICES

APPENDIX A: Research Interviews Conducted

Name	Organization	Position	Date of Interview
Bradley Wagner	Monsanto	Business Development Manager, Global Corporate Strategy	5-Jan-15
Leigh English	Monsanto	Director, International Strategy	5-Jan-15
Azmy Azmy	DuPont Nutrition and Health	Lead, Biotechnology and Product Stewardship	5-Jan-15
Jessica Impson	Heritage Prairie Farms	General Manager	7-Jan-15
Nathan Sumner	Heritage Prairie Farms	Operations Manager	7-Jan-15
Doyle Karr	DuPont	Director, Biotechnology Public Policy	9-Jan-15
Russ Sanders	DuPont Pioneer	Director, Food & Industry Markets (Americas)	9-Jan-15
Morrie Bryant	DuPont Pioneer	Business Manager, Food & Industry Markets Marketing (U.S. Region)	9-Jan-15
Daniel Jones	DuPont Pioneer	Business Manager	9-Jan-15
Kristin Latzo	Post Foods	Vice President of Product Development	12-Jan-15
Ryan Guthrie	Coca-Cola	Director, Government Relations	13-Jan-15
Greg Jaffe	Center for Science in the Public Interest	Director of Biotechnology	13-Jan-15
Michael Schechtman	U.S. Department of Agriculture	Biotechnology Coordinator, Policy Advisor to the Secretary on Biotechnology	14-Jan-15
James R. (Tres) Bailey	Wal-Mart	Director of Agriculture and Food, Federal Government Relations and Corporate Affairs	14-Jan-15
April Kates	Food and Drug Administration	Team Lead, Product Evaluation and Labeling Team	14-Jan-15
Greg Page	Cargill	Executive Chairman	31-Jan-15
Jon Hixson	Cargill	Vice President, Corporate Affairs	10-Feb-15
Kate Houston	Cargill	Director, Government Relations and Policy	10-Feb-15
Randal Giroux	Cargill	Vice President, Food Safety, Quality, and Regulatory Affairs	10-Feb-15
Robert Merker	Food and Drug Administration	Supervisory Consumer Safety Officer (CFSAN)	14-Jan-15
Felicia Billingslea	Food and Drug Administration	Director, Food Labeling and Standards (CFSAN)	14-Jan-15
Jane Andrews	Wegmans	Corporate Nutritionist	16-Jan-15
Dr. Nicholas Kalaitzandon-	University of Missouri	MSMC Endowed Professor of Agribusiness Strategy	23-Dec-14
Charlie Arnot	Center for Food Integrity	CEO	22-Jan-15
Rick Zimmerman	Northeast Agribusiness and Feed Alliance	Executive Director	27-Jan-15
Terry Medley	DuPont	Global Director, Corporate Regulatory Affairs	27-Jan-15
Dr. Ray Goldberg	Harvard Business School	George M. Moffett Professor of Agriculture and Business, Emeritus	28-Jan-15
	Just Label It*	Did not respond to interview requests	
	Archers Daniel Midland*	Would not allow us to interview company officials	
	Whole Foods*	Would not allow us to interview company officials	
	Trader Joes*	Would not allow us to interview company officials	
	Ben and Jerry's*	Did not respond to interview requests	

APPENDIX B: QR Code Implementation Analysis

A QR code is a scan-able code that can be printed on food packaging. Consumers can use their mobile device to scan the code, or retailers could provide scanners for general use similar to "price check" scanners. The code would open a webpage that contains standardized information, per FDA guidelines, regarding the food product. If consumers are interested in further information, they can click a link to detailed information provided by the food value chain.

NATIONAL AND VOLUNTARY

Two important aspects of this proposal are the geographic coverage and its voluntary nature. A state law requiring labels different than those required in another state is unlikely to hold up in court because the FDA has already determined there are no material differences between GE and non-GE products. A state attempting to require special labeling will impede interstate commerce, without a substantial reason for doing so.

Beyond the legality issues, a nationwide label is preferable because it keeps regulations standardized across state borders. Food manufacturers can change recipes or source other ingredients for products sold throughout the U.S., but it is an entirely different situation to ask companies to produce three different products with unique specifications for New York, Massachusetts, and Connecticut. Individual state laws or requirements will increase costs for the consumer and leave retailers in the strictest states searching for products as companies are unlikely to sell their products in states with unreasonable policies.

Currently, a small percentage of U.S. consumers are concerned with GE food labeling. A voluntary label allows food companies to cater to this market, while also requiring the consumers who care about GE ingredients to bear the cost of providing the information. As one government relations director said, "A mandatory labeling requirement is just a regressive tax on the poor, on those who don't care about it and can't afford it."[113] Members of the food value chain concerned with GE ingredients can continue to offer the alternative to their customers and will benefit from the legitimacy associated with a national standard for adventitious presence of GE material.

TRUTHFUL, NOT MISLEADING

The voluntary QR code label falls within FDA's guidelines for a product to have a truthful, not misleading label. The code provides industry with a platform to demonstrate the health and safety of the product. Since the FDA controls the content, most consumers will accept the information as legitimate, similar to the Nutrition Facts panel, and a significant point of contention with GE technology will dissipate.

This type of label will also help prevent biases. Simply placing a label on a product has the tendency to create prejudices either for or against the subject on the label. One needs to look no further than the NOP to see the positive bias created by USDA's organic label.

Another example is the rBST label debate, which is nearly identical to the GE label controversy. Both technologies are production methods rather than material differences. When dairy farmers claimed their milk was from "rBST-free" cows, there was an insinuation rBST was bad for consumers. Thus, the FDA suggested placing an asterisk stating there is no significant difference in milk derived from rBST treated cows and those not treated with rBST. One can easily imagine the same perception with a GE label. A voluntary QR code gets beyond this value statement because there are no words on the outside of the package to form conclusions.

The FDA still needs to ensure the information is truthful. Once a consumer chooses to scan the code, the ensuing page should be controlled by the FDA to ensure the information is accurate. Food producers may desire the opportunity to market to consumers through this label, but the first screen consumers should see when they scan the QR code should be in a standard format controlled by the FDA, similar to the Nutrition Facts panel on all products.

CONSUMER RIGHT-TO-KNOW

Additionally, this approach supports consumers' right to know what is in their food. There is near unanimous consensus that individuals have a right to know what type of food they are consuming. The biotech seed industry has an opportunity to demonstrate its commitment to honest and open production practices by supporting a voluntary QR code label. Fighting individual state initiatives creates the perception the industry is hiding something or arguing against consumer's right to know what is in their food. This is an unpopular position, but the industry can change the context of the debate by energetically supporting a QR code and loudly advocating for this labeling change.

FOOD SECURITY

The QR code is unlikely to cause large shifts in demand for non-GE products, but it may result in more informed consumers. As consumers learn the benefits of GE crops, demand for organic or non-GE food will likely slow or retract. The biotech seed industry can then focus on its goal of increasing yields and protecting crops in order to meet the growing global demand for food.

Political Feasibility of QR Code – Stakeholder Analysis

GE food labeling is a lightening rod for general GE concerns. Therefore successful implementation requires reviewing all stakeholders involved in GE food in general. We identified four groups of stakeholders engaged in the GE food labeling debate: general food value chain members, consumers, regulators, and individuals opposing GE technology. We then used our interview research to understand the major concerns of each group. The following is a summary of our stakeholder analysis.

Food value chain
The food value chain will be completely satisfied with the QR code. Every concern that members of the food value chain express related to GE crop technology is addressed with the QR code label for many of the reasons we have outlined above.

Consumers
Most consumers will be pleased with the QR code label, except for individuals concerned about the environmental impact of GE crops. This is understandable because labeling, both mandatory and voluntary, does not address environmental concerns. One way to remedy the situation is to allow the EPA an opportunity to format a standard environmental impact page for consumers to view when they scan the QR code. This page would need to have the same format across similar product categories to ensure consumers view consistent information.

Perhaps most importantly, the QR code assures the consumer of the health and safety of GE crops. The average young mother does not have time to research the intricacies of GE technology; therefore, she may readily accept the social media conveyed point of view. However, when purchasing products, she trusts what the FDA places on the nutrition label. The QR code builds on this trust and expands it to cover the health and safety of GE products.

The QR code also satisfies consumer's right to know what is in their food. As the Non-GMO Project told us, "Many people ***are*** concerned about GMOs, and their right to know is not negated by others' views on this issue."[114] Providing consumers with the option of learning whether their food was produced with GE ingredients allows those who care about the matter to freely choose without forcing a mandatory requirement on the rest of the food value chain.

Regulators
Regulators, like consumers, are mostly satisfied with the QR code. This method of labeling allows them to display health and safety information and also provides a way for companies to tell consumers what is in their food. Some regulatory agencies concerned with economic impact may not be satisfied with the QR code label because it does not address environmental concerns. We believe an optional EPA page to address these concerns is the best way to proceed.

Anti-GE Movement
The anti-GE movement, even with the range of issues it has with GE products, would be mostly satisfied with a QR code label. Objections based on perceived health and safety risks, as well as the consumer's right to know, would be satisfied. Furthermore, once consumers learn the many benefits of GE crops, demand for non-GE food is likely to decline. This might be one reason

why opponents are so adamantly pursuing a mandatory labeling change: if a false perception can persist over the health and safety of GE products, consumers will continue to pay a premium for organic or non-GE food, even though there is no factual basis for doing so.

Environmental and intellectual property based opposition would not be satisfied with the QR code label because it does not address these concerns. These issues are so much bigger than the labeling debate; there is likely no way to satisfy GE opponents concerned about the environment or intellectual property with a label. Therefore, the QR code satisfies most stakeholders on most issues, even if it does not satisfy every stakeholder on every issue.

Operational Feasibility of QR Code

Finally, the QR code label is relatively easy to implement, and would only affect the companies wanting to provide the information to consumers. As of June 2013, Pew Research determined more than half (61%) of adult Americans own smartphones.[115] Each of these consumers would have the ability to quickly scan the product they are interested in purchasing if it had a QR code. Even if customers did not possess a smartphone, grocery stores could easily integrate the technology into price scanning stations or have scanners at the checkout area for consumers who want to know more about the products they are purchasing.

Beyond the physical equipment necessary to bring this labeling technology to the greater public, implementation must include FDA or other agencies' input regarding the information displayed to consumers. A convenient aspect of a QR code is the format is easily changed in order to meet consumer's information preferences. One could easily envision a future time when consumers may desire more information about a product's production process, amount of water required to produce the ingredient, or any number of other concerns. Instead of having to laboriously determine whether the concern justified a labeling change, the FDA could simply change the format to include the information. Since the label is voluntary, companies remain free to decide whether it is in their interest to include the information or not. Of course none of these changes would lessen FDA's mandate to ensure labeling was truthful and not misleading.

ENDNOTES

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6 "Center for Food Safety | Fact Sheets | GE Food Labeling: States Take Action," Center for Food Safety, accessed March 27, 2015, http://www.centerforfoodsafety.org/fact-sheets/3067/ge-food-labeling-states-take-action.

7 "Researcher Files Lawsuit Against the FDA Over Artificial Trans Fat," accessed March 27, 2015, http://naturallysavvy.com/eat/researcher-files-lawsuit-against-the-fda-over-artificial-trans-fat.

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9 Emily Marden, "Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture," Boston College Law Review 44, no. 3 (2003): 734.

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