

The Debate on Labeling Genetically Modified Food

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Background

In 1992 Calgene Inc., a small biotechnology company, embarked upon a revolutionary endeavor. The company filed a petition with the US Food and Drug Administration (FDA) for approval of a gene used in the development of its FLAVR SAVR tomato. This product would be the first genetically engineered (GE) food to be approved for commercial production. Genetic engineering is a process that enables scientists to splice plant or animal genes with particular traits into the DNA of other organisms. Calgene's actions nearly a decade ago signaled the advent of biotechnology as a means for creating food products that might offer substantial benefits over their natural counterparts. Although many people lauded the virtues and immense potential offered by biotechnology, others vehemently opposed tinkering with an organism's genetic material because of its potential to unleash unforeseen and harmful consequences.

Proponents of GE food insist that ensuring an adequate food supply for the booming population is going to be a major challenge as the world population continues to grow. Biotechnology promises to meet this need through the design of crops that are resistant to pests, herbicides, harsh weather, and disease. Furthermore, by genetically engineering foods to contain additional vitamins and nutrients, malnutrition worries can be alleviated. On the other hand, various environmental activists, public interest groups, professional associations, and government officials have all raised concerns about GE foods and criticized agribusiness for pursuing profit without concern for potential hazards. Concerns about GE foods include their potential to harm other organisms, latent human health risks such as allergies and unknown long-term effects, and the potentially prohibitive pricing of GE seeds that would widen the gap between the wealthy and the poor, on domestic and international levels.

One of the biggest issues in the ongoing debate over GE foods is whether they should be labeled in order to protect the public's right-to-know privileges. Mandatory labeling regulations in European nations and several other countries are drawing greater scrutiny to this issue in the United States. The FDA does not require such labeling unless genetically engineered foods differ significantly from their traditional counterparts. Draft FDA guidelines for voluntary labeling were developed as of 2001, but have not yet been finalized. Some have suggested that voluntary labeling could increase industry credibility and consumer acceptance.

The Genetically Engineered Food Right-to-Know Act, S. 2080

On February 22, 2000, Senator Barbara Boxer (D-CA) introduced in the United States Senate the Genetically Engineered Food Right-to-Know Act, *S. 2080*, to require the labeling of genetically engineered food and authorize funds to study the public health and environmental impact of GE food. *S. 2080* is similar to *H.R. 3377* introduced in the United States House of Representatives by Rep. Dennis J. Kucinich on November 16, 1999. *S. 2080* was referred to the Senate Committee on Agriculture, Nutrition, and Forestry, where it is currently pending consideration.

Food that contains or is produced with GE material would have to be labeled under *S. 2080*. Genetically engineered material is derived from a GE organism. A genetically engineered organism is defined in *S. 2080* as an organism that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes. For example, foods containing genetically modified soy and genetically modified corn would have to be labeled. Plant varieties developed through traditional processes, such as crossbreeding, are not considered to be GE and would not have to be labeled.

Under *S. 2080*, food is considered to be produced with GE material if the organism from which the food is derived has been injected or otherwise treated with a genetically engineered material or the animal from which the food is derived has been fed genetically engineered material. For example, foods that contain milk from a cow injected with GE hormones would also have to be labeled.

S. 2080 would require foods that contain genetically engineered material or are produced with genetically engineered material to bear this label:

GENETICALLY ENGINEERED

THIS PRODUCT CONTAINS GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL.

S. 2080 would require food that contains or was produced with GE material to be labeled at each stage of the food production process from farmers to manufacturers to retailers. Persons who have custody of food at each stage in the production process need not test the food to determine whether it contains GE material and must be labeled. Instead, they need not label the food if they obtain a written guaranty from the party from whom they received the food that the food does not contain and was not produced with GE material. Persons who obtain valid guarantees would not be subject to penalties under the legislation if they fail to label a food later found to contain GE material. Persons who issue false guarantees, however, will be subject to penalties of up to \$1,000 for each violation. Under *S. 2080*, no person can avoid responsibility for misbranding by entering into a contract or other agreement that shifts the responsibility for misbranding to another person. The FDA has the authority to test food to determine whether a false guaranty has been issued and the food should have been labeled. Reasonably available technology permits the detection in food of GE material at levels as low as 0.1 percent.

Activity

Each group will present their arguments for or against the Genetically Engineered Food Right-to-Know Act (*S. 2080*) to the Senators. After all groups have had their say, senators will vote on the legislation.

Groups



Greenpeace (Page 4): Becky Rasmussen, Meghann Jarchow, Nick Ohde, Joseph Malual, Betty Wells

Greenpeace USA is a national non-governmental for the protection and conservation of the environment, utilizing non-violent direct action, lobbying, and research to achieve its goals. Greenpeace USA supports the *Genetically Engineered Food Right-to-Know Act, S. 2080* based on the belief that consumers have a right-to-know the contents of their food, while also maintaining major concerns about the environmental and human health risks associated with genetically engineered food.



Consumers Union (Page 8): Diego Thompson, Michael Stanfield, Karina Crosignani, Annet Abenakyo Mulema, Rob Anex

The Consumers Union (CU) is an expert, independent, nonprofit organization, whose mission is to work for a fair, just, and safe marketplace for all consumers. CU publishes Consumer Reports and ConsumerReports.org, in addition to two newsletters, with combined subscriptions of more than 7 million. Since its founding in 1936, Consumers Union has never taken any advertising or freebies of any kind. CU is in favor of *Genetically Engineered Food Right-to-Know Act, S. 2080*, advocating that consumers have the right to know what is in their food. The labeling of GE foods allows consumers to make informed purchasing decisions based on issues of health, religious beliefs, and personal ethics.

 **FDA (Page 12):** Lisa Wasko, Pete Noll, Elisa Regen, Jennifer Himmelsbach, Gretchen Zdorkowski

The Food and Drug Administration, an agency of the US Department of Health and Human Services was formed in 1906. FDA has an annual budget of \$2.3 billion to regulate more than \$1 trillion worth of consumer goods such as food, dietary supplements, drugs, vaccines, biological products, medical devices, cosmetics and other such products. The FDA establishes and maintains food standards and sets the requirements for nutrition labeling of most foods. The FDA is confident their current approach is appropriate and has not on its own finalized any genetically engineered food labeling program.

 **Monsanto (Page 16):** Amy Sue Alesch, Stefans Gailans, Claudia Prado Meza, Drake Larsen, Clark Wolf

Monsanto Company was founded in St. Louis, MO in 1902. In the past century Monsanto has grown to become one of the largest global producers of biotechnology. Monsanto is focused on agriculture and supporting farmers around the world in their mission to feed, clothe and fuel a growing world. Monsanto opposes *Genetically Engineered Food Right-to-Know Act, S. 2080* and maintains that non-GE foods are no safer than GE foods. Mandatory labeling is, therefore, both unnecessary and problematic.

 **Senators (Page 19):** Laura Christianson (Iowa), Angie Gumm (Massachusetts), Andrea Rich (Virginia), Andy Herringshaw (Illinois), Mae Rose Petrehn (California)

The Senators are representing five states with diverse urban, rural, and agricultural interests: Virginia, Illinois, Massachusetts, Iowa, and California. Each Senator brings the interests of his or her constituency into the decision making process. After deliberating on the arguments made by each of the four groups, the senators will cast their votes in support of, or against, *S. 2080*, according to their own conscience and the needs of their state.



Greenpeace USA believes that the current regulation of GE food in the United States is totally inadequate and represents unacceptable risks to the safety of both humans and the environment. In the effective absence of federal government testing and oversight on GE foods, the organization supports the Genetically Engineered Food Right-to-Know Act as a viable solution for mitigating the significant risks associated with GE.

Risks of GE food to human health

The agri-food industry claims GE foods are rigorously tested and represent no risks to human health. However, since GE foods are tested for safety only by the agri-food companies themselves and effectively fall outside of FDA regulation, such claims are highly dubious. In fact, the FDA never examines the original studies conducted by companies, but rather only the company's summary assessment of its own research. The FDA merely conveys the company's conclusion as to the food's "substantial equivalence," pointedly avoiding any sort of explicit approval of its own. This is perhaps due to liability concerns on the part of the government.

However, studies conducted independently of the agri-food companies reveal serious health risks associated with GE foods as well as inadequate safety testing by the companies. Unfortunately, there is a paucity of information on the safety of GE foods, as agri-food companies often obstruct external peer review of their products and safety testing protocol.

As genetic engineering may involve the transfer of new and unidentified genes from one food into another, there is the potential that these genes could cause allergic reactions and other unintended effects when consumed by humans. Food allergies aren't simply a matter of slight discomfort; they can potentially result in life-threatening anaphylactic shock. Without labeling, people with allergies won't know if they are eating foods that contain genes from other foods to which they are allergic. Similarly, the absence of labeling portends lack of accountability, as the person affected by a GE induced allergic reaction will be unable to identify the reaction's cause or hold the producers liable for such injury.

Though the potential for unintended effects of GE foods is poorly studied, there exist some examples of health risks and lack of oversight by agri-food companies. For instance, in 1996, researchers were stunned to discover that soybeans engineered to include protein-rich genes from the Brazil nut also contained the allergenic properties of the Brazil nut. Animal studies had not revealed the allergenic nature of the mutated soybean. Fortunately, the manufacturer halted the release of the soybean prior to its entering the market.

A similar example of GE product leading to unintended health effects occurred in 1989, when a genetically engineered version of tryptophan, an amino acid used as a dietary supplement, produced toxic contaminants. Before it was recalled by the Food and Drug Administration, the

mutated tryptophan wreaked havoc. Thirty-seven Americans died, 1,500 were permanently disabled, and 5,000 became ill with a blood disorder, eosinophila myalgia syndrome.

Because of these consequences, the leading doctors' organization in England has stated that a ban on GE foods should be considered if they are unlabeled, with a statement by over 2,000 doctors calling the use of antibiotic genes in GE foods "a danger to health that can be avoided." A leading scientific society has noted that infants and children could be especially at risk for food allergies from GE foods.

Further, humans may not actually need to consume GE foods to be affected by the unintended effects of genetic engineering: one study reported that *Bacillus thuringiensis* (Bt), a bacterium that has been spliced into millions of acres of corn, potatoes and cotton, may produce allergies in people. Science News reported in July 1999 that a study of Ohio crop pickers and handlers shows that Bt "can provoke immunological changes indicative of a developing allergy. With long-term exposure, affected individuals may develop asthma or other serious allergic reactions."

Other unknown risks may involve the use of antibiotic markers which appear in almost every genetically modified organism to indicate that the organism has been successfully engineered. It is believed that these antibiotic markers may contribute to the decreasing effectiveness of antibiotics against diseases in humans.

The journal *Microbial Ecology in Health and Disease* reported in 1998 that commercial gene technology may be responsible for the recent resurgence of drug- and antibiotic-resistant infectious diseases. As the author of the report, indicates:

"At the heart of the issue is horizontal gene transfer - the transfer of genes by vectors such as viruses and other infectious agents - which is exploited by genetic engineers to make transgenic organisms. While natural vectors respect species barriers, the barrage of artificial vectors made by genetic engineers are designed to cross species barriers, thus greatly enhancing the potential for creating new viral and bacterial pathogens, and spreading drug and antibiotic resistance. Totally unrelated pathogens are showing up with identical virulence and antibiotic resistance genes.

Risks of GE to the natural environment

The effects of genetically engineered crops on the natural environment are as poorly studied as human health risks, but the unintended consequences may be just as numerous.

One major concern is that GE crops increase the use of pesticide in production agriculture. Many of the new GE crops, such as Roundup Ready soybeans, are designed to allow farmers to spray heavier doses of herbicides on their land. These chemicals will inevitably find their way into our water and food supply, endangering humans and wildlife. *New Scientist* magazine reports that many farmers that have converted to GE production use as many pesticides as their conventional counterparts, while some GE farmers now use more pesticides.

In the same vein as concerns regarding horizontal gene-transfer of GE genes into the genomes of human pathogens, there is significant concern about the widespread release of genetically engineered organisms into the environment. In the United States, millions of acres of land have been planted with GE crops. GE organisms may spread through ecosystems and interbreed with endemic organisms thereby affecting non-GE environments, as well as future generations, in an unforeseeable and uncontrollable way. GE crops can also have major impacts on farmers who

produce natural and organic food because growers can lose their harvest when GE crops contaminate their fields. As such, the release of GE organisms will cause genetic pollution and represents a major threat because they cannot simply be recalled once released into the environment. Unlike other kinds of waste, genetic contamination cannot be cleaned up or contained. Horizontal gene transfer was confirmed in 2000 by Professor Hans-Hinrich Katz, a leading German zoologist, who found that the gene used to modify rapeseed had transferred to bacteria living in the guts of honey bees.

In connection with the preceding issues, extensive planting of herbicide-resistant GE crops could lead to a new class of so-called superweeds that are resistant to spraying. Given that the largest class of genetic engineered foods is pesticide-resistant crops, such as Roundup Ready soybeans, it seems plausible that newly created transgenes may be spread unintentionally by bird, insect or wind from target crops to related weed species, which then also acquire resistance to the pesticide. Nature magazine reported in 1996, for example, that herbicide-resistant GE rapeseed released in Europe has spread to several wild relatives.

Finally, there is concern that genetically mutated crops may damage the soil. Research published in Nature magazine reported that some types of GE crops may be leaking powerful toxins into the soil. For example, corn and potatoes have been engineered to produce toxins to fight pests that eat their leaves and stems. The fear is that beneficial soil organisms may also be killed and that some insects may become resistant to the toxins. Other research has revealed that lacewings that consumed corn borers reared on GE corn had also died, increasing speculation that these crops are indirectly harming beneficial organisms.

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Consumers Union

Nonprofit Publisher of Consumer Reports

"Informed consumers are essential to the fair and efficient functioning of a free market economy."

- Congressional declaration of policy, U.S. Code of Federal Regulations, January 1999

The Consumers Union, representing the best interests of consumers and the public at large, support passage of the *Genetically Engineered Food Right-to-Know Act, S. 2080*, requiring the labeling of genetically engineered food and authorizing funds to study the public health and environmental impact of GE food. Though GE foods were only introduced in 1992, today it is estimated that 70% of all food products sold in the U.S. contain GE ingredients. Roughly two-thirds of Americans are unaware that their food contains GE products.

First and foremost, consumers have a **fundamental right** to know what they are eating, and what they are feeding their families. In multiple polls conducted over the last decade, 85% to 95% percent of citizens favored labeling.* Many laws, at the federal, state and even local level, are designed to inform consumers of facts that are important to food purchasing decisions. Laws already require the labeling of juice made from concentrate, milk that is homogenized, imported food as to its country of origin, food that is frozen or irradiated, as well as any ingredients and additives. Though the US Food and Drug Administration regard these foods as safe, this information is required to be given to consumers at the point of purchase because consumers care and want to know about these aspects of food. With this information, they are able to make informed choices for themselves and their families.

Second, based on our research, we believe that there are clear differences between foods that are genetically engineered and foods that are not, and these differences are significant to many consumers. Genetically engineered foods are foods developed and produced using recombinant DNA technology, rather than traditional breeding techniques. Recombinant DNA technology adds to or alters genetic material in a laboratory that could not be added through normal plant or animal breeding. As examples, this material includes bacterial genes that code for antibiotic resistance, which serve as marker genes, and viral genes that "turn on" introduced genetic material. Other commonly introduced genes include a bacterial gene that causes a plant to produce a substance toxic to insect larvae and a bacterial gene that makes the plant invulnerable to herbicides. It may be FDA's opinion that these differences are not significant, but many consumers regard them as very significant and have told the agency so via tens of thousands of comments to FDA Federal Register notices.

The differences between a genetically engineered potato and a traditionally bred potato are arguably greater than the differences between a frozen potato and a fresh one, or between an Oregon potato and the same variety grown in Canada. Under current law, the last two facts have to appear on the label. Consumers have a right to know about all these differences.

While the FDA claims that genetically engineered foods are substantially equivalent to non-genetically engineered foods and need no additional safety testing or labeling, we are deeply concerned that the federal government does not conduct any of its own tests for the safety of

genetically engineered food. Moreover, it is not even mandatory for a company to inform the FDA when a newly engineered variety of food is going on the market. The very corporations that have a financial interest in selling the products get to decide whether they are safe or not. Given the rapid globalization of the food supply, we are concerned that genetically engineered foods could be grown in foreign countries with no safety assessment systems at all, and then legally sold in the US. *S. 2080* would at least require such foods to be labeled.

A critical question in a safety assessment is whether a genetically engineered food poses a risk of an allergic reaction. A gene that produces an allergen could be transferred from one food to another. For example, when scientists introduced a Brazil nut gene into soybeans to improve its protein content, the engineered soy turned out to cause an allergic reaction in Brazil-nut-sensitive individuals. While this product was never commercialized, it illustrated that this problem can easily occur. There is also a question about whether newly introduced proteins that have never been in the diet before could turn out to be allergenic. Labels could help health professionals identify such a problem. In addition, such labels could help health professionals identify any unexpected effects that might have been missed in a company's voluntary consultation with FDA, in the same way that health professionals identify unexpected difficulties with FDA-approved pharmaceutical products.

Based on the experience of the twelve countries of the European Union that have instituted mandatory labeling of genetically engineered food, we anticipate that the impact on consumer food prices will be negligible. Many of our nationally known food brands are already sold overseas, in countries mandating that food is either free of GE ingredients, or otherwise labeled to inform the consumer. U.S. consumers have the right to the same information.

A mandatory labeling law could also have benefits in terms of agricultural exports. More than three billion people live in countries with laws in place, planned or proposed, to label or ban genetically engineered food. Not only European countries, but also, Japan, South Korea, China, Australia and New Zealand all have mandatory labeling requirements—a labeling law would put the US in a good position to sell products in those markets.

However, the heart of the issue is the consumer's right to make an informed choice about buying genetically engineered food—without GE labels, they remain in the dark. Our choice of food is too important to be left to the corporations selling chemicals and biotechnology contracts to farmers for the purpose of bottom-line stockholder profits. Given the corporate scandals we've seen, why should we trust the food corporations to tell us what regulations are best? We believe that consumers have the right to make informed purchases, and family farmers have the right to be free from corporate control and liability for a technology outside their influence.

Donna Harris, a mother who formed Oregon Concerned Citizens for Safe Foods, sums it up best: "If the food is so safe and the technology is great, why not put a label on it and let me have a choice?" Support *S. 2080* and give consumers the right to make their own decision.

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- *90% of Americans said foods created through genetic engineering processes should have special labels on them (Rutgers University' Food Policy Institute study, 11/01)*
- *90% of American farmers support labels on biotech products if they are scientifically different from conventional foods and 61% support labels on biotech products even if not scientifically different.*

- *(Farm Foundation/Kansas State University, survey of farms throughout the U.S., 9/01). 93% of Americans say the federal government should require labels saying whether it's been genetically modified, or bioengineered. "Such near unanimity in public opinion is rare" (ABC News.com poll, 6/01).*
- *86% of Americans think that the government should require the labeling of all packaged and other food products stating that they include corn, soy or other products that have come from genetically modified crops*
- *(Harris Poll, 6/00). 86% of Americans want labels on genetically engineered foods (International Communications Research, 3/00)*
- *81% of Americans think the government should require genetically engineered food products to be labeled. 89% of Americans think the government should require pre-market safety testing of genetically engineered foods before they are marketed, as with any food additive. (MSNBC Live Vote Results, 1/00).*
- *92% of Americans support legal requirements that all genetically engineered foods be labeled. (BSMG Worldwide for the Grocery Manufacturers of America, 9/99).*
- *81% of American consumers believe GE food should be labeled. 58% say that if GE foods were labeled they would avoid purchasing them. (Time magazine, 1/99).*
- *93% of women surveyed say they want all GE food clearly labeled. (National Federation of Women's Institutes, 1998)."*

For more info on similar legislation (Oregon Measure 27 and HR 5268):

www.sos.state.or.us/elections/nov52002/guide/measures/m27fav.htm

<http://www.thecampaign.org/issues.php#environment>

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Three federal agencies regulate genetically engineered foods. The Food and Drug Administration (FDA), part of the US Department of Health and Human Services, has authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to ensure the safety of all domestic and imported foods for humans and other animals in the United States market. The exceptions are meat, poultry and egg products, which are regulated by the United States Department of Agriculture (USDA). Pesticides are regulated primarily by the Environmental Protection Agency (EPA). Bioengineered foods, food ingredients, and food additives must adhere to the same standards of safety under the FD&C Act that apply to their non-genetically engineered counterparts. This means that these products must be as safe as the traditional foods in the market. We at FDA have broad authority to initiate regulatory action if a product fails to meet the safety standards of FD&C Act.

We rely primarily on two sections of the FD&C Act to ensure the safety of foods and food ingredients:

(1) The adulteration provisions of section 402(a)(1). Under this post-market authority, we have the power to remove a food from the market (or sanction those marketing the food) if the food poses a risk to public health. It is important to note that the FD&C Act places a legal duty on developers to ensure that the foods they market to consumers are safe and comply with all legal requirements.

(2) The food additive provisions (section 409). Under this section, substances that are intentionally added to food are food additives, unless the substance is generally recognized as safe (GRAS) or is otherwise exempt.

The FD&C Act requires pre-market approval of any food additive – regardless of the technique used to add it to food. Thus, substances introduced into food are either (1) new food additives that require pre-market approval by us or (2) GRAS, and are exempt from the requirement for pre-market review. Generally, foods such as fruits, vegetables, and grains are not subject to pre-market approval because they have been used as food for lengthy periods of time.

Under our policy on foods derived from new plant varieties, a substance that would be a food additive if it were added during traditional food manufacture is also treated as a food additive if it is introduced into food through genetic engineering of a food crop. For example, a novel sweetener bioengineered into food would likely require pre-market approval. Generally substances intentionally introduced into food are considered food additives if they have unusual chemical functions, have unknown toxicity, or would constitute new major dietary components of the food.

In our experience, we have not seen biotechnology substances of that type. The substances intentionally added to food via biotechnology are well-characterized proteins, fats, and carbohydrates, and are functionally very similar to other proteins, fats, and carbohydrates that are commonly and safely consumed in the diet. As such, generally-speaking these substances are presumptively recognized as safe. Importantly, our authority under section 409 permits us to

require pre-market approval of any food additive; thus, we require pre-market review of any substances intentionally introduced via bioengineering that are not generally recognized as safe.

However, for the specific case of foods developed utilizing biotechnology, we set up a consultation process to help companies meet our safety requirements. While consultation is voluntary, the legal requirements that the foods must meet are not. To the best of our knowledge, all bioengineered foods on the market have gone through our process prior to being marketed.

In the consultation process, companies send us documents summarizing the information and data they have generated, demonstrating the safety of bioengineered food as compared to conventional food. The documents describe the genes used: whether they are from a commonly allergenic plant, characteristics of the proteins made by the genes, their biological function, and what quantity will be found in the food. They tell us whether the new food contains the expected levels of nutrients or toxins, and any other information regarding the safety and use of the product.

Our scientists review the information and generally raise questions. At the conclusion of the consultation, if we are satisfied with what we have learned about the food, we provide the company with a letter stating that they have completed the consultation process.

In 1999 we held public meetings to solicit views on whether our policies should be modified and to assess the most appropriate means of providing information to the public with regard to bioengineered products in the food supply. As a result, in January 2001, we proposed a rule that would mandate the consultation process. However, this rule was never finalized and is currently not in effect. We also considered a rule requiring labels on foods with gene-altered ingredients, but this did not even reach the proposal stage.

We believe the agency's authority under current law, both pre- and post-market provisions, is sufficient to ensure the safety in the marketplace of foods derived from new plant varieties. We recognize that biotechnology is a rapidly changing field, so we must stay on top of the science as it evolves and is used to make new kinds of modifications to foods. In addition, we will continue to reach out to the public to help consumers understand the scientific issues and the agency's policies.

We are not aware of any information that foods developed through genetic engineering differ as a class in quality, safety, or any other attribute from foods developed through conventional means. A study by the National Research Council released in 2000 concluded, "There is no evidence suggesting that [bioengineered food] is unsafe to eat." The study also found that there is "no strict distinction" between the health and environmental risks posed by genetically engineered plants and those developed through conventional crossbreeding. Therefore our policy declares that genetically engineered foods not differing significantly from non-genetically engineered food be regulated like non-genetically engineered food, and has not to date established any regulations specific to genetically engineered food.

However, any significant differences between the bioengineered food and its conventional counterpart are required to be disclosed in labeling. These would include differences in nutritional properties, the presence of an allergen that consumers would not expect in the food, or any property that would require different handling, storage, cooking or preservation. For example, when a manufacturer produced a line of soybeans that could be used for frying without the chemical process of hydrogenation, a process that creates trans fats, the resulting oil had higher

levels of oleic acid than found in conventional soybean oil, we took steps to label the product "high-oleic soybean oil," distinguishing it from traditional soybean oil. Additionally, food processors may voluntarily label their products to indicate either the presence or absence of a genetically engineered food, so long as the information is truthful and not misleading to consumers.

Our science-based policy was developed through careful consideration of new developments in biotechnology. Our scientists carefully followed the developments in research over previous years to determine the types of commercial foods and food ingredients likely to be developed by recombinant DNA techniques. The scientific principles we use when assessing safety were developed and agreed upon by several prestigious scientific groups, including the National Academy of Sciences, the Food and Agriculture Organization, the World Health Organization, and the Organization for Economic Cooperation and Development.

We take seriously our mandate to protect consumers in the United States and to ensure that the United States' food supply continues to be one of the safest in the world. Our process for evaluating bioengineered foods is one in which the public can have confidence that food biotechnology products must meet the law's safety standards. Our 1992 policy statement and our guidance documents make clear that premarket clearance is required if there is scientific uncertainty about the safety of food derived from bioengineered plants. The policy also makes clear that labeling will be required if the composition of the genetically modified food differs significantly from what is expected for that food, or if the genetically modified food contains potential allergens.

On a final note, we have concerns that the stringent labeling requirements, recommended by *Genetically Engineered Food Right-to-Know Act, S. 2080* may not be in the best interest of consumers. From our end we know that the regulatory burden imposed by labeling can add significantly to production costs of foods, particularly those that are produced from pooled fresh fruits and vegetables. To maintain the accuracy of such a labeling system, we would have to mandate that all GE foods be segregated through all phases of production (planting, harvesting, processing, and distribution), which would add costs and compromise economies of scale. These added production costs constitute, in effect, a special tax levied on producers who use a new technology. They reduce profits to plant breeders, farmers, food processors, grocers, and others in the distribution pathway, while also decreasing competition and increasing prices. Ultimately consumers will bear the brunt of the price increases.

We are confident that our approach is appropriate. The current system allows us to ensure the safety of food products for consumers. Consequently, only foods that have been deemed safe are allowed into the marketplace. Our approach also allows for the use of safe, new biotechnology that gives manufacturers the ability to produce better products and provide consumers with additional choices at a reasonable cost. As a result, we do not see a need to support measures like *Genetically Engineered Food Right-to-Know Act, S. 2080*.

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MONSANTO



Monsanto's focus is on agriculture and supporting farmers around the world in their mission to feed, clothe and fuel our growing world. In 1982, Monsanto scientists were the first to genetically modify a plant cell. Today Monsanto accounts for the vast majority of biotech crops planted in the world. Its biggest class of products has been soybeans, cotton, corn and canola genetically engineered to resist Roundup, enabling farmers to spray to kill weeds while leaving the crop intact.

Since genetically-engineered crops came onto the market, there's been a lot of debate about whether foods containing ingredients from GE crops should be labeled. Some people believe it's a right-to-know issue, and all products containing ingredients from GE crops should be labeled as such. Others believe that since there's no difference between GE and non-GE ingredients, labeling shouldn't be required.

The marketing of, and discussion about, the benefits of non-GE vs. GE foods have created confusion and misperceptions among some consumers about the safety and benefits of each farming system. In actuality, non-GE and GE food all share the same observable physical characteristics. The difference between these foods is in the production practices farmers use when growing the crop. This difference does not necessitate government mandated labeling.

GE and non-GE foods: Differences or Similarities?

A GE or biotech farmer is simply a conventional farmer that chooses to plant a crop variety developed or bred through biotechnology methods. For example, some types of corn have been genetically modified to resist insect pests, thereby requiring fewer pesticide applications to control insect infestations.

But, all food – regardless of whether it is non-GE or GE – must meet the same inspection and food safety standards. “There is no evidence that [non-GE food] is more nutritious. There's no evidence that it's safer. It's not more sustainable. It's not any healthier,” says Dr. Bruce Chassy from the Department of Food Science and Human Nutrition at the University of Illinois, addressing the misperception that one of the benefits of non-GE versus GE food includes being safer or more nutritious.

GE-Food Safety: Tested

In spite of such facts, it is often claimed that non-GE food *are* safer than GE foods. However, before any new GE crop is produced or sold, it undergoes rigorous testing and safety assessments to demonstrate the GE food is as safe to consume as an existing food with the same compositional and nutritional characteristics. Specifically, researchers look for changes in allergenicity, toxicity, nutrient composition and level, unintended effects, and the safety of proteins included with the transgene. As a result, GE crops are the most thoroughly studied, regulated and understood crop or food in history.

In a 2000 report, a committee of the National Academies noted, "The committee is not aware of any evidence that foods on the market are unsafe to eat as a result of genetic modification," and

other groups have reached similar conclusions.

More than 25 Nobel Prize winners and 3,400 prominent scientists have expressed their support for the advantages of biotech crops and safety of genetically modified foods as a "powerful and safe" way to improve agriculture and the environment. Numerous international organizations also have endorsed the health safety of GE food, including the Royal Society (UK), National Academy of Sciences (USA), the World Health Organization, the Food and Agriculture Organization of the United Nations, the European Commission, the French Academy of Medicine, and the American Medical Association.

The bottom line regarding safety: if Monsanto finds a product unsafe, with no exception, the product **will not** be marketed.

The Realities of GE-Labeling

1st Reality: The Food and Drug Administration (FDA) oversees food-labeling laws in the United States. The FDA has determined that since GE crops do not differ from non-GE crops, that products containing them don't have to be labeled. FDA does require the product to be labeled if the ingredient:

- is a potential allergen
- contains toxicants beyond acceptable levels
- somehow changes the nutritional properties of the product

To date, no approved biotech crop is an allergen, is unsafe, or has any significant nutritional differences from non-GE counterparts. Consequently, a non-GE label would be devoid of authentic meaning. Enforcing such a label would undermine the real labels and labeling laws that *do* represent actual health risks.

Again, labeling is not a substitute for safety. If a product is unsafe it should not be marketed. Labeling, as a result, is a non-issue.

2nd Reality: The proposed labeling system gives consumers no context for an informed decision. Recent research indicates 50% of consumers would perceive a label as a warning. When asked, "If there were a product that had a GE ingredient in it, would you purchase that product?" 50% say no. 10% of that 50% say under no circumstances ever would they purchase it. The remaining 40% need to know a lot more information. The proposed labeling system would arguably benefit only those who are currently making the choice to not purchase GE-foods.

3rd Reality: There is a negative connotation with labeling that is often interpreted as a warning. Presenting products to consumers in an unfounded negative light offers no benefit to the manufacturers or the consumers. From a marketing standpoint, there is nothing that makes labeling a benefit to the consumer. The false warning, coupled with the fact that it cannot be overcome by a proven health benefit, makes the idea of GE-labeling very injurious for companies like Monsanto and consequently, the consumer. If forced to label, it will no longer be financially prudent to keep these products on the shelf. So the effect is to drive GE products out of the marketplace and deprive customers of a viable and affordable food choice and the world of "a "powerful and safe" way to improve agriculture and the environment." (*see above safety issue section*)

Mandatory GE-Labeling: Harmful and Unnecessary

Much of the controversy surrounding the labeling of GE-foods is based around the question:

What is the harm in labeling products containing GE ingredients? People must remember, U.S. labeling laws are based on health and safety. Requiring labeling for ingredients that don't pose a health issue would undermine both national labeling laws and consumer confidence. Ensuring that such labeling is accurate would also put a huge burden on regulatory agencies.

A better question might be: *What would be the benefits of labeling products containing GE ingredients?* Individuals who make a personal decision not to consume food containing GE ingredients can easily avoid such products. In the U.S., they can purchase products that are certified as organic under the National Organic Program. They can also buy products companies have voluntarily labeled as not containing GE ingredients. The law allows for voluntary labeling so long as the information is accurate, truthful and avoids misleading consumers about the food. Monsanto supports both options.

Mandatory labeling of food containing GE ingredients might seem like a no-brainer. However, once you consider the facts, it becomes clear there is no sense in mandatory GE labeling.

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Five states are represented in the decider group. Each person will take on the role of a hypothetical senator from one state. You will be responsible for researching the interests and demographics of your constituency. Come to class prepared with questions about GE labeling that are important to your state.

Do not take on the partisan role of a current senator; rather, assume the role of one person speaking for the individual and corporate interests of the entire state. Provided is a set of statistics from the United States 2000 Census. Each state is also provided with a link to their USDA website. This information is intended to give you a brief overview of your state's demographics, but you will probably need to do some additional research in order to best serve the people of your state.

After the other groups have made their presentations, you will need to make a decision and (briefly) explain your choice.

United States Census: Census 2000. Retrieved on November 17, 2008 from <http://factfinder.census.gov/servlet/DatasetMainPageServlet>

California: Mae Rose Petrehn

<http://www.nass.usda.gov/Statistics by State/Ag Overview/AgOverview CA.pdf>

Rural and Urban Populations

Total:	33,871,648
Urban:	31,989,663
Inside urbanized areas	29,950,008
Inside urban clusters	2,039,655
Rural	1,881,985
Filler	0

	Number	Percent
Employed civilian population 16 years and over	14,718,928	100.0
OCCUPATION		
Management, professional, and related occupations	5,295,069	36.0
Service occupations	2,173,874	14.8
Sales and office occupations	3,939,383	26.8
Farming, fishing, and forestry occupations	196,695	1.3
Construction, extraction, and maintenance occupations	1,239,160	8.4
Production, transportation, and material moving occupations	1,874,747	12.7
INDUSTRY		
Agriculture, forestry, fishing and hunting, and mining	282,717	1.9
Construction	915,023	6.2
Manufacturing	1,930,141	13.1
Wholesale trade	596,309	4.1
Retail trade	1,641,243	11.2

Transportation and warehousing, and utilities	689,387	4.7
Information	577,463	3.9
Finance, insurance, real estate, and rental and leasing	1,016,916	6.9
Professional, scientific, management, administrative, and waste management services	1,711,625	11.6
Educational, health and social services	2,723,928	18.5
Arts, entertainment, recreation, accommodation and food services	1,204,211	8.2
Other services (except public administration)	761,154	5.2
Public administration	668,811	4.5
CLASS OF WORKER		
Private wage and salary workers	11,257,393	76.5
Government workers	2,158,071	14.7
Self-employed workers in own not incorporated business	1,249,530	8.5
Unpaid family workers	53,934	0.4
U.S. Census 2000		

Illinois: Andy Herringshaw

http://www.nass.usda.gov/Statistics_by_State/Ag_Overview/AgOverview_IL.pdf

Rural and Urban Populations

Total:	12,419,293
Urban:	10,909,520
Inside urbanized areas	9,737,473
Inside urban clusters	1,172,047
Rural	1,509,773
Filler	0

	Number	Percent
Employed civilian population 16 years and over	5,833,185	100.0
OCCUPATION		
Management, professional, and related occupations	1,993,671	34.2
Service occupations	813,479	13.9
Sales and office occupations	1,609,939	27.6
Farming, fishing, and forestry occupations	17,862	0.3
Construction, extraction, and maintenance occupations	480,418	8.2
Production, transportation, and material moving occupations	917,816	15.7
INDUSTRY		
Agriculture, forestry, fishing and hunting, and mining	66,481	1.1
Construction	334,176	5.7
Manufacturing	931,162	16.0
Wholesale trade	222,990	3.8
Retail trade	643,472	11.0
Transportation and warehousing, and utilities	352,193	6.0

Information	172,629	3.0
Finance, insurance, real estate, and rental and leasing	462,169	7.9
Professional, scientific, management, administrative, and waste management services	590,913	10.1
Educational, health and social services	1,131,987	19.4
Arts, entertainment, recreation, accommodation and food services	417,406	7.2
Other services (except public administration)	275,901	4.7
Public administration	231,706	4.0
CLASS OF WORKER		
Private wage and salary workers	4,771,930	81.8
Government workers	737,903	12.7
Self-employed workers in own not incorporated business	307,691	5.3
Unpaid family workers	15,661	0.3
U.S. Census 2000		

Virginia: Andrea Rich

[http://www.nass.usda.gov/Statistics by State/Ag Overview/AgOverview VA.pdf](http://www.nass.usda.gov/Statistics_by_State/Ag_Overview/AgOverview_VA.pdf)

Rural and Urban Populations

Total:	7,078,515
Urban:	5,169,955
Inside urbanized areas	4,713,302
Inside urban clusters	456,653
Rural	1,908,560
Filler	0

	Number	Percent
Employed civilian population 16 years and over	3,412,647	100.0
OCCUPATION		
Management, professional, and related occupations	1,304,906	38.2
Service occupations	468,179	13.7
Sales and office occupations	868,527	25.5
Farming, fishing, and forestry occupations	16,336	0.5
Construction, extraction, and maintenance occupations	327,733	9.6
Production, transportation, and material moving occupations	426,966	12.5
INDUSTRY		
Agriculture, forestry, fishing and hunting, and mining	43,425	1.3
Construction	250,155	7.3
Manufacturing	387,104	11.3
Wholesale trade	93,477	2.7
Retail trade	389,437	11.4
Transportation and warehousing, and utilities	158,477	4.6

Information	130,592	3.8
Finance, insurance, real estate, and rental and leasing	226,222	6.6
Professional, scientific, management, administrative, and waste management services	395,681	11.6
Educational, health and social services	626,156	18.3
Arts, entertainment, recreation, accommodation and food services	245,967	7.2
Other services (except public administration)	183,695	5.4
Public administration	282,259	8.3
CLASS OF WORKER		
Private wage and salary workers	2,547,990	74.7
Government workers	668,575	19.6
Self-employed workers in own not incorporated business	188,035	5.5
Unpaid family workers	8,047	0.2
U.S. Census 2000		

Iowa: Laura Christianson

http://www.nass.usda.gov/Statistics_by_State/Ag_Overview/AgOverview_IA.pdf

Rural and Urban Populations

Total:	2,926,324
Urban:	1,787,432
Inside urbanized areas	1,114,790
Inside urban clusters	672,642
Rural	1,138,892
Filler	0

	Number	Percent
Employed civilian population 16 years and over	1,489,816	100.0
OCCUPATION		
Management, professional, and related occupations	466,436	31.3
Service occupations	219,837	14.8
Sales and office occupations	385,794	25.9
Farming, fishing, and forestry occupations	15,877	1.1
Construction, extraction, and maintenance occupations	132,530	8.9
Production, transportation, and material moving occupations	269,342	18.1
INDUSTRY		
Agriculture, forestry, fishing and hunting, and mining	65,903	4.4
Construction	91,824	6.2
Manufacturing	253,444	17.0
Wholesale trade	53,267	3.6
Retail trade	179,381	12.0
Transportation and warehousing, and utilities	73,170	4.9

Information	41,970	2.8
Finance, insurance, real estate, and rental and leasing	100,395	6.7
Professional, scientific, management, administrative, and waste management services	90,157	6.1
Educational, health and social services	324,142	21.8
Arts, entertainment, recreation, accommodation and food services	98,819	6.6
Other services (except public administration)	66,286	4.4
Public administration	51,058	3.4
CLASS OF WORKER		
Private wage and salary workers	1,158,392	77.8
Government workers	203,332	13.6
Self-employed workers in own not incorporated business	121,579	8.2
Unpaid family workers	6,513	0.4
U.S. Census 2000		

Massachusetts: Angie Gumm

http://www.nass.usda.gov/Statistics_by_State/Ag_Overview/AgOverview_MA.pdf

Rural and Urban Populations

Total:	6,349,097
Urban:	5,801,367
Inside urbanized areas	5,635,129
Inside urban clusters	166,238
Rural	547,730
Filler	0

	Number	Percent
Employed civilian population 16 years and over	3,161,087	100.0
OCCUPATION		
Management, professional, and related occupations	1,298,704	41.1
Service occupations	444,298	14.1
Sales and office occupations	818,844	25.9
Farming, fishing, and forestry occupations	6,642	0.2
Construction, extraction, and maintenance occupations	235,876	7.5
Production, transportation, and material moving occupations	356,723	11.3
INDUSTRY		
Agriculture, forestry, fishing and hunting, and mining	12,440	0.4
Construction	173,940	5.5
Manufacturing	405,368	12.8
Wholesale trade	103,333	3.3
Retail trade	353,019	11.2

Transportation and warehousing, and utilities	131,820	4.2
Information	118,432	3.7
Finance, insurance, real estate, and rental and leasing	259,538	8.2
Professional, scientific, management, administrative, and waste management services	365,561	11.6
Educational, health and social services	750,610	23.7
Arts, entertainment, recreation, accommodation and food services	214,026	6.8
Other services (except public administration)	138,635	4.4
Public administration	134,365	4.3
CLASS OF WORKER		
Private wage and salary workers	2,528,648	80.0
Government workers	425,573	13.5
Self-employed workers in own not incorporated business	201,219	6.4
Unpaid family workers	5,647	0.2
U.S. Census 2000		