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The Role of Government in the Labeling of GM Food

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Executive Summary

Food labels embody a range of attributes: a salad bag may be "organic," a yogurt may be "low fat," and potato chips may be "all natural." Each year, food companies create new and innovative labels to market their products. In 2008 in the United States, 22,566 new food products were introduced to the market. More than 100,000 types of food products line the shelves of supermarkets and wholesale stores (Economic Research Service, USDA 2009c). With so many different foods and labels, how do consumers make choices, and who ensures that these labels are trustworthy and helpful to consumers? The U.S. government created the Food and Drug Administration (FDA), a regulatory agency "responsible for assuring that foods sold in the United States are safe, wholesome, and properly labeled" (FDA 2008). The FDA works with Congress, the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and other governing bodies to set food-labeling standards. The FDA does not preapprove labels but has the right to request changes or removal of labels that do not meet its specifications. Therefore, food manufacturers have some freedom in labeling and can work creatively to provide consumers with the information needed to make purchasing decisions (FDA 2008).

Opinion polls in the early 2000s suggested that the majority of U.S. consumers want to know if their food products contain genetically modified material. GMOs, or genetically modified organisms, are the result of gene transfer technology. They are used in agriculture to create plants with traits that are desirable to farmers, consumers, or other food system parties. The United States has no government-sponsored food-labeling schemes that state whether or not food products contain GM material. Government regulations do, however, prohibit the presence of genetically engineered material in food that carries the government-approved label assuring that food is produced using organic production processes. Thus, consumers who wish to avoid GM material can buy organic food. Another option for consumers who do not want to buy food that may contain GMOs is to select foods labeled "GMO-free." Such labeling is organized by civil society groups and food companies. To carry the label, foods must comply with standards set by the organizers. The government does not regulate the label but may intervene if there is evidence that the label is misleading. A new initiative for voluntary labeling of "GMO-free" food raises the question of what role—if any—the government should play in monitoring and implementing labeling related to GMOs.

Your assignment is to advise the U.S. government on whether it should engage in the labeling of GMO or GMO-free foods or monitor voluntary labeling organized by the private sector and civil society, and if so, how it should proceed. Would you give the same advice to a developing country? If not, how would it differ?

Background

The Issue

In 2007, 91 percent of soybeans, 87 percent of cotton, and 73 percent of corn grown in the United States contained genetically engineered material. Yet most Americans do not know whether the products they consume contain GMOs. According to federal regulation, organic crops cannot be produced using biotechnology. Certain groups, however, would like to give consumers the option of choosing GMO-free food items that may not be organically produced. One such group is the Non-GMO Project. With the motto "Working together to ensure the sustained availability of non-GMO food and products," the Project has spearheaded an initiative to place a non-GMO label on foods that do not contain GM material (Figure 1). The Project will allow manufacturers to voluntarily label foods with the non-GMO label if the product has undergone specific testing to assure that it does not contain more than 0.9 percent GM material (Non-GMO Project 2009b).

Figure 1: Non-GMO Label of the Non-GMO Project

Source: Non-GMO Project.

Although the initiative may be helpful to consumers, it confronts a much larger issue. First, attitudes toward GMOs in foods vary. At one end of the spectrum, many farmers, food manufacturers, and consumers believe that GMOs are beneficial to humankind and warranted by the improvements in production and food availability. At the other end, some are wary of GMOs and concerned about potential effects on the biosafety of the food supply, human health, and the environment. Some nongovernmental organizations (NGOs) argue that GMOs are a private sector ploy that create dependence on private companies and fail to improve food availability and access in developing countries. The Non-GMO Project initiative may exacerbate public controversy and force the government to take a proactive role in support of or opposition to GMOs, or at least their labeling. Second, the debate raises questions about the constitutionality of labeling requirements and the accountability of the government. In the 1990s, the FDA stated that foods produced by biotechnology are not "substantially" different from foods produced by traditional breeding. Therefore, the FDA uses the same framework to investigate and regulate products made using biotechnology as it does foods produced through traditional breeding. Differences in safety or nutritional status are addressed during review of the final GMO food product, not the process. Likewise, the FDA has no labeling policies that separately address GMOs, and a new policy may be contentious, as well as time consuming and costly. It would require accurate tracking of foods and transfer of information along the supply chain. Third, the Non-GMO Project challenges the efficacy of government intervention. Because the Project encourages voluntary labeling by the private sector, it concerns the role of the private sector and other stakeholders who may find benefit or detriment in the labeling debate. Government intervention may or may not be effective or necessary.

History of Genetic Engineering

The process of genetic engineering is grounded in the fundamentals of genetics. In 1866 Gregor Mendel published his paper "Experiments on Plant Hybrids" on the basic principles of genetics, the science of heredity. He hypothesized that observable traits are based on units called genes. Today, a gene is recognized as a region of DNA that encodes a specific RNA or protein. Mendel, an avid plant breeder, applied his research to agriculture, manipulating genes by mating various plants with a high probability of achieving a desired result. As farmers became educated about Mendelian genetics, they too selectively bred their plants. This primary advancement, used in conjunction with primary farming techniques, raised crop yields and increased food availability (Hartwell et al. 2008).

In the 1970s, geneticists made another revolutionary advance when they began cutting and splicing DNA molecules. This gene manipulation, called recombinant DNA technology, allows scientists to combine DNA molecules of different origins (Hartwell et al. 2008). They can move a gene from one organism to another of the same species, move a gene from one organism to

another across species, or alter genes within an organism. Such alteration may include "shutting off" or activating "silent" genes to change physical properties, chemical properties, or both (Pinstrup-Andersen and Schioler 2000).

Recombinant DNA technology laid the groundwork for biotechnology, a field of science that encompasses all production of altered organisms by use of biological systems. Further advances allowed scientists to manipulate a variety of genes, making biotechnology a routine branch of research (Hartwell et al. 2008). In the 1980s and 1990s, biotechnology quickly became a part of agricultural, pharmaceutical, and other industries. In 1983, the National Institutes of Health (NIH) approved the first release of GMOs out of the lab and into test fields. This GMO was a bacterium that could be used to prevent frost damage on strawberries. Debate followed the approval. In 1992, Calgene Inc. produced the first commercial GMO food: the Flavr Savr tomato had the ideal property of delayed ripening. Therefore, the crop had a longer shelf life and farmers had fewer shipping constraints. The FDA conducted a review of the Flavr Savr tomato and concluded that it was "substantially equivalent" to non-GMO tomatoes in terms of nutritional value, composition, and safety (Mackenzie 2000).

Today, many GM crops and foods have desirable attributes that farmers might not be able to achieve using traditional plant breeding. Beneficial agronomic traits include herbicide resistance, insect resistance, delayed ripening, viral resistance, oil modification, fertility restoration, and male sterility. Farmers generally view these traits as having a positive effect on the environment, especially since insecticide resistance decreases the need for pesticides. For example, corn and cotton have been genetically engineered to produce Bt, *Bacillus thuringiensis,* a protein that is lethal to insects. About one-third of the corn produced in the United States contains Bt. Furthermore, genetically modified quality traits include nutrient fortification, improved flavor, and preservation. "Golden rice," genetically engineered rice that contains beta-carotene, is an example of nutrient fortification, and anti-freeze strawberries, which can withstand harsh weather, are an example of delayed ripening. Both of these products are currently being studied and are not yet approved for consumer purchase.

The traits developed through biotechnology are seen as yielding health and environmental benefits, but they also generate biosafety concerns. For example, because Bt is lethal to insects, some consumers are concerned that it may be toxic to human health. There are no scientifically proven negative health effects, but biotechnology is young, and it is possible that studies of short-term effects may not show long-term effects (Parekh 2004).

In addition to the positive or negative environmental and health effects, GM crops have an important economic impact. According to a recent study, biotechnology increased crop production by 3.9 million tons, lowered crop production costs by US$1.9 billion, and increased growers' net returns by US$2.6 billion in the United States in 2006. Biotechnology crops included alfalfa, canola, corn, cotton, papaya, soybean, squash, and sweet corn (NCFAP 2008).

Mandatory Food-Labeling Policies and Regulation in the United States

Food labels in the United States come in an array of colors, shapes, and designs that aim to attract consumer attention and help consumers make informed food choices. Regulating food labels became a government responsibility in 1938 upon passage of the Food, Drug, and Cosmetic Act (FDCA). Section 403 of this act states that the food label must include four components: the ingredients used to make the food; net weight of the food; the name and address of the manufacturer, packer, or distributor; and the identity or name of the food. Section 201 (n) of the FDCA gives the FDA the right to require more information on food labels to help consumers make food choices. For example, foods containing wheat must declare the presence of gluten to warn consumers with celiac disease of the food contents (Weirich 2007).

It was not until 1990 that Congress required the nutritional information currently on food labels. It amended the FDCA and created the Nutritional Labeling Education Act (NLEA). Similar to the FDCA, the goal of the NLEA was to communicate meaningful information in a clear and understandable manner. It required food manufacturers to disclose essential nutritional information (serving size, calories, fat, protein, cholesterol, carbohydrate) that consumers needed to make prudent food

choices. The NLEA is based upon the notion of "essentiality"; it requires only the information that is needed to allow consumers to make prudent food choices (Weirich 2007).

In the 1990s, Congress became increasingly aware of concerns about biotechnology. The issue was consigned to the FDA, the USDA, and the EPA, which today remain the main regulatory institutions for biotechnology. In 1992, the FDA published a Statement of Policy on GM foods. It concluded that there is no meaningful difference between bioengineered food and other foods so the "key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used." Therefore, it follows the same principles to regulate foods produced through biotechnology as it does for foods produced by traditional breeding methods. It regulates the products, not the process (FDA 1992).

With regard to labeling, the FDA requires that GM food be labeled if it poses safety risks, contains properties that are not found in the food before modification, or contains significantly different nutritional properties. For example, a tomato injected with a peanut protein can no longer be called a common "tomato" because it may cause an unsafe, allergic reaction in some consumers (FDA 1992). The FDA makes case-by-case decisions about foods containing GMOs and maintains its policy that labels should contain only the most basic, pertinent information unless instructed otherwise by the terms of section 201 (n) of the FDCA. Congress has reviewed bills that propose labeling goods containing GMOs, but none has passed into law (Mackenzie 2000).

The most recent attempt to pass such a law is the Genetically Engineered Food Right to Know Act, proposed to the House of Representatives in May 2006. The purpose of the act was "to amend the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly." The act proposed specific labeling requirements and periodic testing of foods by the FDA to ensure compliance. The requirements excluded food served for immediate human consumption, such as that in restaurants, and medical foods. The bill was presented to several subcommittees in the House. It never became law (U.S. Congress House 2006).

Voluntary Food Labeling Policies and Regulations in the United States

Although U.S. government institutions regulate the labeling of consumer goods in the United States, there is a fair amount of freedom in labeling. Not only do manufacturers have the opportunity to decide on their marketed design and image, but they can voluntarily label foods to indicate the presence or absence of bioengineered foods. In January 2001, the FDA published a document called *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*. The publication offered only "draft guidance," and it was issued for the purpose of eliciting comment. Still, this document represented FDA policy and set the groundwork for voluntary labeling. Its main purpose was to recognize that private manufacturers may label their foods that contain or do not contain bioengineered material and to provide suggestions for the most informative and least misleading labeling statements. The FDA does not set standards that the labels must meet, although it does have the authority to intervene once labels are on the market (FDA 2001).

Voluntary labeling efforts also exist outside the scope of bioengineered foods. For example, the Smart Choices program was an initiative to give manufacturers the option of placing a "smart choice" label on their foods. If a food meets certain requirements, set by the private Smart Choices program, the manufacturer can place the seal of approval on the front of the food label. The mission of the program is to "help shoppers make smarter food and beverage choices" (Smart Choices Program 2009). Although the program seems helpful and is fully endorsed by many of the largest food manufacturers, controversy has arisen because foods with a high content of sugar and fat, such as Fruit Loops, mayonnaise, Lunchables, and Teddy Grahams, may be labeled "smart choices." The directors of the Smart Choices program claim that the standards are based on FDA recommendations, but consumers and health professionals are wary of a marketing scheme that they believe displays misleading information. The FDA has decided to intervene and address the concern. It is analyzing

the consumer response and public health effects of the labeling initiative to ensure that consumers receive accurate information. The FDA may choose to clarify the standards, create a new standard, support or prohibit the program, do nothing, or endorse a combination of actions (Neuman 2009b).

Policy Issues

Public Awareness and Acceptance of GMOs

As already noted, there is no consensus in the U.S. population regarding the use of genetic engineering in food production. On the one hand, some are concerned about the biosafety issues—especially allergens, toxins, and environmental and ecological impacts—associated with GMO products. On the other hand, some people support GMO products for their advantages, particularly decreased insecticide use and higher crop yields. This group argues that virtually all breeding techniques, including what are normally referred to as "traditional breeding techniques," have potentially deleterious effects (Bruhn 2003). Survey results suggest that a large percentage of the U.S. population does not substantially understand biotechnology. This lack of understanding often results from a lack of education and exposure to biotechnology and general science (Priest 2000).

In 2000, the Public Policy Research Institute at Texas A&M University conducted a nationwide telephone survey to ask U.S. citizens about their opinions on biotechnology. The study found that as a whole, a little more than half of the U.S. population held a positive view of biotechnology. When asked whether "biotechnology will provide benefits" in the next five years, 59 percent of interviewees responded positively. When asked if biotechnology would "improve our way of life in the next 20 years," 52.8 percent responded positively (Priest 2000).

The Public Policy Research Institute found that the U.S. population has confidence in science and agriculture, but not in government regulators. Support for biotechnology was less, however, than support for other technologies such as the Internet or space exploration, and opposition to biotechnology proved to be generally higher than for other technologies. Support for biotechnology has decreased in the past five years. This decline may be a result of government regulation or media attention, which highlights the potential risks of biotechnology (Priest 2000).

In a global study conducted by the Pew Research Center for the People and the Press, 37 percent of Americans said that genetically modified fruits and vegetables are good, 55 percent said they are bad, and 8 percent did not know (Table 1). Of the seven economically advanced countries surveyed, Americans held the least negative view. Countries with the most negative views included France, with 89 percent of the surveyed group responding that scientifically altered fruits and vegetables were bad, Germany, at 81 percent, and Japan, at 76 percent. The study also found that women held a more negative view of GMO food than men (Table 2).

Table 1: Global Survey of Attitudes toward GMOs

	Scientifically Altered Fruits and Vegetables are …	
	Good	Bad
	%	%
United States	37	55
Canada	31	63
Great Britain	27	65
Japan	20	76
Italy	17	74
Germany	17	81
France	10	89

Source: Pew Research Center for the People and the Press 2003.

Table 2: Men's and Women's Attitudes toward GMOs

	Men Less Negative about Genetically Modified Foods		
Believe GMOs are bad	Men	Women	Diff.
	%	%	
United States	52	73	21
Canada	57	73	16
Great Britain	47	62	15
Japan	69	82	13
Italy	75	85	10
Germany	86	91	5
France	74	74	0

Source: Pew Research Center for the People and the Press 2003.

A study by Rutgers University's Food Policy Institute based on a representative sample of 1,203 Americans found that 90 percent of those surveyed were in favor of mandatory labeling of GM foods. Moreover, 74 percent believed that strict regulation of genetically modified products is necessary and 73 percent agreed that "most genetically modified foods were made by scientists because they were able to make them, and not because the public necessarily wanted them" (Hallman et al. 2002, 29). According to this poll, the American public wants the right to know whether their foods contain GMOs. A paradox arises, however, when they are asked about their purchasing habits. Only 45 percent expressed a willingness to pay more for non-GMO foods, and only 53 percent said they would take the time to look for non-GMO foods. Therefore, it seems that most Americans believe that they have too little information to make an informed consumption decision, but it is unclear whether they are willing to use this information and spend time or money to change their diet and habits. Possibly this issue is one of perceived control over their purchasing and eating power. Similarly, 48 percent of the surveyed public said they would be less likely to purchase fruits and vegetables that were advertised to contain GMOs; 37 percent said it would make no difference in their purchasing decisions; 11 percent said they would be more likely to buy GMO products; and 1 percent were unsure (Hallman et al. 2002).

The strong demand for labeling of genetically engineered foods found in the Rutgers University study was confirmed by a survey conducted by the Center for Science in the Public Interest, which found that 70 percent of respondents wanted foods containing genetically engineered ingredients to be labeled as such. Seventy-six percent of respondents wanted foods that had been sprayed with pesticides to be labeled, and 65 percent wanted food from plants treated with plant hormones to be labeled. The survey also included the following question: "If you had a choice between two boxes of Wheaties, where the label on one box indicated that it contains genetically engineered ingredients and the label on the other box indicated that it does not contain genetically engineered ingredients, which would you choose, or would you not care?" Eight percent responded "Labeled 'Contains genetically engineered ingredients,'" 52 percent responded "Labeled 'Does not contain genetically engineered ingredients,'" 38 percent responded "Would not care," and 3 percent responded "Don't know" (CSPI 2001).

Another paradox of the labeling debate is that the biopharmaceutical industry uses the same principles of bioengineering to produce pharmaceuticals for medicinal purposes but does not receive the same public opposition. Some examples of products include Herceptin produced by Genentech to fight breast cancer, and Enbrel, produced by Amgen to fight autoimmune diseases such as rheumatoid arthritis (Parekh 2004). One reason for the differing public opinion may be the perceived need. Most people believe they need pharmaceuticals to cure their illness or problem. For example, if a woman is diagnosed with breast cancer and given Herceptin by her doctor, she will likely not question whether genetic engineering was used to develop the drug if it avoids the progression of cancer. A mother whose children suffer from hunger is equally unlikely to say no to maize which will alleviate the hunger whether it is produced with genetically modified seed or not.

Nonetheless, acceptance of genetically modified food took an unexpected twist during a hunger crisis in 2002, when Malawi, Mozambique, Zambia, and Zimbabwe rejected U.S. food aid over GM content. Pro-GM groups criticized these countries' governments for putting millions at risk of starvation, while the governments and anti-GM groups cited the unknown long-term health effects of GM food. Since then, GM crops have gained considerable acceptance in Africa, but none of these countries produce GM food (Zerbe 2004). Reasons for the relative lack of trust in GM food may include perceived lack of benefit, lack of control, lack of trust of the biotech industry, or involuntary exposure when consuming GM food.

The Role of Government in Labeling

The FDA has stated that the goal of labeling food products is to provide clear, necessary, and informative communication to the consumer. Therefore, the government must decide on its responsibility in labeling biotechnology, as well as in determining consumer rights and regulating the private sector. As noted, the Public Policy Research Institute found that the American public does not have confidence in the U.S. government on the issue of GM food. Studies show that consumers want more knowledge, but it is unclear whether labeling is an

effective way to restore consumer confidence (Hallman et al. 2002).

Furthermore, the survey results raise the issue of whether labels should include other information about agricultural practices. If the government is responsible for providing information about GMOs, should it also be responsible for informing consumers about the use of pesticides? Whether inorganic fertilizers or manure was used on the fields where the food is produced? And the country of origin? Labeling requirements can spiral out of control, and the government may become responsible for labeling a multitude of characteristics. Furthermore, the biotechnology labeling debate has created significant tension between the private and public sectors. As seen with the Smart Choices Program, a lack of communication between the two parties can also allow private sector initiatives to spiral out of control. At the same time, other initiatives, such as the certified organic food program, have been hugely successful. Therefore, the government must first decide on its role in labeling and then decide on the role of the private sector in self-policing its own standards.

International GMO Labeling Policies: The Global Debate

The amount of genetically engineered crops produced worldwide has increased steadily in the past 12 years. In 2008, global hectarage hit 125 million and the number of countries that produce GM crops increased to 25. Significant increases were also evident in the number of farmers who cultivate GM crops and in the types of GM crops grown. In 2008, the United States was the leading producer of genetically engineered crops, producing on approximately 62.5 million hectares (Figure 2).

Figure 2: Biotech Crop Countries and Mega-Countries, 2008

Source: ISAAA 2008.

Argentina, with 21 million hectares in 2008, was the second-largest producer of biotechnology crops—mainly maize, cotton, and soybeans. The Argentine government regulates bioengineered material on the basis of product rather than process. It monitors products on a case-by-case basis in compliance with its GMO-specific legislation. Biosafety, including concerns about the threat to public health and hazards to the environment, is given the greatest attention when crops are examined for approval by Argentina's National Advisory Committee on Agricultural Biosafety (Parekh 2004).

China was the sixth-largest producer of biotechnology crops in 2008. Next to the United States, China produces the most diverse collection of GM crops, including cotton, tomatoes, poplars, petunias, papayas, and sweet peppers. The most widely produced crop is Bt cotton, which has resulted in large economic gains, especially for the 7.1 million small and resource-poor farmers who have adopted it. A study by the Center for Chinese Agricultural Policy concluded that on average these farmers increased their yields by 9.6 percent and generated an increase in income of US$220 a hectare in 2008. Pesticide use fell by approximately 60 percent, resulting in environmental and health benefits (ISAAA 2008).

Demand for approval of GM seeds, including genetically modified rice, has surged in China. Dr. Dafang Huang, former director of the Biotechnology Research Institute of the Chinese Academy of Agricultural Sciences (CAAS) concluded, "Using GM rice is the only way to meet the growing food demand" (ISAAA 2008). On November 27, 2009, China approved GM Bt rice and GM phytase maize for commercial planting. According to ISAAA (2009), GM rice can generate benefits of US$4 billion a year for up to 110 million Chinese households growing 30 million hectares of rice. Assuming four people per family, the beneficiaries would total 440 million. This approval not only will improve quality of life and sustainability, but also may represent a turning point for worldwide acceptance of GM foods (ISAAA 2009).

Until 2008, South Africa was the only producer of biotechnology crops in Africa. The country began producing GM crops in 1996 and has emerged as the eighth-largest producer, planting 1.8 billion hectares in 2008. The most widely produced GM and traditionally produced crop in the country is maize. Today, South Africa is no longer the only producer of biotechnology crops in Africa. In 2008 Burkina Faso introduced Bt cotton and Egypt introduced Bt maize. In Kenya approval of GM crops is pending.

The 26 countries shown in Figure 2 represent 40 percent of the global population. About 1.3 billion people in Argentina, Brazil, China, India, and South Africa depend on agriculture. Perhaps the strongest argument in favor of GMO foods is the need to expand food production to meet demand and support small and resource-poor farmers. Application of biotechnology can help reduce food insecurity and poverty and prevent excessive food price increases (ISAAA 2008).

The European Union seems most reluctant to adopt biotechnology, although 7 of the 27 member countries planted more than 100,000 hectares in 2008 (ISAAA 2008). The EU first approved GM food in 1995, but a de facto moratorium in 1998 restricted imports. It was not until 2004 that the European Commission lifted the moratorium and reapproved the import of GM products for use in animal feed and for human consumption (Grossman 2005). In contrast to the United States, the EU approves GM foods based on the process rather than the product. The European Commission thus considers that there is a material difference between GM foods and foods produced by traditional breeding. The EU also has stringent labeling guidelines for foods that contain biotech material. If a food product contains at least 0.9 percent GMO material, the label must explicitly state "This product contains genetically modified organisms." This threshold allows for "adventitious or technically unavoidable" GM material. EU member countries are responsible for complying with this rule (Weirich 2007).

Stakeholders

Farmers

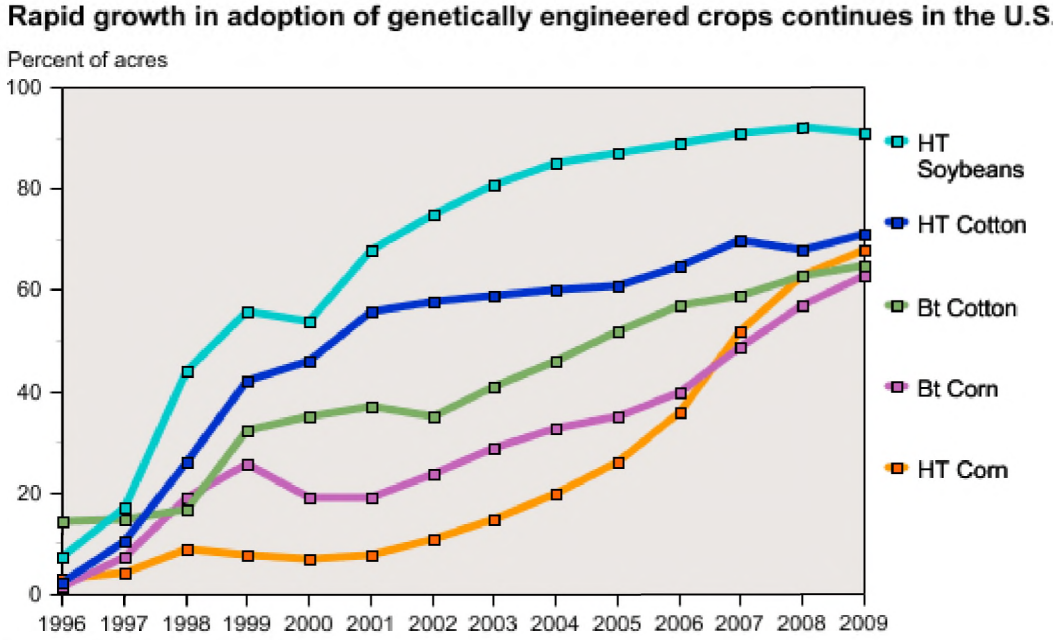
Farmers are the source of genetically modified food and perhaps the primary stakeholder group affected by the labeling debate. GM crops in the United States cover 57.7 million hectares. ISAAA studies report that the farm income gain from biotechnology in agriculture from 1996 to 2006 was US$15.9 billion (James 2007). Herbicide-resistant

plants have resulted in expanded use of one herbicide, glyphosate, and reduced use of other herbicides, while insect-resistant plants have resulted in reduced use of insecticides. The use of herbicide has facilitated minimum tillage practices, which, in turn, has reduced the emission of greenhouse gases from the soil and tractors. Because of the large economic benefits to farmers, adoption of genetically modified crops has increased steadily since it was first introduced in 1996 (Figure 3). This stakeholder group is generally against the labeling of GMO and non-GMO foods because of concern that such labeling would reduce the demand for GM crops (Economic Research Service, USDA 2009a).

Organic Farmers

Organic farming is expanding at a rapid rate in the United States. In 2008, there were 1,030 organic products approved and on the market. The organic production process follows specific certification standards implemented by the USDA's National Organic Program. Under these standards, an agricultural product can be labeled "organic" or "100 percent organic" if it contains 95 percent organic ingredients; a processed product can be labeled "made with organic ingredients" if it is made from at least 70 percent organic ingredients. The standards also stipulate that certified organic crops cannot contain any genetically modified material (USDA 2008). Generally, organic farmers are opposed to the use of genetic modification in agriculture for at least two reasons. First, cross-pollination may introduce GM elements into plants produced under organic conditions and thus contaminate the organic food, which must not contain such elements. Second, many farmers who are dedicated to organic production methods share many consumers' belief that genetic engineering is unnatural and bad for the environment. The majority of organic farmers could be expected to be proponents of labeling GMO and non-GMO foods because such labeling may create a negative connotation for GMO products and result in increased demand for organic products. On the other hand, the availability of foods labeled as containing no genetically modified components might compete with organically produced food.

Figure 3: Growth of GM crops in the United States, 1996–2009



Source: Economic Research Service, USDA 2009a.

Agribusiness

The term "agribusiness" includes "all the activities that take place in the production, manufacturing, distribution, wholesale and retail sales of an agricultural commodity" (Cameron 2006, 4). As a whole, agribusiness accounts for 20 percent of U.S. gross domestic product (Cameron 2006). According to the Food and Agriculture Organization of the United Nations (FAO), agribusiness brings "farm to fork." Agribusiness can have a large impact on the U.S. food supply and economy, and companies must follow strict guidelines to assure consumer safety, product quality, and environmental protection (FAO 2010).

One of the largest companies in the seed business is Monsanto. The company was founded in 1901 in the United States when it launched the production of saccharine. It is now a global agribusiness company and producer of genetically altered seed with traits such as yield potential, herbicide resistance, insect resistance, and drought tolerance. The company's value statement says, "We apply innovation and technology to help farmers around the world produce more while conserving more. We help farmers grow yield sustainably so they can be successful, produce healthier foods, better animal feeds and more fiber, while also reducing agriculture's impact on our environment." The company suggests that farmers should use biotechnology to decrease pesticide use and greenhouse emissions, increase yield, and improve quality of life for farmers in developing countries. Monsanto, employing the phrase "it's all about yield," boasted net sales of US$8.3 billion and net income of US$993 million in 2007. In 2008, net sales increased by 36 percent to US$11.3 billion and net income increased 104 percent to US$2 billion. Analysts forecast continued growth for the company and estimate that gross profit in 2012 will be US$9.5 billion—nearly 2.5 times greater than the 2007 gross profit of US$4.2 billion. Such financial success is a result of increased farmer demand, acquisitions, new technology, and global expansion (Monsanto 2009).

Created in 2000, Syngenta is another global agribusiness company that produces seed and crop protection. According to its website, the company is "committed to sustainable agriculture…through innovative research and new technology" and built upon the vision of meeting global food demand. Like Monsanto, Syngenta reports significant profits. In 2008, it reported net sales of US$11.6 billion, a gross profit of US$5.7 billion, and net income of US$1.8 billion (Syngenta 2009). Other large agribusiness companies that use biotechnology include Pioneer (DuPont), Prodigene, and Epicyte.

These agribusinesses have had huge success and seem to be growing, but they have faced significant opposition because of their market power, resulting in part from the monopoly positions created by seed patenting. For example, the Organic Consumers Association has launched the "Millions against Monsanto" campaign (OCA 2009). Likewise, the transnational NGO Greenpeace targets Monsanto for poor corporate governance and argues that it has used toxic operations in the past and is now trying to avoid responsibility. Greenpeace states, "Monsanto is putting GE foods on the market without concern for the potential health or environmental risks" (Greenpeace 2009).

Monsanto, Syngenta, and other agribusiness companies do not support labeling. They claim that their products are just as safe for consumers as non-GMO products. They support the FDA's present policy of not regulating genetically modified food based on process and of labeling specific products only if they pose a public health concern or contain an allergen or different nutritional property.

Supermarkets

The Non-GMO Project reports that 80 percent of processed foods in supermarkets contain GM material. Most retailers, however, have little control over whether or not they are selling products that contain GMOs. Often, supermarkets are unaware of whether they are selling GM products (Non-GMO Project 2009b).

The Non-GMO Project asks for retail support, requesting that supermarkets endorse the Project and give donations. Whole Foods Market, New Leaf Community Markets, and more than 100 other supermarkets have made a commitment to the Project and offered donations. Large supermarkets such as Safeway, Wal-mart, and Kroger, however, have not publicly endorsed the Project (Non-GMO Project 2009c).

In 2009, supermarkets became the key stakeholders in the country-of-origin labeling (COOL) debate. Congress decided to mandate country-of-

origin labeling in the Farm Security and Rural Investment Act (Farm Bill) to inform consumers where all food products originated (Economic Research Service, USDA 2009b). The bill requires food retailers to include statements such as "Product of U.S.A." or "Imported from Mexico" when selling produce, meat, or fish. Like the GM debate, the COOL debate emerged from the demand for mandatory labeling but faces increased criticism. Proponents argue that consumers have the right to know the source of their foods while opponents argue that the costs outweigh the benefits. The Agricultural Marketing Service (AMS), which is part of the USDA, estimated that the direct costs of country-of-origin labeling would be between US$582 million and US$3.9 billion (Krissoff et al. 2004).

The Non-GMO Project and Other Advocacy Coalitions

The Non-GMO Project is a nonprofit organization that addresses the concern about GM foods. It advocates for voluntary labeling of food products that do not contain GMOs and prides itself on third-party verification. Its website reads, "Our shared belief is that everyone deserves an informed choice about whether or not to consume genetically modified products, and our common mission is to ensure the sustained availability of non-GMO choices." The Project encourages manufacturers to place a "Non-GMO" seal on food labels if the food meets specific standards. The seal is a butterfly on two blades of grass in the form of a checkmark (Figure 1). The Non-GMO Project does not promise that the final products that display the seal are 100 percent GMO-free. Rather, it promises that the process for producing such foods used ingredients with less than 0.9 percent GMO and relied on best practices to avoid contamination. The program is process-based, and manufacturers are responsible for using the best practices to maintain the standards. The Non-GMO Project does not report on how frequently it monitors products with the seal.

The Non-GMO Project also prides itself on collaboration and support from consumers, retailers, and manufacturers alike. In 2009, 421 retailers endorsed the seal, including large retail chains such as Whole Foods Market. The Project approved 1,430 products produced by 66 different manufacturing companies. Consumers have also taken the Non-GMO "pledge." The Project has more than 140 "followers" on Twitter and more than 3,500 "fans" on Facebook (Non-GMO Project 2009).

Other advocacy groups that endorse labeling include the Consumers Union, the Organic and Non-GMO Report, the Institute for Responsible Technology, and the Center for Food Safety. Several other advocacy groups exist.

Consumers

Most polls of the U.S. population suggest that a majority of consumers want the right to know if GMO ingredients are present in their food. The paradox of labeling, however, is that although consumers report wanting this information, they will not spend the money or time to assure that they are consuming GMO-free foods. Policy makers have the responsibility of taking action when the consumer right to know goes too far or causes a decrease in economic profitability. It is unclear whether consumer spending will compensate regulators, along with farmers and food manufacturers, for their labeling efforts (Hallman et al. 2002). Likewise, it is important to note that consumers do not show such disapproval for the biopharmaceutical industry. The FDA has approved many biotechnology health care and medicinal products with little public objection (Parekh 2004).

U.S. Government

In the United States, the FDA and USDA are the principal regulatory bodies involved in food labeling. Congress has mandated labeling regulations but may delegate rules and responsibility to the FDA. The functions and positions of the FDA and USDA have already been described.

U.S. Trading Partners

The World Trade Organization is a global organization whose "goal is to help producers of goods and services, exporters, and importers conduct their business" (WTO 2009). The United States joined the WTO upon the founding of the organization on January 1, 1995. Currently the United States trades thousands of food products with member countries and serves as the headquarters for many global food manufacturers (WTO 2009). WTO member countries have their own labeling policies for food products based on differing government legislation and public demands. Some argue that there should be an international, harmonized label

to standardize product quality, improve global communication, and remove trade barriers, but at present such a label does not exist.

International labeling policies for food products that contain GMOs differ because countries use and regulate these products differently. Therefore, the decision to label or not label may have implications for international trade of GMO or non-GMO products (Jansen and Lince de Faria 2002). In particular, the United States and the European Union differ in their GMO labeling and trading policies. In 2003, the United States, joined by Argentina and Canada, filed a complaint with the WTO about the EU restrictions, claiming that the EU moratorium banning the import of GM foods was not consistent with WTO policies. The United States argued that the moratorium violated the Sanitary and Phytosanitary (SPS) Agreement of the WTO because it was not backed by scientific evidence and assessment. The SPS Agreement spells out the WTO's policy on protecting human health without restricting trade. It states that "any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal, or plant life or health, is based on scientific principles, and is not maintained without sufficient scientific evidence" (WTO 1994, Article 2.2). EU member states removed the moratorium in 2004, but some restrictions remain (Grossman 2005). The WTO works with the Codex Alimentarius Commission in Rome, the World Health Organization, and the FAO to address labeling policies (Codex Alimentarius Commission 2010).

If the United States decides to embark on a policy of mandatory or voluntary labeling, trade barriers might be diminished and markets may open up, even outside of the European Union. On the other hand, the postharvest costs of separating GM and non-GM commodities are likely to increase, and labeling might complicate matters if it interferes with the global demand and economic profitability of foods containing GMOs (Weirich 2007).

Health Advocates and Environmentalists

Health advocates represent two sides of the story. On one side are those who believe that GMO material should be removed from the food supply because of potentially negative but scientifically unproven human health effects. On the other side are those who believe that GMO material is necessary because it increases the global food supply; reduces poverty, hunger, and malnutrition; provides an opportunity for the removal of toxins and allergens; and reduces health risks associated with the application of chemical pesticides. Because of the high-profile nature of GMOs, the issue has received significant mainstream publicity. Writers such as Marion Nestle and Michael Pollan and films such as Food Inc. have voiced opinions about the issue of GMOs in foods.

Opponents of GM food argue that food impurity, allergenicity, and potential toxicity are hard and fast reasons to label. Consumers with a history of allergies and dietary limitations are particularly contentious. They believe that inadvertent production of allergens and changes to nutritional properties may not be noticed by manufacturers and governmental food regulators, or not noticed as a health concern until after harm to human health has occurred. They also argue that because pest-resistant genetically modified crops are toxic to insects, they may also be toxic to humans. Even if GM foods only pose a small risk, this stakeholder group does not want to assume this risk at all. Therefore, these health advocates believe that food producers and the government have an ethical obligation to label food products that contain GM material (Weirich 2007).

A different group of health advocates believes that biotechnology is beneficial because it helps to feed a hungry world. They argue that money should not be spent on giving high-income individuals, such as those in the United States, the right to choose GM or non-GM foods when resource-poor individuals, especially those in the developing world, face the choice of whether to eat GM foods or suffer from malnutrition. Why would the United States want to label and risk decreased production of GM foods if it is part of the solution to global hunger, poverty, and malnutrition (Pinstrup-Andersen and Schioler 2000)?

Environmentalists are similarly torn over the issue. One group believes that the use of genetic engineering promotes environmentally damaging monocultures and contamination of organic crops with genetic material (Weirich 2007). Others argue that biotechnology is advantageous because it decreases pesticide use and greenhouse gas emissions. Pesticides kill innocent insects and artificially disrupt the ecosystem (Pinstrup-Andersen and

Schioler 2000). In 2006, biotechnology reduced pesticide use by 55,000 tons (NCFAP 2008).

Policy Options

Various options are available to the U.S. federal government. Four are mentioned here.

The U.S. Government Does Nothing

The easiest and cheapest solution to the labeling debate may be for the federal government to do nothing. It would maintain its current policies, rules, regulations, and practices. It would continue to base mandatory labeling on product differences and public health concerns rather than on production processes. Along with government inaction, the private sector may choose to do nothing to avoid confusing, non-standardized labels. Proponents of this option argue that extra labeling is not cost-effective and may result in an increase in the cost of food. Opponents argue that consumers have the right to know what they are eating and should not be forced to accept the government's failure to act.

If the private sector chooses to label voluntarily, the FDA would have the power to require label changes under FDCA Section 201 (n). Self-policing by the private sector may result in a lack of standard, consistent information, but it could also result in consumer knowledge and choice. If an organization such as the Non-GMO Project leads the effort for voluntary labeling, this organization would conduct initial examination of food products. The voluntary label could be a seal or a statement that reads "Contains genetically modified organisms," "Does not contain genetically modified organisms," or a similar phrase. This label could be placed anywhere on the food package: on the front, on the back, in the ingredient list, or in the nutritional facts. The biggest issues with this option concern the credibility and effectiveness of the label. The trustworthiness of the Non-GMO Project or other advocacy organizations, consumer interpretation of the label, and compliance by agribusiness are other considerations.

The U.S. Government Implements a Mandatory Non-GMO Label

The government could choose to implement a policy that sets specifications and requires mandatory labeling of foods claimed to be GMO-free. Such a policy could appease consumers without attaching a negative connotation to foods that contain GM material. It could make farmers more inclined to adopt non-GMO practices, and food companies could gain profits if they penetrate a new market for non-GMO crops. A manufacturer could even use the label as a marketing tool to identify itself as a health or environmental leader. The government would regulate and monitor the use of the label.

Opponents of labeling argue that a government policy is pointless because organic food already offers assurance of non-GMO food and the FDA allows voluntary labeling of non-GMO food. GM-specific policies will add extra cost, time, and effort to food manufacturing because products will require tracking from seed to shelf and careful segregation between GM and non-GMO products or continual testing along the food chain. To achieve this segregation of products, farmers and manufacturers may require new equipment, storage, and practices. The government would need to identify a stakeholder group, third party, or itself to be accountable for tracking or testing to maintain the integrity of the non-GMO label. Opponents also argue that GM labeling will crowd more "meaningful" information or might not even fit on the package. The Non-GMO Project has set a threshold of 0.9 percent GM material to be considered GMO-free. The U.S. government may or may not agree with this standard.

The government might choose to implement this labeling policy alone or in conjunction with a program to educate consumers about the meaning of the label. Such an education program could close the gap between consumers who say they want GMO labeling and those who say they will actually use GMO labeling to make purchasing decisions. It might also help to avoid misinterpretation and spread of inaccurate information. An education campaign might be costly, however, and would not ascertain consumer satisfaction or action to purchase non-GMO material.

The U.S. Government Requires GMO Labeling

The U.S. government could create a policy to mandate labels on foods that contain GMO material, similar to the proposed Genetically Engineered Right to Know Act. The government would set specific standards and monitor the use of the label. The policy might apply to foods that contain

more than the EU threshold of 0.9 percent GM material or another specific percentage. The label might be a seal, written statement, or other form of message to consumers that the food contains GM material.

The advantage of this option is that consumers would be given the right to know. Yet one concern about the GMO label is the tone; it may be interpreted as a warning to consumers. Another issue is the extent of the label. The label may be put on processed foods and unprocessed fruits and vegetables that contain GMOs. It could also be placed on meats that come from animals that consumed feed containing GMOs. If this is the case, animal feed must also be labeled. As with a non-GMO policy, regulators would need to determine a way to distinguish GMO from non-GMO products through product segregation, supply chain tracking, or continual testing and then label products accordingly.

To clarify the purpose and explain which foods are labeled, the government may choose to add an education component to its labeling policy. The government could require food companies to label foods that contain GMOs and inform consumers about the meaning of the label. This approach could increase public awareness about the GMO issue and influence public perception. Yet, as with a non-GMO education campaign, the potential market response is unclear. If an education campaign reduces consumer confusion and fear, it might increase economic gains. There is no guarantee, however, that such a campaign would be effective or that the food industry would be fully compensated for its efforts. A campaign would add costs and responsibilities to the government and to the entire food industry.

The U.S. Government Creates a Pro-GMO or Anti-GMO Campaign

The U.S. government, agribusiness, or civil society could implement a pro-GMO or anti-GMO campaign to advocate for the presence or absence of GM material in foods. The campaign could inform consumers about the benefits or risks and even provide incentives for purchasing or not purchasing foods that contain genetically engineered material. The campaign might disseminate or exacerbate negative connotations about GM food. Such campaigns would achieve their goals only if consumers are given the option to execute their choice—that is, through some kind of labeling. A campaign could significantly influence the U.S. population and the food industry, but it would have to be backed with scientific evidence to avoid opposition and criticism from those who disagree.

Assignment

Your assignment is to advise the U.S. government on whether it should engage in the labeling of GMO or GMO-free foods or monitor voluntary labeling organized by the private sector and civil society, and if so, how it should proceed. Would you give the same advice to a developing country? If not, how would it differ?

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