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Labeling of Genetically Modified Foods:

Stakeholder Perceptions of the

Food and Drug Administration's Public Consultation Processes

and

Food Industry Reactions to the

United States Voluntary and European Union Mandatory Policies

A dissertation submitted by

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To Marjorie and Paul Albert

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THESIS ABSTRACT

Genetically modified (GM) foods are widely used in the United States of America (US); however, many consumers are unaware that they are consuming GM foods. Food labeling to inform consumers that a product is GM or is not GM has been proposed to reduce the information asymmetry between sellers and buyers. The guidance for industry for voluntary labeling of GM and non-GM foods proposed by the US Food and Drug Administration (FDA) in 2001 was the main focus of the research. The European Union's (EU) 2003 regulation for mandatory labeling of GM foods was also analyzed.

Representatives of the biotechnology industry, conventional and organic farmers, food manufacturers, critics of agricultural biotechnology and consumer rights advocates, as well as US officials and researchers, were interviewed from May 2003-April 2004. Their views about labeling policies were compared with official records and research about consumer perceptions of GM foods and labeling.

As required by law, FDA held public meetings and obtained public comments to inform citizens and enable them to express their views about the proposed labeling policy. Stakeholder perceptions of these consultation procedures were the topic of one paper. Some stakeholder groups perceived the procedures to be flawed. The study concluded that the technical and legal parameters for labeling in the US were misunderstood by some stakeholders, leading to ineffective use of the procedures.

The food industry's reactions to the US and EU labeling policies were the topic of another paper. Food companies viewed disclosure of information about GM foods and non-GM foods as business risks in markets where consumers were skeptical about GM foods. In the US, food producers did not voluntarily label their products as containing GM ingredients. In the EU, they avoided mandatory labeling by using non-GM

ingredients. Neither labeling policy was enabling consumers to express their preferences through informed purchasing decisions; thus the market was not functioning to serve both sellers and buyers. Contrary to the view that labeling can help to resolve a controversy by allowing individual consumers to make choices, the study demonstrated that controversies over GM technology prevent the implementation of food labeling policies.

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CHAPTER ONE: INTRODUCTION

In a competitive global market, farmers and food manufacturers must be highly sensitive to the milieu in which their products will be sold. More than half of the genetically modified foods (GM foods)[1] grown worldwide are cultivated in the United States of America (US) (James 2006). Therefore, US food producers have a high stake in the regulatory policies that govern the ways that information about GM foods is conveyed to consumers in both the US and foreign markets.

Although GM foods are in their second decade of commercialization, the environment in which these products are marketed remains uncertain. Since the first GM crops were planted as experiments in the early 1980s, there have been claims about the potential positive and negative effects that GM plants and animals might have on human or animal health and the environment; in addition, the ethical, economic and social effects of the technology have been debated (e.g. Krimsky and Wrubel 1996, Rifkin 1998, Ho 2000, Tokar 2001, Bauer and Gaskell 2002). From the early 1990s until the present time, public opinion surveys and consumer studies have indicated that many people in Europe and North America have little information about GM foods. They are wary of the technology and prefer foods that are not GM to those that are (e.g. Harlander 1991, Zimmerman et al.1994, Gaskell et al.2003, Evenson and Santaniello 2004). This study reports on research about one type of consumer information that has been the subject of long-standing debate: labeling policies for GM foods (e.g. Barefoot et al.1994, Degnan 1997; MacKenzie 2000).

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[1] Foods that are derived from crops in which the DNA (deoxyribonucleic acid) has been recombined with DNA from another species are referred to as genetically modified or GM foods in this study. Other common terms used to describe these foods include “transgenic,” “bioengineered,” “genetically engineered” and “biotech” foods, while the technology may be referred to as “agricultural biotechnology.” There has been no international consensus among regulators on which terminology to use in food labeling, for example, the Codex Alimentarius Commission refers to genetically modified/genetically engineered foods (CAC 2007a). The term GM food was chosen for this study purely for consistency and this should not be interpreted as an expression of an opinion about terminology.

Food labeling policies aim to ensure, among other things, that consumers have accurate information about food products and that the information on a food package is truthful and non-misleading. One function of the label is to ensure that both buyers and sellers have access to all relevant information needed for informed consumption decisions. Producers are aware of the fact that a food is GM. Consumers, in the absence of labeling, do not have ready access to this information since the quality of being a GM product cannot be detected without a laboratory. This difference in information that is known to sellers and buyers ("information asymmetry") can lead to inefficient allocation of resources, prices that do not reflect consumer preferences, and unfair competition among sellers (USDA 2003). Governments may develop rules for labeling products to rectify this imperfection in market conditions and to ensure consumer confidence in the information about products, but voluntary labeling policies are effective only if the labels are in fact employed.

Two labeling policies were the focus of this research. The first was the US Food and Drug Administration's (FDA) 2001 draft policy, "Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" (referred to in this study as the "FDA Guidance") (FDA 2001) that provides options for companies to voluntarily label foods as "containing" or "not containing" GM ingredients. The second is the European Parliament's 2003 policy that was put in place by establishing two complementary regulations: Regulation (EC) No 1829/2003 that requires labeling for human food and animal feed containing genetically modified organisms (GMOs), "to enable consumers to make an informed choice" and Regulation (EC) 1830/2003 that states: "[the EU] guarantees the traceability and labeling of genetically modified organisms and products produced from GMOs throughout the food chain" to ensure the truthfulness of labeling and facilitate the monitoring of GMOs (referred to in this study as the "EU regulation") (Europa, 2006a, Europa. 2006b). The EU policy requires that producers declare that their products contain GM ingredients if

the products contain more than 0.9 percent of GM material[2] regardless of whether this is due to adventitious presence (European Parliament 2003).

1.1 Purpose of the study

1.1.1. Stakeholder involvement in and reactions to FDA public consultation procedures

FDA is required by law to inform the public about the development of regulations and other policies and to provide citizens with opportunities to express their views about the proposed policies (US Congress 1997). Stakeholder organizations that represent industry, consumers and other constituencies can have a significant influence in these policy discussions because of their specialized knowledge and interests in the topics. Yet there has been little research about the ways that these stakeholders perceive these processes for informing the public and facilitating dialogue, particularly whether stakeholders consider the procedures to be fair, useful and effective from their perspectives.

In the first part of this study, US stakeholders' involvement in and reactions to FDA's efforts to conduct public meetings and solicit public comments about the draft proposal on labeling were assessed. In the controversy over labeling of GM foods, critics of the US policy have charged that US regulatory decisions have been biased and not transparent and that public views have been ignored (e.g. Nestle 2003). The first paper in this study will demonstrate that the FDA processes of consultation were conducted as intended by the law, and a wide range of citizens had the opportunity to provide their views to the regulatory agency in public settings. The stakeholders'

[2] Although the regulation does not specify how the 0.9 percent is to be defined, Spiegelhalter et al. explain that percentages of genetically modified DNA are reported as a "ratio of target GM DNA relative to the total amount of species DNA present [total equals GM DNA plus non GM DNA]…" (Spiegelhalter, Lauter and Russell 2001, 638).

satisfaction or dissatisfaction with the process was based on their understanding or lack of understanding of all of the factors that FDA must consider or exclude when formulating a policy, appropriate or inappropriate use of the process by stakeholders, and whether or not they had achieved their objectives during the process.

1.1.2 Food industry reactions to the US voluntary and EU mandatory labeling policies

The purpose of labeling is to ensure that consumers have adequate information to express their preferences in the marketplace, so that the market will provide the optimum quantity of goods with the traits that consumers want at prices they are willing to pay. Ultimately, decisions to voluntarily label food products depend upon individual food companies' assessments of the potential benefits and risks of providing consumers with this information. Companies will volunteer to label products when their knowledge of market conditions suggests that the information will stimulate sales. Conversely, they will not volunteer to label foods if their assessment of market conditions or the standards set for labeling suggest that their sales could be at risk. In the case of mandatory labeling, companies will avoid labeling when feasible by reformulating their products and using substitute ingredients if they believe that labeling would have a negative impact on their business.

In the second part of this study, the reactions of leaders in the US food industry to the FDA guidance and the EU regulation are examined. Representatives of commodity producers, conventional food manufacturers and organic food producers were interviewed to assess how the US food industry perceived these labeling policies and the ways that they were responding to the voluntary and mandatory labeling policies. The study found that neither the US nor the EU labeling policies for GM foods were effective due to current evidence about consumer perceptions and preferences that causes food companies

to view labeling of GM foods as being a business risk. As expected, companies chose not to label when labeling is voluntary, and they used non-GM ingredients when labeling is mandatory. In addition to the lack of labeling for products that contain GM ingredients, there was some reluctance to label foods as non-GM because of the stringency in labeling rules. Therefore, the labeling policies that were intended to make it possible for consumers to express their preferences were not being implemented by the US food industry. As a result, US and EU consumers have limited options to express their preferences regarding GM foods, and the use of GM foods is restricted in some markets.

1.2 Broad significance

GM food labeling affects not only the US and EU markets; it is a global issue. Australia, Brazil, China, India, Indonesia, Japan, New Zealand, Norway, Malaysia, South Korea and Thailand, as well as the 27 member states of the EU, have policies requiring that GM foods be labeled (CAC 2007b). When enacting labeling policies for GM foods, governments may be motivated by a number of factors, including: 1) the belief that labels will enable consumers to make informed choices; 2) the desire to allow consumers to express their preferences; 3) the need to enhance consumer confidence in the food supply and regulatory system; and 4) and the need to meet standards in foreign markets.

This study demonstrates that GM labeling policies may not have the impact that policy makers expected. In the world's largest and most affluent markets, the US and EU, labeling policies were not functioning as envisioned since products with labels disclosing the GM ingredients were not being sold. The information asymmetry that exists may distort the functioning of markets, leading to prices that may not reflect consumers' preferences. Mandatory labeling policies limit the presence of GM foods in the market. Such policies have a powerful impact on food producers' decisions regarding the ingredients used in their products. Faced with mandatory labeling, food manufacturers chose to avoid using GM ingredients. Thus, the requirement to label GM foods is having

a negative influence on the markets for GM seeds and the introduction and spread of GM foods in Europe. This makes it impossible for the market to reveal European consumers' willingness to purchase GM foods. The reluctance to label GM foods where labeling is voluntary means that producers have no way to know whether and under what circumstances US consumers would choose to purchase GM foods.

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CHAPTER TWO: US AND EU REGULATORY CONTEXTS

2.1 Introduction

The US and the EU have contrasting policies toward the labeling of GM foods. In the US, labeling is voluntary: producers may label foods as containing or as not containing GM ingredients, but they are not required to do so. In the EU, labeling of GM foods is mandatory: producers must label foods if they have GM content. In order to place the US and EU GM labeling policies in their historical contexts and to better explain why US and EU policy makers arrived at very different approaches to GM food labeling, the salient aspects of US and EU political history and regulations with respect to biotechnology are discussed below.

2.2 US and EU political and legal contexts of regulations

In the US and the EU, the entities that set labeling policies and implement them are remarkably different. In the US, the FDA, a technical agency operated by appointed officials sets and enforces the policies. In the EU, the Parliament, a political body of elected officials sets policies, and a large number of separate technical institutions implement the policies.

2.2.1 United States institutions

The US political system with its executive, judiciary and legislative branches is long-established, and the concept of the separation of powers in the US is a basic component of government structure. The relationships between the laws of the individual 50 states and a federal agency's regulations are fairly well-understood by the stakeholders concerned with labeling of GM foods. Since the enabling legislation, the Food, Drug and Cosmetic Act of 1938 (referred to as 1938 FDCA in this study) was passed, most food

labeling decisions have been addressed within the executive branch.[3] This legislation gave the FDA the authority to develop and enforce new regulations for GM foods under the existing law. The federal legislative and judiciary branches of government had been relatively uninvolved in the issue as of 2007.

Although few bills regarding GM foods have been proposed in the US Congress, there have been public debates in local and state legislative bodies and referenda at the county and state levels in all regions of the US regarding several aspects of agricultural biotechnology (PIFB 2007).[4] During the period 2005-2006, 134 pieces of legislation relating to GM foods were introduced in 33 states and the District of Columbia (PIFB 2007,1). Only eleven of these dealt with food labeling; and the only bill that passed was the Alaska bill that requires labeling of GM fish (Ibid.,6).

With one large technical agency setting and implementing a policy, there is greater consistency in approach than there is in the EU. The FDA has fairly routine criteria it considers in making its decisions about GM food labeling. This allows food companies to predict how a single policy will affect their businesses throughout the country. When policies are made by many political bodies and implemented by different technical agencies, as is the case in the EU, a very wide range of factors may affect an industry. This difference is challenging for US businesses when they are marketing foods within and outside the US.

Rights of citizens in the US

The American public has had access to information about regulations in general since the enactment of the Federal Register Act of 1934, which provided for the

[3] The Nutrition Labeling and Education Act of 1990 was a rare exception to this practice (Shapiro 1995).

[4] Some bills attempted to address issues that are not the under the jurisdiction of the federal government, and others aimed to address regulatory matters that have not been dealt with by the federal government at this stage. In 2005-2006, bills focused on coexistence between GM producers and organic and conventional producers, liability for damages from GM crops, moratoria on producing GM crops and promotion of GM crops (PIFB 2007).

explanation of all new regulations by the relevant government agencies in the daily publication of the *Federal Register* (McDonald 2004). Beyond being informed, citizens have the right to make comments on proposed rules before they are finalized; this right was embodied in law with the Administrative Procedures Act of 1946 (Ibid.). In addition to these broad laws that allow the public to offer comments about FDA proposals for rules, the FDA Modernization Act of 1997 (FDAMA) obliges the agency to actively seek public views when proposing guidance documents. The FDAMA states:

> For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary [of Health and Human Services] shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account. (US Congress 1997, Section 405).

Consistent with these laws, the FDA provided a public forum for stakeholders to present their views when developing its policy for labeling of GM foods and sought public views about the proposed GM food labeling guidance through a public comment process.

The US stakeholder organizations, as well as individual citizens, believe that participation in regulatory decisions is their right, and they often devote substantial efforts to participation in the hope of influencing policy decisions. Although the FDA has a responsibility to seek comments, it is not necessarily obliged to follow the positions advocated by those parties who made comments. Indeed, it would be difficult to accommodate the wide range of stakeholder views in many situations. FDA must base decisions on legal and scientific factors, although some stakeholders may not always appreciate these factors.

Rights of and restrictions on businesses

The 1938 FDCA gave FDA the authority to regulate the information provided on food products in order to prevent consumers from being misled. This law has been interpreted over the years to restrict some advertising statements or claims on food products. However, in the past decade, the First Amendment of the US Constitution has been invoked in lawsuits against FDA in which the courts ruled that the federal government could not abridge the freedom of speech (Dickinson 1999, IFT 2000). The US Supreme Court ruled that FDA could restrict false and misleading information but could not limit truthful commercial speech (Adams 2002). This led the agency to reconsider whether its approach to product labeling was too restrictive and unconstitutional (Kaufman 2002). In addition, the First Amendment has been used to protect the "right not to speak" or to not be "compelled to speak" (IFT 2000), suggesting limitations on FDA's ability to require GM ingredient disclosure. Given this trend in thinking and actions within the judiciary branch of the federal government during the period that the FDA was reviewing its approach to GM food labeling, the FDA lawyers concluded that the agency's authority to mandate labeling was limited, and therefore it would be on safer legal ground if the agency developed a voluntary labeling policy.

2.2.2 European Union context

The commercialization of gene technology has arisen during a time when large parts of European society itself are undergoing a profound political and economic transformation. The establishment of an integrated European economic and political entity began with the formation of the European Economic Community when six nation-states signed the Treaty of Rome in 1957 (Hix 1999). The European Union was formally established in 1992, with the signing of the Treaty on European Union (commonly referred to as the Maastricht Treaty).

Unlike the US, where FDA has responsibility for labeling most GM foods (with the exception of animal products that are regulated by USDA), the European Commission, the European Parliament and the European Food Safety Authority have responsibilities for developing laws to regulate these products. In addition, each national government has a voice in the laws and must enforce the laws.

Interest in public participation processes in regulatory decisions was stimulated by the European political bodies as they sought to gain public confidence in the notion of a new political entity (COR 1978). The procedures and laws that affect citizens' rights to participate in decisions in general and regulatory decisions involving GM foods and food labeling specifically, are evolving rapidly. The mechanisms for participation differ among the countries belonging to the EU. Thus, the mechanisms by which stakeholders and the public at large can have a voice in EU regulatory policies are less established than in the US due to the fact that the political entity itself is less than 20 years old, and the system contains national, inter-governmental and supranational features that make decision-making more complex than in the US (Greenwood 2003).

Regulations in each EU country must be harmonized with the regulations of the other members of the EU if foods are to flow freely throughout the European market. While members of the EU are committed to harmonization in theory, compliance is difficult to achieve. The decision-making processes that affect GM crops and foods within the EU are evolving and they are sometimes ambiguous even to analysts and law practitioners in Europe. In the more complex EU environment, where each release of a GM food is scrutinized by regulatory agencies in different countries and consumer or environmental organizations, and GM products are traced throughout the food supply chain, the costs and risks of labeling food products may mean that the use of GM products is not worthwhile for producers. All of these factors create a regulatory environment that is much less predictable and stable for food companies than in the US.

2.3 United States: trends in regulation

During the Great Depression era of the 1930s when the US Congress enacted the 1938 FDCA, the role of the federal government and use of regulations expanded greatly as the Roosevelt Administration (1933-1945) sought to stabilize the economy (Sunstein 1990). As noted above, this legislation gave the FDA the mandate to regulate information on food packages. Following the social activism of the 1960s and early 1970s, a second era of expansion in regulatory policies occurred under the Nixon Administration (1969-1974), when new federal agencies were formed to address environmental, occupational and consumer safety issues (Eisner 2000).

In the late 1980s and 1990s, the administrations of Presidents Reagan (1981-1989) and Bush (1989-1993) sought to reduce regulatory controls, in part because they believed that reducing the constraints of regulations would stimulate the international competitiveness of American products. In January 1992, then President Bush announced a 90-day moratorium on new regulations, during which time "[the President said] that 'regulations deemed pro-growth were to be accelerated,' while those which might impose substantial economic costs were examined to determine if they would produce sufficient benefits, flexibility, clarity, and use of market mechanisms."(Ibid.,185).

2.3.1 Regulation of biotechnology

Through a steady series of scientific discoveries and technical innovations from the late 1950s onwards, the technology to create GM plants and animals emerged in the 1980s.[5] Although the technology was still under development, and no product had been released commercially, the federal government began to develop its approach to regulation of these new products in the mid-1980s.

[5] For a history of the evolution of the scientific tools of biotechnology see Nicholl (1994) and for an analysis of the development of the agricultural biotechnology industry see Krimsky (1991) and Krimsky and Wrubel (1996).

Under the Reagan Administration, the President's Office of Science and Technology Policy established a coordinated framework for regulating agricultural biotechnology (Executive Office of the President 1986). Under this framework, the FDA, the Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) were to use existing statutes to regulate different aspects of biotechnology. Therefore, FDA would use its regulations pertaining to all processed and packaged foods, animal feed, food additives, veterinary drugs and human drugs. Meat, poultry and eggs would be regulated by USDA, which would also regulate plant pests, plants and veterinary biologics. The EPA would regulate microbial/plant pesticides, new uses of existing pesticides and novel microorganisms (Ibid.).

According to the 1938 FDCA that is the foundation for most FDA policies, the labeling of a product must "reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article" (US Congress 1938). In addition, it is illegal to misbrand a food through labeling which is "false or misleading in any particular …" (Ibid.). Labeling includes written, printed or graphic material found on an article, container or wrapper and accompanying an article (e.g. leaflet or booklet) (IFT 2000). This existing law underpins the FDA approach to labeling of GM foods that was first announced in 1992 and elaborated further in 2001. The rationale for the 2001 FDA guidance is discussed below, and the reactions to this approach are reported in Chapters Five and Six.

In the late 1980s and early 1990s, the Reagan and Bush Administrations had decided that the emerging biotechnology industry should have limited regulation. In 1991, the President's Council on Competitiveness recommended policies to facilitate rapid innovation of biotechnology and said that the technology should be regulated so as "to protect safety without unnecessary burdens" (Quayle 1991).

The FDA approach to regulation of GM foods has been characterized as being "permissive" because the technology developers are not obliged to provide evidence of safety of the products to FDA prior to releasing the products. When FDA issued its 1992 statement describing the approach it would take to regulating GM foods, the agency emphasized that the law already required food producers to ensure the safety of the foods. It underscored that the agency had strong enforcement powers to assure food safety. Furthermore, FDA had the authority to require pre-market review and approval when this appeared to be necessary to protect public health (FDA 1992, 22939). The statement and an article by officials in a widely read journal, *Science*, gave emphasis to FDA's authority to act if an unsafe food entered the food supply. Thus, technology developers would be highly unlikely to release a product without FDA consultation, even though they were not required to seek approval (Kessler et al.1992). The FDA approach was based on the assumption that companies would not take the risk of selling foods if they were uncertain about their safety. Therefore, testing of the GM foods was the responsibility of the industry, not of FDA. On a voluntary basis, the biotechnology companies do in fact consult with FDA prior to marketing products, and they receive a letter from FDA stating that the agency has no further questions about the safety of a product that is about to be marketed. The 1992 FDA statement did not specify the particular circumstances that would lead the agency to require pre-market review and approval.

A key difference between the US and EU approaches is that the US approach assumes that the authorities can correct problems in the food supply if they arise, and this is how the regulatory agency fulfills its responsibility to ensure food safety. In contrast, the EU requires pre-market approval of the GM foods and monitors their use. This is characterized as a "precautionary" approach. These approaches to risk management are highly relevant to food labeling.

When consumers have confidence that the regulatory system is able to protect the safety of the food supply and that unsafe foods will not be marketed they do not seek labels for the purpose of avoiding foods that might not be safe and marketers cannot promote their products by insinuating that one food is safer than another. When consumers lack confidence that the regulatory system is capable of preventing unsafe food from entering the food supply, they may seek labels to help them search for foods in order to distinguish among foods. They rely upon sources of information they trust to determine which foods are safe and which may not be. However, this use of labels to compensate for a weak regulatory system is a fallacy since reliable labeling itself depends upon a functioning regulatory system.

2.3.2 FDA approach to GM food regulation: focus on the final product

In May 1992, the FDA issued the "Statement of Policy: Foods Derived from New Plant Varieties; Notice" that has been the cornerstone of the agency's approach to regulation of GM foods for the past 15 years (FDA 1992). Before the policy was announced, the agency had gained experience with Calgene, the developers of the first genetically modified whole food, the Flavr Savr™ tomato (FDA 1992; Martineau 2001). Anticipating other commercial releases, the FDA published the statement to respond to questions that had been raised by the food industry, government agencies, the academic community and the public (FDA 1992). FDA summarized the inquiries as follows:

> The questions that FDA has received center on issues such as whether the agency will conduct pre-market review of these new foods, whether such foods introduced into interstate commerce would be challenged by FDA on legal grounds, which new plant varieties might come under the jurisdiction of FDA, what scientific information may be necessary to satisfy FDA that such foods are safe and comply with the law, whether petitions would be required by the agency, and whether special labeling would be required. (FDA 1992, 22984)

In this statement, the agency identified potential changes in plants that could cause safety concerns (e.g. toxicants and allergens). They presented a model ("decision tree") for assessing the safety of the foods, which indicated when FDA should be consulted. General explanations were given as to how the agency would address the problems. All of the types of risks which have been raised by critics were anticipated by FDA.

In the 1992 FDA statement, the agency expressed the view that the characteristics of the final product, rather than the process of genetic modification by which it was produced should be the object of regulation.

> The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods were used. (FDA 1992, 22984-22985)

As discussed earlier, this focus on final products rather than the process of genetic modification is the fundamental difference between the US and EU approaches to regulation of GM foods. At the time when the proposed regulation and the accompanying article in *Science* were published FDA officials reasoned that pre-market review of all GM foods would be unwise (Kessler et al.1992).

> Because of the limited nature of most modifications likely to be introduced, the FDA would waste its resources and would not advance public health if it were routinely to conduct formal pre-market reviews of all new plant varieties. We will require such reviews before marketing, however, when the nature of the intended change in the food raises a safety question that the FDA must resolve to protect public health. (Ibid., 1748)

In the US, foods which have been consumed for many years without adverse effects are classified as GRAS ("generally recognized as safe"), and they do not require

regulatory approval. In 1992 FDA assumed that in most cases the GM foods would be "substantially similar" to these common foods (FDA 1992, 22985). Thus, these GM foods would be considered GRAS. When the term "substantial equivalence" has been taken out of context (e.g. Ho 2000), it has been the cause of misunderstanding and controversy because some people assumed that all GM foods would be classified as GRAS, but this is not the case.

As explained by Levidow and colleagues (2007), the concept of determination of substantial equivalence has been accepted by international bodies such as the Organization for Economic Cooperation and Development (OECD) and the Codex Alimentarius Commission (CAC) as a key step in safety assessment, but it is not a safety assessment itself (Ibid.). The widely accepted concept of substantial equivalence refers to a comparison between the GM food and the conventional counterpart to see if they are similar with regard to nutritional content, toxicology and allergenicity. In both the US and EU similar procedures are used to assess GM foods: the analyst determines whether the food is "substantially equivalent" to its conventional counterpart on these dimensions. A conventional counterpart is "a related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food" (Zaid et al. 2001). According to an international group of experts[6] who advised the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO):

> The Consultation concluded that the key message to be conveyed is that *substantial equivalence* (emphasis in original) is a concept used to identify similarities and differences between the genetically modified food and a comparator with a history of safe food use which in turn guides the safety assessment process. (WHO 2000, 22)

[6] The expert participants in the FAO/WHO consultation served in their individual capacities. At the 2000 consultation, the experts included B. Chassy and J. Maryanski from the US; S. Ewen, H. Kuiper and J. Pedersen from EU countries; Y.Goda from Japan, M. Haddadin from Jordan, I. Monro, F. Scott and E. Vavasour, Jr. from Canada, M.R.Nutti from Brazil, J.Thomson from South Africa and X.Yang from China (WHO 2000).

Nonetheless, the EU policy requires labeling of GM foods, irrespective of their 'equivalence,' while the US uses equivalence as the basis for deciding that no further evaluation is required. Although the process of assessment is the same, if the food is substantially equivalent to a conventional counterpart, labeling of the product would not be required in the US, but it would be required in the EU.

Labeling of GM foods

When no material difference is found between the GM food and the conventional food, the FDA took the view that there would be no legal basis for mandating labeling of the GM food. The fact that a food had been developed through recombinant DNA techniques was not considered to be material by the agency. The 1992 policy stated:

> The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components). Consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted. (FDA 1992, 22991)

2.3.3 Reconsidering the 1992 approach to regulating GM foods

Largely as a result of opposition to the use of agricultural biotechnology in Europe, the Clinton Administration (1993-2001) began to review the FDA approach to regulation of GM foods (White House Press Secretary 2000). In 1999, the FDA held public meetings where there was discussion of pre-market approval of GM foods, as well as food labeling (USDHHS 2000). Although the administration believed the consultative process with technology developers had worked well, it still proposed that "FDA … strengthen this [regulatory] process by specifically requiring developers to notify the

agency of their intent to market a food or animal feed from a bioengineered plant at least 120 days before marketing" (USDHHS 2000).

Among the 1992 decisions that were reviewed was the FDA stance on labeling, that is, the fact that a food contained GM ingredients by itself did not trigger a requirement to label. The review of this policy is discussed in Chapter Five. Nonetheless, on January 17, 2001, the FDA announced a draft policy: "Guidance for Industry, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" (FDA guidance) (FDA 2001), which, consistent with its earlier position, said that labeling of foods for GM content (containing or not containing GM ingredients) would be voluntary, unless there was a material difference between the GM food and its conventional counterpart.

Proposals for refining risk assessment and management of GM foods

Risk assessment and management of GM crops and foods are beyond the scope of this study; however, consumer confidence in these processes is highly relevant to perceptions of the safety of GM foods and reactions to information on a package about GM technology. There have been several studies by federal institutions to respond to questions about regulation of GM crops in the US. For example, the US General Accounting Office (GAO) was asked by the US Congress to assess FDA's procedure for evaluating the safety of GM foods (GAO 2002). While the GAO panel found that the tests by companies were adequate, they said that FDA's evaluation process could be improved with better communication with the public and more transparency, as well as random verification of test data submitted by companies (Ibid.). The GAO experts were skeptical about the feasibility of monitoring long-term health effects of consuming GM foods and said that, "the best defense against long-term health risks from GM foods is an effective pre-market safety assessment process." (Ibid., 32). Currently, the FDA recommends, but does not require, that GM food developers consult with the

agency before releasing a new product and the agency publishes information about the consultations that have been conducted on the FDA website (FDA 2006; FDA 2007). Provision of this information is a partial response to the requests for more transparency that emerged during the review of the 1992 policy.

Currently, the GM foods that are on the market are considered to be safe and labeling is voluntary in the US. In the future, foods that may enter the food supply may raise issues that are relevant to health and food labeling. Interest in assessing the potential unintended health impact of GM foods, especially foods with enhanced nutritional characteristics, led the USDA, FDA and EPA to request the National Academies' Institute of Medicine (IOM) and National Research Council (NRC) to convene a "Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health" (IOM and NRC 2004). The committee report provides a comprehensive overview of potential health risks that might result from genetic engineering and makes recommendations for improving methods to assess these risks, including emphasis on dietary surveys and post-market monitoring techniques that might lead to an epidemiological rationale for food labeling. This report assessed the state of scientific knowledge and specified the need for additional information. The committee did not make specific recommendations about regulatory policies or state explicitly under what conditions an action should be mandatory or was merely advised. The committee did not suggest that the way that assessments are currently conducted was inappropriate. The report did include a framework for analyzing compositional changes in foods due to any type of genetic modification and made seven recommendations that are summarized as follows:

1) Changes in the composition of food should lead to appropriate pre-market safety assessment prior to commercialization, based on the presence of novel compounds or substantial changes in levels of naturally occurring substances such as nutrients;

2) Appropriate federal agencies should determine if new GM foods should be evaluated for adverse health effects because of a novel substance or elevated levels of a substance beyond recommended or tolerable levels;

3) For foods requiring evaluations, safety assessment should be conducted prior to commercialization, and continued evaluation should be performed post-market where safety concerns are present.

4) Re-evaluation of current methods to detect and assess the biological consequences of unintended changes in GM food, including toxicity assessment and use of data collection (e.g. NHANES[7]) prior to commercial release to identify susceptible population subgroups who might have adverse reactions to novel substances;

5) When warranted by "altered levels of naturally occurring components above those found in the product's unmodified counterpart, population - specific vulnerabilities, or unexplained clusters of adverse health effects," tracking of potential health consequences should be carried out, and improvements in monitoring, food labeling and traceability should be made;

6) Research efforts should be made to improve analytical methods for food composition; new information should be obtained on "chemical identification and metabolic profiles of new GM foods and proteomic profiles on individual compounds and complex mixtures of major food crops;" and expansion of databases is needed to improve identification and enhance traceability of GMOs; and,

7) Tools should be developed to include "profiling techniques that relate metabolic components in foods with altered gene expression in relevant animal models to specific adverse outcomes identified in GM animal models, develop improved DNA-based immunological and biochemical tags for GM foods to be used as surrogate markers

[7] NHANES refers to the National Health and Nutrition Examination Survey, which is conducted by the US federal government to assess food intakes and nutritional status. The survey uses stratified and multi-stage sampling techniques to obtain a representative sample of the US population (Gibson 1990).

in post-market surveillance activities, and develop techniques to enable toxicological evaluations of whole foods and complex mixtures (IOM and NRC 2004, 8-14).

Taken together, these recommendations suggest a concern that there is not sufficient information about the safety of all potential GM foods and that processes that are adequate for monitoring these foods are not yet established. The report implies an interest in strengthening the regulatory procedures in the US regarding testing, approvals, and monitoring of GM products. As these systems evolve and their results are communicated to the public, consumer confidence in the technology may rise.

As noted earlier, if consumers are confident that GM foods are safe, they would not wish to pay for information to tell them this fact. For the small segment of the market that is interested in the process of production, information could be provided and they would pay the additional cost. They would be aware that they were paying for information that they desire, but that this information is not necessary for their health. Thus, public perception of the regulatory system may be inversely associated with the demand of labeling.

2.4 EU's approach to regulation of GM foods

Because the political system and regulatory procedures in the EU are new and still evolving, and biotechnology has been introduced in an atmosphere of controversy and low consumer confidence in food authorities, the regulation of GM foods in Europe is especially complex. In this section, the main features of the EU approach to regulation of GM foods, including food labeling, are discussed.

2.4.1 Institutional framework in the EU

Throughout the past 15 years, the EU has grappled with how to establish procedures for regulating foods produced with biotechnology. Ostrovsky (2007) described the situation:

> The regulation of GMOs has challenged the unification and harmonization of the European regulatory state like nothing else. In an attempt to mitigate a collision between Community and Member State interests, Europe has devised a complex approval system whereby both Member States and Community institutions have input at discrete stages into the approval process. Despite the Member States' more limited role in the GMO approval process, they have wielded their power mightily, bringing the entire regulatory procedure to a standstill in most instances…The question still remains as to how to organize an efficient and effective regulatory policy for biotechnology. (Ostrovsky 2007, 110-111)

The European Food Safety Authority (EFSA) was established in 2002; it is composed of Member State representatives chosen by the European Council, Commission and Parliament (Ostrovsky 2007). With the establishment of the more politically autonomous EFSA, which oversees risk assessment and approval of GM products and acts as a "hub in an interactive network between Member States, the [European] Commission, and industry" procedures for approving GM products may become clearer (Ostrovsky 2007, 131; Europa 2006a). Previously, individual member states in the EU could propose or veto approvals of GM products by the EU Commission. However, the new authority given to EFSA has not alleviated the contentious process of regulation of GM foods in the EU, and individual members of the EU continue to disagree with the European bodies. As a new agency, EFSA has not had time to obtain the type of influence, power and public confidence that FDA has possessed. These conditions create a business environment for food producers that is less predictable in the EU than in

the US. An additional complication facing US producers is that even when a GM product is accepted at the EU level, there may still be a hostile market environment in some countries of the EU.

2.4.2 Regulation of GM foods: focus on the process of genetic modification

Unlike the US, where the regulatory approach focuses on the characteristics of the final food products, the EU has based its regulations for GM foods on the premise that the process of using biotechnology itself requires regulation. "If GM materials are used in the production process, the final product requires treatment different from that for conventional products, even if the final product is demonstrated to pose no risks different from those posed by the conventional product" (Rafferty 2004, 283). Since the late 1980s "…the EU has chosen to consider 'GMOs' as a *prima facie* object of governance; a distinct class of biological entities requiring special regulatory attention" (Lezuan 2006, 500). This process-oriented approach has led to a "strenuous effort" to distinguish conventional foods from GM foods by imposing "increasingly stringent testing, identification and labeling obligations" (Ibid.).

The underlying motivation for this focus on the transfer of fragments of DNA ("events") is concern over unknown and possibly harmful effects from releasing GM organisms into the environment, and unintended health effects of consuming GM foods. The EU approach to regulating GM crops has been strongly influenced by the "Precautionary Principle" that dictates that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (Rafferty 2004, 282). The precautionary principle stems from Principle 15 of the Rio Declaration on Environment and Development that has the following aims

> … [T]o contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health… (CBD 2000)

FAO has defined the "Precautionary Principle" as, "the approach whereby any possible risk associated with the introduction of a new technology is avoided, until a full understanding of its impact on health, environment, etc. is available" (Zaid et al. 2001). This does not mean that risks can never be taken; it does imply that there must be an understanding of the nature and magnitude of the risks and that a system to manage the risks should exist before a new food may be introduced into the food supply.

The first time that this precautionary concept was invoked in relation to food consumption was when the European Commission banned British beef from export to the European continent in 1998 because of the discovery of BSE[8] in the UK (Pennington 2003). Although the BSE crisis was unrelated to gene technology, the events contributed to a lowering of public confidence in food authorities and this left a strong impact on policy makers in Europe.

In the case of GM foods, the precautionary principle is associated with the EU stance on regulation of the technology. The EU policy requires mandatory labeling policy and the tracing of GM foods as they move through the food supply chain to enable authorities to identify these foods should problems occur and to verify the accuracy of labels. These regulations are discussed in more detail below.

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[8] BSE is the acronym for bovine spongiform encephalopathy, which is found in cows. CJD is the acronym for Creutzfeld-Jakob Disease, a rare disease found in humans: one type of CJD is variant CJD (vCJD); this is believed to be the human form of BSE. Both are incurable illnesses within the family of transmissible spongiform encephalopathies (TSE).

While the US has taken a more "permissive" approach to regulation of GM foods than the EU, precautionary approaches have played a part in US regulations in the past (e.g. Clear Air Act and Clean Water Acts), although the terminology differed (Rafferty 2004). As noted earlier, the US authorities did not see a need to adopt a precautionary approach particularly for GM foods because they already have the ability to take action to remove a food from the food supply if it is found to be unsafe. As new products are being proposed that are unlike conventional foods, the IOM and NRC suggest that a more cautious approach may be required. However, it is not the process of genetic engineering that leads to caution, it is the characteristic of the final product. If new products are released that are unlike their conventional counterparts, the FDA guidance states that they would need to be labeled. The label would pertain to the trait, though, and information about the process that led to the trait would be optional.

The current FDA policy regarding GM foods provides only for voluntary consultation between the developers of GM foods and the regulatory scientists, and for the voluntary submission of risk assessment studies to the agency, despite the IOM/ NRC report, in which the committee of US scientists acknowledged the potential risks of unintended health effects and the need for risk assessment with GM foods. Thus the difference between the US and EU approach is two-fold: first, the EU insists that products be approved in advance by government agencies, while the US may receive evidence of safety testing from industry but does not require it. Second, the EU is establishing a system for tracing foods from "farm to fork" by requiring documentation of the use of GM materials in food at every stage of production and processing. The US government has not set up such a system. However, private systems for segregating GM foods from conventional foods from the farm to the shipping dock do exist (that is, commodity producers do trace the products because they are required to do so by foreign buyers).

2.4.3 2003 EU Regulation: traceability and labeling

The fact that the EU, in contrast to the US, considered all GM foods to be different from their conventional counterparts led the European Parliament to enact two complementary laws regarding GM in 2003 (European Parliament 2003). The first, Regulation (EC) 1829/2003, required labeling for human food and animal feed containing genetically modified organisms, "to enable consumers to make an informed choice," while the second Regulation (EC) 1830/2003 stated that the EU "guarantees the traceability and labeling of genetically modified organisms and products produced from GMOs throughout the food chain...to facilitate monitoring" (Europa 2006a and Europa 2006b). The law requires that operators throughout the food chain keep records of their use of GM products and that this be declared on a food package if the content of GM material exceeds 0.9 percent.[9] Lezaun (2006) provides an analysis of the rationales and challenges of the EU laws on GMO traceability.

> Ensuring that market operators produce an exhaustive record of the GM material present in the food chain will serve to facilitate the labeling of 'GM foods', and to strengthen the monitoring of GMOs more broadly – allowing, for instance, the withdrawal of hazardous products in the event of adverse environmental or health effects. But the traceability has other political uses beyond the strictly regulatory ones. It fulfills the promise of European institutions to foster 'consumer choice' vis-à-vis GM foods. The Regulation was presented by the European Commission as 'a direct response to the voices of consumers who have made it clear that they want – and have a right – to make informed choices. (Ibid., 501)

From a technical perspective, Lezaun points to a number of challenges in implementing traceability rules and the need for an extensive scientific infrastructure (e.g.

[9] The 0.9 percent is a "ratio of target GM DNA relative to the total amount of species DNA present [total equals GM DNA plus non GM DNA]…" (Spiegelhalter, Lauter and Russell 2001, 638).

a network of laboratories) to monitor the flow of materials. Among the challenges are the need to obtain reference samples, the proprietary nature of the information needed, and the difficulty of defining what precisely is to be detected (Ibid.).

2.5 Essential differences between the EU and US approaches

The main features of the US and EU approaches to regulation of GM are summarized below.

1) The US and EU authorities recommend similar approaches to risk assessment of GM foods. Both use the concept of substantial equivalence as part of their safety assessment processes and similar approaches to testing the safety of foods; thus risk assessment *per se* is not a source of controversy.

2) The US focuses on the final product as the subject of its regulation and determines how the final product will be regulated based on the risk assessment. The EU focuses on the process of genetic modification and the "transformation event" that created the product. Thus, all GM foods are regulated regardless of whether they are found to be indistinguishable from conventional foods.

3) The US has adopted a more "permissive" approach in that companies are not required to submit their risk assessment data to FDA prior to commercialization of their products. Instead, companies have consulted with the FDA about their safety assessments on a voluntary basis and not released their products until FDA had no further questions about them. This process is relatively simple and rapid. In contrast, the approval process in the EU has been "precautionary" in that the EU requires approval by government authorities before a GM product can be released. The EU process is very complex, requiring approval by national and EU bodies, and the EU authority to override a national decision is ambiguous and difficult to enforce.

4) In the E.U., traceability is a means to an end; the end is labeling. In the US, labeling may be used in the future as a means to an end, the end being epidemiological studies, but this is not presently the case.

5) The US approach uses existing laws and institutions. The EU approach developed new laws and uses new institutions. In the US, a technical agency has been responsible for developing the labeling policy, and the existing regulatory system is used to implement the policy. In the E.U., a political body created the policy, and the policy must be implemented by a new regulatory system.

6) At the time of the development of the FDA guidance, public confidence in the regulatory agency was fairly high (PIRB 2006). There had been only one incident in which a GM food that was not intended for human consumption, Starlink corn, had entered the food chain. The federal authorities acted quickly to address the problem (CDC 2001). In contrast, the EU policy makers faced a distrusting public in the 1990s, particularly because of the highly publicized and emotional BSE incident that was poorly managed. The US experience led to the conclusion that labeling should be voluntary. The EU experience led to the conclusion that labeling should be mandatory.

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CHAPTER THREE: LABELING, PERCEPTIONS OF GM FOODS AND PARTICIPATION IN POLICY DEBATES

When a government agency formulates a food labeling policy, it must consider legal, scientific, economic, psychological, political and operational factors. The literature on GM food labeling draws upon the theories and methodologies from all of these disciplines. This chapter provides a review of the literature that is directly relevant to the specific issues of public participation in regulatory decisions and food industry reactions to voluntary and mandatory labeling policies in relation to GM foods.

3.1 Food labeling

3.1.1 Economic rationale for food labeling

A market functions properly when resources are allocated in a manner that maximizes production of goods that serve consumers' preferences. Efficiency of the market stems from the fact that buyers and sellers have equal access to all the necessary, relevant information about a product. With this information, both parties use the same criteria to rank products of different quality and to set prices. This leads to a market where products of higher quality are sold at higher prices, and products of lower quality are sold at lower prices. If there are no customers for a very highly priced product or a very low quality product, the product will not be sold.

Adverse selection and asymmetric information

Economic theory provides three closely related concepts that are useful for examining the issues of consumer perceptions and preferences related to GM foods and labeling information about these foods. These three general concepts, adverse selection, asymmetric information, and credence qualities are explained in this section.

When the ranking of products (and consequently the setting of prices) is not based on equal knowledge among buyers and sellers, market allocation becomes inefficient. Sellers may ask a high price for goods that do not necessarily contain ingredients of a high quality, and uninformed consumers may pay for a good that is lower in quality than expected; this phenomenon is termed "adverse selection" by economists (Wilson 1987; Mankiw 1998). In such situations, "…only the sellers can observe the quality of each unit of the good they sell…Without some device for the buyers to identify good products, bad products will always be sold with the good products" (Wilson 1987, 32).

> Consumers with different risk preferences rationally choose different bundles of foods. However, if their perceptions of the quality attributes of foods are incorrect, consumers lose utility… consumers either take more risks than they would ideally like or pay more than they should for a higher than optimal level of food safety. (Caswell and Mojduszka 1996).

Economists use the term, "asymmetric information," to describe the situation in which buyers and sellers do not have equal access to information. Asymmetric information leads to a situation where…

> …[R]esources are allocated inefficiently because the marginal private benefit of the action…is not equal to the social cost.

> More generally, whenever either party to a transaction lacks information that the other party has or is deceived by claims made by the other party, market results will tend to be changed, and such changes may lead to inefficiency. (Lipsey and Courant 1996, 369).

Information asymmetry may be unfair to business competitors in addition to being potentially harmful to consumers.

> Without information, consumers may be unable to accurately match preferences with purchases, and producers may be unable to compete fairly because information about competing product standards is not widely available. If both buyers and sellers have more information, they may be able to reduce their search and verification costs, thereby facilitating trade. (USDA 2003, 1)

In extreme cases, asymmetric information can threaten the existence of a market, if consumers lose confidence in the products being sold because they cannot determine the quality (Fischer and Dornbusch 1983). Government and other non-market corrections may be sought to address the problem of asymmetric information and improve welfare (Postlewaite 1987). One such government intervention is the provision of rules for product labeling.

Credence qualities of foods

The problems of adverse selection and asymmetric information can arise in the market for foods because some qualities of food are not readily apparent to consumers. Foods often possess specific qualities that cannot be identified by ordinary consumers through sensory perception and experience. The types of qualities that are not revealed even after the product has been consumed are known as "credence" qualities (Jahn et al. 2005). The provision of information through labeling can address the problem of asymmetric information about a credence quality of food.

Consumers' confidence in the information they receive about a credence quality depends on the integrity of the certification, inspection and enforcement processes in a food chain (Getz and Shreck 2006). Consumers have confidence in food labels when they are supported by systems that can verify the information.

> [T]he central task of certification, the reduction of information asymmetry within the market, can be fulfilled only if the institutions in charge succeed in assuring certification quality and, thus, the validity of the audit signal. Only if the underlying organizations succeed in establishing a quality reputation in markets will the corresponding labels be accepted as a quality surrogate. (Jahn et al. 2005, 57)

Regulations and protecting the integrity of the information on food labels are discussed in section 3.3.

3.2 Research on trust and information sources

Public confidence in the regulatory authorities that oversee biotechnology is relevant to the debate over food labeling. When a consumer is confident that the regulatory system has the capability of ensuring that an unsafe food product will not be sold, the consumer will assume the food is safe. It is unlikely that they will perceive food labels to be necessary from a safety perspective. If a label does appear, it is unlikely that the consumer would infer that it is a safety warning. However, when consumers lack confidence in the regulatory system, they may use information from other sources to determine whether to purchase a food. The information from other sources must not be misleading. In this section, the factors that determine trust in institutions and information are considered.

Trust in the institutions that provide information or oversee labeling is crucial to the success of a labeling policy. Some label information is mandated and regulated by the government; other package information may include endorsements and claims by businesses, scientific associations, highly respected individuals and consumer organizations (CCFL 2001). These sources of information enjoy different levels of public trust in different societies. In addition, public trust in an information source can

change over time and it may be difficult to restore confidence once it is lost. Government authorities may use public consultation processes and information such as labeling as a way to show that they are being inclusive and transparent.

In their attempts to understand public perceptions of GM foods, social psychologists have examined the issue of trust and information sources. Since few laypersons would be expected to be informed about the technical aspects of biotechnology, researchers expect laypersons to rely on trusted sources of information to help them to form their opinions. Commenting on GM foods, Frewer and colleagues in the UK said:

> In relation to technologies involved in food production… the importance of trust in decision-makers and information sources is likely to be all the more apparent where consumer understanding of those technologies is lacking. People seem to be adverse to ambiguous risks. Trust is all the more likely to be important where there is a perception that accurate estimates of risk are not available, such as in the case of genetic engineering as applied to food production. (Frewer et al. 1996, 485).

Similiarly, Gutteling and colleagues in the Netherlands developed a definition of trust in situations when there are many unknown factors; they stated that…

> [Trust was defined as] an expectation…that this person or organization will act in line with one's own interests. Trust allows a person to take decisions and to act in the absence of complete knowledge of the consequences. The missing information is replaced by trust in order to tolerate the perceived uncertainty of the situation. (Gutteling et al. 2006, 104)

Since the early 1990s, surveys in Europe have shown that Europeans considered consumer and environmental organizations to be the most reliable sources of information, followed by universities (Marlier 1992, 100). Public authorities ranked fourth, and

industry ranked ninth (Ibid.). This pattern continued a decade later. A 2002 study investigated trusted sources of information, and found that consumer organizations, environmental organizations and universities ranked first, second and third, respectively, while national governments ranked fifth (there was more trust in the European Commission than in national governments), and industry ranked seventh (Gaskell et al. 2003, 33).[10]

In the UK, Frewer and colleagues (1996) found that several characteristics of an information source affected public trust in the information provided by the source. Major factors that led to trust in a source included: 1) technical expertise; 2) no vested interest in the topic; 3) a proven record of providing correct, factual information without sensationalism; and 4) a responsibility to the public to provide accurate food-related information (Ibid., 476). Citizens weighed each of these factors to assess whether a stakeholder was a trustworthy source of information. For example, the public was confident that the biotechnology industry had technical knowledge; however, trust in this information source was diminished because the industry had a vested interest in gaining support for the technology (Ibid., 477). Conversely, public interest groups were trusted because citizens believed they did not have a vested interest; however, the public did not have confidence in the technical accuracy of information from these groups, especially if the information was presented in a sensational manner (Ibid., 483).

In the Netherlands, Gutteling and colleagues (2006) examined public trust in governance, government and non-governmental organizations (NGOs). Among Dutch respondents, 73 percent did not want their government to be the sole actor in decisions about GM foods; 68 percent were more confident that NGOs would act in their interest.

[10] The negative public perceptions about GM foods in Europe have been attributed to the differences in the way that biotechnology is covered in the press in Europe. A comprehensive content analysis of 5,404 articles from leading European newspapers in 12 European countries over a 24 year period found that it was impossible to generalize about the European press. However, fluctuations in public opinions within countries were associated with news coverage (Gutteling, et al. 2002)

Fifty percent of respondent thought that private companies would not consider the public interest (Ibid., 110 and 111). Gutteling and colleagues believed that involvement of the public in decision-making about GM foods might affect public acceptance of the technology (Ibid. 2006). The topic of public involvement in regulatory decisions is dealt with in section 3.6.

In the US, research by the International Food Information Council (IFIC) and the Pew Initiative on Food Biotechnology (PIFB) indicate that public confidence in government agencies such as FDA can shift over time. In 2001, when FDA formulated the guidelines for labeling of GM and non-GM foods, the agency enjoyed a higher level of public confidence than the national regulatory agencies in some European countries. When IFIC explained the way that FDA approached labeling, they found that the public supported FDA's priorities in food labeling. (IFIC 2003). PIFB interviewers provided some information to respondents on the way FDA regulates GM foods, and found that "regulation may increase confidence in GM foods." (PIFB 2006).

By 2006, confidence in FDA had declined significantly and this could affect consumer confidence in the safety of GM foods and the integrity of food labels. PIFB found that 41 percent of Americans were confident in 2001, and this had dropped to 29 percent in 2006 (PIFB 2006). The *U.S. News & World Report* stated that: "Confidence in the safety of supermarket food has reached an 18-year low…"(Shute 2007, 68). There have been a number of media reports on the FDA's lack of resources to carry out the multitude of functions needed to regulate thousands of products and the lowering of public confidence in the FDA's capabilities may be the result of underfunding (e.g. Anonymous 2006a and Anonymous 2006b, Shute 2007).

3.3 Ensuring the integrity of food labels

Prevention of misleading information is a core principle in the regulation of food labels, and government agencies have the authority to enforce laws to prevent companies from making misleading claims. Industry associations apply voluntary standards and consumer associations act as watchdogs to prevent companies from misleading consumers as well. In the case of GM foods in the US, both the food industry associations and consumer organizations have sought FDA action to prevent misleading claims on food packages (GMA 2000; Jaffe 2001)

Some misleading information can be detected through testing of the product (e.g. measuring the ratio of recombinant DNA to DNA in a food sample). However, other types of misleading information can only be identified by consumer research and psychological studies of how people perceive information. In the absence of evidence, regulators may have to rely on their own judgment to set a standard for defining what will be considered misleading, and marketers are expected to adhere to the standard. Common ways that labels can mislead consumers include: 1) omission of a material fact that a consumer needs; 2) use of confusing language, symbols or images and 3) inducing the consumer to make false comparisons (e.g. that a product has a special trait when, in fact, all products of its kind have the same trait) (CCFL 2001).

Governments vary in the extent to which they attempt to protect consumers from misleading claims. Some governments expect consumers to recognize advertising hyperbole and hold the consumer responsible for purchase mistakes. Others have a more protective (or paternalistic) approach. For example, in a study comparing health claims regulation in Japan and the US, Kwak and Jukes (2002) found that FDA would not permit a food to qualify for a health claim if it contained an ingredient which was a risk

factor (e.g. high in sodium), while Japanese authorities expected the consumer to decide whether the benefits of the food outweighed the risks.

Although there is no evidence that non-GM foods are better (or worse) than GM foods, some consumers may believe that GM foods are inferior to non-GM foods. In this situation, consumers might pay more for a non-GM food without actually gaining a benefit. Persuading a consumer to pay more for a product by implying that it is safer or superior in some way when it is not different than another product is false and misleading, and foods labeled to suggest this may be considered to be misbranded. Consumers may then pay for an attribute (greater safety or quality) they are not receiving. Following the FDA announcement of the proposal for guidelines on GM food labeling, the Center for Science in the Public Interest (CSPI) complained that nine brands had made misleading negative claims about genetic modification of foods, because they used symbols and language that could cause consumers to think a brand was superior to other similar products. For example, several fruit and oatmeal baby foods had "GMO free" labeling, which could have caused consumers to infer incorrectly that other baby food brands did contain GMOs. Other foods were labeled as "pure foods [that] contained no GM ingredients" implying that foods with GM ingredients were impure; and other labels had large red "banned" symbols (circle with diagonal line) implying the GM foods were inferior (Jaffe 2001). The FDA responded to this complaint and warned the companies to change their marketing messages.

3.3.1 Enforcement

Government authorities must have the resources to achieve the capacity to enforce labeling policies as well as technical and legal capabilities. However, when a government authority lacks capacity or capability to take an enforcement action, unscrupulous food marketers could take advantage of this situation and make false claims. If there are

market incentives to make claims, the situation could be ripe for unscrupulous producers to make misleading claims (Saak 2002). In the case of misleading information, the authorities may lack the capability of conducting consumer research to demonstrate that a label is misleading. With uneven enforcement of labeling laws and the potential for misleading labels, consumer confidence in the regulatory system could be diminished.

When a regulation is put in place, there is usually a measurable and therefore enforceable endpoint. In the case of the EU approach to labeling GM foods, there is a lack of clarity about what is being measured and why (Lezuan 2006). There may be a lack of capacity in terms of the regulatory and scientific infrastructure to test the foods. In the US, there may be lack of capability to determine which labels are misleading and which are not. If the labeling policies cannot be enforced for either reason, the public may lose confidence in the labels; thus, the policies which were intended to promote confidence would be undermined.

Identity preservation

For GM food labels to be credible, processes to segregate foods and preserve their identities must be established to ensure that claims about the products are true. The systems for ensuring compliance vary for each type of food, since the handling of products varies. For example, separating milk produced with the veterinary drug, rBST [11] from other milk may require that the milk be produced in different dairies. Fresh milk has a relatively short food supply chain in comparison corn or soybeans that are transformed into many products and sold worldwide. In these cases, the challenge of segregating GM free foods from GM foods is greater, because of the many stages of processing and marketing, and the many final products made from these commodities.

[11] rBST is the acronym for recombinant bovine somatotropic, a drug that stimulates milk production. This was one of the first GM products to be commercialized amid controversy about its potential social, economic and health effects (Powell and Leiss 1997).

The literature on identity preservation has focused on corn and soy, the most widely used GM crops. Golan and colleagues (2000) examined different labeling experiences and identified the types of economic effects a mandatory GM labeling policy would have in the US. Under identity preservation, farmers must ensure that GM free crops are not mingled with GM varieties. Farmers would need to develop buffer zones to ensure no cross-pollination of GM and non-GM crops and to make sure that planting and harvesting equipment were cleaned between working with GM and non-GM varieties (Golan et al. 2000). The prices obtained for the differentiated crops must justify the costs of differentiation. For some high value foods, these investments may be worthwhile. However, for other foods, they may not, especially considering that the raw commodity may represent a small percentage of the total cost of producing and marketing a food product.

3.3.2 Adventitious presence of GM material and certification

Even when producers make efforts to segregate non-GM from GM products, the potential for adventitious presence of DNA from GM ingredients is high. UK researchers have found that organic and health food soy products labeled as “GM free” and “organic” actually contained small amounts of GM DNA (Partridge and Murphy, 2004). Monitoring foods to demonstrate that they do not contain GM ingredients requires diligence, and preserving foods as GM free is difficult and costly. “The current uncertainty about “GM-free” labeling and the unnecessary dogmatism about GM content in organic food, are causing avoidable, and sometimes costly, problems in the food industry to producers, manufacturers, retailers and consumers alike” (Ibid.,178).

In the EU, marketing imported foods that are below the threshold for mandatory labeling may be difficult, food marketers may decide that labeling their foods as containing GM ingredients makes more sense from a business perspective than paying

for testing and segregating foods. Partridge and Murphy speculate that selling foods at a lower price might attract consumers who value lower prices more than GM-free foods, and this would offset the loss of consumers who wished to avoid GM foods.

> …[T]he cheapest and simplest future option for any importer of soya into the EU, confronted by the realities of the extensive presence of GM throughout the food supply chain, would be to…label all foods as "may contain GM ingredients." Those retailers wishing to omit a GM label… would then incur the considerable additional costs of identity preservation of ingredients and of testing the foods for adventitious GM materials. This may result in market segmentation with GM labeled foods being considerably cheaper and capturing a larger market than those niche products that carry no GM label or a "GM free" label. This is an interesting possibility, and possibly not one desired by those who have advocated mandatory labeling of GM-containing foods. (Ibid.,178).

Some UK and Nordic researchers (Gaskell et al. 2003; Partridge and Murphy 2004; Grunert et al. 2004) suggested that food sellers might be able to sell labeled GM foods in the European market if the products had qualities consumers appreciated, such as better taste, healthful properties, less damage to the environment or lower in cost. However, these researchers were not business analysts, and their views may be overly optimistic. In any case, marketers would have to take the risk of labeling their food as GM in order to find out whether a lower price would overcome aversion to GM foods in the European market. To date, US food exporters have been unwilling to label foods as containing GM ingredients. Knight and colleagues found that food industry buyers in Europe (the "gatekeepers" to the European market) were highly skeptical about consumer acceptance of GM foods (Knight et al. 2005). This suggests that the US food producers' judgment that labeling poses obstacles to selling GM foods in Europe, as described in Chapter Six, were accurate.

3.4. Mandatory versus voluntary labeling

When deciding whether labeling should be mandatory or voluntary, policy makers weigh the costs to the food producers of labeling, the needs of consumers to know the information, and the number of consumers who view the information as important compared to those who are indifferent (Nuffield Council on Bioethics 1999; Crespi and Marette 2003). In a mandatory labeling scheme, the costs of labeling are passed on to all consumers, while in a voluntary scheme, those who wish to have the information pay for it.

Some researchers believe that determining which labeling policy is appropriate under a given set of circumstances is a matter of judgment, not science. Ultimately political calculation may determine the choice of mandatory versus voluntary labeling policy. For example, Fulton and Giannakas (2004) could find little agreement among farmers, consumers and the life sciences companies (biotechnology providers) in the US with regard to whether labeling policies should be mandatory or voluntary, or a clear explanation for different labeling policies in different countries, but stated that "consumer aversion is certainly an important factor in this choice" (Ibid., 57). They considered the influence of different stakeholders to be a critical factor and concluded:

> … [S]ince the groups are unlikely to agree…, the final decision about the [regulation of GM crops, including labeling] is a political one and is likely to involve significant competition and bargaining among different pressure groups and between pressure groups, legislators, and the bureaucracy. The outcome of this bargaining and competition depends on the political effectiveness of each group… (Ibid., 57).

Stakeholder involvement in FDA's process of developing guidance for labeling GM and non-GM foods illustrates the different levels of political effectiveness among stakeholder groups, as described in Chapter Five.

Crespi and Marette (2003) considered the factors that might determine whether a policy is mandatory or voluntary and concluded that a mandatory labeling regime requiring that a label indicate that a product "contains GM" could be justified, "if the ratio of consumers with GMO concerns to indifferent consumers is high" (Ibid., 340). In other words, the EU policy is justifiable given that studies show that a large proportion of European consumers do not wish to consume GM foods (Gaskell et al. 2003). In the US, studies indicate that consumers rank GM labeling as a lower priority than other forms of labeling (IFIC 2002).

3.4.1 Prioritizing labeling information

When a public health authority has determined that information is essential, package space must be reserved for the mandatory information. Priorities must be set in food labeling since there are limits to the capacities of consumers to comprehend and recall information. Magat and Viscusi (1992) conducted experiments with warning labels and found that when the amount of information included on a label increased substantially, the performance of the hazard warning decreased. "Thus, label clutter leads to problems of information overload that may actually reduce the efficacy of the hazard warning" (Ibid, 14).

In the US, policymakers consider certain types of information to be necessary for consumer protection. Thus, food packages in the US contain information about nutrition, ingredients, food preparation, preservation/storage dates (i.e. freshness and expiration), quantity and price. When deciding whether information is to be added to the package, the risk that new information may divert attention from the mandatory information must be taken into account. Consumers may have different priorities in terms of their desires and needs for information. A person who is sensitive to or intolerant of specific ingredients would seek information about the ingredient. Consumers use labels to avoid foods that are prohibited for religious or moral reasons. A consumer who is concerned about

environmental quality might look for foods that were produced with methods that are less polluting than conventional methods. All of these factors need to be considered when deciding whether a label will be voluntary or mandatory.

3.5 Public perceptions of biotechnology and GM labeling

The food industry's responses to labeling policies are influenced by consumer research on public perceptions of biotechnology and consumer preferences regarding GM and non-GM foods. Regardless of the scientific accuracy of these perceptions, the views of consumers can drive business decisions regarding food labeling and sourcing of ingredients. In this section, research about consumers' perceptions of biotechnology and willingness to pay for GM foods that was conducted in the US and Europe is reviewed. Although each study asked unique questions, there is a clear pattern in the findings: consumers in the US and Europe prefer non-GM foods and say that they are willing to pay for information that informs them about this trait. Further, a few studies have found that voluntary labeling is perceived to be a form of advertising and it is believed to be less valuable than mandatory labeling.

3.5.1 Public opinion studies about GM foods and labeling

In the US, there have been a number of national telephone polls to obtain information about attitudes toward GM foods and whether these foods should be labeled. ABC News reported that large majorities of Americans (86 percent in 2000, 93 percent in 2001 and 92 percent in 2003) favored mandatory labeling, based on telephone surveys (Eisner 2000; ABC News 2001; Morris, 2003).

The International Food Information Council Foundation (IFIC) has surveyed the public about attitudes toward GM foods on average once a year since 1997 (IFIC 2002). The IFIC interviewers provided information on FDA's labeling policy and compared

desire for information about biotechnology with desires for other types of information on a label. They found that public support for the FDA voluntary labeling approach fluctuated, ranging from 57 to 78 percent (IFIC 2002 and 2003).

The Pew Initiative on Food and Biotechnology (PIFB) conducted annual studies (polls and focus groups) about "Public sentiment about genetically modified foods" from 2001 to 2006 to examine various questions that the foundation considered to be of "national interest." (PIFB 2006). The surveys have shown that, "consumers have consistently underestimated the amount of GM foods they most likely have eaten" (PIFB 2006). Although it has been estimated that 70-75 percent of processed foods in the US contain GM ingredients, approximately 60 percent of respondents in the 2001 and 2006 surveys believed that they had not consumed GM foods (PIFB 2003a; 2006). Thus, information asymmetry exists in the US with regard to GM foods.

Respondents to telephone surveys may have little information and little time to reflect on the questions they are asked; nevertheless, the public opinion surveys might suggest several factors that policy makers and businesses should consider. The ABC survey findings illustrate that citizens take it for granted that information should be available and that they have a right to it. Hence, when Americans are asked if labeling information should be made available, their quick response is positive. Second, the IFIC studies suggest that citizens weigh priorities and understand that information comes with a cost; support for voluntary labeling may result from the view that costs should be borne by those who desire the information.

As the EU is an important market for US food producers, research on European public opinion is relevant to them. Information about EU consumers' attitudes toward GM foods affects US producers' judgments of the relative benefit of offering (and labeling) GM-free food, with its attendant costs, compared to the relative risk of labeling their food as GM.

The most comprehensive studies on perceptions in the EU are the Eurobarometer surveys that have included questions about biotechnology since 1991 (Marlier, 1992). The most recent study available was the 2002 Eurobarometer survey that included 15 countries[12] with a total of 16,500 respondents (Gaskell et al. 2003,1). In 1991, the survey obtained opinions from random samples of the general population in 12 countries (12,800 interviews) (Marlier, 1992, 53-54).[13] Some of the general patterns that were identified in 1991 were still true in 2002: men were more positive about biotechnology than women; young people were more optimistic about the technology than middle aged and older people; support for applications of biotechnology in medicine was strongest, while support for applications of biotechnology in food production was weakest (Marlier, 1992, 85; Gaskell et al. 2003, 2 and 4).

3.5.2 Consumer appeal: price, taste, health and environment

The GM crops that have been released provide benefits to farmers by lowering pesticide and herbicide applications. To date, GM crops that provide benefits that might appeal directly to consumers, such as nutritionally enhanced foods have not been marketed. If foods with attributes that are attractive to consumers were to be released, food companies might wish to label these products.

Prior to the wave of activism and publicity against GM foods in the UK, Frewer and colleagues (1996) conducted an experiment with 20 males and 40 females in Reading (UK) to assess their reactions to photographs of labeled GM products (yogurt, tomato, and chicken drumstick) that were said to have had one of four benefits: less expensive; stayed fresh longer, health benefit (vitamin, low fat) and environmental benefit in

[12] Belgium, Denmark, Germany, Greece, Italy, Spain, France, Ireland, Luxemburg, Netherlands, Portugal, United Kingdom, Finland, Sweden and Austria (Gaskell et al, 2003).

[13] The 12 participating countries included: Belgium, Denmark, East Germany and West Germany, Greece, France, Italy, Luxemburg, the Netherlands, Portugal, Spain and the United Kingdom (Marlier, 1992).

comparison to their conventional counterparts (Frewer et al.1996, 62-63). With each food, the respondents viewed the GM products as less natural than the conventional foods, and they were less likely to purchase the GM products, with two exceptions: the GM tomatoes that were said to be more nutritious and grown with fewer pesticides were preferred over the conventional tomatoes (Ibid., 64).

A more recent experimental study on the effect of taste on consumer's response to a GM food was conducted among 746 respondents in Denmark, Finland, Norway and Sweden (Grunert, et al. 2004, 99). Recognizing that Nordic consumers were highly resistant to accepting GM foods and that the provision of information had had little impact on consumers' attitudes, the researchers investigated the impact of a tasting experience on their willingness to purchase a GM product. In a controlled deception experiment with sixteen hard cheeses, they identified the cheeses that respondents preferred and told them that the preferred cheeses had been produced with a GM starter. In fact, all of the cheeses had been produced by conventional methods, and the respondents were informed of this after the experiment was concluded (Ibid., 101). The researchers found that taste and price had the greatest positive impact on the respondents' willingness to purchase GM foods once they believed the foods were GM, although health benefits also had a positive effect (Ibid., 102).

Gaskell and colleagues (2003) speculated that consumers' perceptions of GM crops might be more positive if the health and environmental benefits of lower pesticide residues associated with GM crops were promoted. The researchers proposed labeling about positive attributes of GM foods to encourage support for biotechnology:

> These results [of the 2002 Eurobarometer survey] could be taken as indicating a more or less total rejection of GM foods and discussed in terms of the impossibility of introducing such new products. On the other hand, it could be argued that if GM foods actually offered some of these benefits [reduced pesticides, lower fat, and better taste] and

> if they were labeled to give the rejecters the opportunity to express their preference, then the products might capture a sizable market share. (Gaskell et al. 2003, 4).

Larue and colleagues.(2004) conducted a telephone survey of Canadian shoppers (n=1,008) to assess whether health claims and information about production processes had an impact on consumers' choices. They found that "heart healthy" and "anti-cancer" properties made GM tomato sauce and GM potato chips slightly more appealing to consumers than GM foods without health benefits. However, conventional foods and organic foods with health benefits were more appealing. They concluded that GM manufacturers would not benefit from health claims until consumers become convinced that GM foods pose no additional risks to their health (Larue et al. 2004).

3.5.3 Consumer's willingness to pay for GM and non-GM foods

Although survey respondents often say they would like GM foods to be labeled, they may not be aware of the costs of labeling and may not consider whether and how much they would be willing to pay for the information. From the policy and business perspectives, willingness to pay studies that probe for detailed information about preferences can provide useful information for predicting prices and determining whether the public at large or some types of consumers would be willing to pay the costs for labeling. In a number of studies in North America and Europe consumers said that they preferred non-GM foods and they expressed willingness to pay higher prices for these foods. This suggests that companies would gain profits by labeling their products as being non-GM, while companies that produce GM foods might be penalized if they labeled their products as being GM. If consumers knew that a food was GM, the seller might be forced to lower the price for the food. Similarly, if consumers knew that a food was not GM, the seller might be able to raise the price for the food. Therefore, a correction in the information asymmetry that exists at the present time in the US could lead to

changes in pricing, marketing and sourcing of foods if consumers' actual behavior in real supermarkets is the same as their behavior under research conditions.

Willingness to pay research employs several methodologies. In studies about GM foods researchers have conducted experimental auctions that emulate markets for labeling; they tested consumer preferences for different products by randomly assigning labeling to products and allowing study participants to bid for the products, after receiving information from different sources such as biotechnology companies and environmental organizations (Tegene et al. 2003). Tegene and colleagues found that consumer reactions to labeling changed when they were given information from environmental organizations and the biotechnology industry, and that bidding for foods depended on the source of information (Ibid.. 2003).

As discussed in section 3.5.2, researchers have used taste tests to determine whether preferences for some foods would persuade consumers to eat GM foods (Grunert et al. 2004). Other studies used pictures of foods with different types of information to assess how much consumers believe they would pay for GM or non-GM foods (Frewer et al.1996). Each study assessed the perceptions of biotechnology in general, and then asked about willingness to pay for GM and non-GM foods. Although methods vary, the findings of the studies consistently show a preference for non-GM foods. However, some studies found that consumers' willingness to purchase GM foods increased when prices were reduced or there were taste or health benefits.

In practical terms, there are costs involved in producing labeling information and policy makers and food companies need to know whether consumers would be willing to pay for labeled foods through price increases or taxation. In a pilot study (n=54) in New Haven, Connecticut (Mendenhall and Evenson 2002, 56), researchers estimated the demand for non-GM crops by considering variables such as health habits, current purchasing patterns, presence of children in the household, age and income. Of

the sample, 26 percent were very concerned, and more than 50 percent were somewhat concerned about the safety of GM foods (Ibid., 57). Not surprisingly, those who were more concerned were more willing to pay a premium for non-GM foods. "Fifty percent of those surveyed indicated that they would be very likely or somewhat likely to purchase non-GM foods if they cost up to 20 percent more than GM foods" (Ibid., 58). Individuals who were concerned about GM foods were also more concerned about their health and the environment and more likely to purchase organic foods than other respondents. Their willingness to pay was not related to income or household size.

A contingent valuation study was conducted with grocery shoppers[14] (n=334) in three Colorado cities during 2001-2002 to determine attitudes about labeling policies and to quantify the amount that consumers would be willing to pay in taxes and/or higher prices for mandatory or voluntary labeling (Loureiro and Hine 2004, 470-471). They found that Colorado shoppers who desired mandatory labeling were willing to pay, on average, $81 per household per year for the information; those who desired voluntary labeling were willing to pay, on average $66.42 per household per year (Ibid., 479). Since the Grocery Manufacturers of America estimated that the costs of mandatory labeling were $140-200 per household per year, Loureiro and Hine concluded that the premiums consumers were willing to pay would not cover the costs of mandatory labeling, and that the FDA voluntary approach was a "good market solution" (Ibid., 479- 480).

Chen and Chern (2004) estimated consumers' willingness to pay for GM and non-GM foods in Columbus, Ohio by conducting a mail survey (n=141). Households responded to questions designed to assess how much they would pay for GM and non-GM versions of vegetable oil, salmon and cornflake cereal (Ibid., 121). They found that lower prices for GM foods increased willingness to consume them. The willingness to

[14] The contingent valuation method asks study participants how much they would pay for a product, contingent on a specific description of the product. This is a type of stated preference method, with participants expressing how much they value a product attribute.

pay a premium for non-GM foods was 5-8 percent for vegetable oil, 15-28 percent for salmon and 12-17 percent for cornflake cereal (Ibid., 126). Women were willing to pay more for non-GM foods than men, and non-whites were willing to pay more for non-GM foods than whites, a finding that the authors interpreted as lower confidence in the safety of the food supply among some segments of the population (Ibid., 127). Households with children were less willing to consume GM foods than households without children (Ibid., 124).

In Canada, Hu and colleagues (2005) conducted a controlled choice experiment to measure consumer welfare under different labeling regimes. In an internet survey in 2002-2003 (n= 882) respondents were given 16 pre-packaged sliced bread options; some bread options contained information from a hypothetical mandatory labeling policy (Hu et al. 2005, 85). The researchers found that there was a strong preference for bread without GM ingredients. Consumers avoided GM bread, especially when the package contained a label they were told was mandatory. Consumers were informed that some labels were mandatory and others voluntary; mandatory labeling was preferred, and consumers were willing to pay for it in order to be able to avoid the GM products (Ibid., 91).

> Consumers' tolerance for potential price increases under the mandatory labeling regime is much higher than that under the voluntary labeling regime. It is anticipated that mandatory labeling is likely to incur more costs than is the case for voluntary labeling. However, the analysis shows that on average consumers do place higher values on the information obtained from mandatory labeling. Market prices for bread could increase by 3.7 percent (from the conditional logit model) and nearly 15 percent (from the maximum likelihood estimate model) before offsetting the value of the label information. (Hu et al. 2005, 97).

Voluntary labeling tends to be viewed as advertising puffery (Pearce 1999), and the researchers speculated about the lack of interest in it: "One possible reason for the

asymmetry in the value of information provided under mandatory and voluntary labeling policies could be that consumers may simply treat the information provided by negative statements in the voluntary labeling regime as a marketing ploy, and discount the value associated with it" (Hu et al. 2005, 98).

Moon and Balasubramanian (2004) conducted a mail survey with US respondents (n-3,000) and an online survey with UK respondents (n= 2,600) to estimate how much consumers would be willing to pay for non-GM foods (Ibid., 88). The respondents were asked the highest price that they would be willing to pay for non-GM breakfast cereal in comparison to GM cereal. Consumers who were concerned about food safety, who purchased organic foods, and those who thought that biotechnology posed risks to health and the environment were willing to pay a higher price for non-GM cereal than for comparable products not identified as such (Ibid., 92).

In the US, consumers were willing to pay 9.5 percent of the base price for the non-GM cereal, while the UK consumers were willing to pay 18 percent (Ibid.). Although the US price differentials were not as impressive as in the UK, the researchers concluded that the prices consumers were willing to pay exceeded the price of labeling, therefore, labeling could be justified in terms of cost.

3.5.4 Summary of consumer research on GM foods

In summary, consumer research in North America and Europe on consumer's perceptions of GM foods and labels provided consistent evidence to guide businesses. Consumers prefer non-GM foods, and some are willing to pay premiums to avoid GM foods. Negative labeling ("GM free") could lead to a niche market in which the costs of labeling might be borne by consumers who wish to have the information. There is some evidence that consumers may find GM foods more appealing if these foods provide taste, price, nutritional, or safety benefits. However, there is stronger evidence that

health conscious consumers are likely to prefer organic foods, a category that excludes GM foods, and they are willing to pay a premium to avoid GM foods. For GM foods to overcome their negative image and appeal to health conscious consumers, the trait of the GM food would have to be one that could not be achieved in conventional or organic foods. Given the fact that consumers can alter their total diets and substitute many foods to achieve a nutrition goal, it seems unlikely that a low fat GM meat or high micronutrient GM fruit or grain would appeal to consumers who are currently skeptical, since they can reduce their fat intakes and raise their vitamin and mineral intakes by other means.

3.6 Public participation in policy debates

In formulating policies and guidelines for food labeling, US regulatory agencies are required to inform and consult with the public, and public participation procedures such as public meetings and comment periods are frequently carried out. In Europe, public agencies have sponsored various efforts to encourage communication about regulatory issues and new technologies, on their own initiative as well with the urging of the European Commission (Gutteling et al. 2006). Opportunities for citizens to participate in the decision-making processes and the quality of the processes may be a key to trust in governments' decisions regarding new technologies.

Regulatory agencies must weigh the views of scientists and industry representatives, who may be more knowledgeable about the technology. Yet in some countries, there is a "move away from an elitist model in which expert advice acts as the authoritative source for regulation to one in which citizens have a voice in framing government decisions (Rowe and Frewer 2004, 513). An example of how FDA conducted public meetings and comments regarding labeling of GM foods is given in Chapter Five.

In this section, the literature on public participation in regulatory decision making is reviewed. This field of investigation has been inhibited by methodological, theoretical, and practical difficulties: there is no common set of definitions; no accepted framework for analyzing these processes; no validated instruments for measuring these processes; and the collection of data can pose logistical and political difficulties (Rowe and Frewer 2004; Rowe et al. 2005). Nevertheless, interest in this topic is increasing in a number of countries. Controversies over new technologies such as biotechnology and challenges to institutions to be more transparent are stimulating new work in this field.

3.6.1 Typologies of public participation

Widespread disillusionment with bureaucracy in the 1960s and 1970s led to a desire among US citizens for more participation in government decision-making. Arnstein's (1969) seminal work on citizen participation proposed a typology based on degrees of citizen power, using examples from US social programs (i.e. urban renewal, anti-poverty and Model Cities). Ideally, she believed, participation would enlarge citizens' role in determining how information was shared, how goals and policies were set, how resources were allocated, and how programs were operated. Arnstein was highly critical of some efforts in which citizens were informed or educated but had no influence over decisions. A higher level of participation was one in which citizens would hear and be heard, but their views were not heeded. Finally, in Arnstein's highest level of participation, citizens were able to negotiate and to have an influence on the final decisions being made.

The processes for facilitating public participation have been reviewed and rated by US, Canadian and UK researchers (Stern and Fineberg 1996; Leroux et al.1998; Rowe and Frewer 2000). Combining the results of these evaluations, the common methods for including the public in regulatory decisions in North America and Europe are listed as follows: 1) notification, distribution and solicitation of comments; 2) public opinion

surveys; 3) focus groups; 4) referenda; 5) public hearings/inquiries; 6) negotiated rule making[15]; 7) consensus conferences[16]; 8) citizen's jury/panel[17]; and 9) citizens/public advisory committees and task forces[18]. Of these methods, the only one which is binding on officials is the referendum. Other methods may strongly influence decisions, but they must be considered along with other factors. In the case of GM foods in the US, most of these methods have been used either by the federal government, state and local governments or private foundations.

3.6.2 Rationale for public participation

In Germany, Renn and colleagues (1993) elaborated reasons for fostering citizens' participation in environmental policies. First, social acceptance of any policy is closely linked with the perception of a fair procedure in making the decision. The best 'technical' solution will not be accepted if the decision making process is perceived to be unfair or biased. Second, experience indicates that the public contributes valuable information for policy making. Public participation can provide specific information about local conditions and concerns that are often neglected in the decision making process, thus allowing policy makers to avoid potential consequences the experts did not anticipate (Renn et al. 1993, 209). These analysts considered public input to be essential for making the right decisions and strategically necessary to gain acceptance and ensure good

[15] According to Rowe and Frewer (2000), negotiated rule making involves a small group of stakeholders who attempt to reach consensus on a decision.

[16] According to Rowe and Frewer (2000) consensus conferences involve a small number of ordinary citizens with little or no prior knowledge of the topic who are selected to serve as a lay panel that asks questions of experts who have been selected by stakeholders. The meetings are open and reported to the public

[17] According to Rowe and Frewer (2000), citizen's jury/panel is a panel of ordinary citizens who are selected by stakeholders to meet over several days to ask questions of experts. The meetings are closed and the key conclusions are announced to the public

[18] Citizens/public advisory committees are comprised of individuals selected by stakeholder groups; the committee meets over a period of time.

results. Renn and colleagues believed a structure that was conducive to and supportive of discourse was needed so that the public was able to understand technical information and articulate well-balanced recommendations (Ibid.).

A National Research Council (NRC) review in the US examined procedures for deliberation with the public and stakeholders when characterizing a risk (Stern and Fineberg 1996). The NRC committee advocated broad participation and the provision of technical assistance for inexperienced participants. They cautioned that deliberation can lead to demands to reconsider past decisions, and there is no guarantee that the process will end a controversy (Stern and Fineberg 1996, 4-5). However, they believed that broad participation may decrease conflict and increase acceptance of a decision and trust in government agencies (Stern and Fineberg 1996, 23).

> Simply providing people an opportunity to learn about the problem, the decision-making process, and the expected benefits of a decision may improve the likelihood that they will support the decision. Even if participation does not increase support for a decision, it may clear up misunderstandings about the nature of a controversy and the views of various participants. And it may contribute generally to building trust in the process, with benefits for dealing with similar issues in the future. (Stern and Fineberg 1996, 23-24).

3.6.3 Distinctions between ordinary citizens and stakeholders/ lobbyists in policy making

The laws in the US require that all federal regulatory agencies inform and consult with the public before issuing final regulations. However, the citizens who actually participate in consultation procedures may not be average citizens or representative of the general population. In the literature on public participation, a distinction is made between participation of average citizens and participation by individuals representing groups with specific interests and types of knowledge, i.e. stakeholders. Participation

by average citizens and participation by stakeholder representatives have different effects. Some participatory procedures involve average citizens; however, others are normally dominated by stakeholders. If citizens are selected in a manner to represent the general population, this may provide insights into the ways different segments of the population will view a policy. If the lay persons are self-selected, and they do not necessarily represent the public, this could distort the results of the participation process. Stakeholders can contribute specialized types of knowledge and insights based on their particular interest; however, if stakeholders are the only participants in a process, the results could be biased toward the needs of particular interest groups and not serve the broader public. Furthermore, "In the United States, stakeholders have a long tradition of being included in decision making. … the common understanding among stakeholders is that they have a right to be involved, and that this right is not to be given up lightly" (Renn et al, 1993).

According to Crosby and colleagues (1986), the government's attempts to mandate participation in decisions about environmental issues (e.g. location of waste disposal sites and protection of coastal property) had shortcomings in the sense that participation was not representative and had limited impact, especially in the areas of agenda-setting and policy prescription. These authors distinguished between citizen participation and citizen lobbying. Citizen lobbying was defined as involving large numbers of people with a particular interest in contacting officials to change a policy. Citizen participation meant that there was a gathering of a representative group of people and establishment of a dialogue before the policy was made so that policy makers were aware of public views.

Laird (1993) viewed the dominance of diverse stakeholder groups in policy discussions as a desirable part of the political process in pluralist democracies. Participation was successful and of high quality when there were many competing

interest groups, and participation was carried out in a "highly professional way, hiring scientists and lawyers to make their case for them…Pluralists seek high quality to ensure that a group's interests are an important factor in policy outcomes" (Laird 1993, 349). According to Laird, experts possess valuable information and may have privileged status in a technical policy decision, but they should not dominate the process: "Participants need to learn from experts but also to understand that experts often disagree with each other and that their advice is usually a complex mixture of facts and values." (Laird 1993, 354). Regardless of whether a participation process involves representatives of stakeholder groups or individual citizens, Laird held that a successful process requires that the participants improve their understanding of the issues and that they have some power over the outcomes of the policy decision (Laird 1993).

Stern and Fineberg (1996) recognized that there were several strategies for selecting participants. Self-selection was the usual procedure in public meetings and notice-and-comment rulemaking. Although this approach was fair in the sense of allowing equal opportunity, it was limited in that it favored those groups that were organized and those that had enough resources to monitor announcements, mobilize interest group members, submit comments, or participate in other ways. The public meeting process did not address the problem of participation by parties that do not yet realize they may be affected. Also, when there is widespread and intense participation, the organization that is sponsoring the event may not have enough time or personnel to consider all ideas seriously, and this gives the appearance of inviting participation and then ignoring the inputs (Stern and Fineberg 1996, 90).

In an essay on credibility and information in relation to biotechnology, a Canadian researcher, Einsiedel (1998) provided an overview of efforts to communicate and forms of social dialogue in Canada, Denmark, the Netherlands, Germany, the United Kingdom, the European Union and the United States. The analysis included efforts by government authorities as well as best practice examples from the energy and chemical industries of

Canada. Einsiedel characterized the process in the United States as being "multi-channel, multi-level, and multi-actor," with different interest groups using the media and the court system to influence biotechnology decisions (Einsiedel 1998, 71). "The actors involved in actively shaping the information environment are equally diverse, including federal, some state, and some local governments, professional associations (mainly scientific), industry groups, some universities, as well as a range of public interest groups" (Ibid.).

> The highly pluralist, activist nature of US politics is reflected in the information environment for biotechnology. There is a high level of stakeholder activity covering a full range of interests and viewpoints. Industry associations are strong, but so are organizations representing consumer and environmental interests. What differentiates the US context from the European one is that the former is essentially reliant on forces in the marketplace to play important roles in information dissemination. Many organizations with interests in biotechnology are able to mobilize a range of resources to try to influence opinions of various publics or to influence regulatory directions. Other than individual federal agencies exercising consultative or educational roles, the state (i.e. federal government) does not play a primary role in establishing mechanisms for public participation and debate. (Einsiedel 1998, 74)

3.6.4 Perceptions of participatory processes

Crosby and colleagues (1986) found that officials and sponsors of public participation procedures had a variety of attitudes towards the process "generally in accordance with how they liked the recommendations [of the participants]." When the outcomes of participation processes were the ones which a stakeholder or agency desired, then the stakeholders or officials considered public participation to be worth the effort; when the outcomes were not those preferred, there was less support for the processes. Researchers have found that stakeholder groups were ambivalent about public participation methods that gave more power to ordinary citizens (Renn et al. 1993).

3.6.5 Criteria for successful public participation

As noted above, there is not a commonly accepted framework or set of best practices for facilitating public participation. However, the criteria developed by two groups of researchers are presented below.

Crosby and colleagues (1986) considered 6 criteria for assessing the success of citizen participation: 1) participants should be representative and selected in a manner not open to manipulation (e.g. selection of a stratified random sample of citizens to be participants); 2) proceedings should promote effective decision making (by structuring the process to give participants information and time to learn and reflect on the decision); 3) the process should be fair to the parties involved; 4) the process should be cost-effective in relation to the importance of the issue; 5) the process should be flexible for use for different tasks and settings, and 6) there should be a high likelihood that the group's recommendations will be accepted.

Rowe and Frewer (2000) rated each method in terms of 1) representativeness of the population of the affected public; 2) independence and lack of bias, 3) whether the timing of the event was such that it could affect policy decisions; 4) influence of the procedure in terms of having an impact on policy, 5) transparency, accessibility and clarity.

In developing a strategy for public participation, regulatory agencies may consider the advantages and disadvantages of different approaches. Some agencies may apply several strategies; however, it should not be assumed that having more than one strategy ensures that all the criteria for successful participation will be met. A few, well-designed and comprehensive strategies may be preferable to a broader mixture of strategies if the results lead to more meaningful outcomes that are respected by the stakeholders,

public and decision-makers. According to Stern and Fineberg (1996): “A jumble of public meetings, advisory committees, workshops, planning groups, hearings, and panels scattered throughout the process can convey the impression that the organization is not interested in meaningful participation” (Stern and Fineberg 1996, 84).

3.6.6 Summary of the literature on public participation

The literature on public participation provides insights for assessing the processes employed by regulatory agencies in the US in relation to the labeling of foods produced through genetic modification. Each method for facilitating public participation has strengths and weaknesses. Random sample surveys, referenda, and focus groups may include participants who are more representative of the general public and who have no specific interest to defend. These participants may be more independent but they may also be less informed about the topic. There is the risk that their views will not be taken seriously by stakeholders with more knowledge and officials. Consensus conferences, citizen juries and citizen advisory groups are more lengthy exercises but they have the advantage of allowing time for the participants to learn the subject matter and to interact with experts and different types of stakeholders, thereby allowing for more informed discussion.

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CHAPTER FOUR: METHODS

4.1 Stakeholder Perceptions and Participation in the FDA's Consultative Process Regarding the Labeling of GM Foods

4.1.1 Hypothesis

The first part of this study examined how the FDA processes of public meetings and public comments were conducted and whether the perceptions of stakeholders about the fairness and effectiveness of the procedures were consistent with the historic records of the events, that is, whether procedures in fact functioned as intended by the law and the mandate of the regulatory agency. The study hypothesized that the stakeholders' satisfaction or dissatisfaction with the processes was based on several factors: 1) the stakeholders' understanding or lack of understanding of the factors that FDA must consider or exclude when formulating a policy; 2) the appropriate or inappropriate use of the processes by stakeholders; and 3) whether or not the stakeholders had achieved their objectives during the processes.

4.1.2 Study questions

A. How did the stakeholders in the debate over GM food labeling perceive the procedures for participation conducted by FDA?

B. Using criteria such as fairness, access, representativeness, quality of deliberations and influence, were the procedures successful in fulfilling the goals of public participation?

C. How do the stakeholders' perceptions of the participation processes compare with their stances on the topic of GM food labeling?

4.2 Food Industry Reactions to the US Voluntary and EU Mandatory Policies for Labeling of GM Foods

4.2.1 Hypotheses

The second part of this study sought to demonstrate that the US food industry believes that the current environment is not conducive to the successful implementation of the labeling policies that have been developed by the US and EU authorities. Two types of responses were predicted for the conventional food industry and one type of response was predicted for the organic food producers, they are listed below:

1) US food manufacturers will see no benefit at the present time in labeling foods as containing GM ingredients and they will see potential risks. Their response will be to not label foods as containing GM ingredients, and the FDA voluntary guidelines will not be used.

2) US food manufacturers will wish to avoid labeling foods as containing GM ingredients in the EU. Their response to the mandatory labeling policy will be to purchase non-GM food ingredients. Therefore, the EU mandatory policy will not be used.

3) The food producers who do not use GM ingredients will view the option to label foods as "not containing GM ingredients" as a business opportunity to attract consumers who wish to avoid GM foods. However, there will be barriers to the use of labels under the voluntary guidelines.

Thus, neither mandatory nor voluntary labeling will result in producers choosing to label their products in a climate where they perceive that consumers are resistant to the trait that is being disclosed. Even when there is a market for foods that do not have the GM trait, producers will not make use of negative ("does not contain") labeling if the costs of labeling and risks of failing to comply with laws are too high.

4.2.2 Study questions

A. Did the voluntary labeling policy result in products being labeled as containing or not containing GM ingredients or being GM foods?

B. Did the mandatory labeling policy result in products being labeled as containing GM ingredients or being GM foods?

C. Are the policies of the EU or the US conducive to providing consumers with information about products that contain GM ingredients in a truthful and non-misleading way?

D. Can voluntary or mandatory labeling address the lack of consumer information in the market and market failure of asymmetric information when there is evidence that consumers prefer foods that are not GM to those that are GM?

4.3 Qualitative research

The study examined the decision-making process of FDA in relation to a labeling policy and the perceptions of the policy and process among a cross-section of US stakeholder organizations. Qualitative research methods were chosen for this study because information was to be obtained from respondents who were exceptionally well- informed about the topics under review. The aim was to maximize the depth of the information obtained in a way that a closed-question approach would not allow.

4.3.1 In-depth interviews

The intention of conducting open-ended, semi-structured interviews was to allow the respondents to expand on issues spontaneously; to discuss issues which were

not anticipated in planning the study; and to make associations among issues according to their own perspectives (Strauss and Corbin 1990; Holliday 2002). The informal and confidential conversations were conducive to allowing respondents to reveal the underlying reasons for their organizations' public stances. An understanding of the reasons for the public positions of stakeholders is necessary to identify common interests and those issues that cannot be negotiated in efforts to resolve a conflict (Susskind, McKearnan and Thomas-Larmer 1999, 29).

In keeping with the usual ethical practices of research involving human subjects, all interviews were strictly confidential, polite and non-intrusive. The respondents were informed that the information they provided would be reported in such a way that it could not be attributed to them or their organization.

4.3.2 Review of printed and electronic information

From July 1999 to December 2006, technical and popular books, scholarly journals, magazines and newspapers, websites, government reports and transcripts related to agricultural biotechnology and labeling were collected and reviewed. Reflecting the international character of the topic, documents were collected from the US, the United Kingdom, Canada, the Netherlands, Germany, Belgium, Australia and the European Commission.

During the course of this study, the searches for documents usually included key terms such as agricultural biotechnology, genetically modified, food labeling, genetic engineering, regulatory agency, consumer perception, risk communication or organic food. The US Library of Congress, the Boston Public Library, the British Library, the David Lubin Memorial Library of the Food and Agriculture Organization of the United Nations, as well as the libraries of Tufts University and the Massachusetts Institute

of Technology were visited to obtain documents. Through the Internet, information was obtained about the stakeholder organizations, their missions and values, press releases, testimony, comments, annual reports, products and in some cases, biographies of respondents. The Proquest and Eurolaw databases were invaluable for identifying scholarly and news articles and official documents. Other sources of information were the electronic newsletters and press releases of the Pew Initiative on Food and Biotechnology and the Food Navigator.com/Europe.

At different stages during this study, useful insights about qualitative research were obtained from monographs by Flick (2002), Holliday (2002), Strauss and Corbin (1990), Weiss (1994) and Wolcott (2001).

4.4 Data collection

4.4.1 Study population

The study population included stakeholder groups representing the biotechnology industry, the conventional food manufacturers, the organic food producers, commodity associations for corn and soy growers, critics of agricultural biotechnology and consumer advocacy groups. Four stakeholder associations represented many individual organizations and companies. In addition, interviews were sought with non-profit organizations and individuals with expertise in food labeling and regulation of biotechnology. Interviews were also sought with individual companies to gain more detailed information about the reasons for the decisions of individual businesses.

The recruitment aimed to include at least three organizations in the same category to protect confidentiality and gain different viewpoints. For example, three consumer organizations were included in the study. In other cases, it was not possible to obtain three

interviews with organizations of the exact same type, for example, the Biotechnology Industry Organization is unique. The other participants in the biotechnology category were individual businesses, the Monsanto Company and E.I. du Pont de Nemours and Company (DuPont).

The stakeholder groups and individual experts were identified through searches of public reports of meetings, published articles and books, organization websites and professional contacts. As the interviews progressed, additional names recommended by respondents were added to the list of contacts. A total of 106 names were eventually collected, however, many were disregarded if the organization or individual was primarily concerned with issues which were not directly related to labeling or if complete contact information could not be found.

4.4.2 Recruitment

A letter was sent to the contact requesting an interview and explaining the purpose of the research and the conditions for the interview (Annex 4.1). The request for an interview was followed by a telephone call. In most cases, respondents were contacted by phone 4 -7 days after the letter was sent. Scheduling an appointment took several weeks and in a few cases, several months. After the appointment was made, a consent form was sent to the respondent (Annex 4.1).

Attempts were made to alternate among the different types of participant (e.g. conduct an interview with a food industry and consumer organization in the same month), rather than interviewing all participants of the same type during a time period in order to continuously compare different types of stakeholders' views over time. This was useful in providing additional questions; however, it was not always practical, since interviews had to be made at the convenience of the respondents.

Twenty-nine contacts were made with stakeholder groups and 4 individual experts. Of the 33 requests for interviews, 24 individuals representing 20 organizations and 2 individual experts participated in the study (Annex 4.2). One organization and 2 individuals declined to be interviewed. There was no response to repeated attempts to reach the remaining organizations.

4.4.3 Schedule

All of the interviews were conducted Monday to Friday. Contacts for interviews were made from early May 2003 to early April 2004 (see Annex 4.1). In this study, there were no difficulties in conducting interviews during particular times of the year. All of the respondents were meticulous in keeping the appointment and they gave more time (average 47 minutes) than had been requested in the contact letter (30 minutes). A thank you note was sent immediately after each interview.

4.5 Interviews

4.5.1 Preparation for interviews

Conducting in-depth interviews with experts required thorough preparation before each interview so that the interviewer had sufficient up-to-date knowledge of the organization to probe and understand the relationships among topics that the participant was discussing. In some cases, a brief biography of the respondent was given on their organization's website; some respondents had written books and articles that were reviewed before the interview; some respondents were members of committees, and the committee reports were reviewed. This preparation was worthwhile since the respondents usually gave their replies to questions quickly without hesitation, and they changed from one topic to another in ways that the interviewer could not have predicted

in advance. They assumed that the interviewer was aware of their organizations' activities and products, familiar with the basic jargon of their fields, attuned to the latest events, technical debates, and names of influential people and stakeholder groups.

4.5.2 Conducting the interviews

The main questions asked during the interview are provided in Annex 4.3. Depending on the respondent's introductory remarks, the order of the questions was adjusted to allow the conversation to flow in a natural way. Once a topic had been discussed fully, other topics in the interview schedule were raised until all the topics had been covered. At the end of the interview, the respondents were asked if there were other issues that had not been mentioned. Often respondents took this as an opportunity to restate their views and to add points.

All of the respondents gave elaborate replies to most questions. They were very assertive in their responses and their responses were rich in commentary. The interviews covered a range of topics including US policies on labeling, food industry perspectives, international markets, public opinion and consumers, reasons for the controversy over biotechnology and public information about biotechnology (Annex 4.3). The respondents often raised issues such as the US complaint against the EU at the World Trade Organization in 2003, concerns over adventitious presence of GM material in organic crops, and contamination from pharmaceutical crops.

4.5.3 Recording the interviews

No tape recording device was used during the interviews. Notes were taken by hand during the phone conversation; the exact phrases were noted and attempts were made to take verbatim notes. Within hours after the interview, the notes were typed and comments were added to fill in gaps and explain the context of a comment. For security,

the electronic copies were kept on a laptop and a PC computer with passwords known only to the interviewer, and hard copies and diskettes were saved in a locked cabinet. The interview transcripts have not been shown to anyone.

4.6 Analysis of interviews

Each interview transcript was reviewed to identify common responses and themes. A matrix of type of respondent and type of responses was created. The responses fell into 22 broad areas (including questions that had been part of the interview guide and issues that had been raised frequently by the respondents). The responses of the study participants within the same category were compared to identify common views. The responses among the various categories of respondents were compared.

In drafting the text, the identities of the respondents were removed from the collection of quotations and names were replaced by terms such as "industry representative," "consumer association," "researcher," and "government official." The respondents were categorized according to their primary role at the time of the interview. The actual words used by the respondents were used in the text; however, some changes in grammar and punctuation were added if needed to clarify the sentence.

4.7 Limitations of the study

Generally, a limitation of qualitative studies is that they do not yield results that allow one to generalize about entire populations. The number of interviews in this study is too small to allow meaningful use of statistics to describe the study population. However, the organizations that participated in the study represented the majority of food producers and biotechnology providers in the US. Therefore, the views of these stakeholders' representatives were considered to be strong indicators of the most commonly held views of individual companies.

Another limitation is that the participants' memories of events may be influenced by the situation in which the events were recalled. For example, the participants in this study often referred to trade issues, perhaps because the interviewer was affiliated with FAO, an international organization that deals with this subject.

Finally, if the respondent is telling about events or views that he or she had discussed on other occasions, the replies may not be spontaneous. In this study, a number of participants were spokespersons for their organization and some of their responses were their standard replies or position statements (as verified in reviewing their organizations' public statements). However, the length of the interview, personalized questions and the diversity of questions prevented respondents from giving prepared replies for all the questions.

Literature cited

Flick, U. (2002) *An Introduction to Qualitative Research*. London: Sage.

Holliday, A. (2002) *Doing and Writing Qualitative Research*. London: Sage.

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Susskind, L., McKearnan, S. and Thomas-Larmer, J. (1999) *The Consensus Building Handbook A Comprehensive Guide to Reaching Agreement.* London: Sage.

Weiss, R.S (1994) *Learning from Strangers: The Art and Method of Qualitative Interview Studies.* New York: Free Press.

Wolcott, H.F. (2001) *Writing Up Qualitative Research.* 2nd edition. Thousand Oaks, CA: Sage.

Annex 4.1: Contact letter and consent form approved by the Tufts Internal Review Board

TUFTS UNIVERSITY

Gerald J. and Dorothy R. Friedman

School of Nutrition Science and Policy

Dear [Dr.][Mr.][Ms.]._____:

[_____ has suggested that I contact you] [I am writing to you] as an expert on [food regulations; food technology; consumer affairs, etc.] to request an interview to discuss government policies regarding labeling of foods produced through biotechnology. As new applications of biotechnology emerge in the food industry, debates over labeling are evolving in a number of countries. In the U.S., the Food and Drug Administration has proposed options for voluntary labeling to distinguish foods which are derived from biotechnology from those which are not. Others advocate mandatory labeling for these new products rather than voluntary labeling.

In this policy debate, the perspectives of food producers, government officials, consumer advocates, and scientists are vitally important. Since you have been involved in [developing your company's strategy] [formulating government policy] [[articulating consumer concerns] [providing expert scientific advice] on these issues I believe your perspective is extremely valuable and I would very much appreciate the opportunity to speak with you.

This study is being conducted under the auspices of the staff development program of the United Nations' Food and Agriculture Organization in Rome. The study will be produced as a doctoral dissertation on labeling as a method of communication, using biotechnology as a case study. I am working with Dr. Beatrice Rogers and Dr. Jeanne

Goldberg, both of the Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy at Tufts University, Dr. Christine Lewis Taylor of the Food and Drug Administration and Dr. Barry Zoumas of Pennsylvania State University.

I am planning to conduct my interviews by telephone and I anticipate that these conversations will take approximately 30 minutes. If you are able to participate in this study, I will send you the general questions to be discussed and a confidentiality form several days prior to calling you. Although your name would be listed in the acknowledgements of the report of the study findings, no quotations or views will be attributed directly to you or your [company] [agency] [organization][university]. When the study is completed, I will send you an executive summary.

I will contact your office within the next two weeks to make an appointment to speak with you. I look forward to speaking with you.

Sincerely,

Janice Albert

Nutrition Officer

Food and Nutrition Division

Food and Agriculture Organization

E-MAIL: Janice.Albert@fao.org

[Address of the recipient]

TUFTS UNIVERSITY

Gerald J. and Dorothy R. Friedman

School of Nutrition Science and Policy

Dear ___:

Thank you for agreeing to speak with me about labeling of foods produced through biotechnology.

During the interview, you will be asked to give your views on a number of issues. The topics include: U.S policies regarding labeling of foods derived from biotechnology; public opinion about biotechnology; the food industry's views about labeling proposals; the biotechnology industry's views about labeling proposals; the influence of other countries' policies on the U.S.; public information about biotechnology and controversies about biotechnology and labeling. The interview questions are broad to allow you to discuss any matter you believe is important or to decline to reply to any question.

Our conversation will be completely confidential. Although I will take written notes, no tape recording device will be used and the information you provide will be reported in a manner that does not disclose your identity. When the study is completed, I will send you an executive summary of the findings. If you agree, your name and affiliation would be listed in the acknowledgements section of the report.

This study is being conducted under the auspices of the Tufts University Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy and the Food and

Agriculture Organization of the United Nations. The Tufts' Internal Review Board requires that each participant in a research project sign a consent form. I would appreciate it if you could sign this letter in the space below indicating that you agree to participate in this study.

I look forward to speaking with you.

Sincerely,

Janice Albert

I give my consent to be interviewed under the conditions described above.

_____

Signature of participant

_____

Date

PLEASE RETURN THIS LETTER BY FAX, ADDRESSED TO: JANICE ALBERT, FAO Food and Nutrition Division, Rome, Italy

39 0657054593

(39) 06 570-54593.

Annex 4.2: Schedule of interviews with Organizations and Individuals

Name of Organization	Respondent	Interview date
Consumer Policy Institute-Consumers Union	Dr. M. Hansen, Research Associate	May 14, 2003
Organic Trade Association	Ms. K. Di Matteo, Executive Director and Mr. T. Hutcheson, Regulatory and Policy Manager	May 30, 2003
FDA, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements	Ms. F. Satchell, Director, Division of Food Standards	June 1, 2003
FDA, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy	Dr. J.Maryanski, Biotechnology Coordinator	June 2, 2003
International Food Information Council Foundation	Ms. C. Toner, Director of Health Communications and Mr. A. Benson, Vice President of International Relations	June 4, 2003
Grocery Manufacturers of America (GMA)	Ms. K. Kochenderfer Coordinator, Biotechnology Director, Environment & New Technologies	June 20, 2003
Corn Refiners Association, Inc.	Anonymous executive*	July 18, 2003
Center for Science in the Public Interest	Mr. G. Jaffe, JD, Director of the Biotechnology Project for CSPI	August 5, 2003
National Food Processors Association	Dr. Jeffrey Barach, Vice President, Special Projects	August 14, 2003
Consumer Federation of America	Ms. C.T. Foreman, Director of Food Policy Institute	September 4, 2003
USDA Food Safety and Inspection Service	Dr. F. E. Scarbrough, US Codex Manager	September 9, 2003

Annex 4.2 continued

Name of Organization	Respondent	Interview date
Independent Expert	Dr. J.A. Caswell, Professor, University of Massachusetts	September 11, 2003
The Pew Initiative on Food and Biotechnology	Mr. K. Pitts, Director of Public Policy	October 10, 2003
Independent Expert	Mr. M. R. Taylor, JD, Senior Fellow and Director, Risk, Resources, and Environmental Management, Resources for the Future	October 16, 2003
Kraft Foods North America	Mr. M. Mudd, Senior Vice President, Corporate Affairs	October 31, 2003
The Campaign to Label Genetically Engineered Foods	Mr. C. Winters, Executive Director	December 8, 2003
Organic Farming Research Foundation	Mr. B. Scowcroft, Executive Director	December 9, 2003
General Mills	Mr. A. Sullivan, Senior Vice President	January 7, 2004
The Procter & Gamble Company	Anonymous executive*	February 27, 2004
Biotechnology Industry Organization (BIO)	Dr. M. J. Phillips, Executive Director for Food and Agriculture	March 10, 2004
Monsanto Company	Dr. J. Collins, Director, Global Organizations	March 23, 2004
Institute for Social Ecology	Mr. B. Tokar, Biotechnology Project Director	March 22, 2004
American Soybean Association	Dr. K. Nill Technical Issues Director	April 2, 2004
E.I. du Pont de Nemours and Company	Mr. T. Medley, JD, Director of Global and Corporate Regulatory Affairs	April 22, 2004

* Respondent asked to not be identified.

Annex 4.3 Interview questions

Semi-structured, open ended questions
Please describe your involvement in decisions regarding biotechnology and labeling at (organization)?
Why do you think the FDA announced draft guidance for voluntary labeling of foods which have been produced using bioengineering and foods which do not contain bioengineered ingredients?
What do you think of the proposal for voluntary labeling?
For your organization, could labeling serve a useful purpose?
Would you label foods as containing bioengineered ingredients and / or not containing bioengineered ingredients?
Would labeling place an unfair burden on some sectors of the food industry?
Has mandatory labeling in other countries had an impact on your company?
Why did other governments enact this type of labeling requirement?
Have most American consumers heard about biotechnology?
Does knowledge that a product contains ingredients produced through biotechnology affect food purchases?
Why do some people say that they want mandatory labeling?
What are people seeking when they demand a label?
What are the causes of controversy over biotechnology?
Do you think that providing more information would reduce some of the tension which has arisen over biotechnology?
Do you think there is anything the food industry or biotechnology industry should do in response to the critics?
Would more public information about the process and uses of biotechnology affect consumers' feelings about biotechnology?
What kind of information would be needed?

Annex 4.3: Semi-structured, opened ended interview questions (continued)
Who should be responsible for informing the public about new developments in technology?
Would labeling give consumers some of the information they need to make choices?
In this way, will their purchases indicate whether consumers accept or reject this new technology?

CHAPTER FIVE: STAKEHOLDER PERCEPTIONS AND PARTICIPATION IN THE FDA PUBLIC CONSULTATION PROCESS REGARDING THE LABELING OF GM FOODS

Abstract

In the United States of America (US), the 1992 policy of the Food and Drug Administration (FDA) regarding the regulation of GM foods did not consider the use of recombinant DNA techniques to produce food to be a legal basis for mandatory labeling of these foods. In 1999-2001, FDA reconsidered this position and, as required by law, the regulatory agency sought public views about proposed changes in the US approach to labeling. This study assessed stakeholder involvement in and reactions to two procedures conducted by the FDA: public meetings and public comments about a labeling policy for genetically modified (GM) foods.

In-depth telephone interviews were conducted from May 2003-April 2004 with 18 stakeholder groups representing the conventional and organic food industries, the biotechnology industry, consumer organizations, and groups which oppose agricultural biotechnology. The review analyzed the official transcripts from 3 public meetings held in 1999 and a random sample of the public comments sent to FDA in 2001.

The criteria for assessing the participatory processes included: fairness, quality of the deliberations and influence of participation on FDA decisions. The findings demonstrate that the FDA processes were accessible to citizens and that a wide range of views were expressed. The procedures influenced the officials' understanding of stakeholder priorities.

There was not a consensus among stakeholders. The conventional food industry, biotechnology industry and scientific associations supported the FDA voluntary approach to labeling GM foods, while the organic food industry, environmental organizations and

some consumer advocates favored mandatory labeling of GM foods. The stakeholders' perceptions of the procedures were consistent with their stances on the policy under consideration.

Stakeholders were very engaged in the public meetings and the quality of statements indicated a high level of understanding of the topics. In contrast, the comments that were sent in response to the *Federal Register* announcement were less representative and the quality of most messages was low. The critics of the 1992 policy did not provide new information that might be considered as a material reason to require labeling of GM foods. Some critics of FDA appeared to misunderstand the purposes of the process and legal reasons for labeling in the US.

The study concluded that FDA fulfilled its obligations to encourage public participation in the discussion of guidance on GM food labeling and to consider a wide range of views. The study found that some stakeholders are more skilled in participation than others and that those with less effective participation skills were more dissatisfied. The study suggests that FDA assist inexperienced citizens to prepare for participation in policy debates, especially those involving complex technologies. The agency should clearly explain the purposes of the participation processes and inform the public of how the information will be used to avoid disillusionment with participation processes.

5.1 Introduction

Regulatory agencies in the United States of America (US) are required by law to inform the public about the development of regulations and other policies and to provide opportunities for the public to express their views about the proposed policies. There are three rationales for allowing the public to participate in policy debates: 1) Citizens' rights to participate in a meaningful way in public decisions and to be informed about government decisions stem from the principle that government should obtain the consent of the governed; 2) The public may contribute relevant wisdom to the decisions which has not been considered by scientific specialists and public officials; and 3) Participation can build trust and understanding, which may decrease conflict and encourage societal consensus about a policy (Stern and Fineberg 1996).

Public participation is voluntary, and many factors may affect whether an individual chooses to participate in discussions about a regulatory agency's policies. These may include degree of awareness and interest in the topic and motivation to engage in a discussion; access to information and ability to understand the topic; and availability of resources (e.g. time and money) to participate. Those who would be most affected by the policy may be more motivated to participate in public consultation procedures than others.

Often participants in public discussions represent a well-established association, institution or organization. In some instances, an ad hoc group is formed because of a specific interest in the topic. These groups are known as stakeholder organizations ("stakeholders"). They can be valuable contributors to policy discussions because they often have more knowledge of the subject than average citizens (Renn et al.1993). On the other hand, such stakeholder groups should not be considered to be representative of the general public.

5.2 Purpose of this study

Although many stakeholders frequently take part in government procedures to obtain public views, relatively little is known about the ways that they perceive the government procedures for fostering public participation. The purpose of this study was to assess stakeholder involvement in and reactions to a US regulatory agency's procedures for public participation in relation to a controversial policy and new technology. The study focuses on one policy: a 2001 proposal for guidelines for voluntary labeling of foods which contain ingredients derived from biotechnology ("GM foods") or foods which do not contain GM ingredients ("non-GM foods") and two participation procedures: public meetings held by FDA before the guidance was drafted and public comments received by FDA in response to the draft policy. Both procedures were carried out by the FDA, an agency of the US Department of Health and Human Services that is responsible for regulating the vast majority of food products in the US.

In the controversy over labeling of GM foods, critics of the US policy have charged that US regulatory decisions have been biased and not transparent and that public views have been ignored (e.g. Nestle 2003). This study examined how the processes of participation were conducted and whether the procedures functioned as intended by the law and the mandate of the regulatory agency. The study hypothesized that the stakeholders' satisfaction or dissatisfaction with the process was based on the stakeholders' understanding or lack of understanding of the factors that FDA must consider or exclude when formulating a policy, appropriate or inappropriate use of the process by stakeholders, and whether or not they had achieved their objectives during the process.

5.2.1 Relevance of the case study

An examination of the US approach to public participation in decisions regarding labeling of GM foods and non-GM foods is significant and timely for several reasons. First, agricultural biotechnology and the specific issue of labeling are the topics of an ongoing controversy where the extent to which the public has been informed and participated in decision making is a subject that has been raised by critics of FDA. Second, the US has been the world's leading producer of GM crops every year since 1995, when commercialization of genetically modified seeds began. Of the 102 million hectares (252 million acres) of land that were planted in GM seeds worldwide in 2006, 54 per cent were in the US (James 2006). The public image of the US regulatory agency that oversees the safety of these foods is relevant to the future of the technology.

5.3 Methods

Several methods were employed to obtain data about the involvement of stakeholder groups in decision making about GM labeling in the US and their level of satisfaction with the process, as well as information about how the processes were actually carried out. Information on stakeholder perceptions was acquired through in-depth interviews with stakeholder group representatives. The categorization of organizations relates to their primary function or identity; however, some organizations could have been included in more than one group. For example, some organic agriculture organizations actively oppose agricultural biotechnology, and some research organizations receive support from the conventional food industry. At the time of the interviews, 4 individuals who were employed by a consumer association, a biotechnology organization, a biotechnology company and a research institute, respectively, stated that they had been public officials or staff in government agencies previously and

had been involved in policy decisions regarding the technology. Thus, their insights about government processes and policies may have been influenced by their previous experiences.

Of the 29 organizations and 4 individuals who were contacted, 24 individuals representing 20 organizations and 2 individual experts agreed to be interviewed.

5.3.1 Interviews with stakeholder organizations

From May 2003-April 2004, 20 experts from 18 stakeholder organizations representing the conventional and organic food industries, the biotechnology industry, consumer organizations and organizations which oppose agricultural biotechnology were interviewed.

5.3.2 Interviews with government officials and individual experts

In June and October of 2003, one face-to-face and two telephone interviews were held with US government officials with direct involvement in developing regulations concerning biotechnology and labeling. The officials were asked about the same topics as the stakeholder group representatives. Two individuals with expertise in food labeling, regulations and agricultural biotechnology were interviewed during this period.

Table 5.1: Stakeholder groups interviewed about biotechnology and information	
Commodity producers	Corn Refiners Association, Inc. American Soybean Association
Biotechnology industry	E.I. du Pont de Nemours and Company Monsanto Company Biotechnology Industry Organization
Conventional food industry	National Food Processors Association Grocery Manufacturers of America Kraft Foods North America Procter and Gamble Company General Mills
Organic food industry	Organic Trade Association Organic Farming Research Foundation
Foundations	International Food Information Council Pew Initiative on Food and Biotechnology
Critics of biotechnology	Campaign to Label Genetically Modified Foods Institute for Social Ecology
Consumer advocates	Center for Science in the Public Interest Consumer Federation of America Consumers Union

*Names of individual respondents have been removed to protect confidentiality as promised at the time of recruitment into the study.

5.3.2 Archival research on public participation events

To acquire information about public meetings, three complete sets of official transcripts from recordings of public meetings held in 1999 were obtained from the FDA website. The entire contents of the transcripts were analyzed manually, and the types of participants and their views were categorized and counted.

Information about public comments regarding the 2001 proposal on food labeling for GM content was obtained by reviewing individual messages (letters, postcards, and e-mails), which had been sent to the FDA dockets section. One thousand messages were randomly selected from the electronic files. These sample messages were reviewed until there was clear repetition in the messages and no new type of message was expected to appear. After reviewing over 700 messages, it was established that there were 8 types of letters. Within each type, the letters were identical except for unique, personalized statements at the beginning or end of the message. These messages were analyzed manually, and the messages were categorized by contents of messages and address of the sender. Examples of comments are shown in Annex 5.4.

By conducting interviews and archival research, it was possible to combine the concise, public stances of experts; the short letters of citizens who are not experts; and the more in-depth reflections of experts who were not constrained by the formality and openness of a public event to create a richer body of information and to verify information.

5.4 Background

5.4.1 FDA approach to food labeling and regulation of GM foods

According to the 1938 FDCA, the labeling on a product must, "reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article (US Congress 1938)." In addition, it is illegal to misbrand a food through labeling which is "false or misleading in any particular …" (Ibid.).

In keeping with the general laws for labeling, the FDA 1992 "Statement of Policy: Foods Derived from New Plant Varieties" explained the situations that would determine whether products of biotechnology would require labeling:

> …[C]onsumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted (FDA 1992, 22991).

According to the 1992 policy statement on the regulation of foods derived from agricultural biotechnology, the fact that a food had been developed through recombinant DNA techniques was not considered to be material by the agency. In cases where there is no material difference between the GM food and the conventional food, FDA stated that there was no legal basis for mandating labeling of the GM foods.

5.4.2 Decision to re-open the issue of GM labeling

The agency's 1992 stance that labeling should not be required for all GM foods became the subject of review in the period 1999-2001. During this time, the protests

in opposition to agricultural biotechnology, particularly in some European countries, drew attention in the US. For example, a cover of *The Economist* asked, "Who's afraid of genetically modified foods?" (1999), and a cover of *Newsweek* said, "Food Fight: Europe's mad-and America is finally noticing" (1999). Dan Glickman, then Secretary of Agriculture in the Clinton Administration expressed concerns that US food exporters would be affected negatively by the controversy (USDA 1999). These economic and political factors stimulated the administration to take action. Once the decision was taken by FDA to address the topic of labeling, the agency was required by law to follow several public participation procedures.

5.5 Public participation in policy and regulatory decisions in the US

There are several dimensions to public participation. The public must first be informed. In the US, the public has had access to information about regulations in general since the enactment of the Federal Register Act of 1934 (McDonald, 2004). Through the daily publication of the *Federal Register*, official explanations of policies of government agencies are made available to the public. Beyond being informed, citizens must have the right to make comments on proposed rules; this right was embodied in law with the Administrative Procedures Act of 1946 (Ibid.). It is noteworthy that the Administrative Procedures Act also allows agencies to reject information which is "irrelevant, immaterial, or unduly repetitious" (US Congress 1946, Section 556d).

These laws are applied in all federal regulatory agencies, including the FDA. In addition to these broad laws that allow the public to offer comments in response to announcements in the *Federal Register*, the FDA Modernization Act of 1997 (FDAMA) obliges the agency to actively seek public views when proposing guidance documents. The FDAMA states:

> For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary [of Health and Human Services] shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account. (US Congress 1997, Section 405).

It should be noted that while the law requires that FDA actively seek public participation, this is only one of many types of information which the agency must take into account in making policy decisions.

5.6 Interpretations of GM food labeling laws

The laws for food labeling in the US described above are general and subject to interpretation. Since the 1990s, FDA had interpreted the law to require labeling to provide information about: (a) product identity, (b) product ingredients and composition, (c) facts material to consequences of use (including safety concerns), and (d) any special requirements or provisions such as nutrition labeling and the ability to make claims. Thus, only if a GM food differs from its conventional counterpart with regard to one of these factors, would labeling be mandatory.

As noted above, the FDA issued its 1992 policy on GM foods to clarify questions which had been raised by the food industry, government agencies, the academic community and the public (FDA 1992).[19] According to the 1992 policy, the agency did not consider the sole fact that a food had been developed through recombinant DNA techniques to be material. Thus, products of this technology would be assessed on a case

[19] For more information about the US approach to regulation of biotechnology, see Chapter Two of the thesis and Annex 5.2.

by case basis to determine whether labeling was warranted. FDA identified circumstances where omission of information about a change brought through genetic modification would be misleading and pose a health risk if there was no label.[20]

5.7 Public participation processes followed by FDA

As Clinton administration officials began to review several aspects of the 1992 policy, the FDA took steps to ensure public participation in discussions of possible changes in policies. Two procedures are analyzed below: the public meetings, that were held in November and December of 1999, and the written public comments, solicited in January and received through March of 2001.

5.7.1 Public meetings

In late October 1999, FDA announced steps to reconsider the ways the agency dealt with information for the public (FDA 1999). In the announcement, the agency expressed its wish to…

> [S]hare its current approach and experience…regarding safety evaluation and labeling of food products derived from bioengineered plant varieties, to solicit views on whether FDA's policies or procedures should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply. (Ibid.)

The agency explained that the scope of the discussion about public information would include the following questions:

[20] For more information about the assessment of the health effects of genetically engineered foods, see WHO (2000)and IOM/NRC (2004).

> Should FDA's policy requiring labeling for significant changes, including changes in nutrients or introductions of allergens be maintained or be modified?
>
> Should FDA maintain or revise its policy that the name of a new food be changed when the common or usual name for the traditional counterpart no longer applies? Have these policies regarding the labeling of these foods served the public?
>
> Should additional information be made available to the public about foods derived from bioengineered plants? If so, what information? Who should be responsible for communicating such information?
>
> How should additional information be made available to the public: e.g. on the Internet, through food information phone lines, on food labels or by other means? (FDA 1999)

5.7.2 Written comments on guidance for labeling

During this time, conventional food producers whose products may contain GM ingredients were concerned that negative labeling (i.e. food labels indicating that a product does not contain GM ingredients) and marketing strategies would be used to stigmatize their food products that may contain GM material (GMA 2000). They argued that negative labels would mislead consumers into believing that GM foods were inferior to non-GM foods. Misleading labels are a form of misbranding, and this is illegal.

In the spring of 2000, six major food industry associations[21] petitioned FDA seeking clarification on labeling language and suggesting labeling conditions to prevent misbranding (GMA 2000). The petition provided a detailed set of technical and legal

[21] The petitioners included the Grocery Manufacturers of America, the Food Marketing Institute, the American Frozen Food Institute, the International Dairy Foods Association, the National Food Processors Association and the Snack Food Association, which collectively represented producers of hundreds of billions of dollars worth of food and food products (GMA 2000).

arguments to support the request for clarification from the authorities. The petitioners requested the agency to consider whether terms such as: “GM free,” “GMO Free,” “Non-GM,” “Non-GMO,” “No genetically engineered ingredients,” and “No ingredients derived through biotechnology” could mislead consumers. They suggested that a negative label would cause consumers to infer that the product was superior in comparison with products that did contain GM ingredients. This would have been misleading since there was no evidence of superiority.

An initiative to give consumers information about biotechnology was announced by the White House in May 2000 (White House Press Secretary 2000). In taking this action, FDA was responding to the food industry’s request for clear government guidance and to proposals made at the public meetings to carry out consumer research.

To assess consumers’ reactions to labeling, FDA conducted 12 focus groups in Maryland, Vermont, Washington and Missouri to…

> [P]rovide insight into consumers’ awareness of foods produced through biotechnology, their familiarity and understanding of possible terms for describing these foods, and their reactions to options for identifying whether foods are or are not products of bioengineering. (FDA 2000, 1)

The FDA researchers concluded that participants had “an uneven knowledge and understanding of bioengineered foods.” (Ibid., 2). The participants could not identify GM foods, and “Virtually all participants said that bioengineered foods should be labeled as such so that they could tell whether a given food was a product of the new technology” (Ibid., 4).

In preparing the guidance, FDA considered the factors that might mislead consumers [22] and outlined the conditions under which a positive (i.e.”contains GM

[22] In the fall of 2000, FDA prepared a paper on the various ways that labels can mislead consumers which was presented to the Codex Committee on Food Labelling in May 2001. For an explanation of misleading labeling, see CCFL 2001.

material") or a negative (i.e. "does not contain GM material") label would be permitted as a voluntary label and when it would be required as a mandatory label. The main features of the guidance are summarized in Table 5.2.

Table 5.2: Main Features of the 2001 FDA Guidance (adapted from FDA 2001)
Bioengineered
Optional to say "contains (product) developed/produced through biotechnology"
Allowed to claim "developed through biotechnology because (positive reason)" but must substantiate claim (emphasis added)
Cannot claim benefits for whole product if amount of positive ingredient insignificant
Must disclose allergens not found in conventional counterpart
Must change name if significantly different
Optional to say "contains (product) developed/produced through biotechnology"
Allowed to claim "developed through biotechnology because (positive reason)" but must substantiate claim (emphasis added)
Cannot claim benefits for whole product if amount of positive ingredient insignificant
Must disclose allergens not found in conventional counterpart
Must change name if significantly different
Label may apply to human foods and animal feeds
Non-bioengineered
All ingredients must be non-bioengineered
Cannot imply that specific product is non-bioengineered if no products of this type are bioengineered.
Can say all foods of a type are non-bioengineered
Must be able to substantiate "non-bioengineered" through testing, documentation, segregation
USDA certified organic foods are non-bioengineered by definition
Permitted to say biotechnology not used if there is no suggestion that product is superior (emphasis added)
Label may apply to human food and animal feeds

In 2001, FDA acknowledged the comments that had been made previously that expressed desires for mandatory disclosure, but the agency said this was not sufficient cause to alter its approach.

> [The agency] is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act. FDA is therefore reaffirming its decision to not require special labeling of all bioengineered foods. (FDA 2001, 4840)

5.8 Results

The analysis of information obtained from the transcripts of the public meetings and comments sent to FDA demonstrated that the agency followed the law by informing the public of the policies it was considering and inviting public comments. The participation procedures gave FDA information about the priorities of various stakeholders. While the interviews with FDA officials suggested that FDA heard and understood the various viewpoints, the information obtained through the participatory process did not lead to a change in the general approach to labeling of GM foods. Some stakeholder group representatives were disappointed or dismissive of the procedures. The analysis suggests that the reasons for the weak effect on decisions were not related to disrespect by FDA for the democratic process as some critics have charged (Drucker 1999;Annex 5.4). Rather, the limited influence may have been due to a failure of critics to provide new information which might have persuaded FDA that there was a material reason to require labeling. Negative perceptions of the procedures may have been the result of misunderstanding of the process and disagreement with the outcome on the part of some stakeholders.

5.8.1 Criteria for the analysis

The FDA procedures and the nature of the stakeholders' participation were analyzed below in terms of level of participation, fairness of the process, quality of the deliberations, influence of participation on FDA decisions and perceptions of the process among the stakeholders and officials.

"Level of participation" has been defined in terms of the number of participants and the range of views represented.

"Fairness of the process" has been assessed in terms of evidence that all stakeholders had an equal opportunity to participate.

"Quality of deliberations" refers to the soundness of the arguments and their relevance to the laws which determine whether labeling will be required and whether claims are considered to be misleading.

"Influence of participation" indicates whether there was any evidence that the stakeholders were able to influence the decisions or behavior of FDA through their participation. Influence could have affected decisions in many ways: FDA may have decided whether to take an action or to not take an action as a result of the participants' comments.

"Perceptions of the process" are examined in terms of the stakeholders' level of satisfaction with the procedures. Perceptions of a process can be strongly affected by the participants' disappointments when they did not perceive that they had influence or elation when they perceived that their views had been influential. When an outcome meets a stakeholder group's desires, a positive perception of the process would be expected. When the outcome does not meet the desire, the opposite perception would be expected.

5.8.2 Public Meetings (1999)

The FDA organized three one-day public meetings in Chicago, Illinois (November 18); Washington, D.C. (November 30), and Oakland, California (December 13). The public meetings were recorded, and transcripts were made available on the FDA website. In addition, written comments could be sent to FDA.

Organization of the meetings

At the opening of the first meeting, the FDA Commissioner said…

> FDA is here to listen and to ask questions or provide clarification about our current policy. Our goal is not to reach a conclusion by the end of the day. We are beginning a process of listening, not pronouncing. We will not engage in debate on these issues, primarily because we want to hear the views of others. (FDA 1999b)

This approach of listening and not debating with participants was followed at all three meetings.

Each meeting included a morning session, which focused on safety assessment of GM products. The afternoon session dealt with provision of public information, particularly labeling. In each session on information, FDA officials posed the same three questions to the panelists and the audience that were listed in Section 5.7.1.

The officials explained the FDA approach to regulating products of biotechnology and food labeling. Panel discussions followed these presentations. The panelists were invited by FDA as experts and they represented different perspectives of stakeholder groups, including the biotechnology industry, the food industry, consumer organizations, environmental organizations and academic institutions (Annex 5.3). Each panelist made a statement and responded to other panelists' remarks, as well as to points raised by FDA officials.

The last two hours of each event were allocated to speakers from the audience. When these individuals contacted FDA to register for the meeting they were given a number, which determined the order in which they would speak. Their two minute statements addressed topics raised in both the food safety and public information/labeling sessions. Based on the transcripts, there was no clear pattern to audience presentations, although similar positions were occasionally expressed successively by two or three speakers. In addition, the audience could submit written statements to FDA staff at the meetings or send statements to FDA within a period of two months.

The meetings ended after these statements by the audience speakers with no exchanges of views between the audience and the panelists or officials or exchanges among the audience speakers.

By holding the meetings in different parts of the country and inviting a variety of panel speakers, the agency made an effort to include a range of opinions held by different stakeholders. The presence of a panel member who represented a particular stakeholder group demonstrated that their perspective was taken into account by FDA. Failure to include a stakeholder group could have contributed to the perception among these stakeholders that FDA lacked interest in their views.

No organic stakeholder group or expert was present on the panels. Certainly, those groups had been very vocal in their concerns about biotechnology during the debates over the USDA Organic Seal, which were taking place during the same period (Klintman and Boström 2004). The failure to invite a representative from the organic food sector appears to be an error rather than a deliberate attempt to avoid critics since there is evidence that FDA did not exclude critics. FDA invited both an organization which was suing the agency and Greenpeace, one of the most prominent opponents of biotechnology, to speak on a panel.

Level of participation

According to meeting transcripts, participation in the meetings exceeded the agency's expectations (FDA 1999a,b,c). More than 1,000 people attended the three meetings. In addition to the invited panelists, a total of 201 people in the audience spoke. Further, more than 50,000 written comments were sent to FDA (FDA 2001).[23]

While public meetings were open to anyone, the vast majority of audience speakers stated that they represented an organization. To participate in the meetings, one needed to be able to travel to the meeting location and to spend a full day there. For small stakeholder groups and individual citizens residing far from the meeting site, costs of participation may have been prohibitive.

Most speakers represented stakeholders with a direct interest in agricultural biotechnology in the US such as conventional farmers of food and animal feed, producers/marketers of organic and natural foods, biotechnology companies, professional associations (e.g. medical doctors, dieticians, food technologists, plant scientists), environmentalists, food processors and consumer organizations. There were a few advocates for people who may be food insecure (e.g. the rural poor in developing countries, disabled and elderly people in the US) as well as a few individuals (e.g. students, professors, lawyers and mothers) speaking on their own behalf.

Quality of the deliberations

Most panelists were independent experts from universities or high-level representatives of well-established consumer, environmental, biotechnology and conventional food industry organizations. Their statements reflected in-depth knowledge

[23] For comparison, in late 2000, the number of comments sent to USDA with regard to organic labeling exceeded 275,000. However, this outpouring of views was considered to be truly exceptional. (Klintman and Boström, 2004, 621).

about the history of the US policies on regulations of biotechnology. They cited facts or made generalizations based on research on public perceptions of labeling and biotechnology. They based some views on their consultations with their constituencies and their own years of experience working on similar topics. The discussions included criticism and praise for FDA and the biotechnology industry. During the panel sessions, public confidence, information and dialogue were recurring themes for both supporters and critics of FDA policies.

In this study, the contents of the transcripts of the three meetings were reviewed to identify key issues raised by audience speakers and positions taken on labeling of foods derived from biotechnology. It was evident from the transcripts that the vast majority of audience speakers had taken time to prepare for the meeting and to make clear, reasoned statements. Their positions were carefully worded, with important nuances and indications of issues that were of importance to the speakers.

There was a wide range of opinions among stakeholder groups and some clear patterns in the positions taken by different groups (Annex 5.3). Conventional farmers, biotechnology companies and many scientists supported the 1992 FDA policy with regard to labeling (that is, disclosure of GM ingredients should not be mandatory unless there was a material reason to inform the consumer). Most organic food producers, environmental organizations and consumer advocates favored mandatory labeling of all GM foods.

It should be noted that the number of speakers from a particular stakeholder constituency does not necessarily reflect the size of that stakeholder's sector within the US food system. For example, in the meetings, the number of audience speakers from the organic food sector was similar to the number of speakers from the conventional food sector; however, the organic food sector represents a relatively small proportion of total food production in the US. Similarly, there were few speakers representing

food manufacturers, but those who did speak represented nearly all of the major food companies in the US. It is these stakeholders who would be most affected by a mandatory labeling policy.

Influence of participation

During the meetings, the FDA officials did not summarize the discussion or respond to the particular points and they did not indicate to participants whether they thought their views were correct, useful or relevant. The officials did not indicate how they would use the information they had obtained at the public meetings. Without being told this information, the participants could not know whether their participation at the meeting would have an impact on the policy.

The public meetings are not intended to be a referendum or consensus conference. The purpose was to gather relevant information for regulatory agency decisions. There was no agreement among the participants at the meetings with regard to labeling as indicated by the analysis of the participants' statements. On the issue of mandatory labeling, 54 audience speakers favored such a policy and 52 opposed a change (many speakers did not address the topic of labeling) (FDA 1999a,b,c). Furthermore, in weighing the opinions expressed at a public meeting, the number of speakers may be of less significance than the size of the stakeholder group and the degree to which the group would be affected by the policy.

The views of stakeholders and officials regarding influences of participation are discussed below under stakeholders' perceptions.

Perceptions of the process

According to the meeting transcripts, some panelists praised FDA for sponsoring the meetings and indicated that they perceived the procedure to be useful. Among

audience speakers, some expressed satisfaction while others were dissatisfied with the process because they felt they had not been given sufficient time to speak. FDA was also criticized for holding the meetings in venues that were too small to accommodate everyone wishing to attend the meeting in one room. Speakers who criticized the process in terms of logistics were also those who were critical of the FDA policies.

5.8.3 Public comments

Organization of the procedure

When the FDA's Center for Food Safety announced its draft "Guidance for Industry - Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" on January 18, 2001, it sought public comments in accordance with the law (FDA, 2001). In the months following the guidelines announcement, the FDA received nearly 40,000 comments. All public comments regarding the 2001 proposal were scanned and stored by FDA; many were posted on the FDA website in the dockets section.

Level of participation

The sample of the comments indicated that most comments were sent by e-mail. Of the messages in the sample that included addresses, the analysis found that comments came from 43 states, and the District of Columbia. California and New Mexico contributed far more comments than other states. The fact that comments came from many states shows that participation was widespread in geographic terms. Unfortunately, the information provided in the short comments is not sufficient to explain why the vast majority of comments came from a few states.

For the comments which indicated the gender of the writer, 427 were sent by women, while 222 came from men. The fact that more women than men responded to the

FDA call was consistent with US public opinion polls, which have shown that women are more skeptical about GM foods than men (ABC News 2001; Morris 2003).

Compared to other public comment events, such as the USDA comment process on organic food labeling, the number of comments was not very large. Further, it did not provide information from sources with views which had not been heard before. In addition, there was a narrow range of viewpoints expressed in the random sample of messages.

Quality of comments

FDA received comments from stakeholder organizations both in support of and opposing the proposed labeling guidance. Those supporting the guidance did not need to prepare new reasons for their support. The arguments in favor of voluntary guidance had been put forward earlier in the petition to FDA (GMA 2000). For example, a group representing the dairy industry sent a simple letter, encouraging, "the FDA to continue its practice of using sound science to develop policies regarding agricultural biotechnology" (International Dairy Foods Association 2001).

Some stakeholder groups representing consumers sent detailed new comments to FDA. For example, the Center for Science in the Public Interest (CSPI), an organization which advocates for consumers, provided technical comments from their own consumer research that showed that consumers preferred different terminology than the terms used in the FDA proposal, as shown in Table 5.2 (CSPI 2001).

Nearly all comments received by FDA and analyzed in this study consisted of short letters from individual citizens. The vast majority of comments stated that consumers had a right to know if foods were genetically modified, and they favored mandatory labeling of GM foods. The letters sent by individuals gave opinions and made assertions about risks of GM foods, but the authors did not explain the reasons for their opinions in detail or provide evidence to support their arguments (Annex 5.4).

The FDA sought new information in its request for comments; however, the letters did not provide new information that FDA might have considered to be evidence that met the criteria for mandatory labeling. The letters contained points that were not directly relevant to the questions asked in the announcement on voluntary labeling. For example, more than half the comments contained messages that expressed the view that FDA was favoring the biotechnology industry. Nearly half expressed concern about the environmental impact of bioengineering although this is not a food safety issue or a reason used by FDA to require labeling. All of the topics contained in the comments had been raised in the public meetings or other forums and they did not add new information.

5.8.3 Stakeholder perceptions

For this study, several of the issues that were raised in the 1999 public meetings and the 2001 public comments were revisited in 2003/04 in conversations with representatives of stakeholder organizations. The stakeholder representatives' perceptions of the topics and the extent to which they believed that FDA was influenced by the procedures are discussed below.

Prevention of misleading negative labeling

During the public meetings, conventional farmers and food manufacturers pointed to a need for guidance to prevent misleading labeling. These requests at the meetings were followed by a petition from six large food associations. Shortly after the petition was sent, the FDA developed guidelines to address the issue of misleading negative labeling. In the interviews, the conventional food industry representatives recognized that the agency had responded to their concern and said they were satisfied by the agency's actions.

In the interviews, a representative for the conventional food industry reiterated the organization's support for voluntary guidelines.

> The US policy is based on science; this is the 1992 policy. The 2001 voluntary policy is choice-based to give companies a choice to be able to label and say that a product "contains biotech food" or "does not contain" or is "organic." The 2001 policy initiatives were to round out the 1992 policy. It was to reinforce that there is a correct way to do this, to label foods in a way that is truthful and not misleading. This is the goal of labeling policy. [Food industry association]

Although it was the food industry that requested the guidelines to prevent misleading negative labeling, other stakeholders appreciated this guidance. Consumer organization representatives were also concerned about misleading labeling which might cause consumers to pay more for non-GM foods because they mistakenly believe the non-GM foods were superior in terms of quality and safety. The biotechnology industry also supported the guidelines as a means to prevent misleading labeling.

> FDA created the 2001 guidelines because of the underhanded ways people in the organic industry were misleading consumers with labels. The draft guidance is very good, we commend it, and we are extremely supportive of it. The guidance allows positive and negative labeling in a way that is truthful and not misleading. We applaud it. [Biotechnology industry]

Burdens on organic food producers

At the public meetings, statements by the organic food industry concerned the burden placed on organic producers to demonstrate that their products did not contain GM ingredients in order to be able to claim to be organic and to use the negative label "does not contain GM ingredients." Organic food producers wanted mandatory positive labeling (i.e. contains GM ingredients) for GM foods.

Interviews with representatives of the organic food industry revealed a negative perception of the FDA procedures and continued dissatisfaction with agency policies: “In 1999 the government knew there was a growing controversy. [The public meetings were] a public relations spin to say, “we’re looking at it.” They ignored the comments – most people were outraged, but what has become of that… it was a public relations show.” said an organic industry representative. Another organic industry expert said that the number of comments was not high because…”People are wary of how much officials respond to what they think; they don’t think sending comments has an effect.”

Calls for mandatory labeling

In the public meetings, organic producers and environmentalists, as well as some consumer organizations, expressed support for mandatory labeling of GM foods. In the public comments sent in 2001, the vast majority called for mandatory labeling.

In interviews with representatives of the biotechnology and conventional food industries, perceptions of the public comment procedure were negative. Supporters of FDA’s voluntary labeling approach were dismissive of critics who used the process of sending comments to call for mandatory labeling. According to these stakeholders, these comments were not representative of the public. They believed this public participation process should not influence the agency.

“I don’t think there is a demand for mandatory labeling. The activists beat the drums. There is a propensity for form letters. I don’t think form letters are very meaningful.” said a biotechnology industry representative. A food industry representative said: “FDA was required to take the comments into account. But it is important that FDA not be swayed by a small group, whoever shouts the loudest; they should serve the broad public.”

According to officials, soliciting public comments through the *Federal Register* is only one aspect of the process that determines policies. Further, the number of comments is less important than the quality of the comments. In the case of comments on the guidance on voluntary labeling, the quality of the comments was often weak, thus they had little impact. "FDA considers the comments, but this must be seen in light of the statutory authority. Consumers think we don't hear them [but] material fact and consequence of use are what determine labeling. There is nothing in the statutes to require biotechnology labeling." said an official. Another official said: "We have to weigh the comments; there can be a high number of comments, but they are post cards [which say little]. This is always a problem. A few good comments outweigh a large number of (superficial) comments. It isn't a vote."

Public information

Another request made at the public meetings by the conventional food industry, professional societies and organic producers was a desire for FDA to provide more public information about biotechnology and the regulatory process. In the interviews, expressions in support of this came from the biotechnology and conventional food industry. A biotechnology industry representative said: "One piece of information that would be useful would be if the government was more on board, if they told people about the processes they use to assure food safety. Not just biotech foods but food in general. The government websites could do this."

Others appreciated the provision of information by the government but recognized that the government was limited in its ability to carry out this type of activity. A commodity association representative said, "The government has done as well as it could do at providing information. They are very circumscribed by rules and regulations. The USDA Agricultural Research Service has dozens of very good studies. It did what it could by publishing studies."

Although the participation procedures had identified a desire by some stakeholders for FDA to provide more public information about biotechnology in general and regulatory processes for GM foods specifically, some of the experts interviewed for this study did not believe that FDA should respond to this request. An official and a researcher expressed the dilemma of a regulatory agency when faced with demands for information about a new technology and accusations of bias toward the technology provider. They pointed out that the difference between information and promotion could be so subtle as to place the government agencies in a position of being perceived as promoting the technology.

> The government, FDA, has to be careful to be seen as neutral, not as a proponent of biotechnology. We need to be seen as neutral, objective. We explain our policies. Of course, it is hard to not sound like we are promoting biotechnology because we are working on it. [Official]

> What role should the public sector have in providing information in this environment? They have the regulatory role, they can regulate misleading information. But I don't think the government can do anything when biotechnology is in jeopardy. There are strong arguments against it. The government is already seen as promoting biotechnology. [Researcher]

5.9 Conclusion

The US has a long tradition of public participation in policy decisions, which is embodied in several federal laws. In addition to these laws, information technology (websites and e-mail) has made it possible for more citizens to become informed, to participate, and to have their views made public than in earlier times. The information analyzed in this study demonstrated that FDA followed the established procedures and provided information and opportunities for the public to give their views about policies related to the labeling of GM foods as required by law.

The hypothesis presented at the beginning of this paper is supported in the sense that there is ample evidence that FDA fulfilled its legal obligations to encourage public participation and to consider a wide range of views as part of the information used to formulate a policy. There is also ample evidence that some stakeholders are more skilled in using the procedures than others and that those with less effective participation skills were more dissatisfied.

The fact that some stakeholders misperceived the procedures may be the result of agency errors. FDA failed to include one important stakeholder group, the organic food industry in the panels of the public meetings and the presence of environmental organizations, whose concerns are not within the scope of FDA's mandate, may have confused stakeholders and created an expectation that environmental issues would be considered. These two errors could have contributed to the dissatisfaction of some stakeholders who felt that their views had been ignored.

5.9.1 Implications

This study found that there was scope for improvement by FDA. Stakeholders who participate in public meetings and make comments on regulatory issues can improve their contributions as well.

Implications for FDA

In fulfilling its obligations to facilitate public participation FDA could assist the public to prepare for their participation. In general, a regulatory agency should explain the purposes of participation procedures and how the information will be used, in order to avoid misunderstanding and disillusionment by participants (Stern and Feinberg 1996). In the area of labeling, clearer information about the purposes of labeling would help the stakeholder groups and citizens to have realistic expectations when demanding more labeling information.

Various stakeholder organizations called for more public information about regulations during the participation procedures and in interviews. FDA, EPA and USDA should develop approaches to informing the public more clearly about the ways that the federal government regulates biotechnology and should explain their respective areas of responsibility. Although information about the coordinated framework is available on the US government websites, average citizens may be unaware of the distinctions the agencies make in terms of responsibilities or how the agencies interact with each other.

The fact that three agencies (FDA, USDA and EPA) coordinate the regulation of biotechnology presents a challenge to stakeholders who wish to participate in debates about this technology. If citizens and stakeholder organizations address their complaints to the wrong agency and the agency does not consider their views because these issues do not fall under the agency's mandate, the individual citizens and stakeholders may interpret the lack of response as disregard for their views.

In this study, the questions raised about environmental risk should have been addressed to the EPA, but citizens may not have realized this. During the public meetings, the panels included environmental organizations such as Greenpeace, the Environmental Defense Fund and others whose primary focus is the environment (Annex 5.2). This may have given the impression that environmental factors were within the mandate of FDA and that they would be considered in FDA policy decisions. However, environmental considerations which do not relate to food safety are not considered to be a reason for mandatory labeling. When communicating with the public, the agencies should be very clear and explicit about which topics will be considered in a particular policy decision. When a decision is announced, the agency should explain why some views were not accommodated. Since a final decision on the FDA draft guidelines has not been announced, it is not possible to know whether FDA will provide such explanations in the *Federal Register*.

When the agency carries out a participation procedure, it could make an effort to ensure that the participation reflects the true patterns of the society and that the degrees of influence are more transparent. For example, those who represent larger groups or groups with a larger stake in the issue might be given a different weighting than those who represent groups or individuals with less stake in the debate and this should be explicitly said. Participatory exercises such as consensus conferences could be organized to allow sufficient time for the participants to present their views and to interact more with experts and other participants. Alternative participatory methods, for example, citizen panels, that would involve smaller meetings, extending over longer time periods might be more satisfying to participants than the large public meetings conducted by FDA.

The public comments in response to the *Federal Register* announcement were criticized by some stakeholders and appeared to have relatively minor value in terms of influencing decisions. FDA may consider ways to structure their questions and forms of assistance to citizens to improve the comment exercises and enable citizens to prepare comments that are more relevant and useful in the decision making process.

Implications for stakeholder organizations

Stakeholder organizations might have more impact on the decisions of a regulatory agency if they improved the quality of their comments at meetings and in replying to the agency's request for comments.

When FDA issued its draft guidance, the agency specifically said:

> [The agency] is still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed… (FDA 2001, 4840)

Thus, advocates of mandatory labeling were specifically invited to provide these data or information. However, the vast majority of participants did not do this. Legal and scientific expertise is needed to prepare effective comments and public statements. Stakeholder organizations that lack this expertise would benefit from making use of the expertise of larger organizations and coordinating their participation with other organizations and individuals. By combining resources and submitting joint statements to a regulatory agency, the group may have more impact. For example, stakeholder groups that represent a large number of constituents (e.g. Consumer Federation of America) may have more credibility and influence than small groups. In this study, the petition from 6 food industry organizations drew the agency's attention.

To be effective, stakeholder groups must recognize that regulatory agencies operate within strict legal and scientific parameters. Regardless of whether the stakeholder organization agrees with the values of the agency or the way that it has approached the topic, the stakeholder organization should directly address the specific questions posed by the agency. Pursuing arguments that are beyond the mandate of a particular agency is bound to be ineffective.

Recognizing the limits of participation processes sponsored by regulatory agencies does not imply that arguments which fall outside the scope of the agency (e.g. ethical or economic considerations) are not worthy of consideration. However, these arguments should be raised in the public fora which are mandated to address these types of considerations. Stakeholder organizations may believe that they benefit from publicity by participating in any process, however, this should be carefully weighed against the credibility they may lose with other stakeholders, officials or the public if their manner of participating is not considered to be appropriate.

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Annex 5.1: FDA authority regarding foods derived from biotechnology

Under the Reagan Administration, the President's Office of Science and Technology Policy established a coordinated framework for regulating agricultural biotechnology (Executive Office of the President 1986). According to this framework, the FDA, as well as the Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) are to use existing statutes for regulating different aspects of biotechnology. The FDA is responsible for regulating food, feed, food additives, veterinary drugs and human drugs; USDA regulates plant pests, plants and veterinary biologics; and the EPA regulates microbial/plant pesticides, new uses of existing pesticides and novel microorganisms (Ibid.).

In anticipation of the first commercial release of whole foods produced through genetic engineering, the FDA "Statement of Policy: Foods Derived from New Plant Varieties; Notice" was published to clarify questions which had been raised by the food industry, government agencies, the academic community and the public (FDA 1992). FDA summarized the inquiries as follows:

> "The questions that FDA has received center on issues such as whether the agency will conduct pre-market review of these new foods, whether such foods introduced into interstate commerce would be challenged by FDA on legal grounds, which new plant varieties might come under the jurisdiction of FDA, what scientific information may be necessary to satisfy FDA that such foods are safe and comply with the law, whether petitions would be required by the agency, and whether special labeling would be required." (FDA 1992, 22984).

In this statement, the agency identified potential changes in plants that could cause safety concerns (e.g. toxicants and allergens). They presented a model (decision tree)

for assessing the safety of the foods, which indicated when FDA should be consulted.[24] All of the types of risks which have been raised by critics were anticipated by FDA and explanations were given as to how the agency would address the problems.

Food producers were reminded of their legal responsibilities to ensure the safety of the foods and that FDA had strong enforcement powers to assure food safety and the authority to require pre-market review and approval when necessary to protect public health (FDA 1992, 22939).

[24] FDA's approach in 1992 was based on their experience with evaluating the data from Calgene, Inc., producers of the first whole food derived from genetic engineering. For a detailed history of the consultative process between Calgene and FDA from the perspective of a company scientist, see Martineau, 2001.

Annex 5.2: FDA Public Meeting Panels

PUBLIC MEETING (CHICAGO, ILLINOIS, NOVEMBER 18, 1999)

Dr. Ralph Hardy, National Agricultural Biotechnology Council

Dr. Val Gidding, Biotechnology Industry Organization

Dr. Michael Jacobson, Center for Science in the Public Interest

Mr. Charles Margulis, Greenpeace Genetic Engineering Campaign

Dr. Steven Taylor, Food Science and Technology Department, University of Nebraska

Dr. Barbara Glenn, Federation of Animal Science Societies

Dr. Marion Nestle, Nutrition and Food Studies Department, New York University

Dr. Michael Phillips, Biotechnology Industry Organization

Ms. Lisa Katic, Grocery Manufacturers of America

Mr. Carl Loop, American Farm Bureau Federation

Dr. Edward Groth, Consumers Union

PUBLIC MEETING (WASHINGTON D.C. NOVEMBER 30, 1999)

Dr. Peter R. Day, Biotechnology Center for Agriculture and Environment, Rutgers University

Ms. Carol Tucker Foreman, Food Policy Institute, Consumer Federation of America

Dr. Rebecca J. Goldberg, Environmental Defense Fund

Mr. Steve M. Druker, J.D., Alliance for Bio-Integrity

Dr. Samuel Lehrer, Professor of Medicine, Tulane University

Dr. Terry D. Etherton, Dairy and Animal Sciences Department, Pennsylvania State University

Dr. Mario Teisl, Resource Economics and Policy Department, University of Maine

Dr. Mildred Cody, Nutrition Professor, Georgia State University

Mr. Richard Caplan, Environmental Advocate, US Public Interest Research Group

Mr. Richard Frank, Outside Counsel to Food Distributors International

Dr. Kendal Keith, National Grain and Feed Association

Dr. Robert Cohen, America's Dairy Education Board

PUBLIC MEETING (OAKLAND, CALIFORNIA, DECEMBER 13, 1999)

Dr. Calvin O. Qualset, Genetic Resources Conservation Program, University of California, Davis

Dr. John Fagan, Genetic ID

Dr. Philip J. Regal, Ecology, Evolution and Behavior Professor, University of Minnesota

Dr. Susanne L. Huttner, Systemwide Biotechnology Research and Education Program, University of California, Berkeley

Dr. Susan L. Hefle, Food Allergy Research and Resource Program, University of Nebraska, Lincoln

Dr. R. L.Baldwin, Jr., Animal Science Professor, University of California

Dr. Thomas J. Hoban, IV, Sociology and Anthropology Department, North Carolina State University

Dr. Andrew Kimbrell, International Center for Technology Assessment

Dr. Rhona S. Applebaum, National Food Processors Association

Ms. Susan E. Haeger, Citizens for Health

Ms. Diane Joy Goodman, Farm Box Project Consulting

Mr. David A. Bossman, American Feed Industries Association

Annex 5.3: US stakeholders' positions in the 1999 FDA public meetings*

Categories of US stakeholder and types of positions							
Support for policy	Biotechnology Industry	Farmers and commodity associations	Food processors/ manufacturers	Organic food producers/ natural foods	Environmental advocates	Consumer advocates	Professional associations
No change in 1992 policy	14	14	3				21
Information on regulatory process	3	4	2				5
Mandatory notification		4	1		1		3
Mandatory safety testing		2		6	8	5	3
Mandatory labeling		1		19	16	12	6
Precaution/ ban GM foods		1		11	11	4	4
More information on biotechnology		5	1	4	1		6
Labeling burden to organic				12			
Prevent misleading claims		3	3				

*Some participants expressed positions on more than one issue. Some participants did not speak on any of these issues.
(Sources: FDA 1999a,b,c)

Annex 5.4: Examples of comments sent to FDA regarding the proposed labeling guidance

Example A

"I am outraged by your new policies on genetically engineered (GE) foods. Despite overwhelming consumer demand, your agency still fails to require safety testing and mandatory labeling for GE foods. Your "notification" (in original) policy is an insult to consumers, and irresponsibly ignores strong scientific evidence of numerous potential health and environmental risks to GE foods. You should be aware that these foods could be toxic, could cause allergic responses, could have lower nutrition value, could compromise immune responses in consumers, and could cause irreparable damage to the environment.

I am also greatly opposed to your new "voluntary labeling" policy, which denies consumers a basic right to know. Without mandatory labeling, neither consumers nor health professionals will know if an allergic or toxic reaction was the result of a genetically engineered food. Consumers will also be deprived of the critical knowledge they need to hold food producers liable should any of these novel foods prove hazardous.

Your proposed rules ignore serious concerns, and appear to be a decision made to convenience industry at the expense of public health and the environment. I will not accept your attempt to make me and my family guinea pigs of these untested foods, and I trust you will take my concern along with the thousands of others into serious consideration" (Howard 2001)

Example B

"The new regulations and guidelines put forward by your agency on genetically engineered (GE) foods are a disappointment for American consumers. Despite overwhelming and consistent demand, your agency still fails to require comprehensive safety testing for GE foods. The notification policy ignores strong scientific evidence of numerous potential health and environmental risks to GE foods, and allows the current system of laissez-faire oversight to continue. As you know, genetically engineered foods can be toxic, cause allergic responses, have lower nutrition value, compromise immune responses in consumers, and cause irreparable damage to the environment. I am also greatly opposed to your new "voluntary labeling" (in original)policy, which denies consumers a basic right to know.

Without mandatory labeling, neither consumers nor health professionals will know if an allergic or toxic reaction was the result of a genetically engineered food. Consumers will also be deprived of the critical knowledge they need to hold food." (Friedman 2001)

Example C

"Consumers everywhere want to know if the food they are sold is genetically modified. These foods could be toxic, could cause allergic responses, could have lower nutrition value, could compromise immune responses in consumers, and could cause irreparable damage to the environment.

"Voluntary labeling" (in original) policy is NOT enough. Without mandatory labeling, neither consumers nor health professionals will know if an allergic or toxic reaction was the result of a genetically engineered food. Consumers will also be deprived of the critical knowledge they need to hold food producers liable should any of these franken foods prove hazardous.

Your proposed rules ignore serious concerns, and appear to be a decision made to convenience industry at the expense of public health and the environment. I will not accept your attempt to make me a guinea pig of these untested foods, and I trust you will take my concern along with the thousands of others into serious consideration." (Guth 2001)

Example D

"The proposed Food and Drug Administration (FDA) regulations fail to require labels or safety tests on genetically engineered (GE) food. The new rules continue to deny Americans the right to know what is in our food, while protecting the economic interests of biotech corporations.

Labeling GE foods would protect the public from potential health effects that could only be traced if GE foods can be identified. By refusing to require both labeling and mandatory safety testing of foods, the FDA puts consumer's health at risk, and ignores the recommendations of the Biotechnology Consultative Forum, who in December urged the US to require mandatory labeling of GE foods.

I urge you to reconsider this proposal and insure that GE foods are subject to pre-market testing and labeling. Americans have a right to make informed decisions about the food we consume." (Nicholas 2001)

Example E

"I am concerned about the labeling of genetically engineered foods. This important health concern should not be up to the voluntary concerns of the companies developing biotech product. A stringent consumer oriented set of rules that informs the consumer of product content should be in effect." (Weiss 2001)

CHAPTER SIX: FOOD INDUSTRY RESPONSES TO US AND EU POLICIES FOR LABELING GM FOODS

Abstract

Food labeling policies aim to ensure, among other things that consumers have accurate, relevant information about a product so that consumer choices and prices paid can reflect consumer preferences, and producers can compete fairly in the marketplace. When consumers lack information that producers possess about a product trait, the information asymmetry that exists can inhibit the functioning of a competitive market. When traits that are important to consumers are not apparent, product labeling is one mechanism for ensuring that consumers have information about such traits. The case of genetically modified foods (GM) in the United States (US) provides an excellent opportunity for the investigation of the role of labeling in addressing the issue of information asymmetry in the food market. Although an estimated 70-75 percent of processed foods contain GM ingredients in the US, surveys show that many US consumers underestimate the amount of GM foods they consume (PIFB 2006). There is no way to know how consumers would actually react to information stating that the foods they purchase contain GM ingredients, since such information is not available to them.

To address the fact that consumers cannot distinguish between foods that are GM and those that are conventional or organic, the Food and Drug Administration (FDA) in the US in 2001 developed a labeling policy for GM foods. Under this policy labeling is voluntary: label format and content requirements are specified, but marketers may choose whether or not to label their products as GM or non-GM. In contrast, in 2003, the European Parliament enacted a mandatory labeling law that went into effect in 2005 requiring foods with GM content to be so labeled. US food products destined for any of the 27 countries belonging to the European Union (EU) must comply with this mandatory labeling rule for foods that contain GM material above a threshold of 0.9 percent.

This paper reports on an investigation of the responses of the US food industry to these labeling laws. From May 2003-April 2004, in-depth interviews were conducted with representatives of 20 organizations in the US representing food producers, the biotechnology industry, consumer organizations, critics of agricultural biotechnology and government officials. The study found that it does not matter if a labeling policy is voluntary or mandatory; food companies decide whether to label their products based on their analysis of the benefits and risks of informing consumers about a product trait. In the current market environment, in which food producers believe that consumers prefer foods that are not GM; producers avoid labeling foods as GM. Where labeling is voluntary, the companies choose not to label; where labeling is mandatory, the companies choose to produce foods that do not contain GM ingredients. In both the US and the EU cases, labeling laws are not functioning to inform consumers about GM foods in the marketplace. The laws are not enabling the market to reveal consumers' preferences for GM and non-GM foods: the premium they are willing to pay for non-GM foods, and the price at which they are willing to consume GM foods. Even producers of certified organic food in the US, who by definition do not use GM ingredients, and who therefore might see a potential benefit in labeling foods as "not containing GM ingredients" perceive such labeling as risky, particularly because the potential for adventitious presence of GM material in non-GM foods is high. Therefore, voluntary labeling was not widely used even for foods that were not GM.

In the US, commercially available GM foods do not have traits that appeal to US consumers. In this environment, it is unlikely that the food industry will label foods as containing GM ingredients in the near future, and the imperfect market condition will persist in the US. In the EU, a milieu of deep consumer skepticism about GM foods exists, and food producers selling in Europe prefer to avoid GM products rather than label foods as containing GM ingredients. The effect of the labeling policy is to reduce the amounts of GM foods available to European consumers. Therefore, the US and the

EU policy for labeling GM foods have not had significant impacts as measures to provide consumers with information about GM food products and to permit the market to reveal consumer preferences regarding GM foods.

6.1 Introduction

The United States of America (US) is the largest producer of genetically modified crops (GM) in the world: of the 102 million hectares (252 million acres) of land that were planted in GM seeds worldwide in 2006, 54 per cent were in the US (James 2006). It has been estimated that 70-75 percent of processed foods in the US contain GM ingredients, yet many US consumers are unaware of this fact. In surveys of the US general public conducted by the Pew Initiative on Food and Biotechnology (PIFB), approximately 60 percent of respondents believed that they had not consumed GM foods, and the researchers found that, "[C]onsumers have consistently underestimated the amount of GM foods they most likely have eaten…" (PIFB 2006). Given the promotion of the agronomic benefits of GM seeds, American farmers are undoubtedly aware of the presence of GM foods in the food supply. The US farmers who produce soybean, corn, squash, papaya, canola, cotton and alfalfa (products on the market in 2006) with GM seeds must have a license to grow these crops since these products are patented; therefore, they are certainly aware of the types of seeds being used and whether they are GM or not. Commodity dealers, large food manufacturers and retailers may be aware of the presence of these foods if they test foods for the presence of altered DNA. However, individual consumers do not have an easy way of knowing whether they are consuming foods with GM content. Thus consumers cannot show, through their purchasing choices, their willingness to consumer GM foods, the price differential at which they would consume such foods, and the prices they are willing to pay to avoid them.

6.1.1 Information and effective functioning of the market

In order to have efficient markets that serve consumer preferences, both buyers and sellers must have the same information, so that prices can be determined for products that have different qualities. When the buyers and sellers do not have full and equal knowledge, the market allocation of resources becomes inefficient. Sellers may ask a high price for goods that do not necessarily contain high quality ingredients, and uninformed consumers may pay for a good that is lower in quality than expected; this phenomenon is called "adverse selection" (Wilson 1987; Mankiw 1998). When there is unequal access or "asymmetric information" there is the potential for unfair competition among producers as well as unfair prices for consumers.

> Without information, consumers may be unable to accurately match preferences with purchases, and producers may be unable to compete fairly because information about competing product standards is not widely available. If both buyers and sellers have more information, they may be able to reduce their search and verification costs, thereby, facilitating trade. (USDA 2003, 1)

Adverse selection and asymmetric information can arise in the market for foods because some qualities of food are not readily apparent to consumers through experiences of seeing, tasting, smelling or feeling. The types of qualities that are not revealed even after the product has been consumed are known as "credence" qualities (Jahn et al. 2005). The fact that a food contains or does not contain a GM ingredient is a credence quality; this aspect of the specific food product can only be detected with certainty by complicated laboratory analyses.

In extreme cases, asymmetric information can threaten the existence of a market, if consumers lose confidence in the products being sold because they cannot determine the quality (Fischer and Dornbusch 1983). One way for governments to intervene to

protect consumer confidence in the market is by developing rules for labeling products in a manner that is truthful and not misleading. The food labels should be supported by reliable systems that can verify the information about the product.

6.1.2 An individual firm's perspective on food labeling

Acting upon their individual firms' business needs, food producers must decide how to respond to a food labeling policy. Companies base their labeling decisions on consumer research and experiences that suggest how consumers will react to the information on the food label within a given context. They may avoid providing information if they believe it will inhibit the success of their product: "Sellers are not likely to seek to undermine their product by expressing negative values on a label if they do not have to, so it follows that values expressed in labeling will be positive and hence identifiable as a promotional tool…" (Pearce 1999, 33). When labeling is mandatory, companies may comply with the laws by labeling, or they may reformulate the product if possible to avoid the requirement to disclose information if they believe it will harm their business.

6.2 Purpose of this study

GM foods provide a case study to examine why labeling policies can be ineffective in resolving the issue of information asymmetry in the US food market. Since consumers cannot identify the foods which do or do not contain GM ingredients through their own perception or experience, proponents of labeling have argued that adding information about GM content to the package would allow consumers to easily search for products which are or are not GM and to make price and quality comparisons based on this trait. Opponents of GM labeling have argued that such labels would cause consumers to be misled into thinking such products are less desirable, and consumers may be

encouraged to pay more for products unnecessarily or to avoid products for reasons that are not relevant to consumer welfare.

This paper reports on an investigation of the manner in which the food industry in the US is responding to two labeling policies regarding foods that contain GM ingredients: the US Food and Drug Administration's 2001 proposal for voluntary labeling[25] and the 2003 EU policy requiring GM foods to be labeled if the GM material exceeds 0.9 percent.[26]

As explained above, a voluntary labeling policy can only succeed if the food companies choose to label. If they do not perceive incentives for labeling foods and the perceived risks and costs outweigh the benefits, labels will not be used on products. It is also possible that a mandatory labeling policy will not be used if the risks of labeling are perceived to be high; in the case of GM foods, companies will avoid mandatory labeling by sourcing only non-GM ingredients rather than risk losing sales of their products.

6.2.1 Hypotheses

This study sought to explain the factors that the US food industry considers when deciding whether or not to label their food for GM content. The incentives for labeling in terms of additional sales and positive image of the product must outweigh the disincentives such as costs of labeling, risks of lost sales and negative images of the product. The study hypothesized that the conditions in the US and EU are not conducive to the successful implementation of the labeling policies that have been developed by the US and EU authorities. Under these conditions, the following situation will be found:

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[25] "Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." US FDA. Center for Food Safety and Applied Nutrition, January 18, 2001 (FDA 2001).

[26] "Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed." *Official Journal of the European Union* L268: 1-23 (European Parliament 2003).

1) US food producers see no benefit at the present time in labeling foods as containing GM ingredients, and they do see potential risks. Their response to the FDA voluntary labeling policy is not to label foods as containing GM ingredients when the foods are sold in the US.

2) US producers will avoid labeling foods as containing GM ingredients when they are to be sold in the EU. Their response to the European Parliament's mandatory labeling policy is to purchase non-GM food ingredients for products sold in Europe, rather than taking the risk of labeling GM foods.

3) The food producers who do not use GM ingredients may view the option to label foods as "not containing GM ingredients" as a business opportunity. However, the risks and costs of certification required to ensure that the product complies with the criteria for truthful, non-misleading labeling may outweigh the benefits of labeling.

4) In the current milieu of industry perception of consumer preference for non GM foods, neither voluntary nor mandatory labeling laws will address the lack of consumer information in the market (i.e. the market failure of asymmetric information).

The study demonstrates that individual businesses do not view labeling as worthwhile, and they see it as a business risk. Therefore, food companies have not chosen to label, and the problem of asymmetric information persists. In both the US and EU, the milieu is not conducive to allow food labeling policies to be implemented and to foster a true competitive market that satisfies the criteria of fulfilling consumer preferences and technical efficiency. Under conditions in which the market for GM foods and foods that exclude GM ingredients is not functioning properly, the biotechnology industry and others are unable to assess the extent to which consumers accept or reject this technology, and the expansion of GM foods may be hindered.

6.3 Methods

6.3.1 Qualitative interviews

To obtain information about the views of the conventional and organic food producers regarding the US and EU policies on labeling of GM foods, in-depth interviews were conducted with representatives of stakeholder organizations in the US as well as government officials and independent experts. Stakeholder groups were identified through searches of public reports of meetings, published articles, organization websites and professional contacts. This study included US food producers and addressed their decisions for marketing their brands in both the US and Europe. The study did not include European food producers.[27]

Nearly all of the individuals interviewed had extensive expertise in the areas of food production, agricultural biotechnology, food regulations or consumer rights. Of the 29 organizations and 4 individuals who were contacted, 24 organization representatives from 20 organizations and 2 individual experts agreed to be interviewed. The names of the stakeholder groups are shown in Table 1.

[27] There was a moratorium on approvals of GM varieties in the EU from 1998-2003. Therefore, it was extremely unlikely that the European food companies were using GM crops at the time of the interviews.

Table 6.1: Stakeholder groups interviewed about biotechnology and information	
Commodity producers	Corn Refiners Association, Inc. American Soybean Association
Biotechnology industry	E.I. du Pont de Nemours and Company Monsanto Company Biotechnology Industry Organization
Conventional food industry	National Food Processors Association Grocery Manufacturers of America Kraft Foods North America Procter and Gamble Company General Mills
Organic food industry	Organic Trade Association Organic Farming Research Foundation
Foundations	International Food Information Council Pew Initiative on Food and Biotechnology
Critics of biotechnology	Campaign to Label Genetically Modified Foods Institute for Social Ecology
Consumer advocates	Center for Science in the Public Interest Consumer Federation of America Consumers Union

* Names of individual respondents have been removed to protect confidentiality as promised at the time of recruitment into the study.

Collectively, the industry participants in the study represented organizations whose members produce the majority of food products and GM seeds in the US. For example, the Grocery Manufacturers Association (GMA) membership during the period under study included companies that produced 90 percent of the food, beverages and consumer products sold in the US, with national sales of more than $450 billion (Katic 1999). The National Food Processors Association (NFPA) represented many of the same

food companies and "was the voice of the $430 billion US food processing industry on scientific and public policy issues..." (Applebaum 1999). The $15 billion organic food industry was represented by the Organic Trade Association whose membership includes nearly 1,550 farmers, processors, importers, exporters, distributors, retailers, certifiers in North America (Organic Trade Association 2000). The Biotechnology Industry Organization (BIO) was the representative of 503 large and small biotechnology companies producing agricultural and pharmaceutical products (Biotechnology Industry Organization 2003).

The views of these stakeholders' representatives were considered to be strong indicators of the most commonly held views of decision makers within US food companies. In addition, representatives from three large food manufacturing companies were interviewed to gain more detailed information about the reasons for the positions taken by individual companies.

From May 2003-April 2004, telephone interviews were conducted in which questions were posed about biotechnology, the controversy over the technology, FDA policies, labeling, public information and communication to senior representatives of food producers and biotechnology companies (Table 6.2). Representatives of consumer organizations, critics of agricultural biotechnology, US officials and researchers with expertise in labeling and regulation of biotechnology were interviewed as well.

Table 6.2: Interview questions
Please describe your involvement in decisions regarding biotechnology and labeling at (organization)?
Why do you think the FDA announced draft guidance for voluntary labeling of foods which have been produced using bioengineering and foods which do not contain bioengineered ingredients?
What do you think of the proposal for voluntary labeling?
For your organization, could labeling serve a useful purpose?
Would you label foods as containing bioengineered ingredients an/or not containing bioengineered ingredients?
Would labeling place an unfair burden on some sectors of the food industry?
Has mandatory labeling in other countries had an impact on your company?
Why did other governments enact this type of labeling requirement?
Have most American consumers heard about biotechnology?
Does knowledge that a product contains ingredients produced through biotechnology affect food purchases?
Why do some people say that they want mandatory labeling?
What are people seeking when they demand a label?
What are the causes of controversy over biotechnology?
Do you think that providing more information would reduce some of the tension which has arisen over biotechnology?
Do you think there is anything the food industry or biotechnology industry should do in response to the critics?
What kind of information would be needed?
Who should be responsible for informing the public about new developments in technology?
Would labeling give consumers some of the information they need to make choices?
In this way, will their purchases indicate whether consumers accept or reject this new technology?

6.3.2 Review of the Literature and Contemporary Documents

To identify relevant articles for this study, several key terms were used including: agricultural biotechnology, genetically modified, food labeling, genetic engineering, regulatory agency, consumer perception, risk communication or organic food. Documents were collected through the US Library of Congress and the David Lubin Memorial Library of the Food and Agriculture Organization of the United Nations as well as through internet searches using the Proquest and Eurolaw databases. The electronic newsletters and press releases of the Pew Initiative on Food and Biotechnology, the Food Navigator.com/Europe and newspapers such as the *Wall Street Journal* and *The New York Times* provided timely information and analysis.

6.4 Background

In this study, the specific policies for GM labeling in the US and EU are examined within the context of the general approaches to food labeling in the US and the EU. In addition, these policies can be viewed as aspects of the regulatory approaches used in the US and EU with regard to GM crops. In this section, these general approaches are summarized and the US and EU rules for GM labeling are explained.

6.4.1 Purposes of food labeling

Food labeling policies may be initiated to address the problem of asymmetrical information by making invisible ("credence") traits visible, so that markets can function to reveal consumer preferences. Labeling also serves the purposes of giving consumers warnings, instructions and other types of information deemed to be important for their welfare, even if many do not recognize the value of the information and demand it themselves.

Mandatory labeling

For cases when the omission of information would have negative consequences for consumers, the US Congress has given the Food and Drug Administration (FDA) the authority to require that a producer disclose the information (United States Congress 1938). The US Congress itself has enacted mandatory food labeling policies concerning nutritional content, presence of additives, and acceptable health claims (e.g. Nutrition Labeling and Education Act of 1990). By the late 1990s, a range of mandatory food labels had been introduced in the US including information that informs a consumer about: (a) product identity, (b) product ingredients and composition, (c) facts material to consequences of use (including safety concerns), and (d) any special requirements or provisions such as nutrition labeling and the ability to make health claims.

Voluntary labeling

When labeling is desired by producers or consumers, but the information is not considered to be "material" and necessary by the authorities, labeling is voluntary. Food producers may voluntarily provide information on a package to draw attention to specific credence qualities that are viewed positively in order to differentiate their products from those of their competitors (Nilsson et al. 2003).

Misleading labeling

The 1938 FDCA mandates the FDA to ensure that the information made available on food packages is truthful and not misleading to consumers. According to the Act, a product can be considered misbranded and in violation of federal law:

> …[If] the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article …
>
> A food shall be deemed to be misbranded - (a) If (1) its labeling is false or misleading in any particular… (US Congress 1938).

FDA authority to require labeling or prohibit it has been variously interpreted over the years by FDA officials, and sometimes this authority has been strengthened by new legislation. FDA authority has also been reduced at times. In 2002, the US Supreme Court ruled that FDA could restrict false and misleading information but could not limit truthful commercial speech (Adams 2002). Although the case that led to this decision was unrelated to GM foods, the stance taken by the court may have caused FDA lawyers to be wary of attempting to impose a mandatory labeling policy.

In Europe, similar laws have been enacted. In 1978, the European Economic Community stated:

> The labeling and methods used must not be such as could mislead the purchaser to a material degree, particularly: as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production, by attributing to the foodstuff effects or properties which it does not possess, by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics… (European Economic Community 1978).

In a global food market, the laws of other countries are relevant to US food producers. The concept that labels must not mislead consumers has been endorsed by the international food standards setting body, the Codex Alimentarius Commission. The Codex General Standard for the Labelling of Prepackaged Foods states: “Prepackaged

food shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect." (CAC 2005, 2). While Codex standards are voluntary, food traders should expect that regulatory authorities in different countries will respect these standards.

Common ways that labels can mislead consumers include: 1) omission of a material fact that a consumer needs; 2) use of confusing language, symbols or images; and 3) inducing the consumer to make false comparisons (e.g. that a product has a special trait when, in fact, all products of its kind have the same trait) (CCFL 2001).

Even when there are effective efforts to ensure that specific label statements are not misleading, one of the challenges of labeling is that consumers do not know which of the various rationales for labeling led to the specific label on the product they may purchase. Thus, there is the risk that a consumer may be unable to distinguish between information that is given as a mandatory warning, as a voluntary promotional tool, or simply to facilitate choice in a competitive market. When a consumer misperceives the reason for the label (e.g. believes the label is a safety message when in fact it is a marketing tactic), the consumer may pay more than is necessary for the product (Caswell and Mojduszka 1996). Thus, each label must be considered within the environment in which it the product is being sold, and consideration should be given to the prior information that the consumer has received about the product or, in the case of GM foods, about biotechnology.

6.4.2 GM food labeling in the US and EU

Status of GM crops in 2006

Since genetically modified seeds were released commercially a decade ago, planting has expanded to 102 million hectares worldwide in 2006; 54.6 million hectares (54 percent) were planted in the US (James 2006). In contrast, in the EU, farmers in only six countries, Spain, France, Czech Republic, Portugal, Germany, Romania and Slovakia have planted GM crops commercially; the total area amounting to 0.45 million hectares in 2006 (James 2006). The spread of GM seeds in Europe was limited by a de facto moratorium on approval of GM crops that existed for 6 years (1998-2003) in Europe, an action that led to a complaint by the US, Canada and Argentina at the World Trade Organization (WTO) in 2003 (Deily 2003). At the same time that the EU was lifting its moratorium on the planting of GM crops in 2003, it made the policy on labeling more stringent. In 2006, the WTO ruled in favor of the US, Canada and Argentina in their complaint (Fletcher 2006). In spite of the lifting of the official ban on GM crops, the adoption of GM foods in the EU has been very slow, and some individual countries continue to prohibit the cultivation of GM seeds (Fletcher 2007). For example, in 2006 Greece came into conflict with the European Commission (EC) because Greek farmers objected to the planting of GM corn although the EC viewed the seeds to be safe (Miller and Clark 2006; Rosenthal 2006). The farmers believed their conventional corn would be less marketable if the crop became mixed with the GM corn; however, the EC did not consider this to be a justification for banning a crop (Ibid). Greece is among five EU members that have continued to ban the planting of GM foods against the wishes of the EC (Rosenthal 2006).

6.4.3 GM Labeling in the US

Under the first Bush Administration (1989-1993), the administration decided to facilitate rapid innovation of biotechnology and that the technology should be regulated so as "to protect safety without unnecessary burdens" (Quayle 1991). In January 1992, then President Bush announced a 90-day moratorium on new regulations, during which time "[the President said] that 'regulations deemed pro-growth were to be accelerated.' while those which might impose substantial economic costs were examined to determine if they would produce sufficient benefits, flexibility, clarity, and use of market mechanisms" (Eisner 2000,185).

It was within this philosophical context that the FDA "Statement of Policy: Foods derived from new plant varieties," was announced in May 1992. According to the 1992 policy statement on the regulation of foods derived from agricultural biotechnology, the fact that a food had been developed through recombinant DNA techniques was not considered to be material by the agency. In cases where there is no material difference between the GM food and the conventional food, FDA stated that there was no legal basis for mandating labeling of the GM foods. The 1992 policy stated:

> The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components). Consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted. (FDA 1992, 22991).

Although labeling for GM content is generally voluntary, labeling may be considered mandatory if the resultant food is materially different from its conventional counterpart or poses any risks in human consumption.

Largely in response to the international controversy over GM foods and the US food industry's concerns that labels claiming to be "GM free" would stigmatize GM foods, the Clinton Administration (1993-2001) decided to review the 1992 policy in 1999, and the FDA developed guidelines for voluntary labeling of products of biotechnology in 2000 (FDA 1999; GMA 2000; FDA, 2001). On January 18, 2001, the FDA announced the draft: "Guidance for Industry, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" (FDA 2001).

The designers of the guidance attempted to anticipate how a company might want to use a label, and the agency set a standard so that consumers would understand the meaning of the statements and would not be misled by the labels. In a scenario of GM products that possess qualities that might attract consumers, companies could make a positive statement "contains GM ingredients," and the guidance provided options for declarations explaining that a food is produced through biotechnology; however, FDA set rules for making claims or inferences about the benefits of the technology. In a scenario where food companies believe that consumers want to avoid GM foods, the package could have a negative statement "does not contain GM ingredients" and the guidance set rules about claims or inferences concerning the risks of a bioengineered food. The main features of the guidance are shown in Table 6.3.

Table 6.3: Main Features of the FDA 2001 guidance (adapted from FDA 2001)
Bioengineered
Optional to say "contains (product) developed/produced through biotechnology"
Allowed to claim "developed through biotechnology because (positive reason)" but must substantiate claim. (emphasis added)
Cannot claim benefits for whole product if amount of positive ingredient insignificant
Must disclose allergens not found in conventional counterpart
Must change name if significantly different
Optional to say "contains (product) developed/produced through biotechnology"
Allowed to claim "developed through biotechnology because (positive reason)" but must substantiate claim. (emphasis added)
Cannot claim benefits for whole product if amount of positive ingredient insignificant
Must disclose allergens not found in conventional counterpart
Must change name if significantly different
Label may apply to human foods and animal feeds
Non-bioengineered
All ingredients must be non-bioengineered
Cannot imply that specific product is non-bioengineered if no products of this type are bioengineered.
Can say all foods of a type are non-bioengineered
Must be able to substantiate "non-bioengineered" through testing, documentation, segregation
USDA certified organic foods are non-bioengineered by definition
Permitted to say biotechnology not used if there is no suggestion that product is superior (emphasis added)
Label may apply to human food and animal feeds

6.4.4 GM labeling in the EU

In 1992, the European policy makers adopted the Maastricht Treaty, formally known as the 1992 Treaty on European Union. Of relevance to this study is the fact that this major treaty encouraged involvement of consumers, consumer organizations, environmental organizations, and groups representing economically disadvantaged people to bring their useful experiences into policy deliberations (COR 1996). Policy makers responded to demands for comprehensive information on food labels. The Europeans saw a business advantage in labeling:

> [There is] an obvious competitive advantage for foodstuffs producers to give clear, comprehensive information on product content, production methods, animal protection, use of pesticides, etc. Good product information also assists in the control of foodstuffs, since consumer organizations can also participate in the process, together with regional and local authorities. (COR 1996).

As noted in Chapter Two, the EU has taken a cautious approach to the adoption of GM crops, including a 6-year moratorium on the approval of GM crops. By 2003, the moratorium ended, and the European Parliament enacted a law that went into effect in 2005 requiring that genetically modified foods be labeled (European Parliament 2003). The main features of the law are shown in Table 6. 4. This law places the burden of labeling on food producers whose products contained GM ingredients. Those who did not declare that their products contained GM ingredients could be penalized with existing laws if their products were found to contain more than 0.9 percent of GM material[28] even if this was due to adventitious presence (Ibid., 2003). Adventitious presence is the term used to describe the phenomenon whereby pollen flows from GM crops to conventional

[28] Unlike most chemical tests, which are based on an absolute weight percentage, percentages of genetically modified DNA are reported as a "ratio of target GM DNA relative to the total amount of species DNA present [total equals GM DNA plus non GM DNA]…" (Spiegelhalter, Lauter and Russell, 2001, 638).

(non-GM) or organic crops, or GM DNA comes into contact with foods as products move from farms to retailers. For example, contact may occur in farm equipment, storage silos, transport containers, or food processing plants.

Table 6.4 : Main features of the European Union's mandatory labeling law for genetically modified foods (adapted from European Parliament, 2003)
Where the food consists of more than one ingredient, the words "genetically modified" or "produced from genetically modified (name of the ingredient)" shall appear in parenthesis immediately following the ingredient or a footnote.
Where the ingredient is designated by the name of a category, the words 'contains genetically modified (name of organism)' or 'contains (name of ingredient) produced from genetically modified (name of organism)' shall appear in the list of ingredients or a footnote.
Where there is no list of ingredients, the words 'genetically modified' or 'produced from genetically modified (name of organism)' shall appear clearly on the labeling.
Where there is no list of ingredients, they shall appear clearly on the labeling.
Where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers, the information must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.
The law does not apply to foods containing GM material of less than 0.9 percent if the presence of the GM ingredient is adventitious or technically unavoidable. Lower thresholds may be established for particular foods or to take into account scientific and technical advances.

Whether a food producer is located in the EU or another region, when their products are sold in the EU's 27 member countries, the producers are expected to comply with EU regulations for labeling GM foods, as well as with national regulations. Countries that belong to the EU have both national food regulations and the directives that are developed by the EU intergovernmental bodies. The degree to which national

governments adhere to the EU rules is not always consistent. For example, the government of Hungary recently banned a GM crop, in contradiction with the EU decision about the product (Fletcher 2007). Countries within the EU that wish to serve the organic niche market are reluctant to allow GM crops as well because of the problem of coexistence of GM and organic crops due to adventitious presence of GM material in organic crops.

6.4.5 Comparison of US and EU labeling approaches

There are broad similarities in the two general food labeling laws of the US and EU, yet differences in interpretation and emphasis are sufficient to create divergent GM labeling policies. For example, both the US and EU laws prohibit labeling which misleads consumers in a material manner. However, the interpretations of the type of information that is material or misleading may differ. Both the US and EU require information about product identity and composition, but they differ in their interpretations of which components of foods require labeling. The US law is primarily concerned with the consequences of use of the final product. The EU is more concerned with methods of production and origin.

6.5 Research findings

6.5.1 US industry perceptions of the US and EU labeling policies

Study respondents from US food manufacturers and processors (individual companies and associations) as well as commodity associations, gave their interpretations of the reasons for the US approach to labeling and stated their support for the 2001 FDA guidance. In their view, the guidelines provided sufficient opportunities for producers to label according to US market preferences, and the FDA was following the established

principles for food labeling. Although the US producers welcomed the choice of labeling options, they did not intend to apply any of them in relation to foods containing GM ingredients, given the circumstances in the US market in 2003-04.

> The voluntary guidance…was formulated to give companies a choice to be able to label and say that a product "contains biotech food" or "does not contain" or is "organic." The policy was to reinforce that there is a correct way to do this, to label foods in a way that is truthful and not misleading. [Food industry respondent]

US industry representatives strongly disagreed with the EU approach of mandatory labeling. Some study respondents viewed the European policy as an "appeasement" to consumer and environmental organizations and a form of distraction from food safety problems, and/or a trade barrier.

> It [European labeling policy] was … a maneuver with no scientific basis. The scientific committees in Europe said the products were safe, but European politicians ignore their own scientific committees… It is politically driven, part of the lack of confidence in food safety in Europe, but labeling won't improve the situation. [Commodity organization respondent]

6.5.2 Industry reactions to the "contains GM ingredients" label

In 2003, when the interviews began, individual US food companies selling conventional (non-organic) foods, and their associations, the Grocery Manufacturers of America and National Food Processors Association, had been involved in the discussions over the 2001 FDA policy, and they were well aware of the new EU policy. They had already decided how they would respond to both policies. This study found that the US conventional food industry clearly preferred a voluntary approach for labeling because it allowed them to use GM ingredients without having to label. The companies had no

plans for labeling foods that contained GM ingredients in the near future. For the same reason, they did not like the mandatory approach, and rather than be required to label GM foods destined for Europe, they decided to source non-GM ingredients. In contrast, the respondents of organic food producers would have preferred a mandatory labeling policy for GM foods in the US because they believed the burden of labeling should be placed on the producers who were benefiting from the new technology, rather than those who were avoiding the technology.

In making decisions about the use of ingredients and labeling of products, food manufacturers relied on a combination of sources of information, experiences and intuition. The respondents in the studies referred to their companies' market studies but they did not describe these studies in detail and these studies were not available for review. However, studies from the same time period (2000-2004) that are available in the academic literature were consistent with the views expressed by the respondents regarding evidence about how American consumers would react to foods which were labeled as containing or not containing GM ingredients. Research indicated that some American consumers were willing to pay more for non-GM foods and that GM foods became more acceptable when the price was lower; thus, when given information, consumers ranked GM foods as less valuable or preferred than non-GM foods. For example, a study in Connecticut found that, "Fifty percent of those surveyed indicated that they would be very likely or somewhat likely to purchase non-GM foods if they cost up to 20 percent more than GM foods" (Mendenhall and Evenson 2002, 58). Similarly, a study in Ohio found that respondents were willing to pay a premium for non-GM foods in the ranges of 5-8 percent for vegetable oil, 15-28 percent for salmon and 12-17 percent for cornflake cereal (Chen and Chern 2004, 126). Finally, a study by Moon and Balasubramanian found that US consumers were willing to pay 9.5 percent more for cereal that was labeled as non-GM than they would pay for cereal that might contain GM ingredients (2004, 94). For a more comprehensive discussion on consumer preferences, see Chapter Three.

Although studies in which consumers are asked hypothetical questions may not reveal how consumers would actually react in a true shopping situation, the respondents from food industry associations and food companies believed they had sufficient information to make the judgment that labeling foods for GM content would jeopardize sales or lower the status of their brands.

> At least at the moment, there is plenty of evidence that consumers are uneasy…[and] there is nothing in biotechnology of consumer benefit. If there is no tangible benefit to you, and there is this intuitive feeling that experts don't know everything, it is common sense, there is not a strong reason for consumers to accept biotechnology… As a food company, we pay attention to what people think and feel; emotion is more significant than reality. [Food industry respondent]

Lack of motivation for voluntary labeling in the US

Respondents commented that current GM foods lacked traits that appeal to consumers. Food industry respondents said that food companies would label GM foods if there were traits which consumers desired, such as improved nutritional content. The food companies were interested in the potential benefits of biotechnology but disappointed that no products with traits that appealed to consumers had been commercialized. Without traits that consumers find attractive, there was no incentive to label foods as containing GM ingredients.

> Companies would label foods as containing biotech ingredients in the future. This is a future opportunity. Companies will label when there are more developments with biotech products that have nutrition and health benefits. When these products come out, they will have voluntary, positive labels. [Food industry respondent]

The food industry respondents expressed their concerns about consumer reluctance to accept the technology.

> We think it is a potentially good technology; the technology can create meaningful consumer benefits. But the biotech industry focuses on the agronomic benefits. This has tried our patience; we bear the risk of consumer backlash; we don't see the benefits. We are concerned that after all this time, there is no improvement in consumer acceptance, it doesn't seem to be going up. [Food industry respondent]

Avoidance of GM ingredients

While most US food companies decided to take no action in terms of labeling, some decided to publicly announce that they would not use GM ingredients because of consumer wariness of the technology. The examples of GM wheat, potatoes and sugar demonstrate the sensitivity of US food companies to resistance to a new technology within the US, as well as abroad. Business journalists have reported that some leading US food companies were conflicted about the use of GM foods in the sense that they supported biotechnology but were concerned about consumer acceptance. This appears to be especially true of companies that sell products for infants and children. In 2000, Frito-Lay, Gerber, H.J. Heinz and McDonalds announced that they would stop using GM ingredients (Barboza 2000). The decisions of retail and processing companies had an impact on the biotechnology industry. In 2001, Monsanto announced that it would discontinue its line of GM potatoes following the decision of the J.R. Simplot Co., a large French-fry processor, not to use them (Anonymous 2001). Similarly, sugar refiners requested that farmers not plant GM sugar beet varieties developed by Monsanto and Aventis following the expressions of concern about public perceptions by the confectionary producer, Hershey Food Corporation (Kilman 2001).

The most recent example of consumer perceptions having a negative influence on the adoption of GM technology involves wheat. GM wheat was developed by the Monsanto Company, yet consumer and farmer stakeholders petitioned USDA to stop the development of GM wheat because they believed the release of this crop was premature given the slow progress in consumer acceptance of GM foods (*AgBiotech Buzz* 2003; Pollack 2004).

> [C]onsumer acceptance might improve if consumers could see a benefit from a product…companies should wait to introduce GM wheat until they have a product that can be pulled, not pushed, through the market. For example, developing wheat without allergens that cause people to be intolerant to gluten (so-called celiac disease) means an additional 2 million Americans might be able to buy a particular product…that's a huge incentive. (*AgBiotech Buzz* 2003).

Avoidance of mandatory labeling

With regard to mandatory labeling, there was an unequivocal response on the part of US food producers: they would avoid labeling by using non-GM ingredients. One food industry respondent said, "We don't want to label. Nobody labels, because we know what consumer reaction to labels will be…In those markets where there is [mandatory] labeling, we source non-GMO." In spite of their belief that biotechnology was a positive development, they did not wish to risk losing consumers by informing consumers that foods contained GM ingredients. On the contrary, they decided to sell foods that did not contain GM ingredients in markets where it was mandatory to label GM foods even if this raised the costs of food production. For the food companies, labeling was clearly viewed as a business risk.

The US food industry respondents' assessments of European perceptions of biotechnology were consistent with research about the European market and the views of European consumers. The US industry did not agree with the European researchers'

and policy makers' views that labeling would ameliorate the situation. Following a 2002 survey of 16,500 people in 15 European countries, Gaskell and colleagues reported about public attitudes toward biotechnology and made recommendations about how to address these attitudes:

> These results could be taken as indicating a more or less total rejection of GM foods and discussed in terms of the impossibility of introducing such new products. On the other hand, it could be argued that if GM foods actually offered some of these benefits [reduced pesticides, lower fat, and better taste] and if they were labeled to give the rejecters the opportunity to express their preference, then the products might capture a sizable market share. (Gaskell et al. 2003, 4)

The US food industry respondents interviewed for this study did not view labeling as a strategy to gain consumer acceptance for agricultural biotechnology. Rather, they viewed the mandatory labeling laws as indicators of widespread opposition to GM technology.

> In Europe they say labeling will improve consumer acceptance. There is no evidence of this; some studies show 47 percent wouldn't buy. In our business, even a 5 percent drop in sales has a huge financial impact. We aren't in a position to blithely label knowing consumers would reject it. It might take a while to source non-GMO, and it might cost consumers more; that's a business judgment companies would make. [Food industry respondent]

The US respondents in this study believed that the brief experiences in Europe with GM labeling provided sufficient evidence to convince them to avoid labeling in this market.

> Companies prefer to reformulate or to use locally produced ingredients; they prefer this to labeling. There is no way that the companies will label, because the products won't get on the shelves. The retail stores will reject them. In Europe, in the U.K. and France, this is the predominant attitude. [Food industry respondent]

> In France a few years ago, there were about 15 percent of products that were GM. Now there is less than 1 percent. The industry's experience with labeling is that it reduces sales. [Food industry respondent]

The respondents' views were consistent with the findings of researchers who interviewed industry stakeholders in Europe. In 2005, Knight and colleagues reported that food industry buyers (the "gatekeepers" to the European market) were highly skeptical about consumer acceptance of GM foods (Knight et al. 2005).

6.5.3 Industry reaction to "does not contain GM ingredients" labeling

Some food companies that may own brands that do contain GM ingredients, as well as organic brands, expressed their support for the FDA guidelines.

> …the FDA policy addresses how you label the absence of biotech. It's good that there's a market for this; it's more about choice… It is clear that some consumers want to buy non biotech; it's a good market; we serve it. There needs to be a way to declare non biotech without unjustifiably implying that biotech is unsafe. [Food industry respondent]

Some respondents believed that the organic food industry would benefit from the concerns of some consumers about GM foods. According to the US Department of Agriculture (USDA) National Organic Program (7 CFR Part 205) criteria for certified organic foods, foods produced from GM seeds (or ingredients derived from these crops) are explicitly prohibited from using the organic seal; therefore, consumers who wish to

avoid GM foods can do so by purchasing certified organic foods. The FDA guidance specifically refers to the rules for certifying organic foods:

The USDA final rule on certifying foods as organic requires that products or ingredients identified as organic must not be produced using biotechnology methods. The national organic standards would provide for adequate segregation of the food throughout distribution to assure that non-organic foods do not become mixed with organic foods. The FDA believed that the practices and record keeping that substantiate the "certified organic" statement would be sufficient to substantiate a claim that a food was not produced using bioengineering (FDA 2001, 4842)

It is important to note that in the case of organic food, the standard can be met if the producer takes care to segregate its food and to source organic food (including a provision that GM foods should be avoided). The USDA label refers to a process of production. In contrast, the FDA Guidance concerning GM content refers to the actual ingredients found in the product and the adventitious presence of GM in a food labeled as "not containing GM ingredients" could result in the label being considered false and misleading. In this sense, the USDA standard for organic labeling is less stringent than the FDA standard for GM labeling.

6.5.4 Motivations to label

Previous experiences in the dairy industry with labeling information about the veterinary drug, bovine somatotropin (BST) that raises milk production provided evidence that organic producers could gain from labels stating that a product was not GM. Voluntary labeling of milk as "not containing BST" has allowed producers to obtain a premium on a product that was produced without using a bioengineered drug (Kiesel et al. 2004). In the interviews for this study, a respondent from organic producers said:

> BST milk built the organic milk industry, because when it came in, many consumers turned to organic milk. It grew rapidly. Organic milk is now 1.5 percent of the national market and higher in some regions like northern California and New England. [Organic food industry respondent]

> Companies always want to harness profits; non-biotech labeling could be an incentive to them. We have organic and kosher guidelines. But consumer choice comes with a cost… Clearly organic industry will gain from the policy; they are the largest opponents of biotech. [Food industry respondent]

These respondents thought the FDA Guidance would help the large organic companies that had the capacity to ensure that their products met the regulatory agency standards. Large companies can afford to segregate and test products, while smaller firms are less able to meet labeling standards (Golan et al. 2000). A respondent working with organic food producers said: "[Large companies like] Cascadian would [use a negative] label. It's the buying power; a label will sell. The companies will do it."

6.5.5 Disincentives to label foods as not containing GM ingredients

Although food producers who have not adopted GM technology may obtain premium prices for their products from consumers who wish to avoid GM food, these companies had generally not chosen to label their foods as non-GM at the time of the interviews. The risks involved in labeling outweighed the potential benefits, since the credibility of their labels may be threatened by the adventitious presence of GM materials. Very minute quantities of GM DNA (e.g. dust) can cause an organic food product to test positive for GM content, even though the food was produced through authentic organic methods (Spiegelhalter et al. 2001). If this occurs, there are risks to the

producer of organically labeled food including the negative publicity if the presence of GM material were to be made public.

Adventitious presence has an impact on the organic food companies' decisions regarding labeling within the US as well as in the EU. Although a producer is not required to label a product in the US, US consumers believe that organic foods do not contain GM ingredients. Therefore, the credibility of organic producers could be at risk if a certified organic food tested positive for GM DNA. Although the USDA does not consider the presence of GM DNA to be a factor that would disqualify a product from making an organic claim, respondents were concerned about accusations that an organic producer was misleading consumers.

Organic food producers and natural food producers have valid reasons to be concerned about adventitious presence because consumer or environmental groups may accuse producers of misleading consumers if products test positive for GM ingredients. The negative publicity that could harm a company's reputation may be even more significant than the fines that a company might have to pay for incorrect wording on a package. A US official agreed that organic producers had cause for concern: "There is some anxiety there; companies are afraid that if they do a non-GM label, and it is tested and contains GMOs, Greenpeace or some group will give them bad publicity."

Organic producers were not only at risk of enforcement from the regulatory agencies, losses in consumer confidence, and additional costs for doing business abroad; they also feared that the biotechnology companies would take legal action against them if their labels were interpreted as stigmatizing products of biotechnology. As a result of these multiple risks, the FDA voluntary guideline for claiming that a food did "not contain GM ingredients" was not being used by food producers at the time of the interviews.

The EU authorities recognize that operators who avoid GM food and feed may find "minute traces…as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing" (European Parliament 2003). However, there are no exceptions to the EU policy that requires that foods containing GM material above a threshold of 0.9 per cent be labeled as GM products.

The organic industry regarded the testing needed to demonstrate that a product was below the GM tolerance levels in the EU as a burden. The risk that a product would not pass the test of containing less than the threshold of 0.9 percent GM material was significant for organic exporters. If a product that has been accepted as being organic in the US is found to contain more than 0.9 per cent GM material by European inspectors or certifying agents because of contamination, US producers will not obtain the premium from their customers that they expect for selling organic products in Europe.

Organic industry respondents were concerned about their producers' ability to demonstrate to their foreign customers that their products were organic. One respondent from an organic producers' association said: "Europe is asking for certified organic; it has an economic impact on the organic industry. They have to test the foods. It is a burden, an additional expense for producers." Another respondent concurred: "The costs of traceability are a burden on the non-GM users. Testing, affidavits, segregating are costs born by the organic producers. Why should they have to bear the costs? We feel strongly about this."

The respondents claimed that organic producers were losing their markets abroad because "buyers don't accept guarantees" from exporters who state that foods are organic. According to one organic producer association respondent, "There is no advantage for organic producers. Nobody trusts the US; no one trusts the system."

6.6 Summary

This study found that both the US and the EU policy makers believed that their policies for labeling GM foods would give their industries a competitive advantage in the global food market. Yet the labeling policies are not being implemented as the policy makers intended. This study examined the factors that limit the use of food labeling as a means to alleviate the problem of asymmetric information regarding the credence quality GM content.

6.6.1 Conventional food industry responses to labeling policies

According to the food industry respondents who participated in the study, there was a clear, unambiguous view among US food manufacturers that labeling foods as containing GM ingredients would not be beneficial at the time of the interviews. Indeed, industry respondents viewed this type of label as a business risk. They appreciated the option to voluntarily label GM foods in the future if the biotechnology industry develops foods with attributes that consumers find appealing. They did not plan to label under the FDA voluntary guidelines until such foods had become available. Under the present circumstances the voluntary labeling policy is not functioning to inform the consumer about GM foods in the marketplace. The food companies know which foods contain GM ingredients but consumers do not.

The US food manufacturers disapproved of the EU policy that requires labeling of foods that contain GM ingredients because of their perception that consumers would avoid foods so labeled. Since they were unwilling to risk losing sales in the European market, their response to the mandatory labeling policy was to avoid formulating their products with GM ingredients. Thus, the mandatory policy functioned as a disincentive to the food industry for making GM foods available to European consumers, and did not promote labeling. While the 2003 policy was less restrictive than the moratorium that

preceded it, the mandatory labeling policy has the effect of limiting the availability of GM products for European consumers.

6.6.2 Organic food industry responses to labeling policies

The study found that food producers who do not use GM ingredients recognized a potential benefit in labeling foods as "not containing GM ingredients." However, the organic food industry, which might gain from such labeling, found that the rules for labeling foods as "not containing GM ingredients" presented risks, particularly because the potential for adventitious presence of GM material in non-GM foods was high. There is evidence that consumers might be willing to pay more for non-GM foods; however, the organic food industry, which does not use GM ingredients had limited interest in this type of label. The respondents of the organic food producers preferred the EU's mandatory GM labeling policy to the US FDA voluntary policy; overall, they were not satisfied with either policy. The labeling policy in the EU was perceived to be a burden and a risk for US organic producers who export their products.

6.7 Discussion

The labeling policies of the US and EU both provide the possibility for informing consumers and reducing the information asymmetry between sellers and buyers in terms of information about the quality of being a GM food. According to economic theory, the free market functions more efficiently if the consumers possess the information necessary for them to be able to express their preferences. At the present time, many US food manufacturers are selling foods that contain GM ingredients, and many US consumers are not aware that they are consuming these foods. If some consumers place less value on GM foods than non-GM foods, they may be paying more than they would pay if the foods were labeled. There is a problem of adverse selection.

Correcting these information problems might enable the biotechnology industry and others to assess more accurately the value that consumers give to GM foods. However, this study found that individual food companies that must operate under highly competitive conditions were unwilling to take risks in the marketplace by providing information to consumers. Until the biotechnology industry produces GM foods that have traits that consumers find desirable, it is unlikely that the food industry will label foods as containing GM ingredients. Thus, neither mandatory nor voluntary labeling policies will result in the resolution of the information asymmetry problem, and the imperfect market condition will persist.

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CHAPTER SEVEN. DISCUSSION

7.1 Case study about stakeholders

The issue of labeling of GM foods served as a case study to analyze how US stakeholder organizations participated in the development of a regulatory policy regarding consumer information and how they viewed their participation. It also served as a case study in how stakeholders responded to the policy. Stakeholder organizations were the subjects of this study because they may be especially influential in policy making processes due to their technical and legal expertise and the depth of interest in the issue among their constituencies. Representatives from major US food industry, biotechnology industry and consumer associations, as well as officials and researchers, were interviewed during the period May 2003-April 2004. Qualitative research methods were chosen for this study because the respondents were experts in various aspects of the topics under review, and this method allowed the study participants to provide their own interpretations of the relevant topics without the constraints of a highly structured survey. Further, in the US, the number of organizations that are important actors in food production, manufacturing and GM technology, as well as the number of highly influential, national consumer organizations, is relatively small; therefore, a quantitative approach would not have been appropriate.

7.2 Stakeholder perceptions and participation in the FDA consultative process regarding labeling of GM foods

In the US, policy makers have obtained public and stakeholder group views with regard to the labeling of GM foods through official and unofficial sources such as public opinion polls, consumer surveys and experiments, focus groups, advisory committees, consensus forums, referenda and official comment periods. This study focused on stakeholder perceptions and participation in two FDA processes: public meetings and

public comments. These processes aimed to give citizens the opportunity to exercise their rights to speak, to be informed, and to participate in deliberations over regulatory policies as protected by law.

The analysis of official records found that the FDA processes differed in terms of participants, accessibility, and representativeness of different views. Very few ordinary citizens participated in the public meetings in 1999, which were dominated by stakeholder groups. However, the range of stakeholder groups which participated was wide. In contrast, thousands of ordinary citizens were motivated to send a short letter, post card or e-mail to FDA to express their views during the comment procedure in 2001. However, it appeared that these citizens obtained information about the topic from stakeholder groups, since there was a high degree of similarity among the comments. The quality of participation varied as well, with some stakeholders using sophisticated legal arguments to make their points, and others using more general social and ethical arguments using common language.

There was no consensus among the stakeholders. The conventional food industry and biotechnology industry both supported voluntary labeling of GM foods, while the organic food industry and environmental organizations favored mandatory labeling of GM foods. Representatives of scientific organizations did not support mandatory labeling, and this may have carried significant weight among officials in the technical, science-based agency. The leading consumer organizations that often advocate labeling were reluctant to endorse mandatory labeling in the case of GM foods either because of concerns that consumers would be misled and that a promising technology would be hampered or because they placed greater importance on safety assessment than on labeling at the time of the interviews. Thus, unlike the situation in other countries, there was not a strong consumer movement in the US advocating mandatory labeling of GM foods.

In the interviews for this study, stakeholders' views of the FDA participation processes seemed to be determined by their stances on the policy under consideration, and their perceptions of the agency were inconsistent. The perceptions of the specific process corresponded with the outcome of the particular process. Thus, the same stakeholder group could have a positive view of one process and a negative view of another process, depending upon how well the process outcome reflected their views. The outcome of the public meetings favored voluntary labeling, and in this case, the advocates of mandatory labeling charged that the agency officials ignored their views at the public meetings, suggesting dissatisfaction with the process. Based on the analysis of the comments obtained from FDA, the majority of messages called for mandatory labeling. In this case, the critics of mandatory labeling, who supported voluntary labeling, argued that the comments were not meaningful. This suggests that stakeholders view a process as not being worthwhile when the results of the process do not support their case.

When an issue is highly controversial, a federal agency must actively demonstrate that the processes are fair and accessible to all relevant groups and avoid actions that might lead to perceptions of bias. The FDA officials and panels provided background information during the meetings that was appropriate for a non-technical audience. However, the meeting structure and venues did not allow for the audiences to have sufficient time to study the information or exchange views with experts about the information they received. The short, well-phrased statements from the audience were probably prepared before the FDA and panel information had been received. Thus, it appears that each speaker had an opportunity to give a statement, but there was not a dialogue. While hearing each other's views is useful by itself, it is limited. Another participatory process such as citizen panels or consensus meetings might be more effective and more appreciated than public meetings for complex issues such as GM foods.

Nonetheless, through the processes used by FDA, the officials gained an awareness of the wide range of views among stakeholders and citizens and learned that the agency needed to be more transparent and to communicate more clearly about its approach to regulating GM foods. Through the interviews, however, the study found that some stakeholder group representatives and officials believed that the agency should be cautious in communicating with the public about GM foods because this information could be interpreted as promotion of the technology and this would undermine the role of the agency as a regulator of the technology.

While the officials understood the various perspectives, they stated that some stakeholders ignored or failed to understand the legal principles that underpin labeling policies in the US, and they failed to provide any new information that would justify shifting to a requirement to label GM foods.

To achieve greater balance and improve the quality of participatory processes, FDA could assist inexperienced organizations and citizens to prepare for participation in policy debates. The provision of information about the technical and legal aspects of an issue in advance of the process and greater opportunities for interaction could give different stakeholders and average citizens the opportunity to participate more effectively. Such communication would have to be carefully crafted to avoid accusations of bias. Alternatively, another agency within the US government that does not have a regulatory role could carry out communication activities that take into account different perspectives among stakeholder groups.

7.3 Food Industry Reactions to the US Voluntary and EU Mandatory Policies for Labeling of GM Foods

Because of the widespread presence of GM foods in the US marketplace, the US was an ideal location to investigate of the role of labeling in addressing the issue of information asymmetry in the market for GM and non GM foods. Nearly three-quarters of the processed foods sold in the US contain GM ingredients, yet research shows that a majority of US consumers are unaware of the amount of GM foods they consume (PIFB 2006). Further, there is evidence from research in the US that consumers do rank GM and non GM foods differently; these studies found that US consumers expressed their willingness to pay more for non GM foods, and they found GM foods more appealing when their prices were reduced (Mendenhall and Evenson 2002; Tegene et al. 2003; Loureiro and Hine; 2004; Chen and Chern 2004; Moon and Balasubramanian 2004). The fact that consumers do not have the ability to easily identify which products are GM and which are not creates a situation of information asymmetry and the potential for adverse selection. In theory, the policies for labeling GM products developed by governments could rectify this imperfection in market conditions provided that the food industry agrees to disclose information that a product is or is not GM.

The US food industry's response to the 2001 FDA guidance was the focus of this study initially. This guidance provides options for companies to voluntarily label foods as "containing" or "not containing" GM ingredients. Since US food producers have large markets outside the US, and the study participants voiced strong opinions about the EU approach to labeling GM foods, the study was expanded to include US stakeholders' response to the 2003 EU regulation for mandatory labeling of GM foods. The study found that both US and EU policy makers justified their decisions in terms such as providing consumers with choices about food products, ensuring consumer confidence, and enhancing the competitiveness of industry. Yet the EU and US approaches are

dramatically different in that the US labeling policy is concerned with the final product's characteristics while the EU policy focuses on the process of producing the product. Therefore, the US policy, based on the perception that GM foods are not, by virtue of being GM, materially different from their conventional counterparts, does not require labeling. The EU policy considers any GM food to be different and requires labeling because of the process by which the food was produced, despite the equivalence of the final product to its conventional counterpart. Thus, there was the opportunity to examine the effects of two different labeling policies, one voluntary and the other mandatory on stakeholder decisions, consumer information, and the marketing of GM foods.

Regardless of the intentions of policymakers and the type of labeling policy, the study found that neither labeling policy was providing consumers with information. In the US, companies were not volunteering to label their products as containing GM ingredients, and in the EU, companies were avoiding the use of GM ingredients in order to avoid labeling. In the case of organic products, which always exclude GM ingredients, the research found that organic food producers were reluctant to use the voluntary labeling options at the time of the interviews because of the risks of adventitious presence of GM material that could undermine confidence in their products.

Overall, the research found that neither the US nor the EU labeling policies are giving consumers access to the information about the process of producing foods through biotechnology or access to the range of food products that are technically feasible using GM technology. Neither set of labeling policies were enabling consumers to express their preferences through informed purchasing decisions; thus the market is not functioning to serve both sellers and buyers. In terms of correcting the asymmetry of information in the market, both the voluntary policy of the US and the mandatory policy of the EU have been ineffective.

7.4 Conclusion

This study demonstrated that regardless of whether a labeling policy is voluntary or mandatory, it will not be used to provide consumers with information when a technology is controversial and the food industry believes that disclosing information on labels will be harmful to business. Contrary to the view that labeling can help to resolve a controversy by allowing each individual to make a choice, the study demonstrated that controversies over GM technology prevent the implementation of food labeling. The study also found that participatory procedures and provision of information may be useful for understanding different perspectives, but they do not necessarily resolve a controversy. Before a labeling policy can be implemented successfully, consumer confidence and acceptance in GM technology must be attained through other measures such as independent risk assessment, improvements in risk management, public education and development of GM products that are appealing to consumers so that they will be motivated to try the products.

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