

# **Food Labeling**

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## **Abstract**

In addition to facts on nutrition and ingredients, labels can provide readers with relevant, up-to-date information on the product's environmental, social and regional sustainability. Labeling products with respect to the sustainability of their production, processing and transporting is a powerful tool for achieving more environmentally sound, economically viable, biologically diverse, and socially just communities.

Part one of this report attempts to familiarize the readers with U.S. food labeling laws and regulations. Part two deals with the economics of food labeling; part 3 examines the issues surrounding organic foods labeling. Parts four and five look into the growing movement to label biotechnologically-engineered foods in the United States and in the European Union, and lastly, part 6 will be a comparison of the labeling issues for genetically engineered foods and organic foods, both in the United States and in the European Union.

**Keywords:** Label, food, economics, organic, biotechnology.

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## **Introduction**

*A label is an attached paper with information.*

- Webster's 21<sup>st</sup> Century Dictionary

*Labeling relates to any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring, or collar accompanying or referring to such food stuff.*

- EU Food Labeling Directive, 1979.

Food labeling over the years has grown in importance in helping the consumer make purchasing decisions. With consumers having more knowledge about the health effects of certain foodstuffs, there is growing pressure for more detailed food labeling. The study of food allergies has brought into focus a whole new area of knowledge that should be contained within the information provided to the consumer on the food label.

Labeling therefore has an important role to play in ensuring the proper functioning of the market place. This document will systematically explore U.S. food labeling law and regulation, the economics of labeling, organic foods labeling, biotechnology labeling in the U.S., EU biotechnology labeling, and finally, provide a comparative analysis of organic and biotechnology labeling in the U.S. and EU.

# **Section 1**

## **U.S. Food Labeling Laws and Regulations**

### **1.1. Introduction:**

Food is one of the products that is essential to everyone's existence. Our social habits or economic circumstances often dictate our style of eating. Whatever the particular situation, it is vitally important that food law should offer a high degree of consumer and public health protection as its goal.

It is extremely difficult to define the concept of food quality. In the long run, it is the consumer who decides whether or not a foodstuff is a quality product. In that case the question of quality in relation to purchasing a food product becomes a subjective choice/decision of each individual consumer. A frequently used definition for quality is fitness of use. Many others in the food industry believe that quality can be defined as consumer satisfaction which can be demonstrated by the repeated purchase of a quality food product by consumers.

Food identification, according to O'Rourke, has to fulfil three essential requirements: product identification, consumer information, and product manufacturing.<sup>1</sup> To fulfil these requirements, clearly recognizable, understandable, and informative labeling is needed which will not mislead the consumer. Food labeling is a broad term that encompasses several items required on food packages by federal law and regulations, and includes product identity statements, statements of net contents, name and address of the manufacturer, ingredient and nutrition labeling, and nutrition and health claims. Furthermore, food and nutrition labeling remains an important issue for the media, consumers, health professionals, and decision-makers.

## **1.2. Food Labeling in the U.S.:**

Americans enjoy the safest, most abundant and varied food supply in the world. To assist in keeping these favorable conditions throughout the food industry, legal requirements have been developed for food safety, wholesomeness, and truthful labeling. It is believed by many that the industry's understanding of and voluntary compliance with these requirements have been major factors in achieving the desirable situation that exists in the food that is produced, marketed, and consumed in the U.S.

Food labeling in the U.S. is regulated by several federal government agencies. The Food and Drug Administration (FDA), U.S. Department of Health and Human Services regulates most packaged food, produce, seafood, milk, and eggs. The Food Safety and Inspection Service (FSIS), of the U.S. Department of Agriculture (USDA) regulates meat and poultry products. The U.S. Federal Trade Commission regulates food advertising.

The mission of the FDA is to enforce laws enacted by the U.S. Congress, to protect the consumer's health, safety, and pocketbook. These laws include:

- The Federal Food, Drug, and Cosmetic Act (21 U.S.C.<sup>2</sup> 321 to 394), and the Fair Packaging and Labeling Act (15 U.S.C. 1451 to 1461), which apply to foods, drugs, and medical devices for humans or animals, and cosmetics.<sup>3</sup>
- Sections of the Public Health Service Act relating to biological products for human use (42 U.S.C. 262 to 263), mammography (42 U.S.C. 263b), and control of communicable diseases (42 U.S.C. 264).<sup>4</sup>

The Federal Food, Drug, and Cosmetic Act is the basic food and drug law for the United States. With numerous amendments, it is the most extensive law of its kind in the world.<sup>5</sup> Many of the states in the U.S. have

laws similar to the federal law, and some have provisions to automatically add any new federal requirements. The law is intended to assure the consumer that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe, and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive. Another law, the Fair Packaging and Labeling Act, affects the contents and placement of information required on the package.<sup>6</sup> Both the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act require that a food, in package form, bear a label with an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.<sup>7</sup>

The Federal Food, Drug, and Cosmetic Act is a piece of social legislation for the benefit of consumers. The principal aim of the Act is to let the purchaser (consumer) know what the product is, its contents, and its nutritional values. It contains provisions about labeling in general such as, where a label is to be displayed for retail sale, and what is required to be shown on the different types of containers-- rectangular, cylindrical, or otherwise shaped. Apart from general provisions, the Act contains specific food labeling requirements, nutrition labeling requirements and guidelines, specific requirements for health claims, and specific requirements for descriptive claims that are neither nutrient content claims nor health related claims. The Act also contains exemptions from Food Labeling requirements.<sup>8</sup> Upon a brief perusal of its provisions, the Act clearly identifies how food labeling will be done in the U.S., what the labels should contain, so that it is apparent to any interested purchaser what the product contains, and the foods nutritional value.

The basis for food and nutrition labeling in the U.S. is the Federal Food, Drug, and Cosmetic Act of 1938, the Meat Inspection Act of 1906, the Wholesome Meat Act of 1967, and the Poultry Products Inspection Act of 1957. Since passage, these laws have been amended numerous times to

provide consumer protection and safety through labeling requirements and subsequent regulations.

Regulations issued by the FDA are an important part of enforcing the Federal Food, Drug, and Cosmetic Act. Especially important are:

- Current Good Manufacturing Practice Regulations, which set requirements for sanitation, inspection of raw materials and finished products, and other quality controls.
- New Drug Regulations, which tell drug companies what they must do to receive FDA approval of the marketing of a new drug and to assure its continued safety and effectiveness.
- FDA Food Standards, which set specifications for many foods.

Such regulations help both consumers and industry by telling them what must be done to assure acceptable products. All FDA regulations are updated and republished annually in "Title 21, Code of Federal Regulations".<sup>9</sup>

The newest regulations from FDA and the Food Safety and Inspection Service (FSIS) of USDA require that:

- Nutrition information appear in the labeling of almost all foods;
- Labels provide information on how the food fits into an overall daily diet;
- Labels include information on the amount per serving of saturated fat; cholesterol, dietary fiber, and other nutrients of health concern to today's consumers;
- Terms that describe a food's nutrient content light, fat-free, and low-calorie, for example B will meet government definitions so that they mean the same for any product on which they appear;

Claims about the relationship between a nutrient or food and a disease or health related condition.<sup>10</sup> These are helpful for people who are concerned about eating foods that may help keep them healthier longer;

- Standardized serving sizes that make nutritional comparisons of

similar products easier should be specified;

- Declarations of total percentage of juice in juice drinks. This enables consumers to know exactly how much juice is in a product.<sup>11</sup>

Nutrition labeling is required on most packaged foods. Exemptions have been provided for the following types of foods<sup>12</sup> (some of these exemptions are not operative if nutrition claims are made for the product):

1. Foods from small retail businesses that have annual gross sales of less than \$500,000 or low-volume food products from small businesses.<sup>13</sup>
2. Foods for immediate consumption in restaurants, institutional food service, transportation carriers, bakeries, in delicatessens with facilities for immediate consumption, other food service vendors, and foods sold for use in such facilities. Manufacturers must provide nutrition labeling on institutional packs if there is a reasonable possibility that the product will be purchased directly by consumers.<sup>14</sup>
3. Ready-to-eat foods that are not for immediate consumption but are processed and prepared primarily on the premises in stores such as delicatessens and bakeries.<sup>15</sup>
4. Foods of no nutritional significance, such as coffee beans, tea leaves, and food colors and flavors.<sup>16</sup>
5. Donated foods.<sup>17</sup>
6. Dietary supplements.<sup>18</sup>
7. Infant formula and medical foods.<sup>19</sup>
8. Foods shipped in bulk form for use solely in the manufacture of other foods or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.<sup>20</sup>
9. Raw fruit, vegetables, and fish which are covered by a voluntary nutrition-labeling program.<sup>21</sup>

The Federal Food, Drug, and Cosmetic Act prohibits distribution in the United States, or importation of articles that are adulterated<sup>22</sup> or misbranded.<sup>23</sup> Detailed definitions of adulteration and misbranding are in the law itself, and hundreds of court decisions have interpreted them. Food articles may not be distributed if they have not been properly approved by the FDA, the food manufacturers have refused to provide required reports, or inspection of regulated facilities has been refused.<sup>24</sup>

### **1.3. Conclusion:**

While the label itself won't tell the consumer whether a food is good or bad, it can help the consumers be more discriminating. By comparing brands for percentages of the daily values, the label can make it easier for us to choose foods that fit into a healthy diet.

Labeling involves the question of the consumers' freedom to know the facts, and their right to make their own informed decisions about what they eat. Attention must also be paid to increasing consumer wishes and growing consumer demand to receive specific information such as that relating to food allergies, the indication of packaging dates and compound ingredients of finished products.

The area of food labeling is heavily regulated by the federal U.S. government in order to achieve these goals.

## **Section 2**

### **Economics of Labeling**

#### **2.1. Introduction:**

Food product quality conceivably describes a food's safety, its nutritional value, as well as its packaging and processing attributes.<sup>25</sup> These attributes can be regarded as having a demand and supply that interact to determine a market-clearing price. The demand for food safety for example, can be determined by examining the consumers' willingness to pay for additional safety reflecting the value placed upon the benefits that the consumer derives.<sup>26</sup>

Government policies and regulations on labeling, in conjunction with input, process, and performance standards for food products, significantly influence how markets for food quality function and develop. In the United States, the federal government is increasingly using informational labeling as a means of shaping: (1) consumers' knowledge, purchasing patterns and use practice, and (2) manufacturers' product offerings and marketing practices. Examples are mandatory nutrition labels on all food products and safe handling labels for fresh meat and poultry.

Mandatory nutrition labeling has created an environment rich in instructional information, at least for packaged foods. Motivated consumers can access information much more easily than they could before mandatory labeling.

Americans are likewise becoming increasingly concerned about their nutritional and health status. Economic factors, such as food prices, consumers' incomes, etc., all affect the demand and supply forces that control the market. Similarly, an increase in food labeling, as well as the extent of labeling on packaged, canned or frozen foods determines the

consumer's interests and purchases to some extent, in the same way that mandatory labeling and the requirement to comply with the label determines producers decisions. This part examines how labeling impacts the demand and supply cycle, and also briefly examines the role that the government plays in this cycle.

## **2.2. Economics of Labeling: Consumers' Perspective:**

A 1993 study in the Journal of the American Medical Association estimated that 14% of all deaths in the United States could be attributed to poor diet and/ or sedentary lifestyles. The costs associated with these health conditions are substantial. Despite efforts by public and private agencies to educate consumers about how to achieve healthier diets, Americans are far from meeting these recommendations. The question that therefore arises is: how do we motivate consumers to improve their diets?<sup>27</sup>

The economic approach to consumer decisions begins with predetermined consumer perceptions and tastes and describes the logical process of making purchases with limited time, information, and money. The U.S. Department of Agriculture (USDA) and the Department of Health and Human Services lays down a set of national nutritional guidelines and updates the guidelines from time to time.

Frazao, U.S. Food and Rural Economics Division, examines the extent to which dietary recommendations are adhered to in the U.S., and how food intakes from the growing trend of fast food establishments keep up with dietary recommendations and the resulting impact on nutrient intake generally. The questions associated with how much unhealthy eating habits affect nutritional intake and the consequent outcome on public health, by way of premature deaths from coronary heart diseases, cancer, or diabetes, is also examined. Frazao also deals with the question of intake from fats and high cholesterol foods and how much it costs the

country because of unhealthy eating habits. She also examines the potential impact of healthier eating on domestic agriculture.<sup>28</sup>

Consumers generally choose foods within the context of a total diet in order to obtain greater expected utility from their food. Part of that utility derives from using food to maintain or improve health status. Consumers with different risk preferences may choose different types of foods to suit their needs. However, if their perceptions of the quality attributes of foods are incorrect, consumers lose utility. For example, if their perceptions of the risks or hazards associated with foods are incorrect, 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.<sup>29</sup>

Economic studies reveal that as consumers' incomes increase, they may choose to eat more healthful foods, as they become more aware of nutrition. The economic approach to consumer information on nutrition depends on two assumptions – that the consumer believes acquiring information will lead to benefits and that the consumer can use the information to reap the benefits. Nutrition education strives to inform people about nutrition and, ultimately, aims to change eating behaviors so that people reap the benefits of healthful eating and reduced health risks.<sup>30</sup>

The Healthy Eating Index (HEI), developed by the Center for Nutrition Policy and Promotion of the U.S. Department of Agriculture, provides a single summary measure of the overall nutritional quality of the American diet. The 10 components that make up the HEI provide insights into the types of dietary changes needed to improve American eating patterns and call attention to the fact that Americans need to do more than reduce their fat intake to attain healthier diets.<sup>31</sup> The average HEI increased from 61.5 in 1989-90 to 63.8 in 1994-96, with most individuals (70%) having diets defined as "needing improvement," and only about 12% of individuals having diets that could be classified as "good."<sup>32</sup>

Improving information through means such as advertising and labeling may solve or mitigate many consumer information problems. Consumers who read packaging labels on food are more likely to have healthier diets than those who do not, according to a preliminary study released by Texas A&M University.<sup>33</sup>

Consumers' gain from being provided additional information depends on their relative transaction costs for becoming informed (e.g., an increase in the price of the product) and how receptive they are to the messages. Using information imposes costs upon consumers. Those who attach little value to particular quality attributes may choose to ignore information about them.

### **2.3. Economics of Labeling: Producers' Perspective:**

It is known widely that the market for food quality is not perfect. The most significant imperfections are that sellers are better informed about quality attributes than consumers. Consumers may have misperceptions of the risks and hazards of consuming particular foods, and food quality and information about food quality may be under or over supplied.

Producers provide significant amounts of nutritional information in advertising and labeling. Since the mid 1990's, regulation has increased and channeled this information, but consumers still need motivation to obtain it, process it, and change their behavior. The convenience of nutrition information on packages could make nutrition education and information programs more effective if they can provide motivational knowledge as well. The potential benefits to consumers from the regulatory developments in the 1990's will ultimately depend on the ability of education, advertising, and package claims to motivate people to use labels and to improve their diets and health.<sup>34</sup>

Advertising of foods also plays an important role in shaping a consumer's eating habits. Food manufacturers spent \$7 billion on advertising in 1997. Most of this advertising focused on highly processed and highly packaged foods--which also tend to be the foods consumed in large quantities in the United States relative to Federal dietary recommendations, such as the Dietary Guidelines for Americans. Advertising expenditures on meat, fruits, and vegetables are negligible. In contrast, USDA spent \$333.3 million on nutrition education, evaluation, and demonstrations. This is approximately what the food industry spent on advertising just for coffee, tea, and cocoa, or for snacks and nuts; slightly more than half (60%) the amount spent on advertising for carbonated soft drinks, and less than half the amount spent promoting beer, or candy and gum, or breakfast cereals.<sup>35</sup>

#### **2.4. Role of Government:**

The presence of imperfect information, transaction costs in acquiring and using information, and externalities may make private markets for quality work inefficiently. In these cases, policy makers often look for correction tools. One of these tools can be direct government regulation of production processes or product characteristics, but such regulation is often criticized as economically irrational and expensive. In response to this criticism, there has been some movement away from traditional forms of regulation toward interventions that are believed to be more compatible with seller and consumer incentives. This has resulted in increased interest in techniques that ensure consumers have sufficient information to protect themselves against unsafe products or unfair seller behavior. Economists have argued that if the government has the choice between banning a risky product or activity and providing information about the risks involved, it should choose the information provision.

Over the last decade, the government of the United States has placed a stronger emphasis on the use of information programs as a means

of influencing economic behavior. Providing additional or different information is attractive because it is a demand - led instrument, which may be effective in giving consumers the means for making better decisions. If information problems can be solved directly through informational regulation, more stringent forms of regulation such as process or performance standards will not be required. These latter approaches raise concerns because they may restrict both consumer and producer choice and increase costs unnecessarily. Quality signaling through product labeling and information disclosure requirements encourages market incentives with relatively limited government involvement, which is consistent with the regulatory philosophy of many policy makers.<sup>36</sup>

Nutrition information programs aim to enhance life and health through improved nutrition. Government support of nutrition education and regulation of advertising and labeling support this goal. Because these are government programs, policymakers seek cost-benefit calculations for these programs. The high value that consumers place on health and life, means that information programs with demonstrated efficacy in improving health will offer benefits that consumers will likely feel exceed reasonable costs.<sup>37</sup> It was with this purpose in view that President Clinton's Executive Order 12866, "Regulatory Planning and Review," was passed which recognizes and incorporates this principle, requiring agencies to quantify both costs and benefits to the best of their ability and to the extent permitted by law.<sup>38</sup>

Whether they mandate information or simply circumscribe voluntarily-provided information, labeling regulations result in a basic transformation of the information environment in markets for quality attributes. They do so by transforming former experience or credence attributes into search attributes. Mandatory disclosures, for example, make it practicable for consumers to judge quality before purchasing a product by establishing a quality scale, requiring testing of quality, and

mandating a reporting format. Regulation of voluntary claims serves similar purposes.

## **2.5. Conclusion:**

It can be said without hesitation that a price or income change affects the availability of a nutrient of particular interest, as well as the simultaneous effects on the consumers' income. The availability of all nutrients varies depending on how food and income changes manifest themselves through the food demand relationships. These nutrient response estimates provide useful information for studying possible food program effects on the overall availability of nutrients. Further studies are needed to improve the availability of data on prices, quantities, and nutritional profiles for final food products.<sup>39</sup> The purpose of nutrition policy is to change consumers' perceptions so that they consider the health benefits along with enjoyment of food. We cannot therefore say that economic approaches will not cover the full range of policy considerations.

The government can be said to play two roles in determining what nutrition information consumers receive: (1) by regulating advertising and labeling, the government changes business' costs of providing market information, and (2) the government provides information directly through a wide variety of nutrition programs. Estimates of the benefits of these programs, while difficult, are necessary to achieve the most improvement in consumer health. Even imprecise measurements can help policymakers decide which alternative program options yield the most benefits per dollar of public expenditures.

## **Section 3**

### **Organic Foods Labeling**

#### **3.1. Introduction:**

The Oxford American dictionary describes the word organic as "of or formed from living things." Consumers generally define organic foods as those produced naturally, without the use of toxic chemicals, drugs, or factory farm techniques. According to the Organic Foods Production Association of North America (OFPANA), organic refers not to the food itself, but to how it is produced.<sup>40</sup>

Organic food production is based on a system of farming that maintains and replenishes the fertility of the soil. These foods are produced without the use of toxic pesticides and fertilizers; and are minimally processed to maintain the integrity of the food without artificial ingredients, preservatives or irradiation.

While many people maintain that organic foods are expensive, prices for organic foods reflect many of the same costs as conventional foods in terms of growing, harvesting, transportation and storage. Organically produced foods must meet stricter regulations governing all these steps so the process is often more labor and management intensive, and farming tends to be on a smaller scale. There is also mounting evidence that if all the indirect costs of conventional food production (cleanup of polluted water, replacement of eroded soils, costs of health care for farmers and their workers) were factored into the price of food, organic foods would cost the same, or, more likely, be cheaper.<sup>41</sup>

Since 1990, sales of organic food have jumped 20% a year, reaching \$3.3 billion in 1996, and are projected to grow to \$6.5 billion by the year 2000. Total organic cropland has more than doubled since 1991. Sales of organic dairy products are increasing by more than 100% annually. The

adoption of national standards for certification will open up many new markets for U.S. organic producers. Today, approximately 1% of the U.S. food supply is grown using organic methods. By the year 2000, analysts expect that to reach 10%. Worldwide, there are now almost 600 organic producer associations in 70 countries. Nations like Japan and Germany are fast becoming important international organic food markets.<sup>42</sup>

The growing importance of organically produced foods cannot be ignored, and the issues related to labeling these foods are of increasing concern. This part will therefore look into the concept of organic foods labeling.

### **3.2. What is An Organic Food Labeling?**

The Organic Foods Production Act (OFPA) and the National Organic Program (NOP) are intended to assure consumers that the organic foods they purchase are produced, processed, and certified to consistent national organic standards (discussed more in next section). The labeling requirements of the new program apply to raw, fresh produce and processed foods that contain organic ingredients. Foods that are sold, labeled or represented as organic will have to be produced and processed in accordance with the proposed National Organic Program standards.<sup>43</sup>

Under NOP, farm and processing operations that grow and process organic foods must be certified by USDA accredited certifying agents. A certified operation may label its products or ingredients as organic and may use the USDA Certified Organic seal. The term certified organic is followed by the name of the certifying entity, and the entire statement may appear anywhere on the labeling. All words are to be contiguous and of the same size, style and color. Labeling requirements are based on the percentage of organic ingredients in a product. Foods labeled as 100% organic should contain:

- Only organically produced raw or processed products (excluding water and salt),
- Consist of at least 95% organically produced ingredients (excluding water and salt). Any remaining product ingredients must consist of nonagricultural substances or non-organically produced agricultural products approved in the National List.<sup>44</sup>

Products that contain 50-95% organic ingredients can use the phrase made with organic (specified ingredients) and list up to three of the organic ingredients on the principal display panel. For example, organic beef stew can be labeled stew, made with organic beef, potatoes, and carrots. While the certifying agent seal or mark may be used on the package, the USDA seal cannot be used anywhere on the package. However, products that contain less than 50% organic ingredients cannot make any organic labeling claim other than on the information panel, and in doing so, designate specific ingredients that are organically produced.<sup>45</sup>

Labeling, to be submitted for prior approval by the certifying agency, should include:

1. The name of the meat or poultry product, and/ or ingredients used in the meat or poultry products,
2. The certifying entity's name and address,
3. The name and signature of the responsible official at the certifying entity,
4. The date of certification, and
5. The acknowledgment that the entity not only has applied the criteria in certifying the product, but also employs a system for evaluating ongoing compliance with its criteria.<sup>46</sup>

### **3.3. Organic Foods Labeling in the U.S.:**

The quest for national organic standards began in earnest in 1990, when Congress passed the Organic Foods Production Act (OFPA) as part

of the Farm Bill.<sup>47</sup> The OFPA called for the establishment of a 15-member National Organic Standards Board (NOSB) to "assist in the development of standards for substances to be used in organic production" (i.e., the National List) and to "provide recommendations to the Secretary regarding implementation" of the act.<sup>48</sup>

The Organic Foods Production Act of 1990 sought to (1) establish national standards governing the marketing of certain agricultural products as organically produced products, (2) assure consumers that organically produced products meet a consistent standard, and (3) facilitate commerce in organically produced fresh and processed food.<sup>49</sup>

The Organic Foods Production Act authorizes a National Organic Program (NOP) to be administered by USDA's Agricultural Marketing Service (AMS). The program was said to be based on federal regulations that defined standard organic farming practices and on a National List of acceptable organic production inputs. According to it, private and state certifiers would visit producers, processors, and handlers to certify that their operations abide by the standards. Once certified, these operations may affix a label on their product stating that it "Meets USDA Organic Requirements." It will be illegal for anyone to use the word "organic" on a product if it does not meet the standards set in the laws and regulations.<sup>50</sup>

The regulations under the OFPA were intended to set uniform *minimum* standards for organic production. However, under OFPA provisions, states may adopt additional requirements after review and approval by USDA. AMS is supposed to reaccredit certifying agents every 5 years, maintain federal oversight to assure truth in labeling, and provide assurance that imported organic products have been produced under standards that are equivalent to the U.S. standards.<sup>51</sup>

The standards grew out of a 1990 law requested by the organic foods industry to replace a patchwork of state and private certification programs

on what can and cannot be labeled as organic.<sup>52</sup> The standards were also enforced to alleviate the disparity and respond to a growing organic industry, and to have national standards covering the entire industry.<sup>53</sup>

OFPA provided USDA with the authority to develop national organic standards and establish an organic certification program based on recommendations from NOSB. During the period from June 1994 to September 1996, the NOSB submitted its recommendations for national standards and the National List to USDA's National Organic Program staff. The staff drafted the proposed rule based on the Board's recommendations but not in complete conformity with them.

On December 16, 1997, the United States Department of Agriculture (USDA) released its proposed rule for the national regulation of organic food. This proposal followed almost seven years of public hearings organized by the National Organic Standards Board (NOSB). The proposed rule appeared in the *Federal Register* on December 16, 1997. Because of the heavy response to the proposal,<sup>54</sup> USDA extended the comment period from mid-March through the end of April 1998.

Among the new rules were the allowance of irradiation for sterilization, composted municipal wastes for fertilizer, use of genetically engineered crops, and loopholes allowing producers to restrict animal access to the outdoors, use antibiotics on meat and dairy livestock for purposes other than medical emergency, use non-organic feed, and use herbicides and pesticides that were explicitly disallowed by the NOSB recommendations.<sup>55</sup>

Bowing to pressure from the organic food industry – and after receiving a record 200,000 letters, faxes and e-mails from consumers-- Agriculture Secretary Dan Glickman announced in May 1998, that the three controversial practices – irradiation, genetic engineering or

production in sewage-sludge fertilizer – would not be permitted on foods labeled organic under upcoming national standards.<sup>56</sup>

Taking these responses into consideration, the U.S. Department of Agriculture (USDA) released its new proposal for national organic food standards in March 2000 and accepted comments till June 12, 2000. On March 7<sup>th</sup> of this year, Agriculture Secretary Dan Glickman announced a new proposal for uniform and consistent national standards for organic food. According to him:

*This is the most comprehensive and strongest organic standard in the world. I believe this is exactly what American consumers and organic farmers want.*

*A single national organic standard, backed by consistent and accurate labeling, will greatly reduce consumer confusion. Consumers will know what they are buying and organic farmers will know what is expected of them.*<sup>57</sup>

The proposal offers a national definition for the term organic. A single national organic standard, backed by consistent and accurate labeling, is considered to reduce consumer confusion. By accurate labeling, consumers will know what they are buying. At the same time the organic farmers know what is expected of them. The proposed rule seeks to establish clear labeling criteria and rules which enable the consumer to know what he is buying when he purchases organic food. The proposal prohibits the use of genetic engineering, sewage sludge, and irradiation in the production of food products labeled Organic. The proposed rule also prohibits antibiotics in organic livestock production and requires 100% organic feed for organic livestock.<sup>58</sup>

While USDA fixed many problems identified in the 275,000 public comments submitted on the draft standards two years ago, it has not completely closed loopholes that would allow use of genetic engineering,

irradiation and sewage sludge at some time in the future. The new proposed standards also allow animal factories to be considered organic, and impose fees that will drive small family farmers out of organic agriculture. In addition, the proposal does not provide leeway for farmers and certifiers to improve and strengthen organic standards.<sup>59</sup>

Pending finalization of the new rules defining Organic, the Department will permit the use on the label of a meat or poultry product, of a factual statement that the product has been Certified organic by a certifying agency, provided the certifying agency has, (1) Standards for what constitutes an agricultural product that is organically- produced; and (2) A system for ensuring that the products it certifies meets those standards.<sup>60</sup>

At present, state as well as private agencies are certifying, after meeting the above requirements. Food Safety and Inspection Service (FSIS) of the Department of Agriculture is the agency that has the responsibility for assuring that the labeling of meat and poultry products is truthful and not misleading. Labeling bearing claims, such as certified organic by a certifying agency, are evaluated by FSIS prior to use.

FSIS will permit the use of animal production claims and the term natural on meat and poultry labeling, provided they are truthful about how the animals from which meat and poultry products are derived are raised, on the label. Examples of such claims are no hormone implants used in raising, no antibiotics used in raising, corn fed, etc. However FSIS will not be defining the term Organic or the criteria to which the production of agricultural products must adhere in order to apply the term to their labeling.<sup>61</sup>

### **3.4. Conclusion:**

Organic agriculture supports a commitment to environmental stewardship, clean food and a safe work place. It offers a clear alternative to chemical intensive agriculture, now dependent on nearly one billion pounds of pesticides annually.

When the initial standards were first proposed, the organic industry was shocked to see such a watering down of the definition of organic. After eight years of negotiating in good faith with the agency, the industry expected the USDA to do the right thing and create a rule in line with the practices currently used in organic food production. Furthermore, the National Organic Standards Board (NOSB) that was created by Congress to do this work did not produce the new regulations.

It is feared by many that the proposed rule would weaken the meaning of the term Organic, as well as the integrity of the organic foods supporters – be they the consumers, or the producers. The rule would also simultaneously impact opening the market to mass production methods, enabling large-scale operations to create pseudo-organic food and cash in on its high margins.<sup>62</sup> Many certifiers are concerned that the proposed USDA federal regulations will make it illegal for them to uphold stricter standards than what the USDA currently allows.

Clearly, the beneficiaries would be the agribusiness conglomerates who would not have to adhere to the high standards that were developed by the organic industry. The losers, as usual, would be the organic farmers and the consumers who care about how food is produced.

## **Section 4**

### **Biotechnology Labeling in the U.S.**

#### **4.1. Introduction:**

One of the newest developments in United States agriculture is the advent of biotechnology, which seems to be leading us into a sudden new biological revolution. It has brought us to the brink of a new world of engineered products that are based in the natural world rather than on chemical and industrial processes.

The first products of modern biotechnology have entered the commercial market. United States is the world's leading producer of genetically modified crops, with 50% of its soybeans, and 38% of its corn being products of genetically modified seeds.<sup>63</sup> Companies are actively marketing genetically engineered crops, plant products and animal products.<sup>64</sup> And even though federal agencies are defining the appropriate regulatory process and labeling of bio-engineered products, public concern and curiosity continues to be heightened as increased visibility of these products and issues develop. As new advances are made in plant and animal production it is critical to ensure that private and public issues are adequately reviewed.

While many traditional biotechnologies, such as the fermentation of microorganisms to produce wine and cheese, are uncontroversial because they are natural and not controlled by man, genetic engineering has provoked intense public interest and scrutiny.<sup>65</sup> A central consumer concern regarding genetically modified foods is the question of safety. And as the question of what is safe has no fixed interpretation, genetically modified foods provide a new area for further rules on food labeling in order to ensure that the consumer is adequately informed about the food products he or she purchases. This part therefore, will examine the issue of labeling bio-engineered foods in the United States.

## **4.2. Labeling of GMOs in the U.S.:**

The U.S. Office of Technology Assessment concluded in 1992, biotechnology-related risk assessment focuses on the planned introduction of genetically modified organisms into the environment (environmental safety) and on the consumption of products derived from biotechnology.<sup>66</sup> The policy issues identified by the Congress and the regulatory maze of agencies that has developed in this arena of scientific endeavor included the following:

1. Should the products of biotechnology be treated in the same science-based, risk-based regulatory paradigm as other products for which there are safety/ environmental concerns? For example, should the products of biotechnology be treated as new products, requiring protracted approval procedures, even though they are synthetically produced replicas of naturally occurring substances? Alternatively, should disease or pest-resistant plants that are the products of biotechnology be treated any differently from a regulatory perspective than such plants produced by conventional plant breeding procedures?
2. Should transgenic plants (genetic material from another plant or animal inserted) be treated as a food additive and require the complete new additive approval process?
3. Should the same residue tolerances be applied to pest-resistant plants as for pesticide residues in general?
4. What role should the public play in resolving issues of biotechnology regulation faced by the various regulatory agencies?
5. Do consumers have a right to know whether they are buying products of biotechnology (e.g., should food produced from transgenic plants and animals be so labeled?)?
6. Should current laws regulating chemical applications to agriculture be applied to biotechnology where the control mechanism is microorganisms?

7. What steps should be taken to protect the natural gene pool from the genetically modified gene pool when, for example, a new biotechnology derived plant or animal is produced?<sup>67</sup>

Despite such deliberations on the part of OTA almost ten years ago, genetically modified foods are not labeled as such in the United States, because the Food and Drug Administration (FDA) has chosen not to classify alien genes as food additives and therefore does not require that they be listed on food labels. In addition to not requiring labeling of these foods, the FDA does not demand testing them either. It only requires the manufacturer's assurance that they are safe. Similarly, the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) have no comprehensive testing requirements. However, even though federal agencies in the U.S. are still defining the appropriate regulatory process and labeling of bio-engineered products, public interest continues to be heightened as increased visibility of these products and issues develop.

While many within the U.S. have suggested that the decision to require labeling should depend on the specific product, and the method used to produce it; the FDA has indicated in its guidelines on the regulation of food biotechnology that labeling will be required if the character of a food is changed substantially, such as when an allergen not commonly found in a plant is introduced. The questions considered by FDA at regular intervals of time, when deliberating on the issue of mandatory labeling of GMOs include:

1. Whether in an era of biotechnology and food processing innovations and with a policy of encouraging more healthy foods, such standards of identity stand as barriers to progress?
2. Would the alternative of simply allowing consumers to make comparisons, using the mandatory nutritional label, be sufficient?<sup>68</sup>

Labeling is only required on GMOs in the U.S. if the product is a known allergen or the nutritional content of the food is changed. U.S. regulators and industry representatives argue that engineered foods, if anything, are safer than conventional foods. Moreover, they say, since 1992 the FDA has required allergy tests done for all new food made with genes taken from milk, eggs, wheat, fish, shellfish, legumes, nuts, etc., which account for around 90% of American food allergies. The agency maintains that gene-altered foods are nutritionally equivalent to conventional counterparts.

Section 403(a)(1) and Section 201 of the Federal Food Drug and Cosmetics Act (FFDCA), are probably the statutory workhorses. The FDA uses these sections regularly to promulgate various types of statements requiring food identification. These sections state that a product is misbranded if anything said about it is false or misleading in any particular way. That standard is a very general standard. It should be noted that the law goes on further to say that, in considering whether something is false or misleading in particular, one shall consider the representations made or the failure to reveal material facts in light of such representations or the failure to reveal material facts with respect to consequences that may result from the use. This is the critical part of the statute that the FDA has considered in the biotechnology area that is relevant to food labeling: the failure to reveal material facts.<sup>69</sup>

Section 403(g) is another provision within FFDCA that has been used frequently. It concerns standards of identity for foods. The legal or labeling principle that emerges from this provision is that once you call an ingredient or product by a name that corresponds to a standardized food, you cannot vary how it is made or how it is derived, unless it varies according to the prescribed standard. There are various products of biotechnology that may fall under this principle.<sup>70</sup>

Perhaps the most significant provision in FFDCA for biotechnology foods is section 403(i). This provision states that foods shall be identified by their common or usual name and, moreover, that food ingredients shall be designated on the labels of fabricated foods in descending order of predominance by weight and shall be identified by their common or usual name. This naming issue is a very significant one in the genetic engineering area because it can be argued that by altering food composition through genetic engineering the basic nature of food itself is being changed.<sup>71</sup>

The FDA and the food industry also insist that labels should be reserved for the relevant, science-based information. Till now, FDA considered voluntary labeling that a product is not genetically engineered as misleading unless it is accompanied by a statement that there is no difference in healthfulness between a genetically engineered product and non-genetically engineered product. However on May 3<sup>rd</sup> 2000, the White House announced that FDA will develop guidelines for voluntary efforts to label food products under their authority as containing or not containing bio-engineered ingredients in a truthful and straightforward manner, consistent with the requirements of the Federal Food, Drug, and Cosmetic Act.<sup>72</sup> But we have yet to find out what would form the basis of these guidelines. Also, the U.S. has no special regulations applying to imported genetically modified food, and Federal officials are not required to know which imported foods are genetically modified.

Furthermore, the regulatory structure for GMOs in the U.S. appears to be highly fragmented. The USDA approves the release of genetically engineered plants into the environment and approves crops for production. FDA oversees food safety but not pesticides expressed in the food. The EPA regulates pesticides expressed due to genetic engineering but not food. No agency has responsibility for assessing genetically engineered food containing pesticides. The government assumes that if the original food is

safe and the pesticide has been approved as having no adverse effects, then the food containing the pesticide is safe.<sup>73</sup>

### **4.3. Are FDA Standards for Labeling Adequate?**

The broadening and differing scope of perception, based on various representations of the value, safety and usefulness of biotechnology, is affecting the global food trade. The question of the extent to which the consumers right to know should be carried out has evoked varied responses among differing nations, and within nations, among different sections of society.

Labeling is the first step, because it gives people the right to choose, says the chairman of the Consumer Right to Know Campaign, an umbrella organization for numerous groups that are calling for mandatory labeling and long-term testing of all genetically engineered foods. Without labeling, there's no way to trace any health effects, and there is no way to protect consumers.

Because genetically modified (GM) food in the U.S. is not labeled or regulated, it is impossible to track possible long-term problems. Americans have been far more willing to accept such foods without question, but that is now changing. Lawsuits demanding labeling have been filed against the FDA, and last spring, Congress received a half million signatures on petitions calling for labeling of gene-altered foods. Also, 49 members of U.S. Congress recently sent letters to the FDA requesting mandatory labeling of genetically engineered foods.<sup>74</sup>

There is no consensus among scientists on the safety or the risks associated with genetic engineering in agriculture. The international community is deeply divided on the issue. Around the world, protests continue to mount against genetically modified foods. Lack of proper GMO regulations and labeling in the U.S. that are not in accordance with those

in force in its trading partner nations, can result in harming the American agriculture enterprises financially.

#### **4.4. What Do The People Want?**

Labeling of genetically modified foods is also important, for many people do not consume certain foods on religious and moral grounds. For example, Muslims do not eat pork, and Hindus do not eat beef. Some orthodox rabbis also state that their strict dietary laws require them to know when a foreign gene has been spliced into their food. Further, it should be noted that since altered DNA or proteins can disappear during processing, products can often test negative despite their gene alterations.

In a recent survey in the U.S., 70% of respondents wanted labeling of GM foods and 40% wanted more stringent regulation of agricultural biotechnology.<sup>75</sup> A poll by biotech and pharmaceutical giant Novartis, which was released in February 1997, found 54% of American consumers stating they would prefer to see chemical-intensive agriculture move towards organic production. In the same poll 93% said that genetically engineered foods should be labeled, with 73% indicating that they felt strongly about this. A Time Magazine poll of January 1999 found that 81% of Americans wanted genetically engineered food labeled.<sup>76</sup> A USDA funded poll released in January 1996 on BGH (recombinant Bovine Growth Hormone, often known outside the U.S. as BST), in which 94% of consumers said BGH-derived dairy products should be labeled, while 74% felt the biotech drug was unsafe.<sup>77</sup>

#### **4.5. Labeling of GMOs: An Industry Perspective:**

Labeling of biotechnology-derived foods and ingredients, according to the food industry in the U.S., raises several challenges for the food processing industry. The arguments presented by the industry representatives are:

1. In many cases, it is difficult to distinguish between constituents that are introduced via genetic engineering versus traditional plant breeding techniques, particularly in those cases where the cloned gene products are already present in that food.
2. Rapid, reliable and inexpensive methods would need to be developed to identify engineered varieties.
3. In the absence of analytical methods for determining whether or not a plant is engineered, tracking systems for plants and plant-derived ingredients at every stage of the food chain (from the seed to the processor to the grocery store to the consumer) would need to be constituted. The impact and total cost for instituting tracking and separate handling systems is not known; however, the cost of the systems would probably be passed on to the consumers through higher prices.
4. Labeling would encourage more vertical integration in the food industry, as food processors would want to control the source of their raw materials and document the history of their products from the seed to the processing plant. This could influence the structure of agriculture.
5. Labels or symbols on labels are commonly used to alert consumers when a safety issue might exist for certain individuals. A label indicating that a product was derived using biotechnology might be perceived by consumers as a warning signal.<sup>78</sup>

#### **4.6. Conclusion:**

It can be said in conclusion that food labeling is important from both the consumers' perspective as well as for the advantage of agricultural trade. The safety of genetically modified foods is always open to a number of views and arguments, and the propriety of such foods being grown and marketed can be either applauded or criticized. There have been, are, and may continue to be people who would either see no advantages or disadvantages with genetically modified foods.

Labeling of such foods is however open to another venue of perusal. Many countries in Europe and Asia have passed regulations implementing mandatory labeling of GMOs, in view of the increasing demands of their people. For decades farm groups and leaders in the U.S. have emphasized the need to educate the consumer about agriculture. Effort has been taken to stimulate in the consuming public enough interest in agriculture to create a vague sense that food originates on farms, and not supermarket shelves. However, the strategy now being adopted by large corporations (e.g., Archer Daniels and Midland Corporation), of publicly advertising the benefits of introducing genetic engineering, while at the same time ignoring the risks involved, for winning public acceptance for GMOs, is questionable.

While the public is now ready for more information, most farm leaders are now resisting labels on GMOs. This raises the question whether policy makers fear that consumers will use the information given to them and leave the genetically modified foods on the shelves because of personal reasons – be they scientific, religious, or moral.

While it cannot be argued that mandatory labeling of biotechnology-derived foods is obviously a complex issue from the food processing industry's viewpoint; it cannot be ignored that labeling involves the question of the consumers freedom to know the facts, and their right to make their own informed decisions about what they eat. Lack of proper labeling of GMOs has also impacted this nation in the international arena. The U.S. therefore must decide whether it wishes to enforce similar requirements and continue to enjoy its prosperous agricultural trade, or risk losing not only its trading partners but also the goodwill of American consumers who are demanding such labeling.

## **Section 5**

### **EU Biotechnology Labeling**

#### **5.1. Introduction:**

In the past few years, the labeling of genetically modified foods has become a major issue of controversy for the European Union (EU). EU legislation has become more and more detailed ever since the adoption of the main framework food labeling Directive in 1979. Labeling was then defined under the Directive to provide,

*Any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring, or collar accompanying or referring to such food stuff.<sup>79</sup>*

Following the adoption of the novel food regulation in 1997 and various other legislative initiatives since then, the EU is still grappling with the problems of trying to establish a uniform system for the labeling of genetically modified foods. On the question of genetically modified foods, the EU has been faced by the fact that having to ensure that consumers are confident that the information they are provided with concerning these new types of foodstuffs will allay many of the perceived fears about the safety and long term health effects involved in using these foodstuffs.<sup>80</sup>

Europe has taken a precautionary approach, introducing legislation designed to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology. The EU maintains that as with all other technologies, the risks associated with genetic engineering have to be identified, evaluated and appropriate measures taken. Therefore, the approach taken to risk management should be based on the step-by-step development and testing of new organisms, the risk and impact of which have to be analyzed case by case.

The European Union plays a very important role in the world today, and its trade policies impact, both directly as well as indirectly, the economic prosperity of the United States. Therefore this part examines closely EU's policies concerning biotechnology labeling.

## **5.2. GM Labeling Regulations in EU:**

Four laws currently govern the regulatory review and commercialization of genetically modified foods in the EU.

1. Council Directive 90/220 governs the approval for environmental release and commercialization of "living" genetically modified organisms. Bio-engineered foods (or GM foods) in Europe were, since 1990, regulated by the Novel Food Regulation Act and Directive 90/220/EEC of the EU.<sup>81</sup> Risk assessment measures have to be taken by the Member States to avoid not only any direct and immediate effects, but also all indirect and long-term effects.<sup>82</sup>

If no immediate risks are identified, then a general pre-market surveillance system has to be established to enable the rapid identification of unforeseen problems prior to introducing the foods into the market for sale.<sup>83</sup> This monitoring and post surveillance is carried on even after the product is introduced into the market.<sup>84</sup>

2. The Health and Consumer Protection Directorate General has taken over administration of the Novel Foods Regulation (European Parliament & Council Reg. 258 /97) governing food safety assessments and labeling for most genetically modified foods. Regulation 258/97 passed in September 1997, known as the novel foods regulation, provides for labeling of biotech foods when:
  - Any characteristics or food property such as the nutritional value, or intended use of the food has changed so as to render the product no longer equivalent to its conventional counterparts;
  - An allergen is introduced into the food;

- There is material in the food that would give rise to ethical concerns; or
  - The food is derived from a genetically modified organism.<sup>85</sup>
3. Council regulation 1139/98, in force from September 1998, covers labeling of foodstuffs derived from Round-Up Ready soybeans and Novartis Bt-176 corn, as these products were commercialized before the Novel Foods law went into effect. The European Union argued that the second regulation was needed because the soybean and corn varieties were approved before the novel foods regulation was enforced. As a result, manufacturers have been obliged to label their products with the phrase “produced from genetically modified soya” or “produced from genetically modified maize” since September 1998. The regulation established that the presence of protein or DNA from the transformed soybean and corn varieties was enough to render products no longer equivalent and therefore subject to labeling as provided for in the novel foods regulation.<sup>86</sup>

The above regulation (1139/98) has since been amended by Commission Regulation 49/2000, which entered into force on April 10, 2000, setting a 1% threshold for adventitious (accidental) contamination during cultivation, harvest, transportation, storage and processing. This amendment applies to products for which the manufacturer cannot guarantee that each of the ingredients contains less than 1% GMOs. Evidence must be supplied to the competent authorities that appropriate steps were taken to avoid the presence of GMOs.<sup>87</sup>

4. Commission regulation 50/2000, which also entered into force on April 10, 2000, provides specific labeling requirements for food and food ingredients containing additives and/or flavorings that have been genetically modified or have been produced from GMOs, as specified in Directive 90/220/EEC. This regulation applies to

additives (e.g., rennet) and flavorings for use in foodstuffs falling within the scope of Directive 89/107/EEC and Directive 88/388/EEC.<sup>88</sup>

Creating the 1% threshold for ingredients will accommodate small traces of GM material entering the food chain during processing and manufacturing. This was prompted by the knowledge that most of the GM foods on the market contain either genetically engineered soybeans to resist the herbicide Roundup, or genetically engineered corn to kill insect pests by expressing a *Bacillus thuringiensis* toxin. A statement from the EU's Standing Committee for Foods said that the threshold,

*"Aims at solving the problem faced by operators who have tried to avoid GMOs but who due to accidental contamination still find themselves with a low percentage of GM material in their products. It will thus offer legal certainty to those operators."*<sup>89</sup>

In addition to the 1% threshold proposal, the commission has proposed draft labeling rules for foods containing additives and flavorings produced from GMOs. The proposal is a draft commission regulation to ensure that foodstuffs that contain GMO-derived additives or flavorings are labeled in the same way as those which contain other GM ingredients. Labeling is required:

- When the additives or flavorings are, contain, or consist of GMOs;
- When they raise a particular safety (e.g., allergies) or ethical concern; and
- When they are not equivalent to their conventionally produced counterparts, i.e., when they contain protein or DNA resulting from genetic modification.<sup>90</sup>

### **5.3. Labeling in EU: What Do The People Want?**

Under Directive 90/220, the EU Commission had approved for environmental release and for commercialization Monsanto's Round-up Ready soybeans (RRS) in March 1996, Ciba-Geigy's Bt-corn in December 1996, and three more varieties of corn in April 1998. However, despite EU approval, GMO products are facing consumer opposition in certain EU Member States, especially where biotechnology has become a political issue. In fact in 1998, Luxembourg and Austria banned imports of Bt-corn, while France and Italy banned planting but not imports.<sup>91</sup>

The United Kingdom has been the most progressive in implementing the EU's GMO regulations. The British government is firm in its goal of enacting the EU's directive that all restaurants and other food providers must label GMO food products. The British Medical Association is also on record as supporting mandatory labeling of all GMO foods. The group advocates separating GMO from non-GMO crops so that any safety concerns with GMOs can be accurately traced.<sup>92</sup>

On September 10, 1998 the Commission decided that these import and planting bans were illegal, but is moving very slowly on infringement proceedings. In November 1998, France banned two genetically modified rapeseed varieties that already had been approved. These countries all used Article 16 (safeguard) of Directive 90/220 to challenge EU approval.<sup>93</sup> On April 12, 2000, the European Parliament (EP) voted out Article 16 for the revision of directive 90/220. The next step in the process is conciliation of the EP's text with that of the Council, expected to be completed no later than October 2001.<sup>94</sup>

One criticism against the EU regulation voiced by some in the international community (and especially by U.S. food exporters) is that it does not specify the quantity of GMO material present necessary to trigger labeling. The EU now is considering questions like: Can a food avoid

labeling if it has less than 1% GMO ingredients? Does 1% mean 1% of the whole product or of the ingredient in question? The EU regulation has also been criticized by proponents of mandatory labeling who say the regulation is not inclusive. Mandatory labeling does not cover food additives (dietary supplements), flavorings, or extraction solvents. The EU says these products are covered under other legislation, but groups like Greenpeace, GeneWatch, and others, say no regulation exists to ensure that these products are labeled.

There are a number of reasons why European consumers appear more concerned about biotechnology than American consumers. Foremost is the Mad Cow disease problem and its aftermath, which frightened the public, politicized food safety regulation, decreased confidence in governments and scientists, and taught the media that food scare stories sell. Organized opposition from environmental and consumer groups combine a romantic ideal of pre-industrial agriculture with strong anti-corporate values. Further, because of the abuses of European agricultural policy, European consumers see no benefit in increasing yields as they have memories of unwanted surpluses.<sup>95</sup>

In a survey conducted in September 1997, 80% of Europeans considered that biotechnology was useful in detecting hereditary illness and for the production of new innovative medicines. On the other hand, only one in four Europeans would buy genetically altered foods even if it tasted better, and less than one in four Europeans considered that the current legislation was adequate against all the perceived risks they believed were linked with modern biotechnology. The general consensus was that the risks involving modern biotechnology are predominantly concerned with genetically modified foods/ organisms, and that labeling of such food is essential.<sup>96</sup>

Consumers must have guarantees and information about food containing genetically modified organisms, according to Luc Guyau, the

new French president of the EU farmers' organization, COPA. Guyau condemned what he described as the "incoherent attitude" of the French government, which in February accepted imported GMO maize, but refused to let farmers grow it. "Either one says it's dangerous for everyone or one authorizes it for everyone," Guyau said. As a result of these demands, the European Commission is demanding the labeling of all genetically modified farm products, including two strains of GMO maize and soybeans already cleared for sale in the EU.<sup>97</sup>

Indifference and failure to comply with these demands can affect American farmers. The EU has already stopped buying American corn resulting in a trade loss to the US of over \$200 million last year. In June 1999, environment ministers for the 15 EU Member States agreed to a *de facto* moratorium on importing GMOs until new rules regulating them have been established – possibly as late as 2002.<sup>98</sup>

One particular incident goes to prove that even a sprinkling of engineered cornmeal or soy flour from a previous shipment can make an entire grain silo or rail car of otherwise unengineered food test falsely positive as engineered. An excellent example is the case of Prima Terra. In fall 1998, testers in Europe detected traces of genetically engineered corn in organic corn chips made by a U.S. company, Prima Terra Inc., of Hudson, Wisconsin. Some of the corn supplied to Prima Terra from a certified organic supplier was contaminated, it turned out, with minuscule amounts of gene altered corn, perhaps because a few grains of genetically modified pollen blew into the organic grower's fields from a neighboring farm. The positive test forced Prima Terra to recall 87,000 bags of chips value at \$147,000.<sup>99</sup>

#### **5.4. Conclusion:**

In Europe the Precautionary principle is used to regulate genetically modified (GM) foods. Application of this principle means that risk

management provisions have to become more restrictive to match scientific uncertainty in the risk assessment and the complexity of the system.<sup>100</sup> The countries of Europe have used this principle to require that GM food be segregated and labeled.

With consumer sentiment in Europe clearly running against GM products and the supply chain responding accordingly, the issue of GM food labeling may be more or less moot in many European countries. This is so not only because European consumers have made their views widely known, but also because the regulatory authorities are diligently working towards labeling all GM foods and declaring all non-GM foods as GM free.

Efforts are underway to have mandatory labeling on all foods that contain or may contain genetically modified organisms. To conclude in the words of the EU Consumers Association representative:

*LABELING is a step forward but crop segregation is the only way to guarantee consumer choice.<sup>101</sup>*

## **Section 6**

# **Comparative Analysis of Organic and Biotechnology Labeling: U.S. and E.U.**

### **6.1. Introduction:**

Organic farming is truly sustainable agriculture where humans adapt to nature holistically by applying ecological concepts and principles. In contrast, genetic engineering conquers nature through redesigning the cell's genetic structure. Genetic engineering now poses a considerable threat to the organic movement. The entire biotechnology movement-- comprised of the petrochemical and conventional food industries, the bio-scientific community, and allied government agencies-- threaten to merge genetic engineering into organic food production, or at least, blur the boundaries between conventional, novel, and organic foods.

Organic farming and biotechnology are largely opposing forces in modern agriculture today. While the number of consumers embracing organic farming practices and products is constantly growing, government and food industry experts in the U.S. insist that biotechnology is the only sustainable way of meeting the demands of the increasing world population. This notion however is viewed with skepticism by some and fury by many others in this country, and is totally unacceptable in the E.U.

Since the ways in which organic foods and genetically modified (GM) products are defined and received by consumers and producers in the United States are different from that in the European Union, effort has to be taken to maintain a clear cut distinction between them. The previous parts have examined the regulatory framework in the U.S. regarding organic food labeling, as well as biotechnology labeling in both the U.S. and in E.U. This part concludes this examination of the issues surrounding food labeling with a comparative analysis of the problems emerging in the

production and more importantly in the trade of organically and biotechnologically produced food products in the U.S. and in E.U.

## **6.2. Why Do GMOs Place Organics in Danger?**

Although the certified organic label means GMOs are not used, the U.S. Organic Trade Association has noted that some organic products could inadvertently contain small amounts of GMO material from exposure to pollen from GMO crops in the field or incidental GMO ingredients in processing.<sup>102</sup>

All of the organic certification agencies in the United States and abroad have "prohibited the use of genetically engineered organisms, or their products, in any form or at any stage in organic production, processing or handling". Unfortunately, there is no mandatory labeling in the United States of GMOs in food products, and in production agriculture the Bt Seed Corn, "Roundup-Ready" corn and soybeans and other input-trait GMOs are being increasingly used. The potential problem for the organic growers is that they may unknowingly be using GMOs in their operation. Thus, although it is not their intention to violate organic principles, they cannot fight what they can't see.<sup>103</sup> The risk of de-certification for organic producers due to GMO use and/or contamination is a clear and present danger.<sup>104</sup>

OTA pointed out in written comments submitted to the U.S. Food and Drug Administration (FDA), that organic producers take great care to offer customers a quality product with only the limited use of synthetic processing materials or ingredients. However, they said:

*Now, producers are faced with not only the problem of contamination in the field but, more fundamentally, even the inability to be sure they are choosing non-genetically engineered minor ingredients because they are not labeled.*

*The burden of labeling should not be on the producers of conventional or organic food.*<sup>105</sup>

### **6.3. Policy Differences in U.S. Versus in E.U.:**

#### **6.3.1. With Regard to Organic Foods:**

The production, labeling and importation of organic foods is covered by the Council Regulation 2092/91, as amended. Regulation 1804/99 covers livestock products. The word Organic on the label may be used for products conforming to this regulation. Products imported from the U.S. need to be certified and exporters have to work through individual Member States to obtain clearances to import certified organic products on a case-by-case basis.<sup>106</sup>

EU organic products legislation on the other hand requires that organic product certifiers meet criteria as certification bodies defined by EN 45011/ISO Guide 65. Member States are implementing this requirement. USDA's Agricultural Marketing Service (AMS) has developed a program to accredit U.S. organic certifiers to the ISO Guide 65 requirement. To date Austria, the Netherlands, Denmark, Spain, Sweden, the U.K., and Germany have officially recognized AMS's ISO 65 program, but U.S. exporters must continue to satisfy Member State requirements.<sup>107</sup>

#### **6.3.2. With Regard to GMOs:**

The general policy drives that have affected the US's and the EU's approach to GMOs are fundamentally different. Within the U.S., agricultural supply factors, linked to the development of output-enhancing and/or cost-reducing GMOs dominate agricultural application in the US, leading to a strong push for their rapid development and commercial use. On the other hand, in the EU (1) agricultural policy reform provides incentives for lower output and emphasis on quality aspects of products and

productions methods, and (2) food demand, linked to food safety concerns, dominate the agricultural biotechnology debate.<sup>108</sup>

The problem that arises is that the regulatory framework with regard to GMOs is that:

- In the U.S. it's based on a framework established in 1986, and does not contain any rules specifically designed for the use of GMOs in agriculture or for food production; and
- In the E.U. the regulatory framework was designed in the late 1980s. The EU framework consists of both "horizontal" legislation, and product specific legislation.<sup>109</sup>

The impacts of these policy differences are that since 1996 grain shipments from the US to the EU have decreased. This drop has been influenced by several factors:

1. US has been unable to deliver with appropriate guarantees (e.g., corn to Argentina);
2. This situation has caused strains in trade relations between the EU and the US;
3. The obstacles were perhaps initially viewed by the US as a "protectionist trick" by the EU. But, in the words of USDA officials, "We as government officials can approve all we want, but it won't matter if consumers won't buy it";
4. Efforts to restore consumer confidence were not helped by claims that European science was "phony science" or that European consumers were "ignorant";
5. There is a growing understanding in the US that there are real consumer concerns; and
6. Consumer concerns have also manifested themselves in Australia, Japan, and South Korea.<sup>110</sup>

#### **6.4. International Food Trade and The Codex Alimentarius Commission:**

The World Trade Organization (WTO) administers the multilateral trading system. Its rules, contained in a series of agreements (the WTO Agreements), direct the policies of its Member states towards economic liberalization. As well as governing trade in goods, these rules impose disciplines on governments in areas as diverse as intellectual property, investment, services and government procurement. At least two of these agreements must be considered in relation to GMO product labeling:

1. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)<sup>111</sup>; and
2. Agreement on Technical Barriers to Trade (TBT Agreement).<sup>112</sup>

The standards, guidelines, and other recommendations of the Codex Alimentarius Commission are considered by the WTO to reflect international consensus regarding the scientific requirements for protecting human health from food borne risks. A Member's food safety measures are considered justified and in accordance with the provisions of the SPS Agreement if they are based on Codex standards and related texts. Additionally, by the terms of the SPS Agreement, WTO members are committed to considering Codex standards as a basis for their national laws and regulations, and to participate in the development of those international standards.<sup>113</sup>

The Codex Alimentarius is designated by the World Trade Organization as the officially recognized rule-making body for international trade issues related to food. The Codex has been holding a series of ongoing meetings to define the term "organic" internationally. Thus far, the majority of national representatives participating in the Codex meetings have resisted the inclusion of genetically engineered foods under the organic label, although the U.S. government delegation and the

biotech industry have at times lobbied for weaker international standards.<sup>114</sup>

Besides the transgenic foods controversy, the USDA proposed federal regulations will attempt to allow meat, eggs, dairy, and other animal products to be labeled "organic," even if the animals have been kept in intensive confinement. This runs directly counter to the guidelines of organic certification bodies across the world. Humane farming advocates are outraged at the possibility that intensive confinement feedlots, factory-style dairies, or giant corporate hog and chicken installations would be allowed under the new federal regulations to label their products as organic.<sup>115</sup>

Efforts to label products that contain GMOs lie under a cloud of WTO censure. Already, the WTO-compatibility of the European Union's GMO labeling regulation is being challenged by the United States. By threatening to bring the EU before the WTO's dispute settlement body, the United States is pressuring the EU to review and weaken its GMO policy.<sup>116</sup>

### **6.5. Organic Versus Biotech: Where Do We Stand Today?**

A major dilemma is taking shape as more and more consumers worldwide are rejecting biotechnology and embracing organic products. In the United States, organic farming is not only growing by leaps and bounds, but also going mainstream.<sup>117</sup> Similarly, current organic policy in the E.U. is structured to achieve a definitive 20% reduction in surplus output rather than to achieve environmental benefits garnered from organic farming. Organic agriculture is being viewed as the way to attack the glut of food in the marketplace, just as the United States instigated a policy of systematically taking land out of production through the 1985 Farm Bill. With marked enthusiasm, European communities are

advocating programs that will support more farmers to convert from conventional to organic farming methods.<sup>118</sup>

Organic farming research is already strong in countries such as Denmark, Germany, The Netherlands, and Sweden, and the United Kingdom is soon to step up its organic research program. As part of its organic training commitment, Denmark is converting one of its agricultural colleges to educate farmers about organic practices. Germany has already established professorships in organic farming. Support payments are being offered to many farmers who are undergoing the conversion. Scandinavian farmers are being funded around \$300 to \$800 per hectare (it varies from case to case) for a 3 to 5 year conversion program, beginning in 1990.<sup>119</sup>

There are many reasons to develop a method to distinguish between well-researched, almost assuredly beneficial applications of biotechnology and those that promise to deliver few, if any net benefits while posing new, possibly uncertain risks. Dealing with GMOs in the context of organic farming standards is just one of them. The current debate in the U.S. is the first time in recent memory that a significant minority of farmers and citizens have joined together to petition the government to "Just Say No" to a major new set of technologies. This places the government in a box, since it is responsible for implementing the laws of Congress as written, including the "Organic Farming Production Act" passed in 1990, yet it

*"...also has thrown caution to the wind in becoming a tireless promoter of the industry."<sup>120</sup>*

Today, country-of-origin labeling is demanded by many Americans. In a survey, conducted by Wirthlin Worldwide, 78% of respondents supported country-of-origin labeling. The consumers surveyed agreed with the statement that country-of-origin labels should be required so that they can choose whether to buy American or imported meat. 46% of the respondents said their view was exactly like the statement, while 32% said

their view was somewhat like it. In fact the Congress recently approved a six-month pilot study, due in mid-April 2000, to evaluate the costs and benefits of country-of-origin labeling to government, producers, consumers, and multiple industry businesses.<sup>121</sup>

It should be noted that the American Farm Bureau Federation told a congressional panel last year, that as increased trade results in more fresh and processed agricultural products moving across international borders, U.S. consumers deserve to know the origin of their food products. The Imported Produce Labeling Act (HR 1232) was introduced in the U.S. Congress, calling for mandatory country-of-origin labels on fresh produce sold in U.S. grocery stores. A "clear and visible sign" would be required to declare what country the produce originates from, under penalty of \$250 per day for non-compliance. The bill's sponsor, Representative Sonny Bono of California, said the bill was a "common-sense way of providing the American consumer with basic information about the produce they may want to purchase."<sup>122</sup>

U.S. Secretary of Agriculture Dan Glickman voiced concern over possible retaliation against U.S. goods in foreign markets. The laws are being promoted as good trade policy based on the premise that the initiative will harmonize the labeling practices of the U.S. and its major trading partners – most of whom, proponents argue, already require country of origin labeling on imported produce.<sup>123</sup>

On the other hand, a system of identity preservation that would allow genetically engineered varieties of crops like corn and soybeans to be segregated from traditional varieties has long been resisted by commodities groups and agricultural biotechnology leader, Monsanto. They have insisted that any system of identity preservation and labeling of genetically modified crops would make foods produced using biotechnology uneconomical. And it should be noted that, product specific labeling which strives towards identity preservation is one of E.U.'s fundamental policies.

This kind of difference in receptivity and treatment leads one to wonder about the possibility of harmonious and prosperous international trade.

Everyone will agree that people have a fundamental right to know what is in the food they are buying and consuming. A variety of personal, ethical, and environmental considerations make this information necessary, and apparently the American public agrees -- polls show overwhelming support for the labeling of genetically modified foods. The only, and embarrassingly weak, argument for withholding this information is that it might confuse or "frighten" consumers.

One of the fundamental values within organic agriculture is informed consumer choice. Similar to nutrition labeling, irradiation labeling and country of origin labeling, GMO labeling would give consumers control over their food – in this case, the degree of risk they are willing to take with a new technology.

Over the years, Europe has undergone a collapse in consumer confidence in food safety -- so much so that the European Commission has made regaining that confidence one of its top priorities. Although GMOs in agriculture have existed for over a decade, their commercial use has expanded tremendously in just the last few years.<sup>124</sup> And it has to be acknowledged that just as American consumers have a right to know from which country the fresh produce and meats come from prior to purchasing them, the European consumers too have a similar right to know the particulars of what they are eating.

## **6.6. Conclusion:**

Government regulators, the organic community, industry trade associations, professional societies, investors, and consumer and environmental groups are all working toward a way to leverage positive change in agriculture and the food system. We need to have a universal

understanding regarding biotechnologically engineered foods, or else international food trade would not be possible. And this has been noted even by Glickman, when talking about biotech products:

*“...we ... have to keep this in mind: market access isn't enough if, when it comes right down to it, many European consumers fundamentally don't trust and won't buy the products.”<sup>125</sup>*

There is therefore every reason today to develop some kind of a method to distinguish between well-researched, almost assuredly beneficial applications of biotechnology and those that promise to deliver a few net benefits while posing new, possibly uncertain risks. Dealing with GMOs in the context of organic farming standards is just one of them.

The U.S. needs to adopt certification techniques that allow U.S. produced food products to achieve the level of rigor and precision required internationally through third-party inspections, audits, sampling (a critical and often neglected technology for accurate GMO assessment) and testing.

Foods that have been found to be non-GMO by less rigorous means are often tested and found to contain GMOs at foreign ports, causing major revenue losses to the producer. The U.S., therefore, needs regulatory authorities to make rigorous testing within the country mandatory.<sup>126</sup>

Labeling is also an important device in facilitating market acceptance. Consumers are likely to feel less worried if they sense that there is no reluctance to labeling, i.e., that there is nothing to hide. Consumers have a right to know whether products have been genetically modified. Over the long term, finding labeled products in the grocery store is likely to lead to greater acceptance of GM foods.

## **Conclusion**

It can be said in conclusion that food labeling is important from both the consumer's perspective as well as for the advantage of agricultural trade. The safety of food is always open to a number of views and arguments, and the propriety of foods being labeled and marketed can be either applauded or criticized.

This report examines the importance of food labeling in today's world. Part 1 discusses how labeling involves the consumers right to know and their right to make an informed decision about what to eat based on the information provided by labels; Part 2 concludes on the note that a price or income change affects the availability of nutritious food; Part 3 examines how organic agriculture offers a clear alternative to chemical intensive agriculture and to clean food; Parts 4 and 5 conclude on the note that labeling of genetically modified foods is an issue of growing concern that cannot be ignored; and lastly Part 6 points out the importance of having a universal understanding regarding biotechnologically engineered foods as well as organic foods.

There have been, are, and may continue to be people who would see no advantages or disadvantages of labeling foods. Lack of proper labeling can also impact international trade if one country insists on a particular kind of labeling while another country wishes to adhere to something different.

Labeling of foods is also open to another venue of perusal. For decades farm groups and leaders in the U.S. have emphasized the need to educate the consumer about agriculture. Effort has been taken to stimulate in the consuming public enough interest in agriculture to create a vague sense that food originates on farms, and not supermarket shelves. Labeling involves the question of the consumer's freedom to know the facts, and their right to make their own informed decisions about what they eat.

## **Kerr Center Policy Recommendations**

*First*, it is imperative that Congress make labeling of all foods mandatory. This requirement is critically important for genetically engineered foods that are rapidly becoming invisibly incorporated into the U.S. food supply. It is equally important that the country of origin be adequately displayed on all foods offered for sale within the U.S. food supply.

The use of genetically altered crops is growing rapidly in this country and is far outstripping our ability to regulate them. Research into the long- and short-term effects of these products within our food supply is extremely limited. The environmental effects of genetically altered crops have not been adequately researched. Their impact on biological and cultural diversity is unknown. The social and human health consequences of the use of these crops are likewise unknown. All the while, the business machine creating the biotechnology crop revolution is careening down the track promising a more environmentally sustainable agriculture all the way. Whether this promise will be fulfilled is questionable.

*Second*, it is clear that Congress must step up its efforts to address the regulatory void relating to genetically engineered foods, in addition to addressing the research void concerning the public health, safety and welfare issues attendant to the biotechnology industry. Labels help advise the consumer concerning the identity of the food products purchased. By labeling all foods, the consumer may express through his purchases, a preference for environmental protection and even broader ethical and social values.

*Third*, it is equally imperative that the States assume responsibility for directing research at their public institutions. State legislative bodies have the power and authority, through appropriate institutions (land-grant

and other universities that are actively involved in “public” research efforts) towards meaningful research that will address the pros and cons of a genetically engineered food supply. Food technology centers should develop food research and development policies that are beneficial to consumers of all types. States also have the capacity to direct the types of foods that may be offered for sale or consumption at public institutions such as schools or hospitals.

*Fourth*, states likewise have the ability to enact protective legislation for their citizenry. For instance, state legislative bodies may enact statutes requiring that all biotechnology firms doing business within the state are held strictly liable for any harms that their products may cause, not requiring proof of negligence. States can require that agricultural biotechnology firms carry appropriate levels of insurance if doing business within their state and that such firms may not be self-insured. State statutes concerning gene flow, pollen drift, testing for allergenicity and damages for crop failures due to biotechnology should be examined and amended as appropriate.

## Notes

<sup>1</sup> O'Rourke, P. *European Food Law*. Palladian Law Publishing. 1998.

<sup>2</sup> United States Code

<sup>3</sup> Since the passage of the Safe Medical Devices Act of 1990, the authority to regulate electronic products that emit radiation, such as X-ray devices, lasers, microwave ovens, and televisions (formerly the Radiation Control for Health and Safety Act) has been incorporated into the Federal Food, Drug, and Cosmetic Act, as Chapter 5, Sub-chapter C-Electronic Product Radiation Control (21 United States Code, 360).

<sup>4</sup> Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration. (Available at:

<http://www.fda.gov/opacom/morechoices/smallbusiness/blubook.htm>)

<sup>5</sup> Milestones in U.S. Food Labeling:

1906: The Federal Food and Drugs Act and the Federal Meat Inspection Act authorize the federal government to regulate the safety and quality of food. The responsibility falls to the U.S. Department of Agriculture and its Bureau of Chemistry, FDA's predecessor.

1913: The Gould Amendment requires food packages to state the quantity of contents.

1924: In *U.S. v. 95 Barrels Alleged Apple Cider Vinegar*, the Supreme Court rules that the Food and Drugs Act condemns every statement, design or device which may mislead, misdirect or deceive, even if technically true.

1938: The Federal Food, Drug, and Cosmetic Act replaces the 1906 Food and Drugs Act. Among other things, it requires the label of every processed, packaged food to contain the name of the food, its net weight, and the name and address of the manufacturer or distributor. A list of ingredients also is required on certain products. The law also prohibits statements in food labeling that are false or misleading.

1950: The Oleomargarine Act requires prominent labeling of colored oleomargarine to distinguish it from butter.

1957: The Poultry Products Inspection Act authorizes USDA to regulate, among other things, the labeling of poultry products.

1966: The Fair Packaging and Labeling Act requires all consumer products in interstate commerce to contain accurate information and to facilitate value comparisons.

1969: The White House Conference on Food, Nutrition, and Health addresses deficiencies in the U.S. diet. It recommends that the federal government consider developing a system for identifying the nutritional qualities of food.

1973: FDA issues regulations requiring nutrition labeling on food containing one or more added nutrients or whose label or advertising includes claims about the food's nutritional properties or its usefulness in the daily diet. Nutrition labeling is voluntary for almost all other foods.

1975: Voluntary nutrition labeling, postponed from its originally planned 1974 date, goes into effect.

1984: FDA adds sodium to the list of required, and potassium to the list of optional, nutrients on the nutrition panel. Effective in 1985, the new regulation also defines terms, such as low sodium, that may be used on labels to make sodium-content claims.

1988: Surgeon General C. Everett Koop releases The Surgeon General's report on Nutrition and Health, the federal government's first formal recognition of the role of diet in certain chronic diseases.

1989: The Research Council of the National Academy of Sciences issues Diet and Health: Implications for Reducing Chronic Disease Risk, which presents additional evidence of the growing acceptance of diet as a factor in the development of chronic disease, such as coronary heart disease and cancer. Under contract with FDA and USDA's Food Safety and Inspection Service (FSIS), the Food and Nutrition Board of the National Academy of Sciences convenes a committee to consider how food labels could be improved to help consumers adopt or adhere to healthy diets. Its recommendations are presented in Nutrition Labeling: Issues and Directions for the 1990's.

FDA publishes an advance notice of proposed rule-making on food labeling and, with FSIS participating, holds a series of four public hearings around the country.

1990: FDA proposes extensive food labeling changes, which include mandatory nutrition labeling for most foods, standardized serving sizes, and uniform use of health claims.

The Nutrition Labeling and Education Act reaffirms the legal basis for FDA's labeling initiative and establishes an explicit timetable.

1991: FDA issues more than 20 proposals to implement NLEA. In addition, the agency issues a final rule that sets up a voluntary point-of-purchase nutrition information program for raw produce and fish. FSIS unveils its proposals for mandatory nutrition labeling of processed meat and poultry and voluntary point-of-purchase nutrition information for raw meat and poultry.

1992: FDA's voluntary point-of-purchase nutrition information program for fresh produce and raw fish goes into effect.

1993: FDA issues the final regulations implementing NLEA. Regulations covering health claims become effective on May 8. Those pertaining to nutrition labeling and nutrient content claims are effective on May 8, 1994.

1994: FSIS issues regulations for nutrition labeling of meat and poultry, effective July 6.

1997: FDA publishes a Final Rule on the labeling of dietary supplements on September 27.

1999: FDA requires strict adherence to new labeling regulations for dietary supplements sold to the public on March 23.

<sup>6</sup> *Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration.* (Available at: <http://www.fda.gov/opacom/morechoices/smallbusiness/blubook.htm>)

<sup>7</sup> However, the Fair Packaging and Labeling Act was amended by Public Law 102-329 to require that labels printed on or after February 14, 1994, bear a statement of the quantity of the contents in terms of the SI metric

system as well as in terms of the customary inch/pound system of measure. Because the Fair Packaging and Labeling Act pertains only to consumer commodities, metric statements of quantity are not required where products are not marketed to consumers. *Id.*

<sup>8</sup> Subpart A of part 101 contains general provisions for food labeling; Subpart B contains specific food labeling requirements; Subpart C deals with specific nutrition labeling requirements and lay down guidelines; Subsection D deals with specific requirements for nutrient content claims; Subpart E lays down the requirements for health claims; Subsection F deals with specific requirements for descriptive claims; Subpart G enumerates exemptions from food labeling requirements.

<sup>9</sup> *Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration.* (Available at: <http://www.fda.gov/opacom/morechoices/smallbusiness/blubook.htm>)

<sup>10</sup> The FDA has authorized health claims for these relationships;

- Calcium and osteoporosis
- Dietary fat and cancer
- Dietary saturated fat and cholesterol and risk of coronary heart disease
- Fiber-containing grain products, fruits, and vegetables and cancer
- Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease
- Fruits and vegetables and cancer
- Folate and neural tube birth defects
- Dietary sugar alcohol and dental caries (cavities)
- Dietary soluble fiber, such as that found in whole oats and psyllium seed husk, and coronary heart disease.

Reading food labels - Make sense of the numbers. (Available at: <http://www.mayohealth.org/mayo/9305/html/labels.htm>)

<sup>11</sup> FDA Consumer-Food Labeling: Good Reading for Good Eating. (Available at: <http://vm.cfsan.fda.gov/~dms/fdlabel2.htm>).

<sup>12</sup> Required Label Statements. (Available at <http://www.fda.gov/opacom/morechoices/smallbusiness/blubook/reqlblg.htm>)

<sup>13</sup> 21 CFR 101.9(j)(1)

<sup>14</sup> 21 CFR 101.9(j)(2)

<sup>15</sup> 21 CFR 101.9(j)(3)

<sup>16</sup> 21 CFR 101.9(j)(4)

<sup>17</sup> 21 CFR 101.9(a)

<sup>18</sup> 21 CFR 101.36. It is anticipated that future regulations will revise 21 CFR 101.36 in response to the Dietary Supplement Health and Education Act.

<sup>19</sup> 21 CFR 101.9(j)(7) and (8)

<sup>20</sup> 21 CFR 101.9(j)(9)

<sup>21</sup> 21 CFR 101.9(j)(10)

<sup>22</sup> The term adulterated includes products that are defective, unsafe, filthy, or produced under insanitary conditions. (Ss. 402, 501, 601).

<sup>23</sup> The term misbranded includes statements, designs, or pictures in labeling that are false or misleading, and failure to provide required information in labeling. (Ss. 403, 502, 602).

<sup>24</sup> *Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration.* (Available at:

<http://www.fda.gov/opacom/morechoices/smallbusiness/blubook.htm>)

<sup>25</sup> Food producers are required to provide information on labels for a variety of purposes: (1) to give specific information about the product itself, particularly if it is a new product, (2) to differentiate the product from its competitors, (3) to inform consumers about how to use or prepare the product, (4) to warn consumers about potential problems or improper use, (5) to provide manufacturer contact information, and other purposes, and (6) to provide a guarantee through the brand name.

<sup>26</sup> Smith, F.B. *Food Labeling--The Problems of Mandated Information for Biotechnology.* A Consumer Alert publication. [Available at <http://www.consumeralert.org/issues/food/Label-biotech.htm>].

<sup>27</sup> As reported in *The Diet Quality Balancing Act*, Food Review. May 1998.

<sup>28</sup> America's Eating Habits: Changes and Consequences. Edited by E. Frazao, Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture. Agriculture Information Bulletin No. 750 (AIB-750).

<sup>29</sup> Aldrich, L. *Consumer Use of Information: Implications for Food Policy.* Food and Rural economics Division, Economic Research Service, U.S. Department of Agriculture. Agricultural Handbook No. 715. June 1999.

<sup>30</sup> *Id.*

<sup>31</sup> Components 1-5 measure the degree to which a person's diet conforms to the Food Guide Pyramid's serving recommendations for the five major food groups: grains group (bread, cereal, rice, and pasta; vegetables group; fruits group; milk group (milk, yogurt, and cheese); and the meat group (meat, poultry, fish, dry beans, eggs, and nuts). Components 6-10 are based on nutrients specifically mentioned in the *Dietary Guidelines*. Component 6 measures total fat as a % of total energy intake, component 7 measures saturated fat intake as a % of total energy intake, component 8 measures cholesterol intake, and component 9 measures sodium intake. Component 10 addresses the variety in a person's diet one of the key recommendations in the *Dietary Guidelines*. *Id.*

<sup>32</sup> Kennedy, E., S.A. Bowman, M. Lino, S. Gerrior, and P. P. Basiotis. *Diet Quality of Americans: Healthy Eating Index.* America's Eating Habits: Changes and Consequences. Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture. Agriculture Information Bulletin No. 750 (AIB-750).

<sup>33</sup> Chenault, E.A. *FOOD LABELING LAW HAS MADE IMPACT ON AMERICANS' DIETS.* [Available at: <http://agnews.tamu.edu/stories/NUTR/Mar2399a.htm>].

<sup>34</sup> *Id.*

<sup>35</sup> Gallo, A.E. *Food Advertising in the United States.* America's Eating Habits: Changes and Consequences. Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture. Agriculture Information Bulletin No. 750 (AIB-750).

<sup>36</sup> Aldrich, L. *Consumer Use of Information: Implications for Food Policy*. Food and Rural economics Division, Economic Research Service, U.S. Department of Agriculture. Agricultural Handbook No. 715. June 1999.

<sup>37</sup> *Id.*

<sup>38</sup> *Report to Congress on the Costs and Benefits of Federal Regulations*. Office of Management and Budget, Office of Information and Regulatory Affairs. September 30, 1997. This report also stated that an economic analysis cannot reach a conclusion about whether net benefits are maximized -- the key economic goal for good regulation -- without consideration of a broad range of alternative regulatory options. To help decision-makers understand the full effects of alternative actions, the analysis should present available physical or other quantitative measures of the effects of the alternative actions where it is not possible to present monetized benefits and costs, and also present qualitative information to characterize effects that cannot be quantified. Information should include the magnitude, timing, and likelihood of impacts, plus other relevant dimensions (e.g., irreversibility and uniqueness). Where benefit or cost estimates are heavily dependent on certain assumptions, it is essential to make those assumptions explicit, and where alternative assumptions are plausible, to carry out sensitivity analyses based on the alternative assumptions.

<sup>39</sup> Huang, Kuo. *Role of National Income and Prices. America's Eating Habits: Changes and Consequences*. Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture. Agriculture Information Bulletin No. 750 (AIB-750).

<sup>40</sup> *Whose Organic Standards?: USDA Prepares for an "Unfriendly Takeover" of the Natural Foods Industry*. Ben Lilliston, Sustain: The Environmental Education Group (Chicago, Illinois) and Ronnie Cummins, Pure Food Campaign (Little Marais, Minnesota)

<sup>41</sup> *Organic Foods*. New Pioneer Co-op. [Available at: <http://www.newpi.com>].

<sup>42</sup> *Id.*

<sup>43</sup> National Organic Program Revised Proposed Rule: Labeling and Marketing Information. [Available at: <http://www.ams.usda.gov/nop/facts/LABELINGrev.htm>].

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> FEDERAL ORGANIC FOODS PRODUCTION ACT OF 1990. [Available at: <http://www.ams.usda.gov/nop/orgact.htm>].

<sup>47</sup> "Certified Organic" Meat, Poultry Labeling Allowed As USDA Crafts Organic Standards. [Available at: <http://www.primelabel.com/news/labelalert/organic.htm>].

<sup>48</sup> *Using the Claim "Certified Organic By..." on Meat and Poultry Product Labeling*.

Food Safety and Inspection Service, United States Department of Agriculture. March 02, 2000. [Available at: <http://www.fsis.usda.gov/OA/background/organic.htm>]. Congress expected implementation to be complete and the program in operation by October 1, 1993. However, the Board was hampered at the beginning by a lack of

funds, among other factors.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> Currently, organic standards vary among certification boards. California and Oregon have tough standards, while several states such as Illinois, have vague or nonexistent standards.

<sup>53</sup> Rawson, Jean M. *Organic Foods and the Proposed Federal Certification and Labeling Program*. Congressional Research Service. Report for Congress. September 8, 1998. For most of its history, the organic industry has established its own organizations to set standards and to certify that producers, processors, and handlers adhere to them. There are currently 33 private certification operations, according to USDA. In addition, 12 states have established their own organic standards and certification programs. Although there is general agreement among these entities on the basic principles of organic food production, the standards differ from each other in the details. [Available at: <http://www.cnle.org/nle/ag-54.html>].

<sup>54</sup> Approximately 280,000 comments were received.

<sup>55</sup> Although the initial organic standards proposed in December of 1997 by the Agriculture Department did not directly address irradiation, genetic engineering or sewage-sludge fertilizer, the organic foods industry feared those techniques could find their way into the rules and blur the line between high-tech conventional food processing and their back-to-nature approach.

<sup>56</sup> Anderson, Curtis. USDA takes back-to-nature stance on 'organic' labeling. Online Athens. May 9, 1998.

<sup>57</sup> McAvoy, Susan, and Billy Cox. *Glickman Announces New Proposal for National Organic Standards*. A USDA News Release. Release No. 0074.00. Dated March 7<sup>th</sup>, 2000. [Available at: <http://www.usda.gov/news/releases/2000/03/0074>].

<sup>58</sup> *Action Alert: Organic Standards*. PANUPS (Pesticide Action Network Updates Service). June 5, 2000.

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Using the Claim "Certified Organic By..." on Meat and Poultry Product Labeling*.

Food Safety and Inspection Service, United States Department of Agriculture. March 02, 2000. [Available at: <http://www.fsis.usda.gov/OA/background/organic.htm>].

<sup>62</sup> *Huge Organic Response Should Mean No Compromise*. Editorial by Jim Slama. [Available at: <http://www.saveorganic.com/whatsnew.html#victory>].

<sup>63</sup> Quarles, William. *Labeling of Genetically Engineered Foods*. *IPM Practitioner*, XXII(4) April 2000.

<sup>64</sup> *FDA'S Policy for Foods Developed by Biotechnology: Emerging Technologies--Biotechnology*. Food and Drug Administration Center for Food Safety and Applied Nutrition. FDA Education/Compliance Program: 1995. [Available at: <http://vm.cfsan.fda.gov/~lrd/bioeme.html>].

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- <sup>67</sup> *Id.*
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- <sup>70</sup> *Id.*
- <sup>71</sup> *Id.*
- <sup>72</sup> White House. *CLINTON ADMINISTRATION AGENCIES ANNOUNCE FOOD AND AGRICULTURAL BIOTECHNOLOGY INITIATIVES: STRENGTHENING SCIENCE-BASED REGULATION AND CONSUMER ACCESS TO INFORMATION*. Office of Press Secretary. May 3, 2000. [Available at: <http://vm.cfsan.fda.gov/~lrd/whbio53.html>].
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- <sup>74</sup> Label, 2000. *Members of Congress ask FDA for GM labeling*. [Available at: <http://purefood.org/ge.cong49label.cfm>].
- <sup>75</sup> Haslberger, A.G. *Monitoring and labeling for genetically modified products*. *Science* 287: 431-432. 2000
- <sup>76</sup> *What do People Want? Polls on Genetically Engineered Food*. [Available at: <http://www.safe-food.org/-issue/polls.html>].
- <sup>77</sup> *Id.* This drug is banned in Canada and in the European Union.
- <sup>78</sup> Harlander, Susan K. *Unique Characteristics of Biotechnology Products*. Presented at NABC 5 workshop, on Labeling of Biotechnology Products.' Held June 5, 1993, at Purdue University, West Lafayette, Indiana.
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- <sup>80</sup> Some Europeans call biotech foods "Frankenfood" or "mutant." According to a poll conducted by the European Commission, Europeans are more likely than some Americans "to view agricultural biotech as a threat... to the moral order, and more likely to associate [biotech] foods with menacing images of adulteration, infection and monsters." *Wall Street Journal*, January 14, 2000, p. A-14.
- <sup>81</sup> *Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms*. Official Journal L 117 , 08/05/1990 p. 0015 -- 0027. [Available at: [http://europa.eu.int/eur-lex/en/lif/dat/1990/en\\_390L0220.html](http://europa.eu.int/eur-lex/en/lif/dat/1990/en_390L0220.html)].
- <sup>82</sup> Article 4. *Id.*
- <sup>83</sup> Article 5. *Id.*
- <sup>84</sup> Article 16. *Id.*
- <sup>85</sup> *Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients*. Official Journal L 043, 14/02/1997 p. 0001--0007. [Available at: [http://europa.eu.int/eur-lex/en/lif/dat/1997/en\\_397R0258.html](http://europa.eu.int/eur-lex/en/lif/dat/1997/en_397R0258.html)].

<sup>86</sup> *Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.* Official Journal L 159, 03/06/1998 p. 0004-0007. [Available at: [http://europa.eu.int/eur-lex/en/lif/dat/1998/en\\_398R1139.html](http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398R1139.html)].

<sup>87</sup> USDA. *Genetically Modified Foods/ Novel Foods.* Office of Agricultural Affairs. U.S. Mission to the European Union. [Available at: <http://www.useu.be/agri/GMOs.html>].

<sup>88</sup> *Commission Regulation (EC) No 49/2000 of 10 January 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.* Official Journal L 006 , 11/01/2000 p. 0013-0014. [Available at: [http://europa.eu.int/eur-lex/en/lif/dat/2000/en\\_300R0049.html](http://europa.eu.int/eur-lex/en/lif/dat/2000/en_300R0049.html)].

<sup>89</sup> *European Commission Proposes Minimum Threshold Levels for GMO Labeling. Biotechnology: Transgenic Crops.* Pesticide Education Program at Penn State. [Available at: <http://www.cas.psu.edu/docs/casdept/pested/bttgc20.html>].

<sup>90</sup> *Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labeling of foodstuffs and food ingredients containing additives and flavorings that have been genetically modified or have been produced from genetically modified organisms.* Official Journal L 006 , 11/01/2000 p. 0015-0017. [Available at: [http://europa.eu.int/eur-lex/en/lif/dat/2000/en\\_300R0050.html](http://europa.eu.int/eur-lex/en/lif/dat/2000/en_300R0050.html)].

<sup>91</sup> Citizens for Health. *Policy Summary: United Kingdom (UK).* [Available at:

[http://www.citizens.org/Food\\_water\\_safety/geneticengineering/gmo/policy/GMOpolicyuk.htm](http://www.citizens.org/Food_water_safety/geneticengineering/gmo/policy/GMOpolicyuk.htm)].

<sup>92</sup> *Id.*

<sup>93</sup> USDA. *Genetically Modified Foods/ Novel Foods.* Office of Agricultural Affairs. U.S. Mission to the European Union. [Available at: <http://www.useu.be/agri/GMOs.html>].

<sup>94</sup> USDA. *Biotechnology.* Office of Agricultural Affairs. U.S. Mission to the European Union. [Available at: <http://www.useu.be/AGRI/biotech.html>].

<sup>95</sup> *Id.*

<sup>96</sup> O'Rourke, P. *European Food Law.* Palladian Law Publishing. 1998.

<sup>97</sup> [Available at: <http://data.free.de/gen.free.de/gentech/1997/8.96-5.97/msg00364.html>]

<sup>98</sup> Citizens for Health. *Policy Summary: European Union (EU).*

[Available at:

[http://www.citizens.org/Food\\_water\\_safety/geneticengineering/gmo/policy/GMOpolicyeu.htm](http://www.citizens.org/Food_water_safety/geneticengineering/gmo/policy/GMOpolicyeu.htm)].

<sup>99</sup> Grogan, J., and C. Long. *The Problem with Genetic Engineering. Organic Gardening.* January/ February 2000.

<sup>100</sup> Haslberger, A.G. *Monitoring and labeling for genetically modified products. Science,* volume 287, pp.431-432. 2000.

<sup>101</sup> Donkersgoed, E.V. *GM Food Drives Public Scrutiny of Farming. Corner Post.* January 21, 2000.

<sup>102</sup> The following are some of the ways in which otherwise organically produced foods can be later found to have traces of genetically modified organisms:

- Soil amendments / fertilizers / crop protection aids;
- Seed;
- Livestock feed supplements;
- Vaccinations/ artificial insemination; and
- Crop preservatives.

Griffin, Tim. *GMO Alert*. The CROPP Forum. Volume 2000, Number 1.

<sup>103</sup> It is crucial to organic farmers to know where genetically engineered crops are being grown in order to protect the integrity of organic crops grown in the vicinity.

<sup>104</sup> Griffin, Tim. *GMO Alert*. The CROPP Forum. Volume 2000, Number 1.

<sup>105</sup> What's News in Organic OTA Calls for a Moratorium on Using GMOs in Agriculture. Issue #13, February/March 2000.

[Available at: <http://www.lesbrumes.com/nouve.html>].

<sup>106</sup> USDA. *Organic Foods*. Office of Agricultural Affairs. U.S. Mission to the European Union. [Available at: <http://www.useu.be/agri/organic.html>].

<sup>107</sup> *Id.*

<sup>108</sup> Jessen, Anders C. *EU Environment Policy: Regulation of GMOs: Food Safety or Trade Barrier? An EU Perspective*. [Available at: <http://www.eurunion.org/legislat/gmoweb.htm>].

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> The overall objective of the SPS Agreement is to permit countries to take legitimate measures to protect the life and health of their consumers, while keeping them from using those measures in a way that unjustifiably restricts trade. The primary goal of the SPS Agreement is to limit the use of any measures that may restrict trade to those that are justified to provide the necessary level of health protection. It recognizes the right of Member States to protect their consumers at a level they consider necessary, subject to certain principles, such as consistency and transparency.

*Codex Alimentarius*. Food Safety and Inspection Service. United States Department of Agriculture. June 1999.

<sup>112</sup> The TBT Agreement aims to ensure that WTO Members do not use domestic regulations to protect domestic industries from foreign competition. It also seeks to reduce the extent to which regulations operate as barriers to market access, primarily by encouraging governments to harmonize national laws by reference to international standards. Harmonization is expected to improve trade by reducing the variety of different, sometimes incompatible, standards producers must face to gain access to different markets. The TBT Agreement covers a wide range of domestic environmental and health laws, which it divides into two categories: "technical regulations" and "standards". Technical regulations are laws requiring mandatory compliance, including regulations regarding product specifications, labeling, packaging and other "technical" issues, as well as mandatory GMO labeling. Standards, by contrast, are non-binding

rules, and may include voluntary labeling schemes. The TBT Agreement includes obligations relating to the preparation, adoption and application of technical regulations and standards, and the procedures for assessing whether products conform with these regulations and standards. Many of these obligations are set out in a Code of Good Conduct that may apply to private, non-governmental bodies.

Stilwell, Matthew and Brennan Van Dyke. *An Activist's Handbook On Genetically Modified Organisms and the WTO*. Center for International Environmental Law. March, 1999. [Available at: <http://www.consumerscouncil.org/policy/handbk399.htm>].

<sup>113</sup> *Codex Alimentarius*. Food Safety and Inspection Service. United States Department of Agriculture. June 1999.

<sup>114</sup> *Organic Foods*. New Pioneer Co-op. [Available at: <http://www.newpi.com>].

<sup>115</sup> *Id.*

<sup>116</sup> Stilwell, Matthew and Brennan Van Dyke. *An Activist's Handbook On Genetically Modified Organisms and the WTO*. Center for International Environmental Law. March, 1999. [Available at: <http://www.consumerscouncil.org/policy/handbk399.htm>].

<sup>117</sup> Evers, William. *Organic farming vs. biotechnology*. [Available at: [http://hermes.ecn.purdue.edu/Links/cfs\\_in\\_mg/0325.html](http://hermes.ecn.purdue.edu/Links/cfs_in_mg/0325.html)].

<sup>118</sup> Arkinstall, Allison. *A glimpse of the organic scene in Europe*. [Available at: <http://eap.mcgill.ca/MagRack/SF/Winter%2091%20J.htm>]. Proof that the organic movement in Europe has been expanding has been noted through major increases in the number of organic farms, the area of land in organic production, and the size of the organic food market. In the European Community (EC), the organic land base of 103,000 hectares in 1987 rose to 161,000 hectares in 1990. Other countries such as Sweden, Norway and Finland have seen similar expansion, largely due to policies that support farmers who are converting from conventional to organic production systems. Finland's 2,000 hectares of organic land base in 1987 jumped to 11,000 hectares in 1990, and similarly, Sweden's organic land base swelled from 7,500 hectares in 1987 to 29,000 hectares in 1990. The organic movement is catching on in Eastern Europe as well. Lithuania now has over 100 organic farmers and in Hungary, organic farms operate on a combined 3,000 hectares.

<sup>119</sup> *Id.*

<sup>120</sup> Benbrook, Charles M, and Frederick Kirschenmann. *PROPOSED PRINCIPLES FOR EVALUATING THE ORGANIC RULE*. November, 1997. [Available at: <http://www.pmac.net/xroad.htm>].

<sup>121</sup> Lambert, Chuck. *Country of Origin Labeling Endorsed By Consumers--Cattlemen on the Hill*. Public Policy Center. National Cattlemen's Beef Association. [Available at: <http://hill.beef.org/catmak/colec.htm>].

<sup>122</sup> *Labels: Linking Consumers with Producers*. Vol. 1, Number 2. Edited by Judith Brienza, Institute for Agriculture and Trade Policy.

<sup>123</sup> *Id.*

<sup>124</sup> The Common Position on the amended directive 90/220 foresees the monitoring of products after they have been introduced on the market. Labeling creates the possibility to trace products in the production chain.

If problems are detected with a particular product that contains GMOs, these could be identified through the production chain.

*Consumer Federation of America Panel on Genetically Engineered Foods: The Debate over Labeling*. Remarks by Charlotte Hebebrand. Trade Section, Delegation of the European Commission, National Food Policy Conference 2000, Washington, DC. April 17, 2000. [Available at: <http://www.eurunion.org/news/speeches/2000/000417ch.htm>].

<sup>125</sup> Evers, William. *Organic farming vs. biotechnology*. [Available at: [http://hermes.ecn.purdue.edu/Links/cfs\\_in\\_mg/0325.html](http://hermes.ecn.purdue.edu/Links/cfs_in_mg/0325.html)].

<sup>126</sup> An excellent example of such regulatory mandates would be the case in Vermont. The U.S. State of Vermont Governor Howard Dean signed a BST-free labeling law on April 29, 1998, that imposes certain requirements for milk producers and handlers claiming not to use recombinant bovine somatotropin (BST) and forces companies selling the product in the state to register with Agricultural Commissioner. The new law does not require companies selling BST within the state to pay an annual licensing fee. Milk producers are required to sign affidavits that milk from the farm was produced from cows not given BST for at least 90 days. Handlers and processors must also sign affidavits agreeing that milk produced without using BST was kept separate during storage and processing. The state reserves the right to inspect producers and handlers. Howie, Michael, *Vermont Approves BST Labeling Law*, FEEDSTUFFS, May 4, 1998.