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A Tale of Two Systems: A Comparison Between U.S. and EU Labeling Policies of Genetically Modified Foods

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I. INTRODUCTION

Food labels provide an overwhelming amount of information and come in all sizes, from cereal boxes to chewing gum. Food labels provide brand information, nutrition facts, and a listing of ingredients. Food labels identify who the product has been distributed by and how the distributor may be reached. More frequently, food labels provide a "calorie-watchers serving"[1] guide, in addition to the regular serving size facts.

Consumer decisions are generally made upon labeling information—based on the colorful, eye-catching and emotional design of labels, food manufacturers bank on this fact. Try as you might, you will not find a United States ("U.S.") food label that indicates, even in the finest of print, the product has been genetically modified through the modern advances of biotechnology.

Genetically modified foods have been a part of our culture for centuries.[2] Due to the growing population and shrinking availability of farm land,[3] in addition to the constant American-push for increased profitability, genetically modified foods have taken on a new importance in recent years. However, the Food and Drug Administration ("FDA"), the federal agency charged with ensuring the safety of foods, has not significantly amended its regulations in nearly three-quarters of a century.[4] Although science typically outpaces our legal system, in this instance, our legal system has simply decided its sixty-eight-year-old policies related to

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[1] KASHI SALES, L.L.C., KASHI GO LEAN HIGH PROTEIN & HIGH FIBER CEREAL (2005).

[2] The Director-General, *Food and Agriculture Organization ("FAO") Ethics Series 2: Genetically Modified Organisms, Consumers, Food Safety and the Environment*, page 1, U.N. DOC. 92-5-104560-7 (Rome, 2001).

[3] American Farmland Trust, Frequently Asked Questions, http://www.farmland.org/FAQ.htm (last visited Dec. 12, 2005).

[4] 21 U.S.C.S. § 301 et seq. (history) (LexisNexis 2005).

food safety, and ultimately, labeling of genetically modified foods,[5] will do.

This Comment identifies population growth trends for the United States, California, and California's San Joaquin Valley. It presumes, because of an ever-decreasing amount of agriculture producing land,[6] genetically modified foods are a necessary part of our future. The scope of this Comment has been limited to labeling issues of genetically modified foods and its relationship to consumers. It does not consider the effect existing or proposed labeling policies would have on the farming industry or trade practices.

Part II traces the history of genetically modified foods in American society and describes its prevalence in our culture. Part III presents two hypothetical scenarios to introduce labeling options and to highlight some of the issues being debated around labeling of genetically modified foods. Part IV outlines U.S. genetically modified food labeling policies and analyzes the rationale behind the regulation. Next, European Union ("EU") policies are explored in detail, as well as the rationale behind the recently adopted legislation. Part IV concludes by comparing and contrasting U.S. and EU labeling policies. Part V recommends the U.S. adopt a mandatory labeling policy for genetically modified foods, highlighting the interests served through such a policy.

II. GROWING POPULATIONS AND GROWING EFFICIENCY

A. Population Growth Trends and Projections: The Impact on Agriculture Efficiency

Ask anyone: the United States is changing. The United States Census Bureau agrees. The United States is growing at an unprecedented rate. There are more people, more houses, and more industry. According to U.S. Census Bureau statistics, an estimated 294 million people resided within the U.S. in the year 2004.[7] In 2002, there were an estimated 119 million housing units across the country.[8] In 2000, the Census Bureau reported there were 79.6 people per square mile.[9] The National Re-

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[5] 21 U.S.C.S. § 301 et seq. (history) (LexisNexis 2005).

[6] American Farmland Trust, *supra* note 3.

[7] U.S. Census Bureau, California QuickFacts, State and County QuickFacts, http://quickfacts.census.gov/qfd/states/06000.html (last visited Dec. 19, 2005).

[8] U.S. Census Bureau, *supra* note 7.

[9] U.S. Census Bureau, *supra* note 7.

sources Inventory reports the U.S. had a total of 935 million acres of agricultural farmland during the 1997 year.[10]

California's 2004 population was estimated at nearly thirty six million people,[11] representing twelve percent of the country's total population. California hosted 12.5 million (ten percent) of the country's housing units in 2002.[12] California's population per square mile was nearly two and three-quarter times that of the U.S. in 2002, at 217.2 people per square mile.[13]

Unlike California, its San Joaquin Valley evokes popular images of a simpler, agrarian time when the pace of life was slower. To the east lie the giant sequoias of Kings Canyon and Sequoia National Parks,[14] home of the oldest and largest living things on earth.[15] To the west, north, and south, lie seemingly endless miles of fruit, citrus, and fiber that feed and clothe the world.

According to the Department of Finance, the 2000 population for the eight counties that comprise California's San Joaquin Valley totaled 3.32 million.[16] On any given day, the average American is likely eating food grown in this Valley. The San Joaquin Valley provided eighty-eight percent of all agricultural output for California's nineteen-county Central Valley during the year 2002; the Central Valley out-produces all other states in the country in the amount of agriculture it generates.[17]

California's population is projected to increase sixty-two percent by the year 2050, growing to roughly 54.8 million.[18] Somewhat less, yet still staggering, California's San Joaquin Valley population is expected to increase forty-two percent to over 7.9 million.[19]

"Land is being developed" twice as fast as the population is growing; the "acreage per person for new housing almost doubled" during the last

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[10] American Farmland Trust, *supra* note 3.

[11] U.S. Census Bureau, *supra* note 7.

[12] U.S. Census Bureau, *supra* note 7.

[13] U.S. Census Bureau, *supra* note 7.

[14] California State Parks, http://www.parks.ca.gov/parkindex/region_info.asp?regiontab=0&id=4; California State Parks, http://www.parks.ca.gov/parkindex/region_info.asp?regiontab=0&id=7 (last visited Dec. 23, 2005).

[15] Natural History Museum, http://www.nhm.ac.uk/print-version/?p=http://nhm.ac.uk//kids-only/museum/star-attractions/giant-sequoia-tree.html (last visited Jan. 1, 2006).

[16] The Great Valley Center, Population Projections for the State of California by County (2000-2005), www.greatvalley.org (last visited Dec. 19, 2005).

[17] THE GREAT VALLEY CENTER, THE STATE OF THE GREAT CENTRAL VALLEY OF CALIFORNIA: ASSESSING THE REGION VIA INDICATORS, THE ECONOMY 1999-2004 (Jan. 19, 2005), *available at* http://www.greatvalley.org/pub_documents/2005_1_18_13_59_43_indicator_econ05_report.pdf.

[18] The Great Valley Center, *supra* note 16.

[19] *Id.*

two decades.[20] Last year, the U.S. reportedly lost an amount of farm land equivalent to the size of the state of Delaware due to development.[21] A study by the American Farmland Trust ranks the Central Valley as the most threatened farming region in the U.S.[22]

Although the world's population has increased approximately 2.2% each year, the U.S.'s food production has increased only 1.3% annually in recent years.[23] Thus, in order to continue providing food for our growing country and for many across the world, in the midst of shrinking availability of farm land, agricultural producers must be able to produce higher-yield crops with less land.

B. Origins of Genetically Modified Foods

Biotechnologies have been "documented for millennia" as being developed and used by many cultures around the world.[24] These biotechnologies include "manipulating micro-organisms in fermentation to make bread, wine or fish paste, or applying rennin to make cheese."[25]

More recently, genetic engineering has been used in growing food products[26] in order to boost profits and meet the ever-growing demand of our increasing population. Frequently called "genetically modified organisms" or "GMOs,"[27] the genetic material (deoxyribonucleic acid or

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[20] American Farmland Trust, *supra* note 3.

[21] American Farmland Trust, *supra* note 3.

[22] American Farmland Trust, California Regional Office, AFT Around the Country, California Region, http://www.farmland.org/california/index.htm (Dec. 12, 2005).

[23] Checkbiotech.org, From Green Revolution to Gene Revolution (Dec. 9, 2004), www.checkbiotech.org/root/index.cfm?fuseaction=search&search=green%20revolution&doc_id=9257&start=1&fullsearch=0.

[24] *FAO Ethics Series 2: Genetically Modified Organisms, Consumers, Food Safety and the Environment, Report of the Director-General*, *supra* note 2, at 1.

[25] *FAO Ethics Series 2: Genetically Modified Organisms, Consumers, Food Safety and the Environment, Report of the Director-General*, *supra* note 2, at 1.

[26] WORLD HEALTH ORGANIZATION (WHO) FOOD SAFETY DEPARTMENT, MODERN FOOD BIOTECHNOLOGY, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY 3 (Provisional Edition: June 23, 2005).

> "Foods produced through modern biotechnology can be categorized as: (1) foods consisting of or containing living/viable organisms (e.g. corn); (2) foods derived from or containing ingredients derived from GMOs (e.g. flour, products containing protein or oil from GM soybeans); (3) foods containing single ingredients or additives produced by GM microorganisms (e.g. vitamins and essential amino acids); and (4) foods containing ingredients processed by enzymes produced through GM microorganisms (e.g. high fructose corn syrup produced from starch, using [a product of a GMO])."

[27] Vikas Nath, Bio-Engineering Our Food and Our Future, Exchanges, Issue 23, 1998, at 1.

"DNA") of these organisms "has been altered in a way that" would "not occur naturally" through mating or through natural recombination of the organisms.[28] The technology allows selected individual genes to be transferred from organism to organism, and also "between non-related species,"[29] in order to produce a desired trait.[30] The process either injects nucleic acid directly into cells or fuses cells together, in a way that permits the organism to reproduce, unlimited by its "physiological reproductive or recombination barriers."[31]

Genetically engineered crops were originally developed to benefit growers by increasing productivity.[32] Genetic engineering resulted in creating plants resistant to pests and diseases, and tolerant to herbicides "used to kill weeds."[33] Between 1995 and 2004, the primary purpose for developing genetically engineered commercial crops was for herbicide-tolerance; pest resistance was second.[34] These "super crops" yield more food at lower consumer costs.[35] The next generation of genetically modified ("GM") crops is expected to directly benefit consumers.[36] Nutrients are being added to foods to help prevent diseases, reduce allergens and toxins,[37] and "to improve the taste and look of foods."[38]

In 2004, an estimated seven million farmers grew eighty-one million hectares[39] of GM crops in eighteen different countries.[40] Ninety-nine

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[28] Memorandum from the European Union, Question and Answers on the Regulation of GMOs in the EU, Memo/03/196, at 1 (Oct. 9, 2003).

[29] Memorandum on Question and Answers on the Regulation of GMOs in the EU, *supra* note 28, at 1.

[30] Linda Bren, *Genetic Engineering: The Future of Foods?*, FDA Consumer Magazine, November-December 2003 Issue, *available at* http://www.fda.gov/fdac/features/2003/603_food.html.

[31] WHO FOOD SAFETY DEPARTMENT, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY, *supra* note 26, at 1-2.

[32] Bren, *supra* note 30.

[33] *Id.*

[34] WHO FOOD SAFETY DEPARTMENT, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY, *supra* note 26, at 5.

[35] Gordon Wassenaar: Conversations About Plant Biotechnology (Internet Video Transcript) (transcript on file with *San Joaquin Agricultural Law Review*) www.biotech-gmo.com (last visited Nov. 9, 2005).

[36] Bren, *supra* note 30.

[37] *Id.*

[38] CNN.com, U.S. Europe React Differently Over Modified Foods, (July 8, 1999), http://www.cnn.com/NATURE/9907/08/genetics.com.

[39] A hectare is defined as "the customary metric unit of land area, equal to . . . [approximately] 2.47 . . . acres." University of North Carolina, A Dictionary of Units of Measurement, http://www.unc.edu/~rowlett/units/dictH.html (last visited Dec. 23, 2005).

[40] WHO FOOD SAFETY DEPARTMENT, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY, *supra* note 26, at 4.

percent of GM crops were grown by seven of these countries.[41] The U.S. accounted for fifty-nine percent of the total GM production in 2004.[42]

1. A Survey of Genetically Modified Food Products

The world was introduced to the first genetically engineered whole product in 1994[43] – a tomato called Flavr Savr.[44] Flavr Savr tomatoes can be harvested once they become fully ripened.[45] Non-genetically modified counterparts must be harvested while still green and firm in order to keep from being crushed during shipping.[46] Gene manipulation of the Flavr Savr tomato suppresses a naturally-occurring enzyme, and this allows the tomato to soften more slowly making for firm tomatoes in the supermarket.[47] The FDA approved the Flavr Savr tomato, finding it was "as safe as other commercial tomatoes."[48]

Since the Flavr Savr tomato, the FDA has determined more than fifty other genetically engineered foods are "as safe as their conventional counterparts."[49]

The FDA's approval is widespread and can be seen in a variety of foods and food crops. In addition to efficiency, genetic engineering also fosters the quest to consume healthier foods. Genetic engineering reduces the fat-content of foods,[50] alters the nutrition and composition of foods, increases the antioxidant content of foods,[51] and decreases hay fever symptoms.[52]

Potatoes have been genetically engineered to contain a gene for an enzyme that results in the potato having more starch than a non-modified

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[41] *Id.*

[42] *Id.* at 5.

[43] Bren, *supra* note 30.

[44] U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, BIOTECHNOLOGY OF FOOD 1 (May 18, 1994), *available at* http://www.cfsan.fda.gov/~lrd/biotechn.html.

[45] CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, BIOTECHNOLOGY OF FOOD, *supra* note 44.

[46] *Id.*

[47] *Id.*

[48] Bren, *supra* note 30.

[49] *Id.*

[50] PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, HARVEST ON THE HORIZON: FUTURE USES OF AGRICULTURAL BIOTECHNOLOGY 40 (September 2001).

[51] WHO FOOD SAFETY DEPARTMENT, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY, *supra* note 26, at 7.

[52] MSNBC.com, *New Rice May Ease Hay Fever Symptoms* (Nov. 2, 2005) http://msnbc.com/id/9902443/.

potato.[53] As a result of the additional starch, the potato is a lower-fat product because it cannot take up as much fat during frying.[54]

Rice has been altered to contain high levels of beta-carotene, "a vitamin A precursor."[55] The vitamin A-enhanced rice helps fight off disease and safeguards against "visual impairment and blindness."[56]

Genetic modification of rice may prove revolutionary in fighting "the world's most widespread nutritional disorder" – iron deficiency.[57] Rice is traditionally a low-iron food, relied upon by many in developing countries as a "daily food staple."[58] As a result of genetic engineering, rice contains twice the amount of iron as non-modified rice.[59]

Foods have also been genetically modified to increase their antioxidant content.[60] Scientists are now able to create tomatoes and soy with increased amounts of lycopene and lutein – phytonutrients known to improve health and prevent disease.[61]

Finally, a Japanese research team has incorporated an allergy-causing protein into rice.[62] The protein acclimates within the body and thus, is said to immunize against the allergen that causes hay fever.[63]

These are just a few of the many ways in which foods have been engineered to benefit consumers. Further examination of genetically modified foods quickly paints a picture of their widespread prevalence in this country.

C. Current State of Genetically Modified Foods in our Supermarkets

Genetically modified foods "have become a commercial reality."[64] Virtually all of American supermarket shelves are lined with foods[65] that

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[53] PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 50, at 40.

[54] *Id.*

[55] WHO FOOD SAFETY DEPARTMENT, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY, *supra* note 26, at 6.

[56] *Id.*

[57] WORLD HEALTH ORGANIZATION, NUTRITION FOR HEALTH AND DEVELOPMENT, PROGRESS REPORT: A GLOBAL AGENDA FOR COMBATING NUTRITION 16 (2005).

[58] WHO FOOD SAFETY DEPARTMENT, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY, *supra* note 26, at 7.

[59] *Id.*

[60] *Id.*

[61] *Id.*

[62] *New Rice May Ease Hay Fever Symptoms*, *supra* note 52.

[63] *Id.*

[64] Nath, *supra* note 27, at 2.

[65] Raymond Formanek Jr., *Proposed Rules Issued for Bioengineered Foods*, FDA Consumer Magazine, March-April 2001, *available at* http://www.fda.gov/fdac/features/2001/201_food.html.

contain gene-spliced products.[66] An estimated seventy percent of grocery store foods contain ingredients that have been genetically engineered.[67] It naturally follows that virtually everyone living in the U.S. has consumed genetically modified food.[68]

These food products have improved flavor and shelf life, are impervious to insects and other pests[69] and have improved nutritional value.[70] Genetically modified whole foods include "[t]omatoes, potatoes, squash, corn, soybeans,"[71] papaya, and sugar beets.[72]

Because many ingredients contain produce that has been genetically modified (i.e. cooking oil is made from genetically modified corn),[73] things such as ketchup, cola, hamburger buns, cake mixes,[74] cereal, and snacks all contain genetically modified ingredients.[75]

Moving virtually unaccompanied in the other direction is Gerber, the U.S.'s largest producer of baby food.[76] On May 28, 1999, Gerber's Michigan office received a letter via facsimile from Mr. Charles Marguilis, a New Yorker employed by Greenpeace.[77] Shrewdly honing in on the emotional aspect of baby food safety,[78] the letter referenced the "growing concern around the world about genetically engineered food," and asked Gerber what steps it was taking to ensure it did not use any genetically modified ingredients in its baby food.[79] In response to mounting pressures from Greenpeace, Gerber moved to rid its baby food products of genetically modified corn and soy ingredients.[80]

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[66] ScientificAmerican.com, Poison Plants? Genetically Modified Crops, Grown Over Much of the U.S., Remain Controversial, July 5, 1999, www.scientificamerican.com.

[67] The Campaign, Grassroots Political Action, Do You Know What is in Your Food? http://www.thecampaign.org/ (last visited Nov. 11, 2005).

[68] Poison Plants?, *supra* note 66.

[69] Formanek, *supra* note 65.

[70] WHO FOOD SAFETY DEPARTMENT, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY, *supra* note 26, at 7.

[71] Formanek, *supra* note 65.

[72] Bren, *supra* note 30.

[73] MSNBC.com, The Basics on Genetically Modified Foods (March 25, 2005) www.msnbc.com/id/7278294.

[74] Formanek, *supra* note 65.

[75] The Basics on Genetically Modified Foods, *supra* note 73.

[76] Lucette Lagnado, *Strained Peace: Gerber Baby Food, Grilled by Greenpeace, Plans Swift Overhaul – Gene Modified Corn and Soy Will Go, Although Firm Feels Sure They Are Safe – Heinz Takes Action, Too*, WALL ST. J., July 30, 1999, *available at* http://pqasb.pqarchiver.com/wsj/access/43545140.html?dids=43545140;4354510&FMT.

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *Id.*

III. A TALE OF TWO SYSTEMS: HYPOTHETICAL PROBLEMS PRESENTED BY GENETICALLY MODIFIED FOODS

A. Underlying Principle for Presentation of Hypothetical Scenarios

This Comment presumes the need for more efficient, higher-yielding crops, and recognizes the value of improved health and nutrition. Its focus is on whether products must be labeled as being genetically modified and/or containing genetically modified ingredients. The following two hypothetical scenarios are presented to shed light on some of the differences between U.S. and EU policies regarding labeling of genetically modified foods, and to illustrate some of the issues being debated.

B. Hypothetical Scenario One

Son lives in a country that does not require labeling of genetically modified foods. In fact, the food industry has kept the advancement largely under its hat, and most people are not aware of the magnitude of genetic modification.

Son's sixth-grade class has made a field trip to a local farm as part of a science lesson. Farmer owns over a thousand acres and has been farming for a half-century. Farmer excitedly tells the students he is preparing to plant his fiftieth corn and soybean crop. "This is a very exciting time for farming – it is on the cusp of rapid changes."

Farmer explains the principles of modern farming and describes his corn and soybean crops as "genetically modified." Farmer describes the complicated and painstaking process of creating the seeds for these crops, which began in a science laboratory. As a result of the biotechnology, Farmer's crops grow more quickly and there is less soil erosion since Farmer now tills only rarely.[81] The crops are modified so that they can grow during non-traditional times of the year and can be harvested during better weather.[82] As a result, Farmer uses less fuel to dry the crop as he did before it was genetically modified.[83] The crops can be sprayed with potent chemicals to ward off bugs and kill weeds without affecting the ability of the food crop to grow.

At the conclusion of the field trip, Farmer provides a few ears of his specially grown corn to each student. Now at home with the corn, Son and his family wonder how much genetically engineered food they have consumed without ever being aware of it.

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[81] Gordon Wassenaar: Conversations About Plant Biotechnology, *supra* note 35.
[82] *Id.*
[83] *Id.*

C. Hypothetical Scenario Two

Presume a new regulation has recently gone into effect and requires all food manufacturers to include a label on any genetically modified foods or any foods that are derived from genetically modified ingredients. The label must be included near the ingredients, must be in the same size font as the ingredients, and must describe the effect of the genetic alteration.

Consumer is tending to her twice-monthly grocery shopping – her first since the regulation has been in effect. As she maneuvers her way through the aisles with her grocery list attempting to select items, she quickly notices new labels on many of her favorite grocery products. "Free from genetic modification." "Genetically modified to maintain ripeness." "Genetically modified to increase vitamin A content."[84]

Until today, Consumer believed "genetically modified" meant only that the crops processed into ingredients were resistant to bugs, disease, and weeds.[85] She suddenly feels bombarded with the marketing claims and counterclaims. At the same time, however, she recognizes the power that has been given to consumers through this regulation: the choice is hers.

IV. CURRENT LABELING REGULATIONS AND POLICIES OF GENETICALLY MODIFIED FOODS: A COMPARISON BETWEEN THE UNITED STATES AND EUROPEAN UNION

A. United States Policies

To the exclusion of meat and poultry products, the FDA is the principal federal agency charged with ensuring the safety of the commercial food supply.[86] The FDA's authority to ensure food safety is codified in the Federal Food, Drug and Cosmetic Act ("FFDCA"), specifically through sections that prohibit food adulteration, and govern food additives and food labeling.[87]

Notwithstanding the scientific advances of genetically modified foods, the FFDCA regulatory provisions are presented summarily. The FFDCA prohibits the adulteration of food and the introduction of adulterated

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[84] U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, REPORT ON CONSUMER FOCUS GROUPS ON BIOTECHNOLOGY 4 (Oct. 20, 2000).

[85] Scott Kilman, *Food Fright: Biotech Scare Sweeps Europe, and Companies Wonder if U.S. is Next – Hain Labels Its Snacks as Free of Genetic Engineering*, WALL ST. J., Oct. 7, 1999.

[86] Statement of Policy: Foods Derived from New Plant Varieties ("Statement of Policy"), 57 Fed. Reg. 22,984, 22,985 (May 29, 1992).

[87] 21 U.S.C.S. §§ 321(n), 342(a)(1), 348(a) (LexisNexis 2005).

foods into interstate commerce.[88] A food is deemed adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health . . . ."[89] The FDA is authorized to enjoin companies in violation of section 301,[90] may impose criminal penalties against violating food manufacturers,[91] or may seize foods from food manufacturers who fail to comply with the provisions.[92]

The FFDCA further prohibits the addition of food additives that may be "injurious to health," or the introduction of unapproved food additives into interstate commerce, because this would create "adulterated" food.[93] The term "food additive" is defined by the FFDCA as a substance whose intended use "results or may reasonably be expected to result . . . in affecting the characteristics of any food . . . if the [additive] is not generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . ."[94] By definition, "food additive" then does not include additives that are generally recognized as safe ("GRAS") among scientific experts. Thus, such additives are able to avoid additional FDA scrutiny.

Finally, the FFDCA prohibits the misbranding of food or the introduction of misbranded food into interstate commerce.[95] A food is misbranded if "its labeling is false or misleading . . . or its advertising is false or misleading in a material respect . . . ."[96] To determine whether a label is misleading, the representations made on the label are considered, as well as the extent to which the label fails to reveal material facts in light of the representation, or material with respect to the consequences that may result from the use of the article either as described in the label or as would customarily be used.[97]

In 1992, the FDA published its "Statement of Policy: Foods Derived from New Plant Varieties" in the *Federal Register*.[98] The policy intended to clarify the agency's interpretation of the application of the FFDCA with respect to genetically modified foods and food products.[99]

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[88] 21 U.S.C.S. § § 331(a), 331(b) (LexisNexis 2005).
[89] 21 U.S.C.S. § 342(a)(1) (LexisNexis 2005).
[90] 21 U.S.C.S. § 332(a)(1) (LexisNexis 2005).
[91] 21 U.S.C.S. § 333(a)(1) (LexisNexis 2005).
[92] 21 U.S.C.S. § 334(a)(1) (LexisNexis 2005).
[93] 21 U.S.C.S. § § 342(a)(1), 331 (LexisNexis 2005).
[94] 21 U.S.C.S. § 321(s) (LexisNexis 2005).
[95] 21 U.S.C.S. § § 331(a), 331(b) (LexisNexis 2005).
[96] 21 U.S.C.S. § 343(a) (LexisNexis 2005).
[97] 21 U.S.C.S. § 321(n) (LexisNexis 2005).
[98] *See* Statement of Policy, 57 Fed. Reg. 22,984.
[99] Statement of Policy, 57 Fed. Reg. at 22,984.

According to the Statement of Policy, foods derived from methods of genetic alteration are regulated within the existing framework of the FFDCA and "under an approach identical to that applied to foods developed by traditional plant breeding."[100] The policy pronounced genetic modification of foods was not a "material fact" under 21 U.S.C. section 321(n).[101] In this regard, the FDA refuses to mandate labeling of genetically modified foods.

The FDA cautions, however, that consumers must be warned if a genetically modified food "differs from its traditional counterpart" so much so that "the common or usual name no longer applies . . . or if a safety . . . issue exists to which consumers must be alerted."[102] The FDA illustrates by way of example:

> If a tomato has had a peanut protein introduced into it and there is sufficient information to demonstrate that the introduced protein could cause an allergic reaction in a susceptible population, a label declaration would be required to alert consumers who are allergic to peanuts so they could avoid that tomato, even if its basic taste and texture remained unchanged. Such information would be a material fact whose omission may make the label of the tomato misleading under . . . the act (*21 U.S.C. 343*(a)).[103]

B. United States Rationale

The FDA steadfastly holds the "substances expected to become components of food as a result of genetic modification" is the "same as or substantially similar to substances commonly found in" traditionally produced foods.[104] It naturally follows that the FDA believes the risks associated with genetically modified foods are substantially similar to traditionally produced foods. Since, as a class, genetically modified foods do not require labels, U.S. consumers cannot be certain whether they are eating food products that contain genetically modified ingredients.[105]

Because the FDA believes techniques of biotechnology "are not inherently risky,"[106] and because the FDA believes "genetically engineered [foods] are not fundamentally different from non-modified [foods],"[107] its authority is limited to regulating food products, as opposed to the process employed to develop the food.[108]

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[100] Statement of Policy, 57 Fed. Reg. at 22,984.
[101] Statement of Policy, 57 Fed. Reg. at 22,991.
[102] Statement of Policy, 57 Fed. Reg. at 22,991.
[103] Statement of Policy, 57 Fed. Reg. at 22,991.
[104] Statement of Policy, 57 Fed. Reg. at 22,985.
[105] The Basics on Genetically Modified Foods, *supra* note 73.
[106] National Research Council, Genetically Modified Pest-Protected Plants 25 (2000).
[107] *Id.* at 26.
[108] *Id.* at 25.

The FDA's interpretation of these statutes through its Statement of Policy was upheld by the U.S. District Court for the District of Columbia in *Alliance for Bio-Integrity v. Shalala.*[109] The Alliance for Bio-Integrity, a non-profit organization that strives to preserve "the safety of our food, the health of our environment, and the harmony of our relationship with nature,"[110] in cooperation with a coalition of religious and scientific leaders concerned about genetically modified foods, brought an action against the FDA aimed at reforming labeling guidelines.[111] The action alleged, among other things, the FDA erred by failing to consider the widespread consumer interest in having genetically modified foods labeled.[112]

The court responded by highlighting the FDA's limited authority with respect to mandated labeling to situations where a product "differs materially from the type of product it purports to be," and that materiality is a factual predicate.[113] The FDA may consider consumer opinion regarding labeling only after materiality has been established.[114] In an effort to extinguish similar future labeling challenges, the court continued by stating it would be misbranding, a violation in and of itself, to label a product as different, absent a finding of materiality, despite the fact consumers perceive the product as different.[115] Thus, regardless of how many consumers demand genetically modified products to be labeled as such, the FDA lacks a legal basis upon which it can mandate such labeling.[116]

C. European Union Policies

EU legislation for genetically modified foods "is among the strictest in the world, and provides for a high level of scientific assessment, while at the same time safeguards the consumer's right to choose."[117]

After nearly a five-year moratorium on the introduction of new genetically modified foods, the EU passed Regulation 1829/2003 of the European Parliament and the Council of September 22, 2003 on genetically

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[109] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 181 (D.D.C. 2000).

[110] *See generally* Alliance for Bio-Integrity website, http://www.biointegrity.org (last visited Dec. 12, 2005).

[111] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d at 170.

[112] *Id.* at 178.

[113] *Id.* at 179.

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] EUROPEAN COMMISSION'S HEALTH AND CONSUMER PROTECTION DG, HEALTH AND CONSUMER VOICE, EU CONFIRMS QUALITY OF EUROPEAN GMO LEGISLATIVE FRAMEWORK 4 (April 2005).

modified food and feed.[118] The regulation became effective April 18, 2004[119] and bolstered the EU's already stringent genetically modified food policies.

In stark contrast to the U.S. policies, the new EU regulations obligate manufacturers to inform customers when the manufacturer's product is a genetically modified food, or a food that contains a genetically modified ingredient.[120] Where the food consists of more than one ingredient, the list of ingredients must include the words "genetically modified" or "produced from genetically modified (name of the ingredient)."[121] In situations where the product does not include a list of ingredients, the words "genetically modified" or "produced from genetically modified (name of organism)" must clearly appear on the product's label.[122] In an attempt to ensure customer awareness, if the notation is made within a footnote, it must be at least the same size font as "the list of ingredients" or clearly on the label in situations where no ingredients are listed.[123]

Under former EU regulations, labeling was required only when the genetically modified ingredients were detectable.[124] The new regulation requires labeling of all GM foods containing GM ingredients, regardless of whether the DNA is detectable.[125] The threshold for labeling is "if greater than 0.9 percent of the food ingredients" consist of GM material.[126]

Finally, when "a food is different from its conventional counterpart" with regard to composition, nutritional value, intended use, has "implications for the health of certain populations" or gives rise to "ethical or religious concerns," appropriate information shall also appear on the label.[127]

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[118] Commission Regulation 1829/2003, 2003 O.J. (L 268/1) (EU).

[119] An NFPA Overview, *Getting Ready for EU Labeling & Traceability Regulations*, April 5, 2004, at 2.

[120] Commission Regulation 1829/2003, 2003 O.J. (L 268/11) 13 (EU).

[121] Commission Regulation 1829/2003, 2003 O.J. (L 268/11) 13(1)(a) (EU).

[122] Commission Regulation 1829/2003, 2003 O.J. (L 268/11) 13(1)(c) (EU).

[123] Commission Regulation 1829/2003, 2003 O.J. (L 268/11) 13(1)(d) (EU).

[124] Memorandum on Question and Answers on the Regulation of GMOs in the EU, *supra* note 28, at 10.

[125] Commission Regulation 1829/2003, 2003 O.J. (L 268/11) 12(1)(a), 12(1)(b) (EU).

[126] Commission Regulation 1829/2003, 2003 O.J. (L 268/11) 12(2) (EU).

[127] Commission Regulation 1829/2003, 2003 O.J. (L 268/11-12) 13(2) (EU).

D. European Union Rationale

The EU's labeling regulation itself identifies the rationale behind its labeling requirements.[128] First, numerous surveys indicate a large majority of consumers demand labeling requirements of GM foods.[129] Surveys indicate eighty-five percent of Europeans would "shun genetically engineered food if given a choice."[130] Second, the EU regulation presumes labeling GM foods fosters informed consumer choice and precludes misleading consumers regarding the "methods of manufacture or production."[131]

European resistance to genetically modified foods is said to be entrenched within the culture.[132] Critics have dubbed GM foods as "Frankenstein foods."[133] A leading factor to the resistance is that the European public has been exposed to a series of food and health debacles – most notably, bovine spongiform encephalopathy ("BSE"), better known as "mad cow disease" – despite reassurance from scientists and politicians alike that such an event "could not happen."[134] This outbreak, combined with salmonella-contaminated eggs and dioxin-tainted animal feed scares,[135] has created a lack of confidence with the government,[136] and has "fuelled a deep suspicion of science, politicians, and the agri-food industry."[137]

There exists in the EU a pervasive lack of knowledge regarding food production and regulatory control that rises to the level of hysteria among consumers.[138] Consumers also question the "independence and reliability of scientific advice."[139] The public does not readily understand regulatory procedures.[140] The EU has responded and, as a result, EU regulations look markedly different from those of the U.S.

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[128] Commission Regulation 1829/2003, 2003 O.J. (L 268/1-5) 1-45 (EU).

[129] Commission Regulation 1829/2003, 2003 O.J. (L 268/3) 21 (EU).

[130] Nath, *supra* note 27, at 8.

[131] Commission Regulation 1829/2003, 2003 O.J. (L 268/3) 21 (EU).

[132] 22 Neville Craddock, *Flies in the Soup – European GM Labeling Legislation*, Nature Publishing Group, Apr. 2004, 383.

[133] CNN.com, Euro MPs Vote for Draft GM Law, http://archives.cnn.com/2002/WORLD/europe/07/03/eu.gmfood/index.html (last visited Nov. 11, 2005).

[134] Craddock, *supra* note 132, at 383.

[135] Steve Stecklow, *'Genetically Modified' Label Confuses UK Shoppers*, WALL ST. J., Oct. 27, 1999.

[136] U.S., Europe React Differently Over Modified Foods, *supra* note 38.

[137] Craddock, *supra* note 132, at 383.

[138] *Id.*

[139] *Id.*

[140] *Id.*

The EU uses the "precautionary principle" as a basis for regulations, often challenging the developers of new technology to "prove the negative" before the technology is accepted.[141] The regulatory process tends to be transparent and independent, and consumers demand "information and assurance."[142] These "pro-consumer" tenets are evident in the sweeping consumer protections included within the EU labeling regulations.

E. How the Regulations Measure Up

U.S. and EU genetically modified food labeling regulations are clearly at odds with one another. Each arrives at conflicting conclusions based upon the same considerations. The differences between the U.S.'s and the EU's perspectives on the labeling of genetically modified foods illustrate some of the issues that have been deliberated.

On the one hand, the EU recognizes consumers' rights for information and labeling as a tool to make an informed choice. On the other hand, the U.S. places its trust in scientists who make threshold decisions *on behalf of* consumers.

Genetically modified foods are labeled as such in the EU because consumers demand it.[143] At the same time, U.S. regulations preclude consumer input on whether a label is warranted until the FDA has determined the GM food or food product is materially different from its conventional counterpart.[144]

While the EU seems to perceive labels as a venue for informing consumers and preventing them from being misled,[145] U.S. policies hold just the opposite: because GM foods are no different from their non-GM counterparts, labeling is unnecessary and even misleading.[146]

EU regulations are clearly aimed at regulating the *process* of food production as EU policies require disclosure of genetic modification of foods, even when the food or food product is no different from its traditional counterpart.[147] U.S. labeling policies are directed at regulating the food *product* and are limited to situations where the genetically modified product is materially different from its non-genetically modified counterpart.[148]

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[141] *Id.*
[142] *Id.*
[143] Commission Regulation 1829/2003, 2003 O.J. (L 268/3) 21 (EU).
[144] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d at 179.
[145] Commission Regulation 1829/2003, 2003 O.J. (L 268/3) 21 (EU).
[146] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d at 179.
[147] Commission Regulation 1829/2003, 2003 O.J. (L 268/11-12) 12(1) (EU).
[148] 21 U.S.C.S. § 321(n) (LexisNexis 2005).

The EU's approach to labeling seems to balance the competing interests of agriculture, science, and consumers. The U.S. approach balances the same interests; however, they are balanced in favor of agriculture and science.

V. LABELING OF GENETICALLY MODIFIED FOODS SHOULD BE MANDATORY

According to major U.S. corporations, Americans are "hardly hysterical about the issue."[149] McDonalds, Quaker Oats, and Tyson Foods Inc. report only a miniscule number of the total calls they receive from U.S. customers raise concern over genetically modified foods.[150] Hershey, who typically receives hundreds of thousands of phone calls each year, reported receiving fewer than twenty-five calls regarding GM foods during the first nine months of 1999.[151] Consumer silence, however, should not be the standard for determining what level of risk consumers are willing to accept.

A balance can be struck between the competing interests of agriculture, science, and consumers. On one side of the scale, mandatory labeling policies, such as those imposed by the EU, could be imposed to require mere disclosure (e.g. "genetically modified food").[152] Conversely, labeling regulations could require a cautionary statement (e.g. "Caution, contains genetically modified ingredients. Long-term effects have not been determined.")[153] In between the two extremes is something of a statement of purpose (e.g. "genetically modified to increase vitamin A content" or "contains soy from plants genetically modified to be pest resistant").[154]

This Comment suggests the U.S. adopt either a disclosure or statement of purpose labeling policy. A carefully crafted regulation would limit labeling information to simple statements. By removing any food manufacturer discretion in the choice of food label wording, consumers are further protected from a litany of marketing claims.

A mandatory labeling policy promotes informed consumers and consumer-decision making, and appropriately values individuals' religious and philosophical beliefs.

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[149] Kilman, *supra* note 85.

[150] *Id.*

[151] *Id.*

[152] U.S. FOOD AND DRUG ADMINISTRATION, REPORT ON CONSUMER FOCUS GROUPS ON BIOTECHNOLOGY, *supra* note 84, at 4.

[153] *Id.*

[154] *Id.*

A. Mandatory Labeling Requirements Foster Informed Consumer Choices

Consumers have a right to understand what type of product they are buying and ingesting.[155] Information is provided to consumers through food labels and allows consumers to make informed decisions,[156] whether deciding to purchase a GM or non-GM food, or deciding to purchase a low-fat or no-fat food. Labeling genetically modified foods puts more decision-making power in the hands of users (as opposed to creators), allowing consumers to intelligently determine the level of risk they are willing to individually assume.[157]

Opponents argue against labeling GM foods because GM foods are safe and because labeling would wrongfully cause consumers to believe GM foods contained unhealthy or undesirable ingredients.[158] This argument does not give appropriate credit to Americans' understanding of the regulatory process. Americans are generally aware of the level of testing that must occur before a product can be placed into the stream of commerce. There is no reason to believe consumers would exclusively purchase non-GM foods any more than consumers have exclusively purchased "diet," or "low-fat," or "low sodium" products, or that consumers would believe their counterparts were inherently dangerous.

B. Mandatory Labeling Requirements Consider Religious and Philosophical Beliefs

The FDA's guidelines have undervalued issues such as religious and philosophical beliefs, and mandatory labeling of genetically modified foods would better serve these interests. For example, the Jewish population must refrain from eating certain animals and from eating certain parts of permitted animals.[159] Because plants can now be genetically

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[155] *FAO Ethics Series 2: Genetically Modified Organisms, Consumers, Food Safety and the Environment, Report of the Director-General, supra* note 2, at 17.

[156] European Union Biotechnology, http://www.europa.eu.int.comm/food/food/biotechnology/etiquetage/index_en.htm (last visited Nov. 11, 2005).

[157] International Centre for Trade and Sustainable Development (ICTSD), *Agriculture Negotiations at WTO: Context Setting and Intelligence Report, November 2000 – February 2001*, at 37, (Feb. 2001).

[158] Organic Consumers Association, GE Labeling Debate Continues in the US (June 27, 2002), http://www.organicconsumers.org/gefood/uslabels070302.cfm.

[159] Jewish Dietary Laws, http://www.jewfaw.org/kashrut.htm (last visited Dec. 12, 2005).

altered to contain animal genetics, the Jewish population could unknowingly be violating their deeply held religious principles.[160]

Similarly, it seems that a growing number of Americans have opted to eat strictly vegetarian diets, refraining from consuming any meats.[161] Because of the current labeling policies, vegetarians face the potential of unknowingly eating fruits or vegetables that contain genetic material from animals.[162]

Since it is impossible to presently distinguish genetically modified foods from traditional foods under FDA regulations, the religious and philosophical beliefs of many Americans are being blatantly ignored. These values would be better served by a mandatory labeling regulation.

VI. CONCLUSION

This Comment has documented the growing normalcy of genetically modified foods in American commerce, and endeavored to elucidate the benefits of labeling regulations of such food and food products. First, the population growth trends of the U.S., California, and particularly California's San Joaquin Valley were examined to validate the need for a more efficient agricultural industry. These data were juxtaposed with the shrinking availability of farm land as a way to corroborate the importance of agriculture efficiency. The commonplace presence of genetically modified foods was highlighted through a survey of already-existing foods commonly found on the shelves of American grocery stores.

Next, two hypothetical scenarios were presented to introduce labeling regulation options and to illustrate some of the labeling issues currently being debated. United States food labeling policies, regulated by the FDA, were provided in detail. To gain understanding behind the regulations, the FDA's rationale was comprehensively examined and relevant case law was introduced to further clarify the FDA's position. This was followed by a thorough presentation of EU policies regarding labeling of genetically modified foods, and the rationale behind EU policies. The two systems were compared and contrasted, suggesting a balance between agriculture, science, and consumers could be struck.

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[160] Kristen S. Beaudoin, Comment, *On Tonight's Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 83 Marq. L. Rev. 237, 258 (Fall, 1999).

[161] Holly Alley, University of Georgia, *Vegetarianism* (1995), http://www.fsc.uga.edu/pubs/current/FDNS-E-18.html.

[162] Beaudoin, *supra* note 160, at 258.

Since "genetically modified" has moved swiftly from only protecting plants from bugs and disease to altering the composition, nutritional value,[163] and even transferring genes between non-related species[164] (i.e. from animals to vegetables), this Comment suggested the U.S. adopt a mandatory labeling policy. Such a policy supports informed decision-making and empowers consumers to determine the amount of risk they are willing to assume. Additionally, a mandatory labeling policy allows individuals to accurately honor their religious and philosophical values.

Simply put, a mandatory labeling policy would more adequately balance the competing interests of agriculture, science, and consumers. Genetically modified foods are a necessary part of our future. Will they be on your kitchen table? That choice should be yours to make.

RACHELE BERGLUND BAILEY

[163] Bren, *supra* note 30.

[164] Memorandum on Question and Answers on the Regulation of GMOs in the EU, *supra* note 28, at 1.