Genetically Modified Foods: Mandatory Labeling and the Specter of Fear

I. Introduction

A. Thesis

The labeling of genetically modified (GM) food is an extremely contentious issue. The way the law deals with it is of the utmost importance for future research and public acceptance. In this paper I will argue that the benefits of biotechnology outweigh the risks, and that the Food and Drug Administration (FDA) should continue to regulate GM foods under the current system[1] which does not require special labeling if the food is "substantially equivalent."[2] I will also argue that the United States' (U.S.) approach to labeling, as it stands now, will help the GM food industry grow and become more successful both scientifically and financially.[3]

To support these arguments I will demonstrate that many of the most controversial techniques (i.e. gene insertion) are similar to the processes that have been used for several thousand years.[4] Understanding this is important to combating the most common misconceptions regarding what is "natural" and why labeling should not be required. Related to this, I will also argue that it will become necessary to utilize biotechnology due to the increasing number of humans over-occupying the planet. Also, requiring mandatory labeling of GM food (at least with the current uninformed public state of mind[5]) will be deleterious to the advancement of the

[1] The current approach, which will be discussed further in Section III of this paper, has been aptly described as follows: "First, the focus is exclusively on the end product of GM technology, rather than on the fact that the process of genetic modification is used. Second, U.S. policy holds that in the absence of verifiable 'scientific risk,' there is no reason to bar a technology from being introduced and integrated. Finally, the United States maintains that GM technology is on a continuum with other agricultural innovations, and that any risks are of the same kind as those of 'traditionally' produced foods." Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 734 (2003).
[2] Peter Burchett, *A Castle in the Sky: The Illusory Promise of Labeling Genetically Modified Food in Europe*, 23 Penn St. Int'l L. Rev. 173, 182-83 (2001).
[3] Marden, *supra* note 1, at 735.
[4] *See generally* JARED DIAMOND, GUNS GERMS, AND STEEL: THE FATES OF HUMAN SOCIETIES (discussing the evolution of Agriculture throughout history).
[5] Ed Wallis, *Fish Genes Into Tomatoes: How the World Regulates Genetically Modified Foods*, 80 N.D. L. Rev. 421, 421 (2004).

science of biotechnology and the health of our planet. Further, I will demonstrate that currently the FDA probably does not have the statutory authority to mandate labeling of GM foods.

While both plant biotechnology and animal biotechnology are currently important issues, in this paper I will focus solely on plant biotechnology as animal biotechnology brings with it its own unique set of problems and is outside the scope of this paper.

B. Outline and Basic Definitions

The first portion of this paper (Section II) will be a brief primer on the history of biotechnology and mankind for the purpose of setting the stage for the current debate. We cannot discuss what is "natural"[6] or what is "new and dangerous" until we understand where we have come from historically. The second portion of this paper (Section III) will focus on current U.S. statutory law regarding labeling (primarily promulgated by the FDA) and U.S. case law dealing with labeling. The law plays a central part in both the publics' understanding and acceptance of GM foods, and the potential success or failure of biotechnology in the free market. The third portion (Section IV) of this paper will be dedicated to the subject of labeling GM foods and weighing the costs and benefits. It will also bring forth the rationale for and against labeling and the potential impact that labeling (or lack thereof) may have on domestic matters, world hunger, immune deficiencies and the health of the Earth as a whole. The final portion (Section V) will contain my conclusions.

Before discussing the arguments I will establish a few definitions that will be used throughout the paper. First, biotechnology "is defined as the use of biological processes for the development of products such as foods, enzymes, drugs, and vaccines."[7] Genetically modified organism (GMO) is an "imprecise term[ ] that refer[s] to the use of transgenic crops, i.e. those

[6] See *Id.* (saying that Americans generally remain unaware of the prevalence of GM foods).
[7] Donna U. Vogt & Mickey Parish, *Food Biotechnology in the United States: Science, Regulation and Issues, in* FOOD BIOTECHNOLOGY: CURRENT ISSUES AND PERSPECTIVES 1, 2 (Sarah Elderidge ed., 2003).

grown from seeds that contain genes of different species."[8] Genetically modified foods (GM) refers to those foods which are derived from GMOs.[9]

II. Historical Background of Plant Biotechnology

A. The Dawn of Agriculture

Ever since man shed his hunter/gatherer ways and took up agriculture he has sought to modify plants "to improve growth rates and yields, create varieties and breeds resistant to pests and diseases, and infuse special nutritional or handling characteristics."[10] The use of biotechnological techniques "can be traced back thousands of years – for instance, the fermentation of fruits and grains to make wine and beer and, more recently, the use of yeast in baking."[11] Many of the early techniques that might be categorized as biotechnology used a process called "artificial selection, where human interference directs the evolution of varieties."[12] Understanding this is fundamental to understanding the current debate because much of the discussion focuses on the fact that the use of transgenic gene insertion is unnatural and therefore somehow wrong, notwithstanding the fact that without human interference agriculture as we know it today would be substantially different.[13]

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[8] Norman Borlaug, *Are We Going Mad?*, *in* THE ETHICS OF FOOD 74, 76 (Gregory E. Pence ed., 2002). *See also*, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22984 (May 29, 1992) (Stating "'Genetic modification' means the alteration of the genotype of a plant using any technique, new or traditional. 'Modification' is used in a broad context to mean the alteration in the composition of food that results from adding, deleting, or changing hereditary traits, irrespective of the method. Modifications may be minor, such as a single mutation that affects one gene, or major alterations of genetic material that affect many genes. Most, if not all, cultivated food crops have been genetically modified.'").

[9] Burchett, *supra* note 2, at 174.

[10] Geoffrey S. Becker, *Adoption of Genetically Modified Agricultural Products*, *in* FOOD BIOTECHNOLOGY: CURRENT ISSUES AND PERSPECTIVES, *supra* note 7, at 57, 58.

[11] STEPHEN NOTTINGHAM, EAT YOUR GENES: HOW GENETICALLY MODIFIED FOOD IS ENTERING OUR DIET 1 (1998).

[12] *Id.* at 1-2.

[13] *See* DIAMOND, *supra* note 4, at 118 (Stating "Supermarket apples are typically around three inches in diameter, wild apples only one inch. The oldest corn cobs are barely more than half an inch long, but Mexican Indian farmers of A.D. 1500 already had developed six-inch cobs, and some modern cobs are over one and a half feet long.").

While man prior to the 20th century may not have fully understood the underlying processes he was altering, he used his senses, trial and error, and sheer luck to develop more fruitful and hardy crops.[14] With the "rediscovery of Gregor Mendel's work on inheritance" in the early 20th century the work plant-breeding "led to the production of high-yielding hybrid seed varieties, which … resulted in dramatic increases in crop yields."[15] From this foundation of the historical aspects of plant breeding we enter the modern era.

B. The Modern Era

Earlier in mankind's history it was primarily farmers who utilized a rough form of biotechnology to develop more desirous plants, whereas today "crop development is … a conscious, highly specialized effort carried out by professional scientists."[16] This is both a cause for concern to some, and a boon. It is a cause for concern because these scientists now utilize both traditional plant breeding techniques coupled with the use of transgenic technology. It is a boon because it has the potential to provide benefits such as foods with higher vitamin content, "reduced use of pesticides … and increased yields for growers."[17] For those worried about the potential risks the problem is more serious than ever, due to the fact that "U.S. farmers are adopting this technology at a rapid rate."[18] Most consumers in the U.S. are not aware that as much as 60 percent or more of the processed food eaten today may have been genetically modified.[19]

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[14] *See, e.g.*, *id.* at 114-20 (citing specific examples of this process); Nottingham, *supra* note 11, at 2.
[15] NOTTINGHAM, *supra* note 11, at 2.
[16] DIAMOND, *supra* note 4, at 114-15.
[17] Vogt & Parish, *supra* note 7, at 1.
[18] *Id.* at 2.
[19] Ronald Bailey, *Dr Strangelunch: Why We Should Learn to Love Genetically Modified Food*, *in* THE ETHICS OF FOOD, *supra* note 8, at 100, 105.

The concerns arise based on the differences between "traditional plant breeding methods" and "transgenic methods."[20] It is important to understand the differences and similarities in these methods in order to understand the implications of many arguments for and against mandatory labeling of GM foods. Transgenic plants get "specific, well defined genetic modifications," whereas traditional breeding results in "changes that … are usually undefined at the molecular level" and while there may be some tangible benefit (i.e. better taste, faster growth) the traditional breeder "does not know exactly which genes have been gained or lost."[21] GM foods utilize "recombinant DNA (rDNA) technology, whereby a segment of DNA from one organism is extracted and spliced into a recipient organism's preexisting DNA."[22] It is this process that many critics point to when seeking to contrast it with traditional techniques.[23] The transgenic approach is more precise because in "a transgenic approach, specific genes or groups of genes are transferred from a source organism into a target plant."[24] While one of the "major advantage[s] of the transgenic approach … is that theoretically any organism can be a source of transferred genetic material"[25] it is also its Achilles heel because many consumers and advocacy groups fear this process is unnatural and presents grave risks.

This fear of GM "frankenfoods" is an important aspect of the debate. If GM foods are demonized (and therefore avoided) companies will have little incentive to invest in research that may lead to more productive or hardier crops. The value of these crops goes beyond mere

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[20] For a detailed overview on the creation of transgenic plants see Alejandro E. Segarra & Susan R. Fletcher, *Biosafety Protocol for Genetically Modified Organisms: Overview*, *in* FOOD BIOTECHNOLOGY: CURRENT ISSUES AND PERSPECTIVES, *supra* note 7, at 87, 95-97.
[21] *Id.* at 91.
[22] Matthew Rich, *The Debate Over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 890 (2004).
[23] *Id.* at 891 (Commenting on the perceived flaws in considering GM breeding similar to traditional breeding, stating that the most prominent different is that "new rDNA technology allows traits from one species to be spliced into an unrelated species, even from animal to plant.)".
[24] PERRY JOHNSON-GREEN, INTRODUCTION TO FOOD BIOTECHNOLOGY 91 (2002); *see also* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,986 (May 29, 1992).
[25] PERRY JOHNSON-GREEN, INTRODUCTION TO FOOD BIOTECHNOLOGY 91 (2002).

convenience for the producers, or consumer cost considerations, GM crops may aid in preventing more deforestation and help combat world hunger.[26] These arguments will be further considered in Section IV: A Risk-Benefit Analysis with Regard to GM Food Labeling.

III. US Statutory and Case Law on Labeling of GM Foods.

A. US Statutory Law

There are several U.S. governmental organizations involved in the GM and GMO regulatory process. The U.S. Department of Agriculture (USDA) determines "whether GMOs are 'safe to grow'; the Environmental Protection Agency ('EPA') … determines whether GMOs are 'safe for the environment'; and the Food and Drug [Administration] ('FDA') … determines whether GMOs are 'safe to eat.'"[27] While the USDA and EPA are both important in the overall GMO regulatory process, their areas of focus are, for the most part, outside the scope of this paper, which is focused on labeling, and as such I will be dealing solely with the FDA's statutory authority.[28]

The Food and Drug Administration (FDA) is responsible for determining whether foods are safe, and whether they require labeling.[29] The FDA derives this authority from the Federal Food, Drug, and Cosmetic Act (FDCA).[30] The primary provisions of the FDCA involved in determining whether to label GM foods are 21 U.S.C. § 343 (misbranding) and 21 U.S.C. § 348 (food additives).[31] The primary provision regarding food safety is 21 U.S.C. § 342 (adulterated food).[32]

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[26] Julian Wong, *Are Biotech Crops and Conventional Crops Like Products? An Analysis Under Gatt*, DUKE L. & TECH. REV. 27, 4 (2003).
[27] *Id.* at 9.
[28] For more information on the regulatory framework see Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26,1986).
[29] Vogt & Parish, *supra* note 7, at 7-8
[30] Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-384 (2006)
[31] *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22985 (Stating, "Substances that are expected to become components of food as result of genetic modification of a plant and whose

In 1992 the FDA issued a policy statement regarding interpretations of the FDCA as applied to "foods derived from new plant varieties, including plants developed by recombinant deoxyribonucleic acid (DNA) techniques."[33] Within this statement of policy, the FDA said that food developed using these new techniques (including transgenic techniques) would be regulated within the current FDCA framework and that the "regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components)."[34] This caused concern among critics, who want the FDA to regulate and label GM foods specially, either inside or, if necessary, outside this framework.[35] The FDA said that:

> In most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food, such as proteins, fats and oils, and carbohydrates …. FDA has determined that such substances should be subject to regulation under section 409 of the act in those cases when the objective characteristics of the substance raise questions of safety sufficient to warrant formal premarket review and approval by FDA.[36]

While it is possible for GM foods to require formal review, the GM foods are subjected to the same process as all other foods and if found to be "substantially similar" will be regulated as such. If the FDA determines that a food is adulterated "[u]nder section 402(a)(1) [21 U.S.C. § 342] of the act … and thus unlawful if it bears or contains an added poisonous or deleterious substance that may render the food injurious to health or a naturally occurring substance that is

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composition is such or has been altered such that the substance is not generally recognized as safe (GRAS) or otherwise exempt are subject to regulation as "food additives" under section 409 of the act (21 U.S.C. 348)."

[32] *Id.* (Stating "The safety of a food is regulated primarily under FDA's postmarket authority of section 402(a)(1) of the act (21 U.S.C. 342(a)(1)). Unintended occurrences of unsafe levels of toxicants in food are regulated under this section.").

[33] *Id.* at 22,984.

[34] *Id.*.

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

[36] Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 31, at 22,985.

ordinarily injurious."[37] If the GM food is not found to be adulterated and "do[es] not naturally or otherwise contain a toxicant" the FDA will "treat the foods the same as all non-GM foods that are not adulterated."[38]

If a food additive is determined to be generally recognized as safe (GRAS)[39] then "additive" will not need to be formally regulated by the FDA. This is a central issue in the seminal case on the subject of GM foods, *Alliance for Bio-Integrity v. Shalala*.[40] With respect to GM foods "it is the transferred genetic material and the intended expression product or products that could be subject to food additive regulation, if such material or expression products are not GRAS."[41]

Another area of contention, with regard to labeling specifically, is whether the lack of information about whether it is a GM food could constitute misbranding, pursuant to 21 U.S.C. § 343. As the FDA put it in their 1992 Policy Statement:

> Section 403(i) of the act (21 U.S.C. 343(i)) requires that a producer of a food product describe the product by its common or usual name or in the absence thereof, an appropriately descriptive term (21 U.S.C. part 101.3) and reveal all facts that are material in light of representations made or suggested by labeling or with respect to consequences which may result from use (21 U.S.C. 343(a); 21 U.S.C. 321(n)). Thus, consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted.[42]

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[37] *Id.* at 22,988.
[38] Wallis, *supra* note 5, at 427.
[39] The determination of whether something is a food additive is part of a two-step process, "The first step broadly includes any substance the intended use of which results in its becoming a component of food. The second step, however, excludes from the definition of food additive substances that are GRAS. It is on the basis of the GRAS exception of the "food additive" definition that many ingredients derived from natural sources…as well as a host of chemical additives…are able to be lawfully marketed today without having been formally reviewed by FDA and without being the subject of a food additive regulation. The judgment of Congress was that subjecting every intentional additive to FDA premarket review was not necessary to protect public health and would impose an insurmountable burden on FDA and the food industry." Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 31, at 22,989 (May 29, 1992).
[40] Alliance for Bio-Integrity v. Shalala, 116 F.Supp. 2d 166 (D.D.C. 2000).
[41] Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 31, at 22,990.
[42] *Id.* at 22,991.

The crucial term in this determination is the word "material."[43] The FDA, in the 1992 Policy Statement, determined that "using techniques such as recombinant DNA techniques" on plants *not to be* material.[44] It was deemed not to be material because there were no apparent safety issues.[45] Usually, the FDA "will find labeling information 'material' in three general circumstances" which are:

> when (1) the product poses "special health or environmental risks," (2) the product label may mislead the consumer "in light of other statements made on the label," or (3) the consumer is prone to think that because a certain food has certain similarities to another food that they are the same, when they are in fact not the same.[46]

As we will see, these were some of the central issues in the case of *Alliance for Bio-Integrity v. Shalala*.

The FDA has determined "that the new techniques are extensions at the molecular level of traditional methods and will be used to achieve the same goals as pursued with traditional plant breeding."[47] As discussed above, the goals of traditional breeding and the new techniques are the same; the primary difference being that with transgenic technology scientists can utilize genes from a broader spectrum of organisms (which is what some see as "unnatural") and can do so more precisely.

This is not to say that GM foods will never require labeling, in fact, if GM food is different "from its conventional counterpart so that the common name of the item no longer

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[43] Emily Robertson, *Finding A Compromise in the Debate Over Genetically Modified Food: An Introduction to a Model State Consumer Right-To-Know*, 9 B.U. J. SCI. & TECH. L. 156, 159 (2003).
[44] Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 31, at 22,991.
[45] *Id.* at 22,992 (Stating that "the agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding. For this reason, the agency does not believe that the method of development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labeling for the food.").
[46] Robertson, *supra* note 43, at 159-60 (quoting Food and Drug Administration, Center for Food Safety and Applied Nutrition Web site, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (2001), http://www.cfsan.fda.gov/~biolabgu.html).
[47] Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 31, at 22,991.

applied" labeling would be required. [48] Labeling would also be required if the GM food is different in terms of its "safety (i.e. allergenicity) profile.[49] In addition to these instances where labeling would be required, the FDA now allows voluntary labeling, but "it continues to insist that any language suggesting that GM products are different or less safe is false and misleading."[50] With these statutory provisions in mind we turn to the case law.

B. Case Law

In the leading case on the issue of mandatory labeling, *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166 (District Court D.C. 2000), a group brought suit over the FDA's policies with regard to the labeling of genetically modified foods.[51] The group consisted of "a coalition of groups and individuals including scientists and religious leaders concerned about genetically altered foods."[52]

At issue was the FDA's decision not to regulate genetically modified foods as food additives, but instead to "presume that foods produced through the rDNA process were 'generally recognized as safe' (GRAS) under the Federal Food, Drug and Cosmetic Act."[53] The court held that the FDA could do this and were not determining GRAS status, but merely creating a presumption.[54]

The plaintiffs in this case also argued "that the Statement of Policy's presumption that rDNA-engineered foods are GRAS violates the GRAS requirements of the Federal Food, Drug, and Cosmetic Act ('FDCA'), 21 U.S.C. § 321(s), and is therefore arbitrary and capricious."[55]

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[48] Marden, *supra* note 1, at 762.
[49] *Id.*.
[50] *Id.* at 785.
[51] Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d 166, 169 (D.D.C., 2000).
[52] *Id.* at 170.
[53] *Id.*.
[54] *Id.* at 173.
[55] *Id.* at 175.

The plaintiffs wanted the "transferred genetic material and the intended expression product" to be subject to additive regulation because they felt the process was not GRAS.[56] The FDA held that because "the only substances added to rDNA engineered foods are nucleic acid proteins, generally recognized as not only safe but also necessary for survival" of living organisms, they were GRAS and not subject to regulation as a food additive.[57] The FDA did say that a GM food could "trigger application of the food additives petitioning process" if it differed "significantly in structure, function, or composition from substances currently found in food."[58] The court upheld the FDA's decision to presume that GM foods altered with nucleic acid proteins are GRAS.[59]

Part of the reason the court deferred to the agency was that "'[t]he rationale for deference is particularly strong when the [agency] is evaluating scientific data within its technical expertise.'"[60] While the court upheld the FDA's decision it did say that "To be generally recognized as safe, a substance must meet two criteria: (1) it must have technical evidence of safety, usually in published scientific studies, and (2) this technical evidence must be generally known and accepted in the scientific community" and that subsequent to the FDA's decision the plaintiffs were able to produce documents which demonstrated "significant disagreements among scientific experts."[61] The court could not consider this in the context of the case, however, because it could only consider "the record before the agency at the time it made its decision."[62] The debate regarding risks and benefits, and hence whether a GRAS presumption is warranted, will be discussed further in Section IV.

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[56] *Id.* at 176.
[57] *Id.*.
[58] *Id.*.
[59] *Id.* at 177.
[60] *Id.*.
[61] *Id.*.
[62] *Id.*.

The plaintiffs in this case also argued that GM foods should be required to be labeled as such.[63] This challenge is based on the argument that GM foods should not be presumed to be GRAS.[64] The plaintiffs challenged the FDA's interpretation of the word "material" in 21 U.S.C. § 321(n), which "grants the FDA limited authority to require labeling."[65] The court held that because "Congress has not squarely addressed whether materiality pertains only to safety concerns or whether it also includes consumer interest …. interpretation of the § 321(n)'s broad language is left to the agency."[66] The FDA interpreted "material change" to only apply if there were "unique risks to consumer health or uniform changed to food derived through rDNA technology" and the FDA also did not interpret "§ 321(n) to authorize labeling requirements solely because of consumer demand."[67] The court held that:

> Plaintiffs fail to understand the limitation on the FDA's power to consider consumer demand when making labeling decisions because they fail to recognize that the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact.[68]

The FDA simply does not have the power to label at will if "the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different."[69] The plaintiffs also argued that the very "*process* of genetic modification is a 'material fact' under § 321(n) which mandates special labeling," but the court upheld the FDA's determination that "foods produced through rDNA techniques do not 'present any

[63] *Id.*.
[64] *Id.* at 178.
[65] *Id.*.
[66] *Id.*.
[67] *Id.* at 179.
[68] *Id.*.
[69] *Id.*.

different or greater safety concern than foods developed by traditional plant breeding,'" and concluded that labeling was not warranted.[70]

In a final push, the Plaintiffs argued that failure to require labeling violated their right to free exercise of religion, but the court upheld the regulation with little discussion because "'neutral laws of general applicability do not violate the Free Exercise Clause, even if the laws incidentally burden religion.'"[71] In the end the court upheld the FDA's 1992 Policy Statement and did not require the FDA to change their stance on labeling.[72]

Alliance for Bio-Integrity is a case that brings forth many of the current legal issues and safety concerns regarding GM foods. The best argument, at least under the current regulatory scheme, that the supporters of mandatory labeling could make would be to show that GM foods are not GRAS. To do this the proponents of labeling would need to show that GM foods are not generally recognized as safe. As discussed above, the court implied that there may have been a different outcome on the GRAS determination if the FDA would have had all the information provided at trial during their notice and comment period while developing policy.[73] This information, regarding agreement in the scientific community, will be discussed further in Section IV: A Risk-Benefit Analysis with Regard to GM Food Labeling.

If proponents of labeling cannot show that the "additives" to GM foods are not GRAS, then they will probably have to get Congress to change the law to allow the FDA to label GM foods as such because as it seems (and the court in *Alliance for Bio-Integrity* held) that the FDA does not have the power to label at will if "the product does not differ in any significant way

[70] *Id.*.
[71] *Id.* (quoting Employment Division v. Smith, 494 U.S. 872 (1990)).
[72] Alliance for Bio-Integrity, 116 F.Supp.2d at 179.
[73] *Id.* at 177.

from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different."[74]

The determination that GM foods' "additives" are GRAS is crucial because the food additive approval process is "very involved"[75] and could potentially dampen producers' enthusiasm for GM foods. On the other hand, since "ingredients that are determined to be GRAS are implicitly recognized as an exception to the food additive" it helps avoid the lengthy food additive process. Because the FDA has determined GM foods to be "presumed to be … GRAS," GM foods will generally not be subjected to the lengthy additive review process.[76]

The FDA, while not mandating labeling, has not been inactive. One proposal currently being considered, which was brought forth in 2001, proposed "a new rule that would require manufacturers of 'plant derived, bioengineered foods and animal feeds' (GM foods) to notify the FDA at least 120 days before the products are marketed in a 'Premarket Biotechnology Notice.'"[77] In this proposal the FDA has reviewed the comments it received during the formulation of the 1992 policy, as well as subsequent comments, and found that "these comments did not provide data or other information regarding consequences to consumers from eating the foods or any other basis for FDA to find under … [21 U.S.C. 321(n)] of the act that such a disclosure was a material fact."[78] The comments primarily focused on the potential, unknown benefits, and this is not enough to constitute a material fact.[79] Even though the GM

[74] *Id.* at 179.
[75] Marden, *supra* note 1, at 746.
[76] *Id.* at 747.
[77] *Id.* at 757.
[78] Food and Drug Administration, Center for Food Safety and Applied Nutrition Web site, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering* 5 (2001), http://www.cfsan.fda.gov/~dms/biolabgu.html.
[79] *Id.*.

food industry has generally approved of this proposal, as of the writing of this paper this proposed rule has not yet been finalized.[80]

Overall, the FDA utilizes a "product based, rather than process based approach" and as such has determined GM foods, in general, do not require mandatory labeling and are treated in the same manner as their traditional counterparts.[81] With this statutory framework and case law in mind, we turn to the heart of the matter: the scientific debate regarding the potential risks of GM foods weighed against their potential benefits.

IV: A Risk-Benefit Analysis with Regard to GM Food Labeling

A. Introduction to the Risk-Benefit Analysis

Both supporters and detractors of GM foods, and derivatively the issue of labeling, are prone to exaggeration. For example, supporters of GM foods make grandiose claims about how GM foods are going to feed the third world[82] without fully considering the geo-political circumstances, while critics apply labels like "frankenfoods" and "mutant foods" as fear mongering tactics in order to scare the malleable populace into eschewing GM foods.[83] Supporters of mandatory labeling argue that consumers have a right to know, that the risks of GM foods have not been fully explored, and that unleashing GM foods into the environment could have disastrous environmental consequences. Those who oppose mandatory labeling point to the populace's lack of knowledge (which could engender fear based reactions to a GM food label), the potential benefits (for both producers and consumers) both domestically and abroad, and the potential environmental benefits of utilizing GM foods.

[80] Marden, *supra* note 1, at 758.
[81] *Id.* at 759.
[82] NOTTINGHAM, *supra* note 11, at 160.
[83] GREGORY E. PENCE, DESIGNER FOODS 82 (2002).

In this section I will demonstrate that GM foods, while not without potential risks, are safe,[84] have a variety of potential benefits and are a necessary element to ensure the continued sustainability of agriculture without drastic expansion of farm acreage at the expense of our remaining forests.

B. Human Health

First and foremost, when considering the risks of GM foods, are the risk considerations which directly affect humans as consumers. While "[g]enetically modified foods are unlikely to present direct risks to human health" there are "two main areas of concern: a) the possibility of allergic reactions to genetically modified foods, and b) the possibility that bacteria living in the human gut may require resistance to antibiotics from marker genes present in transgenic plants."[85] I will discuss each of these in turn.

The concerns about allergens[86] arise because "[t]ransferring genes to a food product may alter the degree to which that product causes allergic reactions in sensitive people"[87] but, currently "the U.S. Food and Drug Administration (FDA) [has] stated that genetically engineered food must be tested and labeled for allergy sensitivity if they have been created using DNA from any foods known to cause an allergic reaction."[88] This procedure of testing has proven effective for non-GM foods and within the current FDA framework there are a variety of tests in place to

[84] *See* Borlaug, *supra* note 8, at 77 (stating, "To date, there has been no credible scientific evidence to suggest that eating transgenic agricultural products damages human health, or the environment. Virtually all of the scientific debate has been [about] possible damage and the risk factor society is willing to take.").
[85] NOTTINGHAM, *supra* note 11, at 91.
[86] An example of how allergens might cause a problem and what the FDA has to say about it, "FDA's principal concern regarding allergencity is that proteins transferred from one food source to another, as is possible with recombinant DNA and protoplast fusion techniques, might confer on food from the host plant the allergenic properties of food from the donor plant. Thus, for example, the introduction of a gene that encodes a peanut allergen into corn might make that variety of corn newly allergenic to people ordinarily allergic to peanuts." Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 31, at 22,987.
[87] NOTTINGHAM, *supra* note 11, at 92.
[88] *Id.*., *see also* Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 31, at 22,987 (May 29, 1992) (containing the FDA's policy statement on allergens).

check for these allergens in GM foods.[89] One example for the potential risks involved taco shells which contained "genetically modified corn that was unapproved for human consumption due to possible allergic reactions" that were sold in U.S. grocery stores and had to be recalled.[90] While the risk of allergens entering the U.S. food supply is real, it is important to note that in this case the potential risk was caught by the FDA and the product was recalled. The current system for detecting allergens has proven effective and does not need to be supplemented – assuming that mandatory labeling would even help – by a requirement of mandatory labeling.

Some groups are concerned that bacteria may acquire resistance to antibiotics through the use of "marker genes [which] are routinely integrated into transgenic crops to select transformed plants from untransformed plants."[91] Recent studies have concluded "that antibiotic resistance genes present no risks to humans."[92] Critics remain skeptical, stating "concern that antibiotic resistance genes will be transferred to bacteria living in the guts of humans or animals. This could reduce the efficiency of antibiotic drug treatments."[93] Both sides of the argument are largely speculative[94] and as such bear further study, but as of yet there do not appear to be any studies which directly link problems with "antibiotic resistance to GM foods."[95] Without a scientific basis, it would be unlikely that the FDA could mandate labeling on this basis.

In addition to these practical, science based protections the companies involved have self-interest in protecting consumers.[96] Critics argue that the companies will have self-interest only in making the most money, but this same self-interest should guide these companies into exercising an abundance of caution because any outbreak of health problems related to GM foods would be

[89] BILL LAMBRECHT, DINNER AT THE NEW GENE CAFÉ 83 (2001).
[90] Wong, *supra* note 26, at 6.
[91] NOTTINGHAM, *supra* note 11, at 93.
[92] *Id.*.
[93] *Id.* at 93-94.
[94] *Id.* at 95.
[95] Kathleen Hart, *An Introduction to Genetically Modified Foods*, 10 RICH. J.L. & TECH. 6, 19 (2004).
[96] Burchett, *supra* note 2, at 173.

detrimental to their business, especially considering the current fragile and volatile atmosphere of public opinion regarding GM foods.[97] Not only would there be a negative impact on public opinion, but there would be the potential for tort claims.[98]

Overall, GM foods "pose the same types of inherent risks to human health: they can cause allergic or toxic reactions" and as such are subjected to tests to ensure they are comparable with the conventional variety.[99] There is nothing in the scientific record to indicate that GM foods are "adulterated" or that the process of genetic modification is somehow inherently unsafe. Since the potential risks posed by GM foods are the same as those with traditional foods the FDA should continue to regulate both under the same, proven system.

C. The World's Hungry

There are estimates that "perhaps a billion people are hungry now and perhaps two billion will be hungry in the twenty-first century."[100] How can GM foods help? In the future, it may be possible to genetically engineer food "to contain more proteins, vitamins, or minerals" and thus be beneficial in more ways than simply making it easier to grow or process.[101] One potential benefit of GM foods is that they may be able to be fortified with vitamins needed for human survival.[102]

One example of this kind of GM food is Golden Rice. Golden Rice is "enhanced by vitamin A precursor, beta carotene, and marketed in Southeast Asia where vitamin deficiency is

[97] LAMBRECHT, *supra* note 89, at 83.
[98] Brian P. Rafferty, *The Door Opens Slightly: Recent European Union Regulations on Genetically Modified Products and the Ongoing United States-European Union GM Product Dispute*, 16 GEO. INT'L ENVTL. L. REV. 281, 283 (2004).
[99] U.S. GEN. ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTERS: GENETICALLY MODIFIED FOODS, GAO-02-566 9 (2002), *available at* http://www.gao.gov/new.items/d02566.pdf.
[100] PENCE, *supra* note 83, at 144.
[101] LAMBRECHT, *supra* note 89, at 67.
[102] Burchett, *supra* note 2, at 177.

high."[103] It could help combat the deficiencies of "one million children" who "die every year because they are weakened by vitamin A deficiency."[104] While there are uncertainties regarding "Golden rice's" full potential (including uncertainty with regard to how much of the Beta-carotene can be absorbed) it is still "a tremendous technological achievement and an excellent example of the power of transgenic technology to improve human health."[105]

One of the most active critics of biotechnology, Greenpeace, stated that by its calculations "an adult would have to eat at least 3.7 kilos of dry weight rice … to satisfy his/her daily need of vitamin A from 'Golden Rice.'"[106] While critics have a valid point, in terms of the potential benefit of this particular crop, they miss the larger point. Instead of focusing on the fact that Golden Rice on its own cannot single-handedly cure vitamin deficiencies, they should consider that it does help bolster vitamin intake and the potential, in the future, for GM crops that provide even greater benefits.

Notwithstanding the potential benefits and the current work being done, some critics cite the fact that most of the major research is being directed at the industrialized world, not for the benefit of the developing world.[107] While it is true that biotechnology will help developed nations first, "New technologies, whether reaping machines in the 19th century or computers today, are always adopted by the rich before they become available to the poor."[108] Such is the nature of the world and "the fastest way to get new technology to poor people is to speed up the product cycle so the technology can spread quickly."[109]

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[103] Wong, *supra* note 26, at 3.
[104] LAMBRECHT, *supra* note 89, at 67.
[105] PERRY JOHNSON-GREEN, *supra* note 25, at 119.
[106] Greenpeace International, *Golden Rice is Fool's* Gold, *in* The Ethics of Food, *supra* note 8, 71, 72.
[107] LAMBRECHT, *supra* note 89, at 83.
[108] Bailey, *supra* note 19, at 115.
[109] *Id.*.

There are also practical, political considerations when considering the potential for GM crops to help the third world and critics argue that "this claim seems to ignore the complex social and political factors that contribute to hunger."[110] This argument brings forth an important point, but seems to ignore the fact that while transgenic crops cannot resolve all ills they will make it easier to combat hunger and deficiencies. The other practical problems will also have to be dealt with, but the situation is far from hopeless, for example "since 1991, Michigan State had spent about $20 million … to hasten the arrival of the genetic era to the world's least-developed countries. The university works not just with the science of biotechnology, but with its bureaucracy, helping countries set up the regulatory machinery to oversee a new brand of agriculture."[111] In the end, food biotechnology has the potential to help cope with the worldwide food shortages expected as soon as later this century.[112]

D. Religious and Ethical Considerations

There are a variety of religious and ethical concerns regarding GM foods. These are some of the most hotly contested issues because religious, moral and ethical concerns rarely rest on scientific grounds, but instead on personal beliefs. While these particular concerns alone would probably not be sufficient for the FDA to mandate labeling, they play an important part in the public debate.[113] The public debate is relevant because if the voice of America turns against GM foods, and the public demands labeling, it may convince Congress to act and require the FDA to mandate the labeling of GM foods.

[110] NOTTINGHAM, *supra* note 11, at 156.
[111] LAMBRECHT, *supra* note 89, at 13.
[112] Burchett, *supra* note 2, at 178.
[113] *See* Alliance for Bio-Integrity v. Shalala 116 F.Supp.2d 166, 179 (D.D.C. 2000) (reiterating the position that "'neutral laws of general applicability do not violate the Free Exercise Clause, even if the laws incidentally burden religion.'").

One example of how a religious concern could arise is if genetic material from an organism a particular religious group cannot eat (for example swine with respect to Jewish and Muslim believers) were used in the creation of a GM food.[114] Even among these groups there is debate as to whether the transferred gene would still be considered impure.[115] For example, "Some, like a Jewish group felt the genes take on the 'nature of the organism into which they had been transferred' while Muslim groups did not."[116] Most of these concerns, however, are limited to animals and "the production of transgenic plants raises fewer ethical concerns than does that of transgenic animals."[117] However, similar to the concerns raised above, are concerns for vegetarians when genes from "fish and animals have been integrated into crop plants."[118] This concern is a relatively minor one, however, because "the majority of genes transferred to transgenic plants … are derived from bacteria or other plants."[119] As we can see transgenic plants present fewer religious problems than the same techniques with regard to animals do, and thus would seem to be less contentious, but groups who cannot rely on religious grounds will often turn to ethical grounds.

One example of an ethical concern is that "genetic modification or engineering of crops is not a natural extension of traditional plant breeding techniques as it violates a 'natural order' which should be respected and not violated."[120] While ethical concerns of this nature are not without some importance, they are illustrative of the arbitrary ethical line drawing that proponents of this philosophy engage in. Traditional breeding techniques are similar to the new

[114] Vogt & Parish, *supra* note 7, at 21.
[115] NOTTINGHAM, *supra* note 11, at 99.
[116] *Id.*.
[117] *Id.* at 98.
[118] *Id.*.
[119] *Id.* at 99.
[120] Wong, *supra* note 26, at 6.

transgenic techniques which are used to create GM plants.[121] The primary difference between the two techniques, as discussed above in Section II, is that rDNA from organisms that otherwise could not be bred, can be used. While this is a real distinction, I do not think that this fact can be fairly categorized as the difference between what is natural and what is unnatural. Further, there are ethical concerns in favor of GM plants, one of which being the potential benefits to the worlds hungry (discussed above in Section IV: C) and the potential to salvage what remains of the "natural" world by preserving biodiversity and preventing further deforestation (discussed below in Section IV: E).

E. The Environment and Bio-diversity

One area of concern today, regarding the environment, is the current rate of deforestation.[122] This is an area where transgenic crops have a potential to make a difference. Even assuming that the current crop yields are enough to sustain the current global population, we will soon be faced with a dilemma because:

> It took some 10,000 years to expand food production to the current level of about 5 billion tonnes (sic) per year. By 2025, we will have to nearly double current production again. This cannot be done unless farmers … have access to … new biotechnological breakthroughs that can increase the yields, dependability, and nutritional quality of our basic food crops.[123]

Transgenic crops have the potential for crop yields to be increased.[124] If crop yields are increased it may "translate to less urgency to convert lands for agriculture."[125] Many of the lands that have the potential to be converted are our forests, which are invaluable sources of biodiversity and important for the continued sustainability of our global ecosystem. According to some estimates, farmers in the near future will have to grow as much as "six hundred bushels of

[121] Burchett, *supra* note 2, at 177.
[122] *See*, *e.g.*, AL GORE, AN INCONVENIENT TRUTH 220 (2006).
[123] Borlaug, *supra* note 8, at 79.
[124] Wong, *supra* note 26, at 3.
[125] *Id.* at 4.

corn per acre to feed the world" and if they can't the rainforests may have to be razed to make way for more farmland.[126] To put this in perspective, the average yield per acre in 2003-2004 was "A record [but the] average yield [ ] [was] 142.2 bushels per acre."[127]

Another area of concern is whether GM crops will impact biodiversity. One study that is often cited by critics is the effect of GM corn "on Monarch butterflies, which reported the harmful effect of pollen from corn producing Bacillus thuriniensis (Bt), a bio-pesticide."[128] In this study they found that 44 percent of the caterpillars who at the Bt corn had died while none of those who ate "either the plain milkweed or leaves dusted with regular corn pollen were dead."[129] This study is constantly referred to by critics, however, later studies "found that only one variety of Bt corn sold in the U.S." produced enough toxins to "kill the butterflies in the wild" so the problem is not as severe as it is made out to be.[130] In sum, these studies demonstrate that while we should continue to monitor and test GM crops they are not the biodiversity killers critics make them out to be.

An oft cited potential risk is that of unrestricted gene flow.[131] This would "most likely occur in the form of the transfer of bio-engineered traits to wild relatives through pollination" which could lead to such "undesirable consequences … as the conferring of herbicide-resistant traits of the GMOs to weeds, creating uncontrollable 'superweeds.'"[132] This is one of the concerns regarding "long-term risks and consequences of cross-pollination and of the disruption to the 'cellular ecology' of plants."[133] An added concern is that if the cross-pollination proved

[126] LAMBRECHT, *supra* note 89, at 102.
[127] U.S. Dept. of Agriculture, Economic Research System Website, *Feed Situation and Outlook Yearbook* (2004), http://usda.mannlib.cornell.edu/reports/erssor/field/fds-bby/fds2004s.txt.
[128] Wong, *supra* note 26, at 4.
[129] Hart, *supra* note 95, at 11.
[130] *Id.*.
[131] Wong, *supra* note 26, at 5.
[132] *Id.*; *see also* Vogt & Parish, *supra* note 7, at 1(discussing the possibility of superweeds).
[133] Vogt & Parish, *supra* note 7, at 24.

disastrous it could be widespread and uncontainable.[134] While all of these claims merit further study, there is no substantiated evidence to back these theories up.[135] These theories are based upon conjecture and speculation, neither of which are valid basis to mandate labeling.

On the balance, the environmental concerns weigh in favor of continuing to regulate GM foods under the current system. The potential risks will continue to be monitored, but remain largely unsubstantiated, while the demand for increased yield is a real and looming problem.

V. Conclusion

While there are legitimate concerns about the potential negative effects of transgenic crops, overall the FDA's policy is sufficient to protect the public from harm, and moreover a move to require mandatory labeling would impede development of GM crops that have a wide variety of potential benefits for producers, consumers and the environment. These requirements are sufficient because the FDA already "ensures that GMO foods, which are not subject to additional labeling requirements, are nutritionally equivalent to non-GMO foods" and if there are additional allergens or particularized risks to human health the FDA will mandate labeling of such.[136] Another potential problem with mandatory labeling is the potential that consumers will see "GM" as a black mark,[137] potentially viewing non-GM foods as superior, which could cause problems of "misbranding" pursuant to 21 U.S.C. § 343.[138]

Even if the public should demand a "right to know," the FDA probably would not have the authority to implement mandatory labeling as the FDCA stands now.[139] Congress would

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[134] *Id.* at 27.
[135] U.S. GEN. ACCOUNTING OFFICE, *supra* note 99, at 3.
[136] Robertson, *supra* note 43, at 160.
[137] *See* Hart, *supra* note 95, at 17 (Stating that "In May 2000 the FDA held nine focus groups across the country to gauge public opinion of GM foods in the U.S. When told that more than sixty percent (60%) of the processed foods contained genetically engineered ingredients, participants, many of whom are college educated, were outraged.").
[138] Robertson, *supra* note 43, at 161.
[139] Marden, *supra* note 1, at 760.

have to change the law, but I think it would be unwise to do so. The current laws have adequately protected the American public, and a requirement of mandatory labeling would increase costs and impose a significant burden on the U.S. food industry and, derivatively, one of their primary regulators, the FDA. It would require a two-tier system that would ensure that foods derived from transgenic crops be kept separate those that are not throughout the entire process, from farm to family.[140] It would also require someone, probably the FDA, to educate to public to the point that "GM" type claims would not be seen as misbranding under the FDCA.[141] This public mindset would prove to be expensive either way. If labeling is mandated the FDA (or some other arm of the government) would have to undertake the task of educating the public. That education would be financially taxing. If they do not provide education, or are unsuccessful – a likely prospect – the cost to our economy and GM food producers and researchers will be great.

The public and our lawmakers must not lose sight of the fact that "scientific advance always involves some risk that unintended outcomes can occur."[142] The public's unsubstantiated fear about GM foods is like an unfounded fear of ghouls and specters upon entering an ancient house, both are based on presupposition and conjecture, neither have much basis in reality. We cannot let the specter of fear overwhelm the scientific evidence. The current regulatory scheme protects the public[143] without putting an undue burden on GM crop producers, farmers or regulators. The current scheme also provides for mandatory labeling if the situation warrants it.[144] It is an "illusory promise" to contend that mandatory labeling would even solve the

[140] Burchett, *supra* note 2, at 195-96.
[141] 21 U.S.C. § 343 (Misbranding); *see also* Marden, *supra* note 1, at 761.
[142] Borlaug, *supra* note 8, at 77.
[143] *See* Hart, *supra* note 95, at 17 (Stating that "U.S. regulators often point to the fact that 280 million Americans have been eating this food on a regular basis since 1997…with no apparent harm.").
[144] Marden, *supra* note 1, at 762.

potential problems (i.e. a right to know) because it is difficult to track every GMO and GM food throughout the regulatory process.[145] As it stands now, the United States is a world leader in biotechnology and GM food technology.[146] We should continue our current, successful labeling system to ensure we remain the world leader by maintaining a friendly and reasonable environment for GM food technology to thrive in.

[145] Burchett, *supra* note 2, at 200.
[146] Marden, *supra* note 1, at 734.