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GENETICALLY MODIFIED FOOD AND INFORMED CONSUMER CHOICE: COMPARING U.S. AND E.U. LABELING LAWS

INTRODUCTION

Although you might not know it, chances are that the salad you have for lunch or the crackers you eat as an afternoon snack contain some amount of genetically modified (“GM”) plants.¹ Those ingredients almost certainly do not bear labels disclosing their genetic modifications. Even if they did, would you understand what the labels mean enough to make an informed decision whether to purchase and consume GM or non-GM food?

The labeling of genetically modified foods is an extremely complicated subject—one that falls at the intersection of a complex scientific field and deeply held religious, moral, and personal beliefs about what one puts into one’s body. It is possible that there is no right answer to the question whether foods should be labeled to indicate genetic modification.

Developments in the genetic engineering of food have been heralded by proponents and reviled by detractors. Proponents argue that genetically modified plants² provide important benefits, such as decreased pesti-

1. See *infra* note 47.

2. Unless specified otherwise, for the purposes of this Note, “plant foods” means crops grown for human consumption and products produced from those crops. This is in contrast to animals that are raised for human consumption. To date, the debate over biotechnology has centered around plants, as plants have been the GM products most widely available commercially. See AMERICAN MEDICAL ASSOCIATION, REPORT 10 OF THE COUNCIL ON SCIENTIFIC AFFAIRS (I-00) FULL TEXT: GENETICALLY MODIFIED FOOD AND CROPS (2000), available at <http://www.ama-assn.org/ama/no-index/about-ama/13595.shtml>. Thus, this Note will restrict its discussion to the debate surrounding GM plant foods. Regarding the scope of this Note, see *infra* note 24 and accompanying text.

The genetic modification of animals meant for human consumption raises many issues similar to those involved in the genetic modification of plant foods. However, as GM animals meant for human consumption are not currently available commercially, and since different laws apply to animals and plants—and different governmental agencies are responsible for monitoring the raising of food animals—labeling of GM food animal products is beyond the scope of this Note. The debate over labeling requirements with respect to animals will likely intensify as animals meant for human consumption increasingly become the focus of biotechnology developments. For example, regulatory approval of “Enviro-pigs” engineered to digest a higher percentage of phosphorous, resulting in waste that is less toxic to the environment, could come soon. Megan Ogilvie, *Genetically Engineered Meal Close to Your Table*, TORONTO STAR, Nov. 22, 2008, at A1, available at <http://www.thestar.com/comment/columnists/article/541710>.

cide use,³ increased vitamin content,⁴ and increased crop yields,⁵ and that they have great potential to yield even more impressive benefits in the future.⁶ Opponents claim that the technology poses significant risks, such as gene drift, the production of new allergens or toxins, and the transfer of genetically modified proteins to human cells.⁷ Still, genetically modified organisms (“GMOs”) have not been demonstrated to be unsafe—in fact, they are safer than conventional or even organic food products by some measures.⁸

GM plants have received relatively little public attention in the U.S., but they have been hotly debated and strongly resisted in Europe. In response to public fears in Europe, the European Union tried to ban the growth and importation of GMOs entirely, but the U.S., Canada, and Argentina successfully challenged this ban at the World Trade Organization (“WTO”).⁹ The WTO ruled that the E.U.’s GMO ban violated the Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS Agreement”).¹⁰ To control the importation and domestic growth of GMOs, the E.U. now relies on strict approval processes for GMOs coupled with a labeling regime that has become the most complicated and stringent in the world.¹¹

The E.U.’s anti-GM attitude has spread to other countries, including Australia, New Zealand, Japan, Indonesia, and South Korea, all of which

3. See *infra* note 48 and accompanying text.

4. See *infra* note 45.

5. U.S. Dep’t of Agric., Biotechnology FAQ, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&navid=AGRICULTURE&contentid=BiotechnologyFAQs.xml (last visited Apr. 11, 2010).

6. See discussion *supra* note 2. Other possibilities include plants used to manufacture pharmaceuticals, such as “blood and hormone peptides, proteins, antibodies, antigens and vaccines.” John Davison & Yves Berthau, *EU Regulations on the Traceability and Detection of GMOs: Difficulties in Interpretation, Implementation and Compliance*, CAB REVIEWS: PERSPECTIVES IN AGRICULTURE, VETERINARY SCIENCE, NUTRITION AND NATURAL RESOURCES, Dec. 2007, available at http://www.prodinra.inra.fr/prodinra/pinra/data/2008/07/PROD2008c17b92d_20080707114922058.pdf.

7. See *infra* note 61 and accompanying text.

8. See ALAN MCHUGHEN, PANDORA’S PICNIC BASKET: THE POTENTIAL AND HAZARDS OF GENETICALLY MODIFIED FOODS 230–42 (2000) (noting that consumers who consume organic food in an attempt to avoid the perceived dangers of genetically modified food may be putting themselves at greater risk); Cass Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1010 n.27 (2003).

9. See *infra* notes 78–81 and accompanying text.

10. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A—Result of Uruguay Round (1994), available at <http://www.wto.org> [hereinafter SPS Agreement]; see discussion in Part I.

11. This has resulted in a *de facto* ban on GMOs. See *infra* notes 76, 77, 155.

currently have some form of GM-labeling law in place.¹² It has also caused particularly strong opposition to the planting of GM crops in Africa due to the fear that they would endanger African exports to the E.U.¹³ This fear has led some African governments to reject shipments of GM food aid, resulting in unnecessary starvation.¹⁴

Proponents of labeling in these countries and others argue that the consumer has a “right to know” whether his or her food has been genetically modified.¹⁵ The U.S. Food and Drug Administration (“FDA”), however, rejects this view, stating that the consumer’s “right to know” is not a sufficient justification for mandatory labeling under existing law.¹⁶ The FDA’s position is that, because GM technology does not result in an end product that is materially different from similar products produced by conventional agricultural methods,¹⁷ neither the fact that the food is GM nor the fact that it was produced using biotechnology needs to be disclosed on the label.

12. See *infra* notes 188–91 and accompanying text.

13. Zambia’s agriculture minister “claimed that the corn could [thus] contaminate Zambia’s agriculture, risking the loss of its cash-crop export markets in Europe.” Peter Mitchell, *Europe Angers US with Strict GM Labeling*, 21 NATURE BIOTECHNOLOGY 6 (2003), available at <http://www.nature.com/nbt/journal/v21/n1/full/nbt0103-6a.html>.

14. Some African governments have gone so far as to order shipments of food aid at their shores to return to the U.S. if the shipments contain GM corn, citing worries that farmers would save and replant the grain instead of eating it. *Id.* at 6. In October 2003, “Zambia refused 63,000 tons of GM corn from the United States intended to help relieve . . . famine.” *Id.* Zimbabwe has similarly refused shipments worth millions of dollars. Andrew Meldrum, *Starving Zimbabwe Shuns Offer of GM Maize*, THE GUARDIAN, June 1, 2002, at 19, available at <http://www.guardian.co.uk/science/2002/jun/01/gm.zimbabwenews>. These governments have chosen to let their people starve rather than give them food that American consumers have been eating for close to 20 years, with no demonstrated adverse health effects. Further, African farmers who choose to grow non-GM crops forego the increased yields available from GM crops. These farmers, the vast majority of whom are women, remain in poverty. They could potentially pull themselves out of poverty, as farmers in India and China did, by adopting GM varieties. ROBERT PAARLBERG, *STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA* 23 (2008). Thus, the debate over GMOs is a world trade issue, a globalization issue, a human rights issue, and a women’s rights issue.

15. See Arthur E. Appleton, *The Labeling of GMO Products Pursuant to International Trade Rules*, 8 N.Y.U. ENVTL. L.J. 566, 567 (2000); J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD DRUG L.J. 105, 109 (2000); Emily Robertson, Note, *Finding a Compromise in the Debate over Genetically Modified Food: An Introduction to a Model State Consumer Right-To-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 165 (2003); see also discussion *infra* Part III.

16. See *infra* notes 132, 133, 142, and 143 and accompanying text. In other words, the FDA does not agree that the consumer has a *right* to know whether food is GM.

17. See *infra* notes 132–35 and accompanying text.

The FDA has approved many varieties of GM plants for commercial sale in the U.S.¹⁸ In light of the FDA's position, the U.S. currently does not require producers of plant foods to disclose the presence of GM material by labeling their products.¹⁹ Some labeling is permitted, however. For instance, the FDA allows producers to label their products "GMO-free,"²⁰ and the "USDA-Organic" label indicates that food is free of GMOs and GM material, among other things.²¹ The E.U., on the other hand, has not approved most GM crop varieties for commercial sale.²² For the few varieties it has approved, it requires that plant foods with more than 0.9% genetically modified content be labeled as "genetically modified."²³

18. The list of approved crop varieties, now numbering more than 40, is available on the FDA's website. U.S. Food & Drug Admin., The FDA List of Completed Consultations on Bioengineered Foods, <http://www.cfsan.fda.gov/~lrd/biocon.html#list> (last visited Apr. 11, 2010). Crops that have been the subject of successful modifications include plums, cantaloupes, papayas, tomatoes, corn, canola, soybeans, squashes, potatoes, radicchio, sugar beets, and cotton. *Id.* By far the largest commercial application of GM technology is in three crops: corn, cotton, and soybeans. *See infra* note 47.

19. *See infra* note 142 and accompanying text.

20. *See infra* note 143 and accompanying text.

21. 7 C.F.R. § 205.105. The F.D.A. regulation states that "to be sold . . . as '100 percent organic,' 'organic,' or 'made with organic (specified ingredients or food group(s)),' the product must be produced and handled "without the use of: . . . (e) excluded methods," which § 205.2 of Subpart A defines to include genetic engineering methods such as "cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology."

22. For an overview of the approval process in the E.U., see GMO Compass, The European Regulatory System: Genetic Engineering, http://www.gmocompass.org/eng/regulation/regulatory_process/156.european_regulatory_system_genetic_engineering.html (last visited Apr. 8, 2010). GMO Compass is a website established by the European Union within the European Commission's Sixth Framework Programme (from January 1, 2005 until February 28, 2007). For a database of GMOs approved for commercial sale in the E.U., see GMO Compass, GMO Database—Authorisation and Approval Status in the EU, <http://www.gmo-compass.org/eng/gmo/db/> (last visited Apr. 11, 2010). Even with European Commission-level approval, some countries refuse to allow domestic planting or sale of approved GMOs: the European Food Safety Authority ("EFSA") recently condemned the 2008 decision by France to not allow domestic production of an approved GM corn variety. European Food Safety Authority, *Scientific Opinion of the Panel on Genetically Modified Organisms*, EFSA J., Oct. 31, 2008, <http://www.efsa.europa.eu/en/efsajournal/doc/850.pdf>. For a description of the role of the EFSA, see *infra* notes 167, 168 and accompanying text.

23. Council Regulation 1829/2003, 2003 O.J. (L 268); Council Directive 2001/18, art. 21 ¶ 2, 2001 O.J. (L 106) 13. For further discussion of the *de minimis* threshold, see *infra* note 180 and accompanying text. "'Organism' means any biological entity capable of replication or of transferring genetic material," *id.* art. (1), and "'genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the

This Note proposes a framework for a U.S. labeling regime derived by comparing current regulations in the United States and the European Union that deal with genetically modified plants that are grown for human consumption.²⁴ This scope is intended to address the most commercially significant applications of biotechnology to food. As yet, GM animals are not commercially available for human consumption.²⁵ However, GM corn, cotton, oilseed rape (canola), and soybeans are widely available to consumers.²⁶

Part I provides background on biotechnology generally and the state of the debate between the U.S. and the E.U. regarding genetically modified food. Part II discusses the rationale behind labeling laws—that it is important for consumers to know the contents of the foods they purchase so that they may make informed choices. Part III examines the labeling regime in the U.S., which is currently voluntary at the federal level because regulators assume that biotech crops do not pose any dangers greater than those posed by conventional foods.²⁷ Part IV examines the labeling regime in the E.U., which requires producers to label food products that contain at least 0.9% GM content. Part V proposes a labeling regime for the United States that would be a compromise between the polar positions taken by the U.S. and the E.U. Such a regime would consist of a federal law requiring plant foods that are GMOs or that contain more than a certain threshold GM content to be labeled “genetically modified.” The discussion of how to design a labeling regime highlights the difficulties associated with ensuring informed consumer choice, shedding further light on why the U.S. does not currently require labeling. Finally,

genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.” *Id.* art. (2). This definition is incorporated into the Directive on Traceability and Labelling of GMOs, Council Regulation 1830/2003, art. 3, 2003 O.J. (L 268) 25–26, and the Directive on Genetically Modified (GM) Food and Feed, Council Regulation 1829/2003, 2003 O.J. (L 268). Together, these two sets of laws currently govern the labeling of GM content in food in the E.U.

24. To comprehensively address the concerns of consumer autonomy discussed in Part IV, any labeling regime would have to include labels on animal products grown for food as well. In the first instance, any direct modification of the genome of an animal grown for human consumption would have to be disclosed. Furthermore, even if the genome of an animal is not modified directly, the labeling regime should disclose whether the animal is fed genetically modified plant or animal products. However, laws applying to animals grown for human consumption are outside the scope of this paper.

25. *See supra* note 2.

26. GMO Compass, GMO Cultivation Area by Crop, http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/144.gmo_cultivation_area_crop.html (last visited Apr. 11, 2010); *see also infra* notes 46, 47.

27. Some state labeling regimes require mandatory labeling of specific products. *See infra* note 125.

this Note concludes with a discussion of the potential effects of the proposed labeling regime, the most significant of which are monetary cost and a potential consumer shift away from GM food products.

I. THE DEBATE OVER GENETICALLY MODIFIED ORGANISMS

The U.S. is strongly in favor of the current growth and further development of GMOs because this technology has been demonstrated to be safe and beneficial.²⁸ The U.S. produces the most GM crops of any country,²⁹ resulting in large financial investments in the technology. Conversely, the E.U. has resisted the importation and growth of GMOs, focusing on the theoretical risks of the technology³⁰ and opposition from farmers and consumers.³¹

GMOs have a relatively long history in the United States. They were first grown in the U.S. for public consumption in 1996.³² To date, no significant occurrence of harm has been reported.³³ Scientific studies and safety tests conducted on animals have shown GMOs to be safe.³⁴ The

28. See *infra* notes 33, 34 and accompanying text.

29. The U.S. planted 64 million hectares of GM crops in 2009. Int'l Serv. for the Acquisition of Agri-Biotech Applications [ISAAA], Global Status of Commercialized Biotech/GM Crops: 2009, tbl.1, Brief 41–2009, available at <http://www.isaaa.org/resources/publications/briefs/41/executivesummary/default.asp> (last visited Apr. 11, 2010). The U.S. is followed by Brazil, at 21.4 million hectares planted, Argentina, at 21.3 million hectares, India, at 8.4 million hectares, Canada, at 8.2 million hectares, and China, at 3.7 million hectares. *Id.*

The ISAAA describes itself as a “not-for-profit international organization that shares the benefits of crop biotechnology to various stakeholders, particularly resource-poor farmers in developing countries, through knowledge sharing initiatives and the transfer and delivery of proprietary biotechnology applications.” ISAAA, ISAAA in Brief, <http://www.isaaa.org/inbrief/default.asp> (last visited Apr. 11, 2010).

30. See *infra* notes 58–62 and accompanying text.

31. See *infra* notes 63–72.

32. PAARLBERG, *supra* note 14, at 26.

33. *Id.*; Mario F. Teisl & Julie A. Caswell, *Information Policy and Genetically Modified Foods: Weighing the Benefits and Costs* 18 (Univ. Mass., Amherst, Working Paper No. 2003–1), available at <http://ssrn.com/abstract=387240> (“ . . . the existing scientific evidence has not shown any substantial health or safety difference between GM and non-GM foods.”).

34. Studies so far have been done in mice, rats, chicken and cattle (as intentional consumers of *Bt* corn), and on non-target organisms such as Monarch butterflies in one highly-publicized study. “An experiment performed at Cornell University showed that large amounts of pollen from *Bt* corn . . . could kill larvae . . .” Center for Science in the Public Interest, Biotechnology Project: Frequently-Asked Questions, <http://www.cspinet.org/biotech/faq.html> (last visited Apr. 11, 2010). However, subsequent research showed that harm was unlikely to occur in nature because, *inter alia*, “Monarch larvae are not often present when pollen [containing the *Bt* toxin] is found on the milkweed leaves.” *Id.*

U.S. public, however, remains largely uninformed of these findings, as well as of the processes and science behind genetic engineering in general. A 2005 consumer opinion survey found that “only 25 percent of respondents believed they had ever eaten genetically modified foods,”³⁵ but it is fair to say that most Americans eat genetically modified foods regularly.³⁶ Nevertheless, most Americans are opposed to consuming GMOs.³⁷ When American consumers are “asked directly if they would

Research initially appeared to show “negative effects on rats of eating GM potatoes,” but “further analysis revealed [the assertions of negative effects] to be at best uncertain, and at worst, groundless.” AMERICAN MEDICAL ASSOCIATION, *supra* note 2. To date, there have been no safety tests conducted in humans (although the experience of the populations of countries in which GMOs have been commercially available for more than a decade shows no negative results).

35. PAARLBERG, *supra* note 14, at 23 (discussing a survey by the Pew initiative). Another survey by the International Food Information Council conducted earlier in 2005 found that “only one-third of consumers in the United States were aware that GM foods were being sold in stores.” *Id.* This reflects widespread lack of knowledge of the state of the market in GM foods, as well as lack of consumer understanding of the food supply, given the prevalence of GM foods as discussed *infra* in note 47.

36. See PAARLBERG, *supra* note 14. In a focus-group study, when participants were told that “most processed foods probably contain some GM ingredients, some participants seemed upset because they felt that they should have known this information” and yet did not. Mario F. Teisl et al., *Focus Group Reactions to Genetically Modified Food Labels*, 5 J. AGROBIOTECHNOLOGY MGMT. & ECON. 6, 7 (2002).

On the other hand, the researchers also found that “other participants found the information comforting; these participants combined the fact that GM foods are prevalent with the notion that they had not heard or known of anyone getting sick as positive news.” *Id.* The study was conducted by researchers at the University of Maine, Ohio State University, and Unity College, and was funded in part by the USDA. *Id.* at 9. It is not possible to generalize the results of this study, as the sample size was limited, but this effect might repeat itself in the general public. In Europe, fear of the unknown has not been tested, as consumers have not been exposed to GM plant foods. If GM foods are introduced with labels and the non-harmful effects perpetuate themselves as they have so far in the United States, perhaps consumers will come (albeit slowly) to accept GMOs as safe.

37. A 2005 survey by the Pew Initiative found that 33% of consumers said they would oppose GM food “strongly.” PAARLBERG, *supra* note 14, at 22; PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, PUBLIC SENTIMENT ABOUT GENETICALLY MODIFIED FOOD, NOVEMBER UPDATE (2005), available at <http://pewagbiotech.org/research/2005update/2.php>. A 2002 study found that consumers in two urban Midwest areas would pay a “14 percent premium for foods items (vegetable oil, tortilla chips and potatoes) they perceived as non-GM,” where the genetically modified food items were labeled as such. Teisl & Caswell, *supra* note 33, at 8–9.

Conversely, the results of this study could be characterized as the amount of price reduction consumers demand in order to eat GM food. In other words, consumers will choose GM, but only when it is significantly less expensive than non-GM. For example,

like to see all GM foods labeled, 94 percent say yes.”³⁸ This desire for labels is likely the result of popular fear of the unknown. People are often skeptical of the unfamiliar, so it is not surprising that most consumers are against eating GM food despite inadvertently having already made it part of their daily diets. But genetic modification is not a new technology, and even non-GM foods are affected by human intervention in the evolutionary process.

Manipulating the genome of an organism can be accomplished via several methods. These methods fall under two general umbrellas: conventional plant breeding³⁹ and biotechnology⁴⁰ (the latter of which may also be referred to as genetic engineering (“GE”), genetic modification, gene splicing, and “recombinant Deoxyribonucleic Acid” (“rDNA”) technology).⁴¹ Conventional plant breeding is a process by which scientists select particular plant specimens with desirable traits “from a great variety of naturally occurring types of plants”⁴² and reproduce them by pollinating

in a Japanese study, “consumers would only be willing to purchase GM [foods] if there were a 60 percent discount” as opposed to non-GM foods. *Id.*

38. PAARLBERG, *supra* note 14, at 23.

39. Conventional plant breeding involves cross-pollinating genes from different varieties of plants to produce hybrids that will express the desirable traits of the parents. For example, crossing a plant that is disease resistant with a plant that produces flowers of a desired color in order to produce a disease resistant plant with such flowers. For a general discussion of conventional plant breeding, see ROBERT W. ALLARD, *PRINCIPLES OF PLANT BREEDING* (2d ed. 1999).

40. “Traditional breeding techniques are limited to genetic mating between related species, and require several generations (often years) to achieve the desired results. With transgenic technology, a genetic trait can be introduced into a selected plant via the direct introduction of the gene responsible for that trait.” AMERICAN MEDICAL ASSOCIATION, *supra* note 2. “Genetically engineered animals used for research, such as mice, have been commercially available for several years.” Center for Science in the Public Interest, *supra* note 34.

41. For an explanation of these and other methods of genetic engineering, see NAT'L RES. COUNCIL & INST. OF MED. OF THE NAT'L ACADS., *SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS*, ch. 2 (2004), available at <http://www.nap.edu/openbook.php?isbn=0309092094>.

42. Nuffield Council on Bioethics, *The Use of GM Crops in Developing Countries*, http://www.nuffieldbioethics.org/go/browseablepublications/gmcropsdevcountries/report_132.html (last visited Dec. 1, 2008). “This has led to completely new varieties such as Triticale (a hybrid between wheat and rye). Another technique, mutation breeding, involves the exposure of plants and seeds to radiation or chemical substances.” *Id.*

However, the progeny of this first cross inherit a mix of genes from both parent plants and so both positive and negative traits may be inherited. Breeders have to look at all the progeny and select the ones with the most positive traits and least negative traits. They then cross this selected progeny back to one of the

other plants with the pollen carrying desirable traits. Genetic engineering, on the other hand, involves isolating a gene from one organism and inserting it into the genome of another, unrelated organism.⁴³ Because genetic engineering involves the *direct* modification of an organism's genome, it generates more opposition than conventional plant breeding.⁴⁴

Genetic engineering has been used to produce a wide range of effects in plants, such as tolerance to herbicides, toxicity to certain pests, resistance to viruses, increased yields, tolerance of extreme growing conditions (such as drought, high winds, and acidic or excessively salty soil), extended shelf life (also known as "delayed ripening"), increased vitamin content, altered oil content, and decreased acid content.⁴⁵

The introduction of a pesticidal gene from a soil bacterium, *Bacillus thuringiensis* ("Bt"), into corn and cotton,⁴⁶ and the introduction of an *Agrobacterium* gene producing a degradative enzyme that confers tolerance to the herbicide glyphosate into soybeans have been the most monetarily significant and widespread applications of genetic engineering in the United States.⁴⁷ The introduction of the Bt gene makes the plants

original parent plants to try and transfer more of its positive traits into the following generation.

Commonwealth Scientific and Industrial Research Organisation ("CSIRO"), What is the Difference between Conventional and GM Plant Breeding?, <http://www.csiro.au/resources/ps3nj.html> (last visited Dec. 1, 2008). CSIRO describes itself as "Australia's national science agency and one of the largest and most diverse research agencies in the world." CSIRO, About CSIRO, <http://www.csiro.au/org/About-CSIRO.html> (last visited Apr. 11, 2010).

43. Merriam-Webster defines "genetic engineering" as "the group of applied techniques of genetics and biotechnology used to cut up and join together genetic material and especially DNA from one or more species of organism and to introduce the result into an organism in order to change one or more of its characteristics." Merriam-Webster, <http://www.merriam-webster.com/dictionary/genetic%20engineering> (last visited Dec. 1, 2008).

44. AMERICAN MEDICAL ASSOCIATION, *supra* note 2.

45. *Id.*; Stella G. Uzogara, *The Impact of Genetic Modification of Human Foods in the 21st Century: A Review*, 18 BIOTECHNOLOGY ADVANCES 176, available at <http://www.sciencedirect.com/> (search for author "Uzogara"); U.S. Dep't of Agric., *supra* note 5.

46. Interestingly, organic food producers make extensive use of the 'natural' pesticidal effects of Bt. They spray large quantities of the bacteria on their plants to kill pests. The only difference between organic and non-organic Bt crops, therefore, is that the pesticidal gene is incorporated into the GM crop genome rather than the genome of the bacteria coating the non-GM plant. University of California, San Diego, *Bacillus thuringiensis*, http://www.bt.ucsd.edu/organic_farming.html (last visited Oct. 9, 2009).

47. "As of 2006 an estimated 61 percent of all corn grown in the United States and 89 percent of all soybeans were GM varieties." AMERICAN MEDICAL ASSOCIATION, *supra* note 2 ("glyphosate-tolerant plants, especially soybeans, have received the most widespread commercial use"); PAARLBERG, *supra* note 14, at 22–23. Because these plants,

produce a protein that kills insect pests, thus allowing farmers to grow *Bt* crops entirely without—or with significantly reduced levels of—synthetic chemical pesticides.⁴⁸ The introduction of the *Agrobacterium* gene enables farmers to more efficiently kill weeds in soybean fields with the herbicide glyphosate (marketed commercially under the brand name “Roundup”).⁴⁹ Glyphosate is preferable to chemical herbicide alternatives used in conventional agriculture because “[u]nlike many herbicides, glyphosate has low toxicity, is safe for humans and animals, and degrades quickly in the soil.”⁵⁰

These changes in plant characteristics have produced many important benefits, including lower average levels of fungal toxins on produce,⁵¹ increased shelf life,⁵² reduction in the use of chemical pesticides (and thus reduction in pesticide residues on produce),⁵³ tillage practices that

particularly corn and corn derivatives, are incorporated into so many processed foods, “roughly 70 percent of all supermarket products in the United States have at least some GM content.” *Id.*

The United States accounts for two thirds of bioengineered crops produced globally. Other major suppliers include Argentina, Canada, and China. More than 20% of the global crop acreage of soybeans, corn, cotton, and canola is now biotech varieties. In addition, biotech ingredients and biotech processes are used in producing a wide selection of food and beverage products such as meat, poultry, cheese, milk, and beer.

Colin A. Carter & Guillaume P. Gruere, *International Approaches to Labeling Genetically Modified Foods*, CHOICES MAG., Second Quarter 2003, at 1 (internal citation omitted), available at <http://www.choicesmagazine.org/2003-2/2003-2-01.htm>.

48. PAARLBERG, *supra* note 14, at 29.

49. The plants are known as “Roundup Ready” soybeans or corn. Monsanto U.S. Ag Products, Input Traits, http://www.monsanto.com/monsanto/ag_products/input_traits/products/roundup_ready_soybeans.asp (last visited Apr. 10, 2010).

50. AMERICAN MEDICAL ASSOCIATION, *supra* note 2. Glyphosate cannot be used on plants that have not been genetically modified to be tolerant to it, because as a broad-spectrum herbicide, it will kill them. *Id.*

51. PAARLBERG, *supra* note 14, at 28. Insect damage to produce tissue gives these fungi the opportunity to grow. Thus, pesticides that kill the insects that cause damage to plant tissue deny these fungi such opportunity. *Id.*

52. *Id.*

53. Other benefits include “[s]ubstantial[] reduc[tion] in the use of broad-spectrum and highly poisonous insecticides”; fewer applications of herbicides, which results in less herbicide in the environment and more time for farmers to attend to other matters; and the “adoption of conservation tillage, which conserves soil [that] is more easily eroded when fields are conventionally cultivated” and decreases the amount of crops lost to pests, thus reducing commodity costs. Center for Science in the Public Interest, *supra* note 34. Some studies have shown reduction in the spraying of chemical pesticides through use of *Bt* corn and soybeans by 40–60%. PAARLBERG, *supra* note 14, at 29.

encourage soil conservation,⁵⁴ and increased crop yields.⁵⁵ In turn, pesticide reduction preserves biodiversity, prevents environmental degradation, safeguards workers' health, and reduces the amount of diesel fuel burned by the machines that apply such pesticides.⁵⁶ Increased yields could help prevent starvation in countries prone to hunger.⁵⁷ These benefits are widely ignored in regulatory regimes that ban the growth and importation of genetically modified plants, to the detriment of consumers and the environment.

On the other hand, even though no harm has yet been reported, the use of genetic engineering in plants grown for human consumption does pose potential risks to both the environment and human health.⁵⁸ These risks include the possibility that the plants might produce "new allergens or toxins, or unexpectedly increased levels of naturally occurring toxicants or allergens found in crops."⁵⁹ Additionally, there is the unlikely possibility that the modified plant could produce unknown harmful substances,⁶⁰ and there is the exceedingly remote possibility that the proteins engineered into the plants could be transferred to human cells.⁶¹ Notably,

54. PAARLBERG, *supra* note 14, at 29.

55. *Id.*; see also U.S. Dep't of Agric., *supra* note 5.

56. PAARLBERG, *supra* note 14, at 29.

57. *Id.*

58. Other risks associated with the technology but not relevant to consumption of food include environmental risks, such as reduction in biodiversity, harm to non-target organisms, gene pollution, increased pest resistance, increased herbicide resistance, and the development of super-weeds. All of these risks may occur with conventional agricultural methods as well, with the exception of gene pollution and super-weeds. For a discussion of the reasons for which all of these risks are minimal at most, and the outlook with respect to each is likely better with use of biotech plants and methods than with conventional agricultural methods, see AMERICAN MEDICAL ASSOCIATION, *supra* note 2.

59. Center for Science in the Public Interest, *supra* note 34. However, "[t]here are no known cases of allergic reactions caused by marketed foods derived from GM plants. Of note, genetic engineering also offers the opportunity to decrease or eliminate the protein allergens that occur naturally in specific foods through the use of, among others, anti-sense technology." AMERICAN MEDICAL ASSOCIATION, *supra* note 2.

60. Center for Science in the Public Interest, *supra* note 34.

61. See AMERICAN MEDICAL ASSOCIATION, *supra* note 2.

The transfer of plant DNA into microbial or mammalian cells under normal circumstances of dietary exposure would require all of the following events to occur: (1) the relevant gene(s) in the plant DNA would have to be released (excised), probably as linear fragments; (2) the gene(s) would have to survive nucleases in the plant and gastrointestinal tract; (3) the gene(s) would have to compete for uptake with dietary DNA; (4) the recipient bacteria or mammalian cells would have to be competent for transformation and the gene(s) would have to survive their restriction enzymes; and (5) the gene(s) would have to be inserted

labeling is already required under current law if any of these effects occurs, as they amount to material changes in the composition of the food.⁶²

Fears over these potential risks have produced some opposition to the development and growth of GMOs in the United States, and have produced strong (sometimes violent) opposition in Europe⁶³ and some developing countries.⁶⁴ Among those opposed to GMOs are religious groups,⁶⁵ organic food groups (such as local food cooperatives⁶⁶ and The

into the host DNA by rare repair or recombination events, and the inserted gene would have to be stably maintained.

Id. To date, studies have shown that no such gene transfer has occurred. *Id.*

62. See *infra* note 142 and accompanying text.

63. EuroPol characterized the Greenpeace destruction of GM crops in Portugal in 2008 as “terrorist attacks.” EUROPOL TE-SAT 2008: EU TERRORISM SITUATION AND TREND REPORT 41 (2008), available at www.europol.europa.eu/publications/EU_Terrorism_Situation_and_Trend_Report_TE-SAT/TE-SAT2008.pdf.

The protests of José Bové, probably the most well-known European anti-GM activist, have included destroying a facility producing GM seeds and ‘hijacking’ GM corn. José Bové: Profile, BBC, http://www.bbc.co.uk/bbcfour/documentaries/profile/jose_bove.shtml (last visited Oct. 20, 2008). To protest another aspect of the globalization of food and food politics, Bové drove his tractor into a local McDonald’s restaurant. *Id.*

64. Vandana Shiva is one of the most outspoken critics of biotechnology in India. See generally MANIFESTOS ON THE FUTURE OF FOOD AND SEED (Vandana Shiva ed., 2007). Perhaps surprisingly, farmers (in both the United States and the European Union) at all levels of income have not been opposed to the introduction of GM crops. PAARLBERG, *supra* note 14, at 63.

65. Press Release, Pew Charitable Trusts, Views on Genetic Modification of Food Influenced by Religious Beliefs, Not Just Science (July 26, 2001), available at http://www.pewtrusts.org/news_room_detail.aspx?id=33476.

When asked specifically about their own religious or moral views in regards to agricultural biotechnology, a majority of Christians (Protestants, born-again Christians and Catholics) and a plurality of Muslims say they are opposed to moving genes from one species or organism to put into another, the poll found. Jews were the only religious group polled that had a majority that supported this technology.

Id.

66. Park Slope Food Coop, Environmental Policy (July 1998), <http://www.foodcoop.com/go.php?id=39>. The Coop’s policy is that it will “[s]ell no products that are genetically engineered or contain products of genetic engineering, except that sales of genetically engineered products shall not be discontinued unless there is a similarly priced equivalent product that is not genetically engineered.” Because

genetically engineered products or products containing genetically engineered inputs are not labeled as such . . . products shall be considered to be genetically engineered if they contain non-organically produced ingredients that are known

Campaign to Label Genetically Engineered Foods⁶⁷), and environmental groups (such as Greenpeace⁶⁸ and Friends of the Earth⁶⁹). Some opponents of GM food “believe that ‘it is not natural’ and implies ‘tampering with nature.’”⁷⁰ Environmental groups argue that the unknown risks of biotechnology, the severity of the theoretical risks to human health,⁷¹ and certain risks to the environment of gene pollution and reduction of biodiversity are in fact already occurring and significantly outweigh the benefits of GMOs.⁷² Critics in developing countries argue that intellectual property rights in GM technology prevent traditional seed-saving practices, thereby harming traditional agrarian cultures.⁷³

A fundamental flaw in GM opponents’ arguments is that all of the categories of unexpected changes they find disconcerting “can occur through traditional forms of plant breeding that have been carried out for many decades.”⁷⁴ According to the Center for Science in the Public Interest, a non-partisan think tank, “the only known cases of increased or new harmful compounds have been [the results of] traditional breeding methods, not genetic engineering.”⁷⁵ Thus, as opponents of genetic modification through biotechnology do not oppose traditional plant breeding, their arguments against biotechnology are specious.

Whether or not these anti-GM views are flawed, they have taken hold in Europe. In 1997, in response to European consumer concerns, the Eu-

to be commercially available in genetically engineered form, or that are known to be produced with commercially available genetically engineered inputs.

Id.

67. See Campaign to Label Genetically Engineered Foods, <http://www.thecampaign.org/> (last visited Mar. 1, 2009).

68. See generally Greenpeace, Sustainable Agriculture and Genetic Engineering, <http://www.greenpeace.org/usa/campaigns/genetic-engineering> (last visited Dec. 1, 2008).

69. Friends of the Earth, What is Synthetic Biology, <http://www.foe.org/healthy-people/what-synthetic-biology> (last visited Mar. 1, 2009) (“Friends of the Earth is against the assumption that humans can re-design or create superior forms of life . . . Challenging and attempting to improve upon the original design of life disrespects and ignores the perfect balance of the natural world.”).

70. THOMAS BERNAUER, GENES, TRADE, AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY 33 (2003).

71. Arpad Pusztai, *Genetically Modified Foods: Are They a Risk to Human/Animal Health?*, ACTIONBIOSCIENCE.ORG, June 2001, <http://www.actionbioscience.org/biotech/pusztai.html>.

72. See generally Greenpeace, *supra* note 68.

73. See generally MANIFESTOS ON THE FUTURE OF FOOD AND SEED, *supra* note 64. Farmers are not forced to use GMO seeds; therefore, those who want to use non-GMO seeds and continue seed-saving practices are free to do so.

74. Center for Science in the Public Interest, *supra* note 34.

75. *Id.*

European Union instituted a requirement that GM content in food be disclosed on labels,⁷⁶ and in 1998, the E.U. introduced a moratorium on the importation and domestic growth of genetically modified organisms.⁷⁷ The United States, together with Argentina and Canada, challenged the European Union ban via the Dispute Settlement Understanding (“DSU”) of the WTO in *European Communities—Measures Affecting the Approval and Marketing of Biotech Products* (“EC-Biotech”).⁷⁸ In late 2006, the WTO Dispute Settlement Body adopted a ruling that the E.U. ban violated Annex C(1)(a) of the Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS Agreement”) because the ban did not “undertake and complete the approval procedures without undue delay,” and the ban violated Articles 2.2 and 5.1 of the SPS Agreement because the state safeguard measures “were not based on risk assessments satisfying the definition of the SPS Agreement and hence could be presumed to be maintained without sufficient scientific evidence.”⁷⁹ The panel ruling allowed the plaintiff countries to impose punitive sanctions on the E.U. in the amount of exports lost due to the ban,⁸⁰ but the parties are currently arbitrating whether—and the extent to which—the plaintiff countries

76. By that point, “most retail stores had already decided voluntarily not to stock any GM products so as to avoid boycott campaigns from activists.” PAARLBERG, *supra* note 14, at 23.

77. *Id.* at 17.

78. Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, ¶ 7.68–7.70, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006) [hereinafter *EC-Biotech*]. The United States and the European Union are members of the World Trade Organization (“WTO”). The WTO’s binding procedure for resolving disputes involving trade between member countries is to submit the disagreement to the organization’s Dispute Settlement Board, which comprises a panel of judges from member countries. For an overview of dispute settlement under WTO procedures, see WTO, Dispute Settlement Gateway, http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm (last visited Apr. 11, 2010). For a chronology of the U.S.—E.U. dispute over GMOs, see WTO, Dispute Settlement—The Disputes—DS291, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm (last visited Apr. 11, 2010).

79. Simon Lester, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, 101 AM. J. INT’L L. 453, 454 (2007). “Sanitary or Phytosanitary measures include . . . packaging and labeling requirements *directly related to food safety*.” *Id.* at 454 (emphasis added) (quoting SPS Agreement Annex A(1)). Thus, labeling for GM content would arguably not be an SPS measure at all (and therefore not under the WTO framework) because it is not a regulation intended to ensure food safety.

80. While the ban was in place, “United States corn exports to Europe . . . plummeted from 3.3 million tons in 1995 to 25,000 tons in 2002, costing American farmers an estimated \$300 million annually in lost sales.” Paul Meller, *Europe Rejects Looser Labels for Genetically Altered Food*, N.Y. TIMES, Sept. 9, 2004, at W7, available at <http://www.nytimes.com/2004/09/09/business/worldbusiness/09seed.html>.

will actually impose such trade sanctions.⁸¹ Thus, an outright ban is not an option available to the E.U. under current WTO law.⁸²

The U.S. could challenge the E.U.'s current labeling regime in the WTO, arguing that, like the outright ban on GMOs, labeling requirements violate the SPS Agreement because they are not supported by science.⁸³ Such a challenge might not succeed under the *EC-Biotech* holding because required labeling does not disrupt trade as severely as an outright ban.⁸⁴ Moreover, if the U.S. challenges the E.U. labeling law in the WTO, it risks rendering the WTO impotent. If the citizens of member countries feel that WTO decisions ignore their values, the WTO will lose credibility and States will feel justified in ignoring its decisions.⁸⁵

Therefore, it is unlikely that the U.S. will bring such a challenge; rather, the U.S. and the E.U. will persist in disharmony on this subject. This Note explores whether a change in U.S. labeling law would be a feasible method of harmonizing this regulatory divide.

II. THE RATIONALE FOR LABELING LAWS: INFORMED CONSUMER CHOICE AND INCREASED DEMOCRATIC INPUT IN RISK MANAGEMENT

Both the E.U. and the U.S. labeling regimes claim to have the facilitation of informed consumer choice as a goal, but neither regime in fact accomplishes this goal.⁸⁶ While governments battle on the international

81. *EC-Biotech*, *supra* note 78.

82. U.S. regulators and consumers have recently been much more in favor of GMOs than their European counterparts. However, unless precipitated by a change in circumstances, a ban on GM or GMO products is not a viable option for the U.S. under current WTO law should U.S. regulators and consumers change their favorable views of GMOs. For example, a public health scare with scientific evidence of a GMO as the cause of harm would be a ground for banning that particular organism, and potentially all GMOs produced using the method of production of the harmful GMO, if the method produced the same harm in other organisms.

83. Lester, *supra* note 79, at 454.

84. This assumes that labeling requirements are applied in the same manner to domestic crops and products as they are to imports, or they could be viewed as a disguised restraint on trade. Depending on its requirements, a labeling regime may run afoul of the SPS requirement that distinctions be made based on a scientific risk assessment. However, the United States has yet to challenge the current E.U. labeling regime, so there has not yet been any decision that such is the case.

85. See Caroline E. Foster, *Public Opinion and the Interpretation of the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures*, 11 J. INT'L ECON. L. 427, 427 (2008).

86. The European Council Regulation of 2003 on Genetically Modified Food and Feed states that one of its goals is to "enable[] the consumer to make an informed choice . . ." Council Regulation 1829/2003, ¶17, 2003 O.J. (L 268). The U.S. FDA states that "[t]he central purposes of food labeling are to inform and educate consumers to enable

stage over whether GMOs will be prohibited, many scholars and activists say that the layperson is cut out of the debate even though the effects of allowing GM food in the market touch consumers personally.

What we put into our bodies is tremendously important to most people. People follow restricted diets for religious reasons (some Jews keep Kosher, some Muslims only eat Halal food, and some Hindus refuse beef), for moral or personal reasons (many vegetarians and vegans restrict their diets for moral reasons), or because they physically cannot eat certain foods (those with celiac disease cannot eat wheat, those who are lactose intolerant cannot consume dairy products, and those with other food allergies face similar restrictions). In the last case, eating the food in question could cause severe physical harm or death. In the first two cases, while the diets may be driven by personal choice rather than physical necessity, the beliefs behind the choices are often deeply held. If a Muslim eats soup that is labeled vegetarian but in fact contains pork, or if a vegetarian eats cereal that contains mouse parts,⁸⁷ the mislabeling that led to the inadvertent consumption is likely to be extremely offensive.

The majority of people in the U.S. do not grow their own food and therefore necessarily depend on others to grow it for them. Producers are thus endowed with public trust. Consumers expect that the information producers use to market their products is consistent with the actual contents of food products they sell, and the public expects that every ingredient or process that would be material to a consumer's purchasing decision is disclosed on the product label. In addition to major ingredients, examples of other processes or contents that would be material to consumers include allergens, animal parts or products, and pesticide residues.

The question then is whether genetic modification of food is material to consumers in their decisions to purchase and consume food. At what point does public demand for disclosure of GM content become "material to consumers"? As mentioned above, one survey showed that 94% of consumers would like labels to indicate the presence of GM content.⁸⁸ Some things can be tremendously important to some consumers and

them to wisely choose food and improve their health." Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology under the Federal Coordinated Framework*, 12 *DRAKE J. AGRIC. L.* 439, 452 (2007).

87. This would probably upset even nonvegetarians eating cereal, but vegetarians would be particularly offended because they have intentionally chosen a food that they reasonably expect not to contain animals, but that in fact does contain animals or animal parts.

88. PAARLBERG, *supra* note 14, at 23.

quite unimportant to others, such as whether food is Kosher, contains animal parts, or contains specific allergens.

The fact that some would characterize restrictive dietary choices as irrational is irrelevant; people should be able to control what they eat. In order to address the current lack of control, many scholars have called for increased democratic input in national and international risk assessment and risk management procedures. Risk assessment refers to the process of measuring risk (defined as potential adverse effects), while risk management refers to measures taken to avoid the occurrence of risks.⁸⁹ While public participation is inappropriate at the risk assessment stage (the task properly belongs to experts and is not subject to democratic or unscientific input⁹⁰), risk management can and should accommodate diverse perspectives, including those of the public.

On a national level, scholars say these procedures should be “responsive not only to expert views, but also broader public perspectives on risks and concerns over possible uncertainties.”⁹¹ Internationally, these scholars argue that state practice as a source of international law should affect the WTO’s decisions more,⁹² and state practice in the area of labeling is tending more to require labeling than prohibit it.⁹³ Furthermore, scholars argue that the WTO owes more deference to public opinion.⁹⁴ If the public feels strongly that it does not want to run a given risk, even where the evidence shows that technology is safe, the WTO should not impose that risk on the population of a member State.⁹⁵ In other words, risk management in this area should be less technocratic and more democratic. Allowing increased public participation in risk management will “help ensure consistency between international economic law and broad-

89. See Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255, 1275–77 (2004).

90. See *id.* The fact that a person feels afraid of something should not enter into the assessment of whether that thing is in fact risky, but that person’s fear may be an appropriate consideration in the context of how the product is presented, so as to allow that person to avoid it.

91. Jacqueline Peel, *International Law and the Legitimate Determination of Risk: Is Democratizing Expertise the Answer?*, 38 VICTORIA U. WELLINGTON L. REV. 363, 363 (2007).

92. See Mark Wu, Recent Development, *Small States, Big Veto: Customary International Law in the WTO After EC – Biotech*, 32 YALE J. INT’L L. 261 (2007).

93. See *infra* notes 188–91 and accompanying text. States with labeling laws currently include the countries of the E.U., Australia, China, Indonesia, Japan, New Zealand, Russia, Saudi Arabia, South Korea, Switzerland, and Thailand. BERNAUER, *supra* note 70, at 62.

94. Foster, *supra* note 85, at 427.

95. *Id.*

er public international law, including international human rights treaties and international environmental law.”⁹⁶

Neither the U.S. nor the E.U. government has adequately addressed this lack of consumer participation, and neither U.S. nor E.U. consumers are able to make informed choices: “[i]n the United States consumers have a choice between GMO and non-GMO but no information, while in Europe consumers are guaranteed information but with no choice, since only non-GM products can be found on the shelf.”⁹⁷ Proponents of GM foods feel that, in light of their safety, labeling is an unwarranted cost and would steer consumers away from a beneficial product, but these proponents “have failed to inform the public sufficiently about this new technology or to convince consumers of the benefits that may accrue from it.”⁹⁸ Detractors are often inflammatory, citing fears that are not based on science and refusing to consider the possible benefits of the technology.⁹⁹ Because the average consumer does not understand the technology, public participation in risk analysis is difficult. Neither the E.U. nor the U.S. has articulated a framework for meaningful public debate on biotechnology.¹⁰⁰

Labeling strikes a balance by allowing producers to grow GMOs and send them into national and international commerce¹⁰¹ while simultaneously educating consumers about the large array of genetic modifications and altered attributes of GMOs so that they may make informed choices and may avoid GMOs if they wish.¹⁰² By giving consumers a choice in what they consume, labeling for GM content is a preferable alternative in response to arguments for increased democratic input in risk management systems. As consumers acquire more information and more familiarity with GM foods,¹⁰³ they are likely to become more comfortable with the technology, and in turn, they are likely to support it

96. *Id.* at 427, 453.

97. PAARLBERG, *supra* note 14, at 23.

98. AMERICAN MEDICAL ASSOCIATION, *supra* note 2.

99. *Id.*

100. *Id.*

101. Traceability is a goal addressed by the current E.U. regulations. It would be a significantly expensive component in the U.S. labeling regime and is ancillary to the goal of informed consumer choice; thus, it should be considered only as a second step to any labeling regime. *See* discussion in conclusion.

102. *But see* MCHUGHEN, *supra* note 8, at 203–14 (describing a range of problems that McHughen says combine to render informed consumer choice impossible in the area of GM labeling).

103. In other words, as consumers gain personal experience of the benefits and lack of harmful effects of GMOs.

more. At the same time, a labeling regime is not a ban—producers would still be permitted to grow GMOs in the United States.

Of course, such a labeling regime would have direct costs,¹⁰⁴ as well as costs in terms of decreased revenue (perhaps only temporarily) as a result of consumers refraining from purchasing foods once they realize they are genetically modified. But these costs, discussed in Part V, are not prohibitive to a labeling regime.

Theoretically, an American labeling regime is desirable. However, it remains to be seen whether a labeling system can adequately inform the consumer and thereby allow him or her to choose GMO or non-GMO, particularly considering the public's limited familiarity with GM technology and the inherently limited information-conveying capacity of food labels.

III. THE LABELING REGIME IN THE UNITED STATES

American laws governing the approval of new varieties of GMOs and their labeling are much laxer than E.U. laws due to social priorities and two facets of the relative regulatory approaches. Socially, American consumers have been more tolerant of GMOs¹⁰⁵ and have not demanded harsher laws. In terms of regulatory approach, the U.S. is more tolerant of risk than the E.U.,¹⁰⁶ evaluating only the product of biotechnology rather than both the product and its method of production (or process).¹⁰⁷

American consumers have not been as troubled by GMOs as European consumers: the International Food Information Council (“IFIC”) released a survey in early 2008 that deemed U.S. consumer confidence in the domestic food supply “high,” at 68%.¹⁰⁸ The same survey showed that “the majority of [American] consumers (53%) continue to have neutral im-

104. See discussion *infra* in conclusion.

105. See *infra* notes 109–15.

106. See *infra* notes 116–17 and accompanying text.

107. See *infra* notes 131–34 and accompanying text.

108. Int'l Food Info. Council, *2008 Food Biotechnology: A Study of U.S. Consumer Attitudinal Trends*, available at http://www.foodinsight.org/Resources/Detail.aspx?topic=Food_Biotechnology_A_Study_of_U_S_Consumer_Attitudinal_Trends_2008_Report [hereinafter *IFIC Report on Food Biotechnology*]. The survey was conducted using 1,000 adults in the U.S. between July 29 and August 18, 2008. *Id.* The International Food Information Council (“IFIC”) is a non-profit organization that describes its mission as to “effectively communicate science-based information about food safety and nutrition to health professionals, government officials, educators, journalists, and consumers.” Int'l Food Info. Council, FAQs, <http://www.ific.us/About/FAQ.aspx> (last visited Apr. 8, 2010). Its projects are supported by the broad-based food, beverage, and agricultural industries, as well as the U.S. government. It does not represent any product or company, and it does not lobby for legislative or regulatory action. *Id.*

pressions of plant biotechnology,” with 31% holding favorable impressions, and 16% holding negative impressions.¹⁰⁹ Furthermore, consumer attitudes are generally positive when consumers are informed of potential benefits associated with biotechnology. Approximately 70–75% of consumers in the survey stated that they would be “somewhat likely” or “very likely” to purchase GM foods if they were notified that the modifications were for the purposes of providing healthful fats such as Omega-3s, requiring less pesticide, reducing the content of saturated and trans-fats, or producing better-tasting or fresher foods.¹¹⁰

Another reason American laws regarding GMOs are less stringent is that American consumers are simply unaware that GMOs are almost certainly in the foods they are eating.¹¹¹ There is also a strong farmers’ lobby in the United States that is generally in favor of GM technology,¹¹² as is true for the biotechnology industry, which has invested vast sums of money in the development of these gene manipulation methods.¹¹³ Whether for these or other reasons, anti-biotechnology groups have not been able to mount the kind of coordinated campaigns here that European groups have been able to mount across the pond.¹¹⁴ While the United States has generally accepted the precautionary principle as a guiding

109. *IFIC Report on Food Biotechnology*, *supra* note 109.

110. *Id.*

111. See *supra* note 35. There was one widely-publicized contamination scandal in the United States: in 2000, a variety of corn (named ‘Starlink’ corn) engineered with “a different *Bt* gene than other *Bt* corn varieties and microbial *Bt* sprays used by conventional and organic farmers” that had not yet been approved for human consumption by the EPA, because sufficient allergenicity tests had not yet been performed to ensure that it would not cause allergic reactions in consumers, was incorporated into taco shells sold to restaurant chains. Taco Bell recalled these taco shells immediately when they discovered that they contained these genes. Center for Science in the Public Interest, *supra* note 34. “Starlink is no longer grown, even for animal feed use.” *Id.*

112. One reason for widespread farmer support of GM technology is that generally, the increases in productivity produced via GM corn and soybeans are scale-neutral, meaning that small farmers (as well as large ones) capture benefits of increased productivity pro-rata to the acreage of crops they have planted with GM seeds. PAARLBERG, *supra* note 14, at 18. By contrast, small farmers have been opposed to many other types of agricultural technology because it often benefits large farmers much more than small. *Id.*

113. These companies include Monsanto, Pioneer Hi-Bred International, Inc. (a DuPont business), and Astra-Zeneca. See AstraZeneca, Corporate Responsibility: Genetically Modified Micro-Organisms, <http://www.astrazeneca.com/responsibility/research-ethics/genetically-modified-organisms?itemId=7538775&nav=yes> (last visited Nov. 1, 2009); Monsanto, Our Products—Seeds and Traits, http://www.monsanto.com/products/seeds_traits.asp (last visited Nov. 1, 2009); Pioneer, Products and Services, <http://www.pioneer.com/web/site/portal/menuitem.0128f8e2dab251f7bc0c0a03d10093a0/> (last visited Nov. 10, 2009).

114. See PAARLBERG, *supra* note 14.

tenet of domestic law,¹¹⁵ American consumers and regulators are still much more tolerant of risk in the service of biotechnological advancement than their European counterparts.¹¹⁶

Because of this tolerance, there is no current federal law requiring labeling of GMOs or GM food products. Federal labeling laws have been proposed numerous times since 1999 in both the U.S. House of Representatives and the U.S. Senate, but none has passed. Most recently, on July 29, 2008, Representative Dennis Kucinich introduced to the House the “Genetically Engineered Food Right to Know Act,”¹¹⁷ a bill that would amend the Federal Food, Drug, and Cosmetic Act (“FDCA”) § 403¹¹⁸ to require that foods that contain genetically modified material, or that are produced with genetically modified material, be labeled with the text “Genetically Engineered” or “[t]his product contains a genetically engineered material, or was produced with a genetically engineered material.”¹¹⁹ The bill would exempt from the labeling requirements food served in restaurants or retail establishments,¹²⁰ and would institute civil penalties and authorize private suits for violations.¹²¹ The bill is currently held up in the Subcommittee on Specialty Crops, Rural Development, and

115. “Ironically, notwithstanding strong American criticisms of the E.U.’s use of the precautionary principle to prevent or delay the approval of GMOs, no country has so fully adopted the essence of the precautionary principle in domestic law as the United States.” DAVID VOGEL, *SHIPS PASSING IN THE NIGHT: THE CHANGING POLITICS OF RISK REGULATION IN EUROPE AND THE UNITED STATES* 2 (2001). Perhaps American regulatory tolerance of risk is also reflective of the idea that Americans “tend to use litigation after the fact rather than pre-emptive regulation to ensure consumer and environmental safety” as opposed to the European precautionary regulatory approach. PAARLBERG, *supra* note 14, at 18.

116. VOGEL, *supra* note 116, at 3.

117. H.R. 6636, 110th Cong. (2008). The bill was co-sponsored by 10 Democrats and 1 Republican, although previous versions of the bill had more bipartisan support. Senator Barbara Boxer introduced a bill that was similar to an earlier version of H.R. 6636 into the U.S. Senate. That bill—S. 2080, 106th Cong. (2000)—also died in committee and has not been reintroduced. For Senator Boxer’s statement accompanying the introduction of her bill, see <http://www.thomas.gov> (search for Bill Number ‘S2080’).

118. 21 U.S.C. § 343-1 (2006). The provision of current federal law that addresses food nutritional labeling requirements. *See* discussion *infra* note 144–147 and accompanying text. The act would also have amended provisions of the Federal Meat Inspection Act, 21 U.S.C. § 601–95 (2006), and the Poultry Products Inspection Act, 21 U.S.C. § 451–71 (2006), to institute similar labeling requirements with respect to GM meat and poultry.

119. H.R. 5269, 109th Cong. (2006). The Act further specifies the font required and that the label be “clearly legible and conspicuous.” *Id.* at § 3(a).

120. *Id.*

121. H.R. 6636, 110th Cong. (2008) § 311.

Foreign Agriculture of the House Agriculture Committee.¹²² Previous versions of the bill all died in subcommittees, but Representative Kucinich reintroduced the bill each time.¹²³

Despite the lack of a federal labeling law, there is some form of labeling requirement under the laws of nine U.S. states, and other states are debating labeling laws.¹²⁴ For instance, the New York State Legislature is considering New York Assembly Bill 500 (State Senate Bill 2052),¹²⁵ which would require foods containing GM material¹²⁶ to have labels that say: “[t]his product contains a genetically modified material,” or “[t]his product was produced with a genetically modified material.”¹²⁷

The absence of a federal framework for labeling GMOs is a result of two aspects of regulatory philosophy in which the U.S. diverges from Europe: the theory of risk evaluation and the focus on end product only as opposed to the end product as well as the production process.

First, European regulators are guided by the precautionary principle, whereas American regulators use risk-benefit analysis. There are various formulations of the precautionary principle, but in essence it is the idea that regulators must always err on the side of caution, even in the absence of any demonstrable risk.¹²⁸ Regulations should focus exclusively

122. Thomas (Library of Congress), <http://www.thomas.gov> (search for Bill Number ‘HR6636’).

123. For Representative Kucinich’s views regarding biotech and organic foods, see Congressman Dennis Kucinich, <http://kucinich.house.gov/Issues/Issue/?IssueID=1459> (last visited Nov. 10, 2009).

124. Farquhar & Meyer, *supra* note 86, at 459. These states include Alaska, Maine, Michigan, Minnesota, Mississippi, Pennsylvania, Vermont, Virginia, and Wisconsin. *Id.* For example, Alaska requires labeling of GM fish sold in-state. *Id.* In addition, some states and some counties have laws banning the growth of GMOs in the area. PAARLBERG, *supra* note 14, at 25–26.

125. Assemb. 500, 2009 Leg., 231st Sess. (N.Y. 2009). Previous versions of this bill were considered in 2001–02. *Id.* Each one died in committee.

126. The bill defines “Genetically Modified Material” as “material derived from any part of a genetically modified organism, without regard to whether the altered molecular or cellular characteristics of the organisms are detectable in the material”; it defines GMOs as organisms “that [have] been altered at the molecular or cellular level by means that are not possible under natural conditions or processes,” detailing a variety of processes that are intended to be exhaustive of currently known methods of genetic modification. N.Y. Assemb. 500 § 1. It is thus much wider in scope than even current law in the E.U. and individual States that require labeling, which exempt processing aids such as yeast used in beer production. *See infra* notes 179, 189.

127. The Act also provides for penalties for violations. N.Y. Assemb. 500 § 3(A).

128. The precautionary principle has been described in the following way: “If there is a potential for harm from an activity and if there is uncertainty about the magnitude of impacts or causality, then anticipatory action should be taken to avoid harm.” PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRE-

on minimizing risk; potential benefits are thus excluded from the calculation. By contrast, the American regulatory approach has been to use risk-benefit analysis, which weighs the potential benefits of a technology against the reasonably foreseeable risks to human and environmental health.¹²⁹

The second regulatory difference is that regulators in the United States focus on the end product resulting from a new technology, whereas European regulators focus on the product as well as the process by which it is produced. The product approach compares the safety risks of a product produced by the new technological process to products produced via conventional processes. The process approach, by contrast, compares the risks inherent in an approved (conventional) technological process with the foreseeable risks of the new technological process at issue.¹³⁰

In the U.S., the FDA's policy regarding food safety regulation generally is that "safety concerns should be characteristics of the food product, rather than the fact that new methods are used."¹³¹ With respect to biotech foods specifically, the agency has stated that it "has no basis for concluding that bioengineered foods 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."¹³² Accordingly, the regulations do not address the use of biotechnology technique; they address the use of GMO end-products, such as food or seeds.¹³³

Thus, genetically modified foods and food products are evaluated pursuant to the same laws as their conventionally produced counterparts¹³⁴

CAUTIONARY PRINCIPLE 1 (Carolyn Raffensperger & Joel Tickner eds., 1999). However, the editors immediately acknowledge that "we can never know with certainty whether a particular activity will cause harm." *Id.*

129. See ROGER W. FINDLEY & DANIEL A. FARBER, ENVIRONMENTAL LAW IN A NUTSHELL 168–69 (6th ed. 2004).

130. *Id.* at 167–69. Thus, the FDA approach focuses on the *product* of genetic engineering (comparing the characteristics of the GM product to the same product produced conventionally), as opposed to the *process* by which it is produced.

131. FDA Statement of Policy: Food Derived from New Plant Varieties, 57 Fed. Reg. 22,984–85 (1992).

132. CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING (DRAFT) 7 (2001), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm> [hereinafter DRAFT GUIDANCE FOR INDUSTRY].

133. *Id.*

134. In other words, there are no American federal laws governing biotechnology separately from conventional agricultural methods.

under the Coordinated Framework promulgated by the White House's Office of Science and Technology Policy.¹³⁵ This framework encompasses the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA");¹³⁶ the FDCA;¹³⁷ the Toxic Substances Control Act (the "TSCA");¹³⁸ and the Federal Plant Protection Act (the "FPPA").¹³⁹ The USDA has general responsibility for ensuring that new biotech plant varieties are safe to grow regardless of the purpose for their genetic modification; the EPA is charged with "ensuring that new pest-resistant [plant] varieties" will not harm the environment; and the "FDA is responsible for ensuring that new plant varieties are safe" for human consumption.¹⁴⁰

Consistent with the end-product approach, the FDA has maintained the position that:

Labeling of GM foods should only be mandatory if they are shown to differ significantly in composition from their conventional counterparts in some way that might pose a risk to the consumer—such as through

135. Farquhar & Meyer, *supra* note 86, at 445.

136. 7 U.S.C. § 136–136y (2006). FIFRA is administered by the Environmental Protection Agency ("EPA"), and was somewhat amended by the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996). FIFRA set up the basic U.S. system of pesticide regulation to protect applicators, consumers and the environment. U.S. Env'tl. Prot. Agency, Summary of FIFRA, <http://www.epa.gov/lawsregs/laws/fifra.html> (last visited Nov. 1, 2009).

137. 21 U.S.C. § 301–392 (2006). The FDCA is administered by the EPA and the Food and Drug Administration ("FDA"). Section 408 of the FDCA

authorizes EPA to set tolerances, or maximum residue limits, for pesticide residues on foods. In the absence of a tolerance for a pesticide residue, a food containing such a residue is subject to seizure by the government. Once a tolerance is established, the residue level in the tolerance is the trigger for enforcement actions. That is, if residues are found above that level, the commodity will be subject to seizure.

U.S. Env'tl. Prot. Agency, Summary of FFDCA, <http://www.epa.gov/lawsregs/laws/ffdca.html> (last visited Nov. 1, 2009).

138. 15 U.S.C. § 2601–92 (2006). The TSCA "was enacted by Congress to give EPA the ability to track the 75,000 industrial chemicals currently produced or imported into the United States. . . . [It] provides EPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures." U.S. Env'tl. Prot. Agency, Summary of TSCA, <http://www.epa.gov/lawsregs/laws/tsca.html> (last visited Oct. 9, 2009).

139. 7 U.S.C. § 7701–72 (2006). Administered by the United States Department of Agriculture's ("USDA") Animal and Plant Health Inspection Service ("APHIS"). FINDLEY & FARBER, *supra* note 130, at 169.

140. AMERICAN MEDICAL ASSOCIATION, *supra* note 2. The FDA also has authority to ensure the safety of animal feed. *Id.*

the presence of an allergen, a changed level of a major dietary nutrient, an increased level of toxins, or a change in the expected storage or preparation characteristics of the food.¹⁴¹

The FDA does not consider consumer demand to be “a sufficient justification [under existing law] to require labeling without an underlying nutritional or safety concern.”¹⁴²

While FIFRA, the TSCA, and the FPPA all regulate the products of biotechnology, only the FDCA sets regulations concerning food-labeling requirements.¹⁴³ The National Uniform Nutritional Labeling clause of the FDCA¹⁴⁴ requires labeling on food that discloses serving size, the presence of adulterations such as chemical preservatives and colorings, and nutritional data such as the content of calories, cholesterol, saturated and unsaturated fat, sodium, total and complex carbohydrates, sugars, dietary fiber, total protein, and vitamins and minerals.¹⁴⁵ According to the FDA’s Center for Food Safety and Applied Nutrition (the “Center for Food Safety”), “[t]he central purposes of food labeling are to inform and educate consumers to enable them to wisely choose food and improve their health.”¹⁴⁶

In 2001, the Center for Food Safety promulgated draft “guidance for industry”¹⁴⁷ titled, “Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.”¹⁴⁸ The guidance “spell[s] out what needs to be labeled on genetically-modified food, and what labeling is voluntary.”¹⁴⁹ As reflected in the title, the guidance encourages voluntary labeling of GM content in food but does not require that manufacturers label food as “genetically modified” or “genetically

141. PAARLBERG, *supra* note 14, at 23. Interestingly, pharmaceutical drugs that are produced using biotechnology are labeled “genetically modified.” *Id.* at 21.

142. Farquhar & Meyer, *supra* note 86, at 449. But the FDA encourages voluntary labeling, and it is conceivable that the agency could come to view mandatory disclosure as justified in order to deal with intense (even if baseless) concern over the potential dangers of biotechnology.

143. 21 U.S.C. § 343–1 (2006).

144. *Id.*

145. *Id.*

146. Farquhar & Meyer, *supra* note 86, at 452 (quoting DRAFT GUIDANCE FOR INDUSTRY, *supra* note 133, at 7).

147. This draft guidance was a proposal of regulations for comment by interested parties. It was never adopted as law, although parties remain free to follow its guidance as to voluntary labeling. *See id.*

148. DRAFT GUIDANCE FOR INDUSTRY, *supra* note 133; Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 757 n.106 (2003).

149. Farquhar & Meyer, *supra* note 86, at 469.

engineered.”¹⁵⁰ However, the FDA reiterated in the Guidance that biotech food products are subject to the same labeling requirements as conventional foods under the FDCA. The FDA applied the FDCA requirements to biotech foods as follows:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.
- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue.
- If a bioengineered food has a significantly different nutritional property, its label must reflect the difference.
- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.¹⁵¹

Thus, while the label need not say specifically, for example, “this tomato *has been genetically engineered* to contain a brazil nut gene,” it must say something to the effect of, “this tomato contains proteins that may engender allergic responses in people allergic to brazil nuts.”¹⁵² Further, the FDA identified examples of voluntary statements that companies could use, such as: “[t]his product contains cornmeal that was produced using biotechnology”; “[t]his product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat”; or “[t]hese tomatoes were genetically engineered to improve texture.”¹⁵³

The cumulative effect of these regulations is that U.S. producers are not required to label their products as genetically modified, but are free to label their products as not genetically modified—in other words, “GM-free”—to the extent that such labeling is not misleading. In addition, consumers who wish to avoid GM foods may limit their purchases to foods bearing the “USDA-Organic” label.¹⁵⁴ But even with this seem-

150. DRAFT GUIDANCE FOR INDUSTRY, *supra* note 133, at 7–8.

151. *Id.* at 3–4.

152. *Id.*

153. *Id.* at 7–8.

154. 7 C.F.R. § 205.105; *see also infra* note 21.

ing variety, U.S. consumers do not enjoy informed choice—they cannot assume that foods that do not bear labels are not GM, and they likely do not understand what labels they do encounter.

IV. THE LABELING REGIME IN THE EUROPEAN UNION

Regulations regarding approval and labeling of GMOs are much stricter in Europe than in the U.S. for two reasons. Distrust of regulators has led consumers to demand harsher regulations, and European regulators approach risk regulation conservatively—they evaluate both the product and the production process, and they use the precautionary principle. The E.U. would prefer to ban the importation and growth of GMOs altogether, as discussed in Part I. As this is not a viable option, regulators have instituted the world's broadest and harshest regulations. These regulations have led to a *de facto* ban on GMOs in the E.U.¹⁵⁵

The strong distrust of government and opposition to GMOs in Europe are the result of regulatory failures. These failures have included the Sang Contaminé (contaminated blood) scandal,¹⁵⁶ contamination of eggs and meat with the highly carcinogenic industrial chemical dioxin in Belgium,¹⁵⁷ and, most memorably, the Bovine Spongiform Encephalopathy (“BSE” or “mad cow disease”) scare in the United Kingdom.¹⁵⁸ The strongest driver of the intensely negative consumer reaction to the BSE scare was not the fact that humans contracted the disease, or that some

155. GMO Compass, <http://www.gmo-compass.org/eng/home/> (“No genetically modified fruits or vegetables are on the market in the EU. Any GM plants authorised in the EU are not intended for direct consumption.”).

156. The Sang Contaminé scandal was a public health scandal in France, Canada, and China. It was said that AIDS deaths resulting from infusions to hemophiliacs of infected blood could have been averted because public health officials knew of the causal link and refused to institute a moratorium on blood transfusions until screening procedures for HIV (the virus that causes AIDS) could be implemented. See generally ANNE-MARIE CASTERET, *L'AFFAIRE DU SANG* (1992).

157. Failure to properly clean industrial tanks first used to hold mineral and industrial oil, then used to store animal fats used in the manufacture of animal feed, was cited as the cause of a dioxin contamination in animal food products and led to an E.U.-wide recall of “Belgian agricultural exports of eggs, chickens, pork and beef” as well as the destruction of “livestock that were given animal feeds believed to be contaminated with dioxin, a serious carcinogen.” Richard Tyler, *Dioxin Contamination Scandal Hits Belgium: Effects Spread Through European Union and Beyond*, WORLD SOCIALIST WEB SITE, June 8, 1999, <http://www.wsws.org/articles/1999/jun1999/belg-j08.shtml>.

158. Relatedly, polio vaccines were withdrawn from the E.U. market at the time of the BSE scare because they had been produced from calf fetuses and it was feared that the fetuses had been infected with BSE that the vaccine might pass on to humans. *Polio Vaccine in BSE Scare*, BBC NEWS, Oct. 20, 2000, <http://news.bbc.co.uk/2/hi/health/980968.stm>.

died, but the anger over E.U. regulators' "belated failure to recognize" the health hazards of BSE.¹⁵⁹ This failure "severely undermined public trust in E.U. food safety regulations and the scientific expertise on which they were based."¹⁶⁰ Both the government of Britain and the European Commission denied the validity of consumer concerns and placed no restrictions on the sale of British beef until there had been a significant number of human deaths.¹⁶¹

As a result of these food supply scandals and regulatory failures, European consumers are distrustful of food modification in general, and they are not confident in their national and supranational regulators' abilities to ensure the safety of the food supply. This general distrust also applies to GM foods: "a majority of Europeans do not support GM foods. [They] are judged not to be useful and to be risky to society."¹⁶² Interestingly, the level of support differs by country: "[w]hile GM crops are supported in Spain, Portugal, Ireland, Belgium, [the United Kingdom], Finland, Germany, and the Netherlands," the public is generally opposed to GM crops in "France, Italy, Greece, Denmark, Austria, and Luxembourg."¹⁶³

Before the integration of the European Union, food safety was regulated at the national level in each member country by myriad individual state agencies. With the creation of the European Common Market, the free flow of goods took priority over food safety.¹⁶⁴ In 1985, the European Community ("EC") moved to a labeling regime as an alternative to attempting to harmonize member countries' regulations regarding approval of individual biotech varieties. The labeling "indicate[d] the differences in composition and production methods," which aimed to allow consumers to make informed decisions.¹⁶⁵

159. Trust is important because it functions as a proxy for knowledge. If consumers cannot trust their regulators to make adequate tests for safety, they face the choice of either trying to replicate those safety tests themselves (something that is functionally impossible in the context of food GMOs) or foregoing the product they distrust (something that is also nearly impossible, unless one grows all of one's own food, or restricts oneself to consuming *only* organic foods, meaning avoiding processed foods entirely).

160. VOGEL, *supra* note 116, at 24.

161. *Id.*

162. GEORGE GASKELL ET AL., EUROBAROMETER 58.0: A REPORT TO THE EC DIRECTORATE GENERAL FOR RESEARCH FROM THE PROJECT 'LIFE SCIENCES IN EUROPEAN SOCIETY' 1 (2002), available at http://ec.europa.eu/public_opinion/archives/ebs/ebs_177_en.pdf.

163. *Id.*

164. Emilie H. Liebovitch, *Food Safety Regulation in the European Union: Toward an Unavoidable Centralization of Regulatory Powers*, 43 TEX. INT'L L. J. 429, 432 (2007). For a more in-depth discussion of the development of regulations affecting food in the European Union, see *id.* at 432-33.

165. *Id.* at 432.

The labeling regime was considered a success, but as the E.U. succeeded at integrating the markets and the political systems of its member countries, the regulatory focus shifted to ensuring food safety. In 2000, responding to calls from various groups for increased “excellence, transparency, and independence”¹⁶⁶ of food regulation, the European Commission created the European Food Safety Authority (EFSA).¹⁶⁷ While the EFSA is charged with risk assessment, risk management remains entrusted to each individual member state.¹⁶⁸

Under the old guidelines, which were part of the E.U. novel food regulation of 1997,¹⁶⁹ “[g]enetically modified foods required labeling only if GM content could be detected in the final product. Proof of GM content could be obtained by testing for characteristic, genetically modified DNA fragments.”¹⁷⁰ In April 2004, the European Union replaced the previous product-oriented set of labeling laws covering genetically modified foods and animal feed with a more conservative, process-oriented set of regulations. The Directive on Genetically Modified (GM) Food and Feed¹⁷¹ and the Directive on the Traceability and Labelling of GMOs¹⁷² require producers to label more products and the food production industry to put in place a compliance system for monitoring the presence of GM material throughout the supply chain.¹⁷³

166. *Id.* at 433 (citing Winn S. Collins, *The Commission's Delegation Dilemma: Is the European Food Safety Authority an Independent or an Accountable Agency?*, 10 U.C. DAVIS J. INT'L L. & POL'Y 277, 281 (2004)).

167. The EFSA was established pursuant to Council Regulation 178/2002, 2002 O.J. (L 31); Liebovitch, *supra* note 164, at 433.

168. Liebovitch, *supra* note 164, at 434. As with many aspects of the legal integration of the E.U., there remains a tension between national and supranational competence with respect to approving and labeling GM foods. There is a strong concern in all of the countries of the E.U., and particularly in the countries with strongest cultural identification with agrarian society, that ceding competence to a supranational authority will destroy countries' distinctive identities and cultures.

169. PAARLBERG, *supra* note 14, at 17.

170. GMO Compass, New Labelling Laws for GM Products in the EU, http://www.gmo-compass.org/eng/regulation/labelling/93.new_labelling_laws_gm_products_eu.html (last visited Apr. 11, 2010).

171. Council Regulation 1829/2003, 2003 O.J. (L 268).

172. Council Regulation 1830/2003, 2003 O.J. (L 268).

173. GMO Compass, Labelling of GM Foods: Frequently Asked Questions, http://www.gmocompass.org/eng/regulation/labelling/96.labelling_gm_foods_frequently_asked_questions.html.

Feeds containing GM plants or ingredients from GM microorganisms must be labelled. The foods made from animals raised with GM feed, however, such as meats, eggs, and dairy products, do not require labelling. They are considered

The stated goals of the new regulations are to protect “human life and health, animal health and welfare, [and] environment and consumer interests,”¹⁷⁴ to ensure “the effective functioning of the internal market,” to “lay down provisions for the labeling of genetically modified food and feed,”¹⁷⁵ to promote “the right of consumers to information,”¹⁷⁶ and to “enable[] the consumer to make an informed choice and facilitate[] fairness of transactions between seller and purchaser.”¹⁷⁷ This is not a hierarchy of purposes, as nothing is explicitly given priority, and the various goals are distributed throughout the regulations.

The labeling requirements apply to virtually all foodstuffs, including “processed, pre-cooked or packaged food . . . bulk or unpacked goods, and catered food in restaurants and canteens.”¹⁷⁸ There are two important exceptions, however. Processing aids are exempt,¹⁷⁹ and “[u]nintentional and technically unavoidable mixing only needs to be labeled if the GM content exceeds 0.9 percent (of the original ingredient).”¹⁸⁰

The regulations divide food into three categories: pre-cooked or packaged food with a list of ingredients, packaged food without a list of ingredients,¹⁸¹ and unpackaged food¹⁸² or very small package sizes. For

foods made ‘with the help of GMOs’ and are therefore exempted from labelling requirements.

Id.

174. Council Regulation 1829/2003, art. 1(a), 2003 O.J. (L 268).

175. Council Regulation 1829/2003, art. 1(c), 2003 O.J. (L 268).

176. Council Regulation 1829/2003, § 17, 2003 O.J. (L 268).

177. Council Regulation 1829/2003, § 17, 2003 O.J. (L 268). The labels aim to facilitate informed choice in part by assuring that labels are not misleading.

178. GMO Compass, *supra* note 173.

179. See Council Regulation 1829/2003, § 16, 2003 O.J. (L 268).

180. GMO Compass, *supra* note 22. Council Regulation 1829/2003, art. 12, ¶2, 2003 O.J. (L 268). In order to qualify for the safe harbor, the producer must meet two conditions. First, “[t]he affected producer must prove that the traces of GMO were technically unavoidable. If GMOs are mixed intentionally, labelling is always required.” GMO Compass, *supra* note 173. Second, “[t]he GMO that is present must be authorised in the EU and thereby considered safe.” *Id.* (interpreting Council Regulation 1829/2003, art. 12, ¶3, 2003 O.J. (L 268)). Council Regulation 1829/2003 requires that producers “be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.” Council Regulation 1829/2003, art. 12, ¶3, 2003 O.J. (L 268).

181. Foods without a list of ingredients include, for example, sugar or packaged fruits or vegetables. GMO Compass, GMO Labelling: What Does Labelling Look Like?, http://www.gmo-compass.org/eng/regulation/labelling/90.gmo_labelling.html (last visited Apr. 11, 2010)

182. Unpackaged food includes bread sold in an open display or candy sold from bins.

Id.

each category, the regulations detail the exact form, location, and content of the label. For pre-cooked or packaged foods with a list of ingredients, the GM ingredient “must be labeled, in the form of an addition to the ingredient concerned, either as ‘genetically modified’, or as ‘produced from genetically modified’ material.”¹⁸³ This text may be added in a footnote to the list of ingredients.¹⁸⁴ For packaged foods without a list of ingredients, the text must be clearly visible on the label.¹⁸⁵ Lastly, for unpackaged foods or for very small package sizes, the text must be attached to the display, or be displayed in direct connection with the relevant product.¹⁸⁶ The use of symbols or logos is not allowed for any of the three categories.¹⁸⁷

The E.U. is not alone in requiring labeling; many other countries have some form of labeling law. Canada and Argentina (the other large producers of GM crops) allow voluntary labeling, as does the United States.¹⁸⁸ Australia and New Zealand require that GM content that makes up more than 1% of the total weight of a product be labeled, and provide exemptions for “vegetable oils, food additives, and food processing aids (such as enzymes used in cheese and brewing).”¹⁸⁹ Japan similarly requires labeling, but with a threshold of at least 5% GM content, and provides exemptions for “feedstuffs, alcoholic beverages, and processed foods, such as soya sauce, corn flakes, and other vegetable oils.”¹⁹⁰ South Korea and Indonesia require labeling, with 3% thresholds.¹⁹¹

The complexity and scope of the E.U.’s current labeling laws render them the harshest in the world.¹⁹² The effect of these regulations, combined with strict approval procedures for introducing GMOs to the E.U.

183. Council Regulation 1829/2003, art. 13, ¶1(a), 2003 O.J. (L 268). The footnote must be in the same font size as that of the ingredient list. *Id.*

184. Council Regulation 1829/2003, art. 13, ¶1(d), 2003 O.J. (L 268).

185. Council Regulation 1829/2003, art. 13, ¶1(b), 2003 O.J. (L 268).

186. Council Regulation 1829/2003, art. 13, ¶1(e), 2003 O.J. (L 268).

187. GMO Compass, *supra* note 22.

188. Carter & Gruere, *supra* note 47.

189. *Id.*

190. *Id.*

191. *Id.*

192. As of 2003, in addition to the E.U., “Australia[] and New Zealand require labeling if a food contains more than one percent GM ingredients (with important exceptions for some foods, e.g., foods served in restaurants). Japan’s policy is similar except its threshold before labeling is required is five percent.” Teisl & Caswell, *supra* note 33, at 2. “Currently, Taiwan and Hong Kong are moving to implement labeling rules similar to Japan’s and China recently issued regulations that appear to require all GM foods to be labeled.” *Id.* at 9.

market,¹⁹³ has been to maintain the prior legal moratorium on the importation and growth of GMOs *de facto*.¹⁹⁴ Producers and grocers do not want to run the risk of consumer boycotts or penalties for incorrect labeling, so GMOs are not commercially available in the E.U.¹⁹⁵

V. PROPOSED LABELING REGIME

The E.U. would prefer to ban GMOs altogether but has settled for harsh approval requirements and strict labeling for those varieties it does approve. The U.S., on the other hand, does not consider the “consumer’s right-to-know” a sufficient justification for requiring labeling. The purpose of a U.S. federal labeling law for GM content is to reconcile the nation’s interest in preserving the legality of GMO growth and consumption¹⁹⁶ with the underappreciated importance of facilitating informed consumer choice.¹⁹⁷

Still, there are six factors that affect how useful a label is to the consumer, including (A) the level of complexity of the label; (B) whether the label is positive or negative; (C) whether the system is mandatory or elective; (D) whether the label contains information only about the end product or also about the production process; (E) what threshold of GM content triggers labeling requirements; and (F) the scope of the regulations, or the definition of genetic modifications that must be labeled. Each of these factors must be evaluated in light of the purpose of facilitating consumer choice.

193. GMO Compass, EU: GMO Authorisation Procedures, http://www.gmocompass.org/eng/regulation/regulatory_process/157.eu_gmo_authorisation_procedures.html (last visited Apr. 8, 2010). For an amusing cartoon version of the approval process, see GMO Compass, Animation: The Authorisation Process in Motion!, <http://www.gmocompass.org/flash/popup.php?lang=eng> (last visited Apr. 8, 2010).

194. *See supra* notes 76, 77, 155.

195. *See supra* note 155.

196. Consumers do not truly have a choice in a regime that bans GMOs, because they cannot then purchase GMOs if they wish to do so. Furthermore, as a matter of policy, avoiding a total ban on what already is and promises to be increasingly of significant benefit to farmers, consumers, and the world’s hungry is as important as providing consumers with information and choice. It should be noted that consumer autonomy and rejection of GMOs are not synonymous. It is quite possible that, given the choice, consumers will choose GMOs over non-GMOs, especially in light of lower prices for GMOs.

197. A goal of the E.U. regime is also to facilitate the identification and flow of GM content through the food production chain, so that GM content may be traced in the event of contamination or a public health scare. Given that this same concern applies to all types of food and food production, and is not required of conventional methods, the argument in favor of these extra requirements is weak. This is particularly true in light of the onerous burdens they place on farmers and producers in terms of identification and document retention.

A. Label Complexity

The level of complexity denotes how much information a food label conveys. “Simple labels,” or labels that only indicate whether a product is or is not genetically modified (as opposed to explaining why the product was genetically modified or what changes result to the product from the modification), “do not maximize potential benefits because, by not providing enough detail, they do not allow consumers to adequately rank competing products by key attributes.”¹⁹⁸ The benefits of labeling are maximized “if either 1) the information is important to a large number of consumers, even if the information may be of relatively small importance to each consumer or 2) the information is extremely important for even a small number of consumers.”¹⁹⁹ With respect to the first factor, studies indicate that a large percentage of American consumers would like genetically modified content in food to be labeled.²⁰⁰ Thus, the labels should, at minimum, denote the presence or absence of GM content.²⁰¹

In order for a labeling regime to effectively facilitate consumer choice, the label must convey information that consumers understand, consumers must trust the information,²⁰² and the information conveyed must allow consumers to differentiate among products.²⁰³ Conveying information that consumers understand via a food label is very difficult. The science of genetic modification is unusually complicated and technical and does not lend itself to facile distillation. While it is easy to set a daily caloric intake for oneself and to add up the calories in the foods one eats in a day to roughly approximate one’s daily allowance, understanding biotechnology well enough to make one’s own individual assessment of whether GMOs are safe or beneficial requires extensive scientific training. This difficulty of distillation presents a high hurdle for any labeling regime.

Labeling that only conveys whether a food product is or is not GM will not adequately assist consumers in differentiating among products, as the reason a product was modified also factors into the consumer’s choice to

198. Teisl & Caswell, *supra* note 33, at 19.

199. *Id.* at 6.

200. *See supra* note 38 and accompanying text.

201. With respect to the second factor, awareness of the presence of allergens is extremely important to a small percentage of the population. Teisl and Caswell refer to peanut allergens as substances that can be life-threatening if consumed by some people, *supra* note 33, at 6. Notably, the presence of allergenic genetic content, even if introduced into a product in which it does not naturally occur, is already required to be labeled. *See supra* notes 142, 152.

202. To trust the information, consumers must also trust the source of the information.

203. Teisl & Caswell, *supra* note 33, at 18.

buy or avoid the product.²⁰⁴ Consumers may choose to consume GMOs as opposed to non-GMOs in order to obtain benefits such as increased nutritional content or reduced pesticide or herbicide residue. They cannot *choose* GMOs if the GM food products are not labeled in a way that explains not only that they are modified, but why they are modified.²⁰⁵

B. Positive Labels, Negative Labels, or Both

One of the most significant factors in the success of a label is whether the label is either positive or negative, or both positive and negative. "So-called 'positive' . . . labeling requires companies to tell consumers when biotechnology has been used in production or when cross-contamination from bioengineered products is above a defined threshold."²⁰⁶ In other words, a positive label is one that says, "This product *contains* GMOs or genetically modified material." By contrast, "'negative' . . . labeling allows companies to tell consumers that their product is a non-[GMO]."²⁰⁷ Thus, a negative label is one that says, for example, "This product *does not contain* GMOs or genetically modified material."²⁰⁸

To fully inform, a regime must require both positive and negative labels if it requires either.²⁰⁹ Comprehensive labeling is unnecessarily cost-

204. *Id.* "[M]ost individuals can identify the color of a product rather easily," or compare the calorie content of two different foods, "while verifying that a product [is] not genetically modified would be difficult." *Id.* at 6. Moreover, a label that only discloses whether a product is genetically modified does not disclose the full range of information necessary for the consumer to understand what he or she is choosing.

205. Consumers may still be eating GMOs but not choosing them. At least one study offers evidence that not only would consumers choose to purchase GM foods over non-GM foods when the relative benefits (such as "reduced use of pesticides, improved nutritional or organoleptic characteristics, or longer shelf life") of GM foods are disclosed on the label, but that consumers would pay a 10 percent premium for such GM foods. *Id.* at 9. Moreover, this study was conducted in Italy, where consumer attitudes against GM foods have generally been stronger than in the U.S.

206. *Id.* at 5. Note that 'positive' labels are not synonymous with mandatory labels. However, due to negative consumer sentiment toward GMOs, manufacturers do not voluntarily disclose the presence of GMOs in their products because they fear consumers will not buy them. Thus, 'negative' and voluntary are often synonymous in practice, as are 'positive' and mandatory.

207. Again, if it meets standards for such a claim.

208. Surprisingly, in a focus-group study conducted by researchers at the University of Maine, Ohio State University, and Unity College, and funded in part by the USDA, almost all focus group participants reacted negatively to "GMO-free" labels, viewing such labels "with skepticism." Teisl et al., *supra* note 36, at 6-9.

209. In such a system, the costs of monitoring are increased and borne by both those producers reaping the benefits of consumer choice (organic producers) and those producers forced to label involuntarily (non-organic producers). These increased producer costs are balanced by the increased information available to the consumer.

ly, however, if it is possible for the regime to only require either positive or negative labeling and capitalize on consumer assumptions as to the GM status of non-labeled foods. For example, where foods are labeled positively, consumers assume that products that are not labeled are not GM²¹⁰ even if they are GMOs or contain GM material. The converse is true in a regime that requires negative labeling: where products are labeled, consumers know they do not contain GMOs. Where there is no label, consumers assume the product is GM.²¹¹ These assumptions are only correct to the extent that the regime is “symmetric,” meaning that all instances of absence and presence are properly labeled.²¹²

An asymmetric regime would be most efficient, but to succeed it would have to capitalize on consumer assumptions. If the regime is only positive, it must require all GM foods to be labeled as such, and it must not allow any non-GM foods to be labeled as “GM-free.” However, implementing an asymmetric regime in the U.S. presents a catch-22. If the regime required positive labeling and did not allow negative labeling, the regime would encounter strong opposition from organic food producers, who currently label their foods as GM-free to capture a certain market segment. On the other hand, if the regime required negative labels, these organic groups would be allowed to substantially continue their current labeling practices but the regime would be incredibly costly and confusing to consumers, as focus group studies have shown that consumers distrust negative labels.²¹³

C. Mandatory or Elective Regime

The question whether labeling should be positive or negative is closely related to the question whether labeling should be mandatory or elective. Studies show that consumers do not trust negative labels that say “this product is not a GMO.”²¹⁴ Further, consumers assume that in a regime that requires GM products to be labeled positively, the absence of a label means that the product is not GM.²¹⁵ Given these assumptions, it would be most efficient to require positive labeling and to proscribe negative labeling.²¹⁶ However, a regime that prohibited voluntary negative labeling

210. Teisl & Caswell, *supra* note 33, at 5.

211. *Id.*

212. *Id.*

213. *See supra* note 36.

214. Teisl & Caswell, *supra* note 33, at 6–9. Perhaps this is because consumers incorrectly assume that all foods are non-GMO unless specifically labeled.

215. *Id.* at 5.

216. In a regime that required positive labeling, allowing voluntary negative labeling would defeat the purpose of capitalizing on consumer assumptions. Consumers would no

ling would encounter strong resistance from organic food producers. These producers currently capitalize on the fact that their products are non-GM by labeling them as such,²¹⁷ attracting customers who wish to avoid GMOs. The labeling regime should not bow to the will of organic producers because to require both positive and negative labeling would impose significant costs, and those costs would be borne by groups that are not reaping the benefits of the labels.²¹⁸ The costs of the labeling regime are discussed further in Part V.

D. Regulatory Focus: End-Product and/or Production Process

The fourth factor addresses the differing approach to regulation in the U.S. and E.U.—while the U.S. regulatory focus is limited to the end-product, the E.U. focuses on the product as well as the production method or process. According to the Center for Science in the Public Interest, there is no *a priori* reason for the FDA to restrict the focus of its biotechnology labeling policy to the product only.²¹⁹ By comparison, other

longer be able to assume that an unlabeled product were non-GM if some products were labeled as non-GM and others remained unlabeled.

217. In addition to higher sales volume, producers are often able to charge more for their non-GMO products. Andrew Martin & Kim Severson, *Sticker Shock in the Organic Aisles*, N.Y. TIMES, Apr. 18, 2008, at C1, available at <http://www.nytimes.com/2008/04/18/business/18organic.html> (“organic food . . . typically costs 20 percent to 100 percent more than a conventional counterpart.”).

218. If either positive or negative labeling is required or allowed (i.e., if we are going to have labeling at all), both positive and negative labels are necessary to ensure that labels do not violate the FDCA requirement that labels not be misleading. “Section 201(n) of the act . . . states that labeling is misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates.” DRAFT GUIDANCE FOR INDUSTRY, *supra* note 133. “The legislative history of section 201(n) contains little discussion of the word ‘material.’” However,

historically, the agency has generally interpreted the scope of the materiality concept to mean information about the attributes of the food itself. FDA has required special labeling on the basis of it being “material” information in cases where the absence of such information may: 1) pose special health or environmental risks (e.g., warning statement on protein products used in very low calorie diets); 2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying).

Id.

219. Center for Science in the Public Interest, *supra* note 34.

federal labeling programs, such as organic labels and irradiation labels, disclose information about process attributes.²²⁰ Still others, such as “dolphin-safe” labels on canned tuna, address “the public consequences of product consumption.”²²¹

Both the current E.U. labeling regime and the proposed U.S. “Genetically Engineered Food Right to Know Act”²²² consider the product *and* the process. They provide for product-oriented labels that say, “This product contains a genetically modified material,” *and* process-oriented labels that say, “This product was produced with a genetically modified material.”²²³

The reason that the FDA currently does not consider process attributes is its philosophy that “safety concerns should be characteristics of the food product, rather than the fact that new methods are used.”²²⁴ However, the FDA also maintains that food labels should not be misleading.²²⁵ It is potentially misleading to only provide for product labels, because, while foods produced with GM materials (e.g., beer fermented using GM yeast) are not necessarily GM themselves, the fact that their production used GM materials is still important to some consumers.

Thus, the labeling regime should provide primarily for product-oriented labels but should also consider, on a case-by-case basis, whether a given method of production would be material to a sufficient number of consumers so as to require process-oriented labeling in that instance.

E. Threshold GM Content

“Threshold GM Content” refers to the percentage of GM content that is allowed before a plant food is required to be labeled as “genetically modified” or as “containing GMOs.”²²⁶ *De minimis* thresholds have a long history in food law in the U.S.²²⁷ and the E.U.²²⁸ Although “conta-

220. Teisl & Caswell, *supra* note 33, at 6.

221. *Id.*

222. See *supra* notes 118–24 and accompanying text.

223. See H.R. 5269 § 3(a), 109th Cong. (2006); Council Regulation 1829/2003, art. 13, ¶1(a), 2003 O.J. (L 268).

224. See *supra* note 132 and accompanying text.

225. See *supra* note 219.

226. It may be thought of as a level below which products are exempted from labeling requirements; it thus determines to a significant extent the scope of labeling regulations.

227. See MCHUGHEN, *supra* note 8, at 212.

228. GMO Compass, GMO Labelling Guidelines: Why a Threshold?, http://www.gmocompass.org/eng/regulation/labelling/89.gmo_labelling_guidelines_threshold.html (last visited Apr. 8, 2010). In the E.U., “[l]abels on honey, for example, will often indicate the plant the honey was produced from (i.e. acacia). If the label states only one plant, the honey must be ‘predominantly’ from the nectar of that plant, i.e. 60–70 percent.” *Id.*

minants are present in all foods,” food batches are only “rejected when the contaminants reach the threshold level.”²²⁹ When contaminants are present at levels below the threshold, no labeling is required. Contaminants are present in small amounts in most foods, although most consumers are probably unaware of their presence. According to one study, “21% of 567 cereal-based foods tested in the UK . . . contained mites.”²³⁰ This use of *de minimis* thresholds in general food law supports the use of such a threshold with respect to GM content, but does not provide a specific level at which the GM threshold should be set.

Theoretically, if the point of labeling is to inform consumers, the threshold should be set at whatever level consumers consider material. However, this requires a determination of the amount of GM content that would trigger an average consumer’s desire to know of the GM nature of the product. This method of determining the threshold is impracticable because there is no such level. Most consumers do not understand GM technology and, therefore, cannot come up with any meaningful level at which they consider modifications “material” to know about.²³¹

Of course, some consumers would prefer to see all food products with any GM content labeled. Some groups are completely opposed to GM technology and—if they cannot convince the government to ban GMOs—want to see comprehensive labeling at the very least.²³² But even the E.U. recognizes that it is practically impossible to label all instances of genetic modification.²³³ Thus, the labeling regime must provide some threshold percentage below which labeling is not required.

229. MCHUGHEN, *supra* note 8, at 212.

230. *Id.* McHughen notes that some consumers in the same group that wants to see GM content labeled (such as vegetarians opposed to GM) should like to see mite (or rat or other pest) content in food labeled as well, “particularly as these contaminant animals contribute far more animal DNA and protein to the food than GM will.” *Id.*

231. MCHUGHEN, *supra* note 8, at 204–13 (explaining in detail the many different types of mistakes consumers may make in interpreting labels generally, and specifically with regard to GMOs).

232. Institute for Responsible Technology, Petition to President Obama to Support Mandatory Labeling of GM Foods, <http://www.responsibletechnology.org/GMFree/Home/index.cfm> (last visited Apr. 11, 2010).

233. GMO Compass, *supra* note 230.

During the production, transportation, and processing of agricultural products, a small amount of mixing between different fields and different shipments is difficult to prevent. For this reason, even when a product was intended to be completely GMO-free, traces of GMOs can often still be detected. Products containing these unintentional or technically unavoidable mixtures with GM material do not require labelling, as long as the GM content does not exceed 0.9 percent.

As the U.S. does not currently require labeling, it has not attempted to determine what threshold percentage is appropriate, but four factors would be significant to such a determination: cost, consumer confidence, the type of genetic modification, and whether the mixing of GM and non-GM crops was intentional. The incredibly high cost of a zero-tolerance threshold suggests the need for a non-zero tolerance level.²³⁴ A recent study suggested that labeling “costs rise nonlinearly as the threshold for purity is decreased.”²³⁵ Thus, a 1% purity threshold would be *more than* five times as expensive to ensure as a 5% purity threshold.

Of countries that do require labeling, the E.U. has set the lowest threshold. All crops that are intentionally GM must be approved for commercial sale in the E.U., and those products approved for commercial sale must be labeled as GM.²³⁶ Where producers intend to use non-GM crops, “[p]roducts containing . . . unintentional or technically unavoidable mixtures with GM material do not require labeling, as long as the GM content does not exceed 0.9 percent.”²³⁷ Nothing in the E.U. regulations or on the E.U. website for consumer outreach explains how the 0.9% figure was calculated or what the figure represents in terms of policy. Of countries that maintain mandatory labeling regimes, the most permissive is Japan—the threshold is 5%.²³⁸

The trade-off is that while a high threshold is more practical and less costly to enforce, the label becomes less meaningful to consumers, who will therefore become more distrustful of labels in general. If something containing 3% GM content is labeled as not GM when consumers feel that 3% GM content is material, they lose confidence in the label. There is no evidence available as to what threshold consumers consider material in their decision to consume or avoid GMOs. To date, because the technology is so complicated, scientists have been the ones who decide what threshold is material.

In addition to different types of genetic modifications, there are different methods of measuring the percentage of GM content. Take GM soybeans for example. Should GM content be measured by the percentage of genes that are GM? Perhaps it should instead be measured by the percentage of proteins the plant expresses that are coded for by genes that are foreign to the original plant?—or by the weight of GM proteins as a per-

Id.

234. The current grain elevator system in the U.S. also necessitates a *de minimis* threshold level, as mixing of different producers’ grains is inevitable.

235. Teisl & Caswell, *supra* note 33, at 14.

236. GMO Compass, *supra* note 22.

237. *Id.*

238. Carter & Gruere, *supra* note 47.

centage of total proteins produced by the plant? Or, maybe a bag of 100 soybeans should have to be labeled if more than one of the individual seeds is found to contain a genetic modification?

Thus, a threshold is necessary and in keeping with food labeling law generally. However, due to the differences in methods of genetic modification, a threshold will have to be worked out for each category of modification, and perhaps even more specific thresholds will be needed for different products within each category. If you, the reader, do not understand the foregoing distinctions, would you understand labels enough to make an informed choice? The average consumer has never thought about these issues and does not have the scientific knowledge to make an informed choice as to the test to use for the threshold or the numerical percentage at which to set the threshold.

F. Scope of the Regulations and Definition of Material Genetic Modifications

In addition to the different methods of measuring threshold GM content, there are many different types of genetic modifications, and no single threshold will apply to all types. For example, a single gene engineered into a tomato could hypothetically represent 1% of the proteins expressed by the tomato plant.²³⁹ Does that fact make the entire tomato GM? On the other hand, a beer produced using GM yeast could result in a finished product with no GM protein content at all. Is that beer non-GM? Citrus are routinely grown using rootstock. The root of the plant is from one variety, while most of the trunk and all of the branches are from another variety. If the root is GM but the branches are not, are the oranges GM?

Professor McHughen notes that while it is relatively easy to label individual tomatoes, the products that will be the most expensive to segregate and label are those products at the bottom of the market, such as generic or store-brand ketchup, which is commonly produced using whatever tomatoes are available at the time of production of each batch.²⁴⁰ Thus, the cost of labeling will fall primarily on the people who

239. McHughen raises the question whether labeling in this case would be required on each individual tomato, or on the bin containing the tomatoes. Individual labeling is needed in the context where food is sold in open bins, because if tomatoes are not individually labeled, they can easily be accidentally or intentionally mixed with non-GM tomatoes, which would destroy the efficacy of the intended label. See MCHUGHEN, *supra* note 8, at 214. It seems feasible to label the tomatoes individually, as bananas currently are labeled with stickers bearing the brand name "Chiquita." In this situation, the cost is borne by the producer of the GM product.

240. See MCHUGHEN, *supra* note 8, at 214.

buy store brands—i.e., the less well-off.²⁴¹ This is an important consideration. A possible solution would be to only require labeling on the items that are the easiest to label, such as whole fruits. This would potentially be misleading based on the consumer assumptions with asymmetrical labeling, discussed in Part IV, but it would comport with E.U. law, which exempts many types of processing aids and processed foods from labeling requirements.²⁴²

In addition to the direct cost of a labeling regime, adding GM data dilutes information already included on the label; more information means each item gets less space on the label and less attention from consumers. We live in a world that is already full of information. Any further information we consider putting on labels must be material to our decision whether to buy the product.²⁴³ “Simply increasing the amount of information content on a label may actually decrease the consumer’s ability to process other[,] more important label information.”²⁴⁴

CONCLUSION

All things considered, an American labeling regime is feasible. A federal framework for labeling GM content in plant foods would address calls for increased regulation and democratic input into the risk management process, while still allowing the continued development and cultivation of GM crops for human consumption. Such a labeling regime would go far to quiet fears about personal risk through involuntary exposure to GM food, and, in conjunction with a public information campaign, would likely increase consumer confidence in such food in the long run.

241. In addition to being less able to bear the cost of labeling, the poor are arguably less able to make informed choices with regard to food, because they are in general less educated than wealthier consumers.

242. See *supra* note 179 and accompanying text.

243. Recently, Sweden has floated plans to label food with regard to how much carbon was required to produce it (i.e., the food’s ‘carbon footprint’). “Next year, Sweden will start labeling food products so that shoppers can look at how much emission can be attributed to serving steak compared with, say, chicken or turkey.” Elisabeth Rosenthal, *As More Eat Meat, a Bid to Cut Emissions*, N.Y. TIMES, Dec. 4, 2008, at A1, available at <http://www.nytimes.com/2008/12/04/science/earth/04meat.html>. A recent New York Times opinion piece by a prominent American rancher suggests that carbon emissions are not necessarily a straightforward affair; rather, the amount of emissions depends up to a factor of tenfold on the method of production of the meat. Nicolette Hahn Niman, Op-Ed., *The Carnivore’s Dilemma*, N.Y. TIMES, Oct. 31, 2009, at A21, available at <http://www.nytimes.com/2009/10/31/opinion/31niman.html?scp=1&sq=niman&st=cse>.

244. Teisl & Caswell, *supra* note 33, at 10. This is an argument against the unconditional “consumer right-to-know” argument.

Logistically, the labeling regime would best balance cost with the goal of facilitating consumer choice if it required positive labeling and prohibited negative labeling, set a threshold GM content to trigger labeling requirements at a percentage that varies depending on the category of modification, and provided exemptions for processing aids²⁴⁵ and processed foods at the lower end of their respective markets.

The proposed labeling regime would have both positive and negative effects. Any labeling regime would impose costs on producers (and consumers, if producers pass on these costs). It would require a large-scale change to the current system of grain production in the U.S. This overhaul would be costly in the short term. Further, it is likely that consumers would avoid purchasing GM crops and food products in the short term, thereby decreasing nonorganic producers' profits (but correspondingly benefiting organic producers). In the long term, it is likely that U.S. consumers would accept GMOs and market forces would adjust the percentage of consumers choosing organic food as opposed to conventionally produced food. Stricter labeling laws would go far to bolster consumer confidence in the food supply and in regulatory authorities.²⁴⁶ Labeling requirements in the U.S. would partially harmonize the U.S. system with that of much of the rest of the world.²⁴⁷ Finally, a federal labeling law would preempt existing state labeling laws, producing beneficial regulatory uniformity but potentially destroying some currently meritorious claims.

Foremost among the concerns with any labeling regime is cost: any labeling regime would be expensive to implement.²⁴⁸ The costs involved include both direct costs (in terms of the actual cost of physical labeling)

245. In order to ensure compliance, the regime would have to institute penalties for non-compliance. To do so, it could look to penalties currently in effect in foreign regulations or U.S. state regulations, or the proposed federal regulations. However, penalties are outside the scope of this Note.

246. *But see IFIC Report on Food Biotechnology*, *supra* note 109 (indicating that consumer confidence in the U.S. food supply is high).

247. It would put the U.S. out of step with its current allies in the large GM-producing countries, Canada and Argentina. However, given the U.S.' economic prominence, it is likely that Argentina and Canada would eventually adopt similar labeling laws.

248. Instituting a labeling program for GM foods may have relatively large costs, which may differ significantly across types of programs. *See infra* notes 259–64 and accompanying text. In addition to the cost of implementing a labeling regime, producers worry that adding labels to GM foods (particularly in the U.S., where so much of our food contains GM material) could cause markets to collapse if consumers refuse to buy products with GMOs in them. Alternatively, consumers may embrace these products, an effect that has been observed recently as a result of rising food prices caused by the global food crisis.

and indirect costs, such as increased label complexity and competition of GM-related information on the label with other types of information. Some of these costs are more significant in the short-term, while others are incurred on an ongoing basis and, thus, remain significant.

Implementing a labeling regime involves developing “a set of standards, actions to meet the standards, certification of the actions, and governmental enforcement of the program.”²⁴⁹ There is evidence that “the costs of the actual physical labeling (e.g., label design and printing) are a tiny fraction of the costs of compliance and certification (supply chain costs)”²⁵⁰

Various studies have estimated the monetary cost of instituting a labeling regime in the U.S. One study “estimated the monetary costs per unit of segregating nonbiotech crops along the marketing chain . . . [at about] \$0.22 [per] bushel for corn and \$0.54 [per] bushel for soybeans.”²⁵¹ Dividing these quotations by the USDA average reported price per bushel for corn²⁵² and soybeans²⁵³ between 2006 and 2008 (\$4.14 and \$8.73, respectively)²⁵⁴ shows that these costs represent an increase of 5.3% in the price of corn and an increase of 6.2% in the price of soybeans attributable to labeling costs. A second study found that “[Intellectual Property] systems²⁵⁵ . . . raised the price of soybeans by 0.6–1.3%, while providing traceability for oilseed rape (canola) raised prices by 2.8–4.1%.”²⁵⁶ The results of these studies suggest that “while the costs are not small, they do not imply that disarray would occur in the grain marketing

249. Teisl & Caswell, *supra* note 33, at 5.

250. *Id.* at 9.

251. *Id.* at 13. Neither estimate included any premium paid to the producer. *Id.*

252. Econ. Res. Serv., U.S. Dep’t Agric., Feed Grains Database, Yearbook Tables—Corn: Cash Prices at Principal Markets, <http://www.ers.usda.gov/data/feedgrains/StandardReports/YBtable12.htm> (last visited Nov. 3, 2009).

253. Econ. Res. Serv., U.S. Dep’t Agric., U.S. Soybean Industry: Background Statistics and Information, <http://www.ers.usda.gov/News/SoyBeanCoverage.htm> (last visited Nov. 3, 2009).

254. Calculated by averaging the prices reported for these years in the sources cited in notes 260 and 261.

255. In other words, systems designed to ensure traceability of GMOs and GM material throughout the food production system (i.e. from ‘farm to fork’). The European system of traceability is to assign each GMO an ID number. GMO Compass, *supra* note 170.

256. Teisl & Caswell, *supra* note 33, at 13. Two other studies, both by KPMG, yielded cost estimates as low as “0.43% of sales in Australia and 0.23% of sales in New Zealand,” and as high as a 10% increase in retail food prices and 35–41% increase in producer prices in Canada. *Id.* at 15. Thus, costs may vary by country and by region within a country.

system if non-biotech crops were handled on a larger scale.²⁵⁷ Thus, cost is not an insurmountable obstacle to a U.S. labeling regime.

Changing the current system of grain production in the U.S. would be very difficult. Producers would have to segregate their products in order to certify that they are GM-free. In the current system, GM and non-GM crops mix freely. The Starlink episode,²⁵⁸ in which a variety of GM corn that had only been approved for animal consumption accidentally made its way into the human food supply, showed that "it is difficult to segregate different varieties of commodity crops like corn, soybeans, or wheat from each other in the current grain-handling system."²⁵⁹ The Starlink accidental release ultimately caused the Starlink variety to be withdrawn from the market entirely.²⁶⁰

Both short-term and long-term costs are involved. For example, overhauling the grain-elevator system might cost a significant amount at first, but it would not have to be repeated. Monitoring costs are incurred, on the other hand, on an on-going basis. In the short term, it is likely that consumers would reduce their consumption of products labeled as containing GMOs. However, this effect may be at least partially alleviated where the labels describe why the food was modified, so as to lessen the view that positive labels are warning labels. Further, it is likely that the shift away from GM foods will be short-lived, because organic produce is significantly more expensive than nonorganic produce. As consumers observe the lack of negative effects and the benefits²⁶¹ of consuming GMOs, they are likely to trust GMOs more and more, and therefore choose to purchase them.

A federal regulatory scheme would preempt state labeling laws to the extent that they impose similar requirements, thus ensuring national regulatory authority regarding labeling requirements but potentially eliminating some plaintiffs' claims based on state law or current federal law. Current state labeling laws would be nullified if Congress imposed affirmative labeling requirements through the National Uniform Nutritional Labeling clause of the FDCA.²⁶² A state can challenge the FDA's

257. Teisl & Caswell, *supra* note 33, at 18.

258. *See supra* note 112.

259. Center for Science in the Public Interest, *supra* note 34.

260. *Id.*

261. An example of the benefits of GMOs is the reduced consumption of synthetic chemical pesticides. *See supra* note 48 and accompanying text.

262. Farquhar & Meyer, *supra* note 86, at 469 ("Congress has expressed a desire to preempt state labeling requirements through the National Uniform Nutritional Labeling clause of the FDCA." (discussing 21 U.S.C. § 343-1(a))). The Nutrition Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.), however, only provides for express preemption, and specifically

striking down the state's proposed label, but the state bears the burden of showing that its label is not unduly burdensome to interstate commerce.²⁶³ State courts "may not impose liability upon a pesticide manufacturer," for example, "if that liability is premised on an inadequate label, as the manufacturer would be required to change the label in order to avoid liability."²⁶⁴ Additionally, claims of failure to warn premised on the completeness and accuracy of disclosure of risks on a label under both current federal law and state law would be preempted.²⁶⁵ The basis of failure to warn claims is that the consumer has involuntarily exposed herself to risk; in other words, "I would not have bought or eaten this product had I known what it was made of." If the label discloses the presence of GM content, then there is no failure to warn; self-exposure to risk from consuming GMOs is voluntary. Claims of actual harm from unsafe products²⁶⁶ or gene pollution would not be preempted. The proposed Genetically Engineered Food Right to Know Act would go even further than current law, authorizing private suits for damages as a result of gene pollution.²⁶⁷

Traceability is a separate but related issue. Europe's labeling regime incorporates traceability requirements in European Council Directive 1830/2003 on the Traceability and Labelling of GMOs. This set of laws

prohibits implied preemption using its provisions: the FDCA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1]" of the FDCA. *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009).

263. The United States District Court for the Southern District of New York issued two conflicting decisions in related cases in 2007 and 2008. In the first case, the court struck down a state regulation, determining that the Nutritional Labeling and Education Act preempted the state regulation because the state regulation imposed different requirements than the federal act. *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 509 F. Supp. 2d 351 (S.D.N.Y.) (2007). In the second (related) case, the court declined a restaurant association's motion for a preliminary injunction to stop the enforcement of a new city regulation requiring restaurants to post the calorie content of food items on their menus, because there was not the substantial possibility of success on appeal of the association's claim that the regulation was preempted by the Nutrition Labeling and Education Act. *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 545 F. Supp. 2d 363 (S.D.N.Y.) (2008).

264. Farquhar & Meyer, *supra* note 86, at 465.

265. Ideally, in order to provide the most consistency and thereby facilitate consumer understanding and ease of use, the labeling regime should be supranational. Given the lack of congruence between current E.U. and U.S. policy, however, the emergence of a supranational regime is highly unlikely in the near future.

266. For example, claims that GM content acted as a poison or induced an allergic response.

267. See *supra* notes 118, 122 and accompanying text.

requires that all operators²⁶⁸ at all marketing stages of GMO-containing food products must notify the operators of subsequent stages (to whom they are passing on the food material) in writing that the food contains GM material or GMOs, and they must supply the next operator with the GMO's ID number.²⁶⁹ All operators must retain documentation of the source of their products, the identities of operators to whom they passed on their products, and the ID numbers of their products, for five years.²⁷⁰ Incorporating traceability requirements like those in the European system would make it easier to trace problems with the food supply and identify *or rule out* the possibility that a contamination or problem was associated with a GMO. Thus, traceability requirements are an investment now to avert future costs, perhaps even future injuries and deaths.²⁷¹ However, traceability requirements are not essential to providing the consumer with choice in the form of a label that discloses whether a product has or has not been genetically modified. Because they are superfluous to the central purpose of the labeling regime and they add costs, traceability requirements should be a second step in the regime, adopted after enough time has passed to determine whether labeling requirements have served the purpose of facilitating consumer choice.

Finally, any labeling regime would benefit from a contemporaneous governmental public information campaign.²⁷² Such a campaign should be based on scientific studies as to health and environmental risks. It could present the positive nutritional attributes and theoretical risks of consuming GMOs along with the societal costs of foregoing GMOs, such

268. "Operator" is defined as "a natural or legal person who places a product on the market or who receives a product that has been placed on the market in the Community, either from a Member State or from a third country, at any stage of the production and distribution chain, but does not include the final consumer." Council Regulation 1830/2003, art. 3(5), 2003 O.J. (L 268).

269. Council Regulation 1830/2003, arts. 4(A)(1) & (2), 8, 2003 O.J. (L 268).

270. GMO Compass, *supra* note 170 (paraphrasing Council Regulation 1830/2003, art. 4(A)(4), 2003 O.J. (L 268)).

271. This would be true if a problem traced to a GMO is identified early enough to stop consumers from eating the problematic product, or if GMOs can be ruled out as a cause in time to direct resources to the real cause of a public health scare.

272. Teisl & Caswell, *supra* note 33, at 19. "To avoid confusion, it is likely that any labeling program for [GMOs] will require a significant information campaign to educate consumers." *Id.*

as starvation in developing countries, environmental degradation, and harm to agricultural workers from continued use of chemical fertilizers and pesticides. With a balanced approach, such an information campaign might contribute to public acceptance of GMOs and to the ultimate goal of the labeling regime: ensuring informed consumer choice.

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