

**RETHINKING RISKS: SHOULD SOCIOECONOMIC AND
ETHICAL CONSIDERATIONS BE INCORPORATED INTO THE
REGULATION OF GENETICALLY MODIFIED CROPS?**

*Dorothy Du**

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* Harvard Law School, J.D. Candidate, 2013; B.A., Biology & Society, Cornell University, 2010; Student Fellow, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, 2011–2012. I would like to thank Harvard Law School Associate Professor Benjamin Roin and Academic Fellow Jeffrey Skopek of the Petrie-Flom Center for their insightful comments and guidance on this Note. I would also like to thank Sam Spears, Katherine Booth, and the rest of the editors of the *Harvard Journal of Law & Technology* for their insightful suggestions.

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I. INTRODUCTION

This Note surveys a range of non-scientific concerns associated with transgenic or genetically modified (“GM”) crops and argues for their incorporation into the regulatory process. A number of scholarly articles have critiqued the regulatory process for genetically modified organisms (“GMOs”), but none has systematically examined whether the relevant agencies are taking into account all the factors that they ought to consider in regulating GM crops.¹ This Note attempts to fill that gap. Building on Gary Marchant’s recognition of the need to incorporate social and ethical issues into the regulation of emerging technologies,² this Note applies Marchant’s insights to GMO regulation. Non-scientific concerns relate broadly to public participation in GMO regulation and to the overall utility of genetic engineering. Many who share these concerns reject product-based regulation of GMOs and assign paramount importance to the processes involved in the creation of GMO products.³

Transgenic or genetically modified crops are crops whose genetic codes have been directly altered by insertions, deletions, or other modifications of DNA in the laboratory.⁴ The commercialization of GM crops has grown tremendously since their introduction in 1996.⁵ By 2012, 93% of soybeans, 94% of cotton, and 88% of corn grown in

1. See, e.g., Bratspies, *Genetically Modified Organisms: Philosophy, Science, and Policy: Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 KAN. J.L. & PUB. POL’Y 393, 394 (2007) (exploring the structural question “whether we have created an appropriate framework within which to make decisions about safety and efficacy” in relation to GM crops).

2. See Gary Marchant et al., *Integrating Social and Ethical Concerns into Regulatory Decision-Making for Emerging Technologies*, 11 MINN. J. L. SCI. & TECH. 345 (2010).

3. See, e.g., Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525, 581 (2004).

4. See 7 C.F.R. § 340.1 (2012) (defining genetic engineering); Bratspies, *supra* note 1, at 399–400 (2007) (“In a process called transformation, genes can now be isolated and transferred to a food crop across species, class, phylum and kingdom. In other words, genetic engineering enables breeders to recombine genes themselves.”).

5. See JORGE FERNANDEZ-CORNEJO & MARGRIET CASWELL, USDA ECON. RESEARCH SERV. ECON. INFO. BULL. NO. 11, *THE FIRST DECADE OF GENETICALLY ENGINEERED CROPS IN THE UNITED STATES* 8 (2006), available at http://www.ers.usda.gov/media/255908/eib11_1_.pdf; see also Bratspies, *supra* note 1, at 403 (noting that “[i]n 2006, 10.3 million farmers in 22 countries planted 252 million acres with biotech crops,” and that this marked a sixty-fold increase from a decade before).

the United States was transgenic.⁶ Nevertheless, the modern U.S. regulatory scheme for GMOs derives from the Coordinated Framework for Regulation of Biotechnology (“Framework”), a policy document issued in 1986 by the Reagan administration’s Office of Science and Technology Policy (“OSTP”).⁷ Regulatory policy has changed little since the adoption of the Framework.⁸

Multiple scholars have noted that the principles set forth in the Framework seem to presume biotechnology’s relative safety and utility.⁹ First, the Framework is based on “a determination that the process of biotechnology [is] not inherently risky.”¹⁰ GMO regulation is “product-based”; the Framework regulates only the products of biotechnology rather than the process of producing them.¹¹ Accordingly, the FDA has adopted the substantial equivalence doctrine, which states that GM products that are “substantially equivalent” in biochemical composition to their non-GM counterparts should be regulated in the same way as their conventional counterparts.¹² Under this

6. USDA ECON. RESEARCH SERV., GENETICALLY ENGINEERED VARIETIES OF CORN, UPLAND COTTON, AND SOYBEANS, BY STATE AND FOR THE UNITES [sic] STATES, 2000–12 (2012), available at <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx>.

7. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986); Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 738, 743 (2003) (describing the genesis of GMO regulation in the Reagan and Bush administrations); see also Bratspies, *supra* note 1, at 405; Diane E. Hoffmann, *The Biotechnology Revolution and Its Regulatory Evolution*, 38 DRAKE L. REV. 471, 518 (1988–1989) (describing the adoption of the Framework). See generally SHELDON KRIMSKY, *BIOTECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS* (1991) (chronicling the first decade of genetic engineering and its regulation).

8. See Marden, *supra* note 7, at 743.

9. See, e.g., SHEILA JASANOFF, *DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN EUROPE AND THE UNITED STATES* 131 (2005) (remarking that the introduction of GM food products in the 1990s was “as much a process of making the world safe for the introduction of GM as making GM safe for introduction to the world”); Bratspies, *supra* note 1, at 405–06; Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2216 (2004); Hartmut Meyer, *Systemic Risks of Genetically Modified Crops: The Need for New Approaches to Risk Assessment*, 23 ENVTL. SCI. EUR., no. 7, 2011, at 1, 3, available at <http://www.enveurope.com/content/23/1/7> (“Expecting a revolution in biology and an immense impact on business, genetic engineering was declared as equivalent to conventional breeding methods, meaning a GMO . . . does not require specific regulation.”).

10. Mandel, *supra* note 9, at 2216; PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS 6* (2001), available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf [hereinafter PEW GUIDE].

11. Kysar, *supra* note 3, at 557–58; Mandel, *supra* note 9, at 2242; see Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984–85 (May 29, 1992) (“The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.”).

12. See Kysar, *supra* note 3, at 557 (“[T]he substantial equivalence determination accords no significance to the fact that a product has been developed using modern genetic engineer-

doctrine, if a non-GM counterpart is “generally recognized as safe” (“GRAS”), then the GM product is typically considered to be GRAS.¹³ This product- rather than process-oriented framework has led to a regulatory scheme that relies largely on voluntary consultations with the industry, based on the premise that GM crops are usually “substantially equivalent” to their conventional counterparts.¹⁴ The result is that GM products are regulated without regard to any unique ethical dilemmas or undesirable social or economic consequences raised by their production.

Second, the Framework divides responsibility for overseeing GMOs between three federal agencies. Under the Federal Food, Drug, and Cosmetics Act (“FFDCA”), the Food and Drug Administration (“FDA”) evaluates food and animal feed safety.¹⁵ Under the Federal Insecticide, Fungicide, and Rodenticide Act¹⁶ and the Toxic Substances Control Act,¹⁷ the Environmental Protection Agency (“EPA”) regulates environmental risks posed by plants modified to produce their own pesticides.¹⁸ Under the Plant Protection Act,¹⁹ the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture (“USDA”) ensures the safety of GMO meat and egg products and regulates plant pests and noxious weeds.²⁰

ing processes. Rather, substantial equivalence is determined solely with reference to the compositional and other tangible characteristics of the modified organism and its conventional counterparts.”); Marden, *supra* note 7, at 784–85.

13. Bratspies, *supra* note 1, at 409; see Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,944–45 (proposed Apr. 17, 1997) (to be codified at 21 C.F.R. pts. 170, et al.).

14. See Ronald E. Bailey & Linda M. Bolduan, *Genetically Modified Foods: Labeling Issues Are Driving the Regulators and Counsel*, 68 DEF. COUNS. J. 308, 310–11 (2001); Peter Newell, *Democratising Biotechnology? Deliberation, Participation and Social Regulation in a Neo-Liberal World*, 36 REV. INT’L STUD. 471, 479 (2010) (noting that the EPA “accepts the lab and field studies of biotech companies” and that “[v]oluntary private consultations with the agency before a product is marketed are considered adequate”); Claire Althouse, Note, “Farming Out” Regulatory Responsibility: Private Parties in the Biotechnology Age, 23 GEO. INT’L ENVTL. L. REV. 421, 424–25 (2011); see also FDA, CONSULTATION PROCEDURES UNDER FDA’S 1992 STATEMENT OF POLICY — FOODS DERIVED FROM NEW PLANT VARIETIES (1997), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096126.htm>.

15. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2006 & Supp. V 2011); see also Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,304 (June 26, 1986); PEW GUIDE, *supra* note 10, at ii.

16. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 (2006 & Supp. V 2011).

17. Toxic Substances Control Act, 15 U.S.C. § 2601 (2006 & Supp. V 2011).

18. See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303–04; PEW GUIDE, *supra* note 10, at iii.

19. Plant Protection Act, 7 U.S.C. § 7701 (2006 & Supp. V 2011).

20. 7 C.F.R. §§ 2.22(a), 2.80(a)(36) (2012); see Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304; PEW GUIDE, *supra* note 10, at ii–iv; Bratspies, *supra* note 1, at 407; Kysar, *supra* note 3, at 558–59; Mandel, *supra* note 9, at 2216.

Third, the Framework declares existing laws and agencies sufficient to accommodate GM foods, though it noted that congressional action could become appropriate as the field advances.²¹ No new legislation has been passed specifically to address GMOs,²² even though Congress was unlikely to have considered genetic engineering when it enacted previous legislation. This exclusive reliance on preexisting statutes excludes socioeconomic and ethical risks by binding federal agencies to use only scientific risk assessment in deciding whether to authorize the testing and commercial release of GM crops.²³

Part II of this Note describes the primary non-scientific concerns about GMOs that the current regulatory process does not consider. Part III applies to GM crop regulation arguments first identified by Gary Marchant for incorporating non-scientific considerations into regulatory decision-making. Part IV identifies and addresses major arguments against integrating non-scientific considerations into the regulatory process. Part V concludes.

II. “NON-SCIENTIFIC” CONCERNS OVER GM CROPS

Since the late 1990s, the American public has expressed a number of non-scientific concerns regarding GMOs,²⁴ reflecting a growing desire to reestablish an understanding of the origins and ingredients of the food we consume.²⁵

A. Moral and Religious Objections to Genetic Engineering

One set of concerns stems from some Americans’ deeply held moral and religious convictions. Some believe that altering an organ-

21. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303 (“[T]his comprehensive regulatory framework uses a mosaic of existing federal law”); Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856, 50,858 (Dec. 31, 1984); *see also* Bratspies, *supra* note 1, at 406; Hoffmann, *supra* note 7, at 518.

22. *See* Kysar, *supra* note 3, at 558–59 (“Because the Coordinated Framework and subsequent executive branch position statements embraced the substantial equivalence doctrine . . . policymakers determined that no new laws were required to regulate GM organisms. Instead, federal agencies would share regulatory oversight duties . . . under a pastiche of existing statutes.”); Mandel, *supra* note 9, at 2218, 2228.

23. *See* FDA, A DESCRIPTION OF THE U.S. FOOD SAFETY SYSTEM (2000), available at www.fsis.usda.gov/OA/codex/system.htm [hereinafter FDA FOOD SAFETY]; NICHOLAS P. GUEHLSTORF, THE POLITICAL THEORIES OF RISK ANALYSIS 21 (2004); *see also* Marchant et al., *supra* note 2, at 346 (“While current U.S. regulatory regimes usually address issues such as costs and impacts on health, safety, and the environment, such regimes are generally structured to ignore the social and ethical issues that arise in response to emerging technologies.”).

24. Marden, *supra* note 7, at 743; *see* Susanna H. Priest, *US Public Opinion Divided Over Biotechnology?*, 18 NATURE BIOTECHNOLOGY, 939, 939–942 (2000).

25. *See* Lynn J. Frewer et al., *Societal Aspects of Genetically Modified Foods*, 42 FOOD & CHEM. TOXICOLOGY 1181, 1182 (2004) [hereinafter Frewer et al., *Societal Aspects*].

ism's genetic makeup in a manner that could never occur through natural reproduction immorally "play[s] God" or commoditizes living things.²⁶ By this view, there is something sacred and important about the natural limits to the genetic code, such that creating distinct new species in the laboratory degrades nature and society. Others fear that GMOs may actively interfere with the dietary restrictions dictated by their religion — for example, genes found in food forbidden by their religion could be inserted without their knowledge into the foods that they are permitted to eat.²⁷

B. Contamination and Coexistence

Contamination or commingling refers to the inadvertent mixing of GM and non-GM crops before they reach the marketplace.²⁸ Contamination greatly affects the ability of conventional farming to coexist with GM farming.²⁹ For example, in the fall of 2000, scientists discovered StarLink corn, a type of GM corn approved for animal feed and ethanol production only, in Kraft taco shells.³⁰ StarLink corn expressed a transgenic protein that resembled known human allergens, but the EPA could not determine whether the corn would cause allergies in humans.³¹ Companies linked to StarLink corn had to halt pro-

26. See Hoffmann, *supra* note 7, at 482; Jamie E. Jorg Spence, Note, *Right to Know: A Diet of the Future Presently upon Us*, 39 VAL. U. L. REV. 1009, 1019–20 (2005) ("Moral objections to genetic engineering include that it is like 'playing God,' it 'violates the integrity of living organisms' by showing no respect for the 'otherness' of animals and by using them purely as an object or a research instrument, and that it is 'unnatural.'" (citations omitted)).

27. See Bailey & Bolduan, *supra* note 14, at 313; Valery Federici, Note, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws*, 35 BROOK. J. INT'L L. 515, 530 (2010) ("If a Muslim eats soup that is labeled vegetarian but in fact contains pork, or if a vegetarian eats cereal that contains mouse parts, the mislabeling that led to the inadvertent consumption is likely to be extremely offensive.").

28. Although U.S. food manufacturers now employ identity preservation and traceability systems, traditionally, independent farmers sold their harvests to loosely regulated elevators and cooperatives via loosely regulated transportation providers. See GREGORY S. BENNET, FOOD IDENTITY PRESERVATION AND TRACEABILITY: SAFER GRAINS 47 (2009) ("Mixing and processing occurred nearly continuously . . . [and the] final product was made up of many ingredients and numerous processes."); see also *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 834 (N.D. Ill. 2002); Linda Beebe, Note, *In re StarLink Corn: The Link Between Genetically Damaged Crops and an Inadequate Regulatory Framework for Biotechnology*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 511, 512 (2004).

29. Miguel A. Altieri, *The Myth of Coexistence: Why Transgenic Crops Are Not Compatible with Agroecologically Based Systems of Production*, 25 BULL. OF SCI., TECH. & SOC'Y 361, 361 (2005); cf. A. Bryan Endres, *Revising Seed Purity Laws to Account for the Adventitious Presence of Genetically Modified Varieties: A First Step Towards Coexistence*, 1 J. FOOD L. & POL'Y 131, 152 (2005) ("[C]oexistence is concerned with the economic viability of sustaining different farming practices, as opposed to the environmental or health consequences . . .").

30. Mandel, *supra* note 9, at 2203–04; see also *In re StarLink Corn*, 212 F. Supp. 2d at 833–35.

31. Mandel, *supra* note 9, at 2203.

duction and pull corn products from their shelves.³² Shipments of U.S. corn meant for export were turned away, costing farmers tens of millions of dollars.³³

The StarLink corn incident exemplifies the difficulty of separating GM and non-GM food and highlights the inadequacy of GMO regulation in preventing commingling.³⁴ The EPA failed to monitor StarLink production effectively and had instead relied on voluntary compliance with requirements to warn growers that the corn was not for human consumption.³⁵ In a suit brought by farmers against Aventis CropScience, the makers of StarLink, the district court sustained the farmers' negligence, public nuisance, and private nuisance claims.³⁶ The claims arose from the defendants' (1) representations that the seed was safe for human consumption, (2) failure to communicate EPA-approved warnings to downstream grain elevator operators and transport providers, and (3) design of a defective product that would inevitably cause contamination due to pollen drift and commingling.³⁷ As GMOs become more prevalent, accidental mixing occurs with increasing frequency.³⁸ It is now nearly impossible to assure that any U.S.-originating corn or soybean shipment is 100% non-GMO.³⁹

Contamination and commingling affect farmers who build their livelihoods selling non-GMO crops. Gene flow through pollen drift and the movement of seeds can devastate conventional and organic farmers whose crops may be devalued or rendered unmarketable by the presence of recombinant DNA.⁴⁰ If an organic farmer's crops are

32. *See id.* at 2204–05.

33. *Id.*

34. *See* Bratspies, *supra* note 1, at 414.

35. *See* Blake Denton, Comment, *Regulating the Regulators: The Increased Role for the Federal Judiciary in Monitoring the Debate over Genetically Modified Crops*, 25 UCLA J. ENVTL. L. & POL'Y 333, 359 (2006).

36. *In re StarLink Corn*, 212 F. Supp. 2d at 843, 847–48.

37. *Id.* at 837.

38. One author notes that “[i]n a pilot study to assess the extent of adventitious presence of genetically modified DNA in conventional seed supplies, the Union of Concerned Scientists found conventional varieties of corn, soybeans, and canola ‘pervasively contaminated with low levels of genetic sequences originating in transgenic varieties.’” Endres, *supra* note 29, at 153 (quoting MARGARET MELLON & JANE RISSLER, *GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY 12* (2004), available at http://www.ucsus.org/assets/documents/food_and_agriculture/seedreport_fullreport.pdf).

39. Bratspies, *supra* note 1, at 414.

40. *See* Endres, *supra* note 29, at 138; Paul J. Heald & James C. Smith, *The Problem of Social Cost in a Genetically Modified Age*, 58 HASTINGS L.J. 87, 111 (2006). Recombinant DNA is DNA that comes from multiple organismal sources, which are joined together using recombinant DNA technology. Genes inserted from one organism into another through recombinant DNA techniques are called transgenes, and the resulting organism is transgenic or genetically modified. *Glossary of Agricultural Biotechnology Terms*, USDA, <http://www.usda.gov/wps/portal/usda/usdahome?contentid=BiotechnologyGlosary.xml&navid=AGRICULTURE> (last visited Dec. 22, 2012).

contaminated, he could lose his certification and, with it, the premiums that consumers are willing to pay for organic produce.⁴¹

Contamination affects crop exporters because international standards may be more restrictive than domestic ones.⁴² The European Union GMO regulatory framework operates under the “precautionary principle,”⁴³ and the European Union maintained a de facto ban on GM foods between 1997 and 2006.⁴⁴ As a result of contamination and commingling, U.S. non-GMO farmers suffered sizeable collective economic losses during this period, including more than \$814 million in lost foreign sales over the course of the five years preceding 2004.⁴⁵ Although the European Union no longer bans GM crops, genetically engineered food continues to be extremely unpopular in Europe.⁴⁶

Despite the intrusive nature of GM crops, the burden of keeping them out of farms is primarily on the non-GM farmer.⁴⁷ Conventional farmers thus far have not been successful in suing GMO farmers for unwanted contamination,⁴⁸ although recovery for economic injury may exist under several theories of liability, including private nui-

41. See Endres, *supra* note 29, at 138; Heald & Smith, *supra* note 40, at 88–89 (“The market for non-GMO crops is enormous, and such goods often command a premium price, but due to the widespread planting of GMO crops, non-GMO farmers run the constant risk of contamination”); *id.* at 113 (“A recent study reveals that in American supermarkets, the price premium for organic versus conventional fresh produce was from 11% to 121%.”); Matthew Rich, Note, *The Debate over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 898 (2004) (“Genetically modified crops also pose a risk to non-modified growers Since the market price for organic foods is much higher than for non-organic foods, the result is a substantial decrease in the worth of the crop.”).

42. Endres, *supra* note 29, at 142–44.

43. Kysar, *supra* note 3, at 556–57 (defining the “precautionary principle” as “a decisionmaking heuristic that ‘counsels serious contemplation of regulatory action in the face of evidence of health and environmental risk, even before the magnitude of risk is necessarily known or any harm manifested’” (quoting David A. Dana, *A Behavioral Defense of the Precautionary Principle*, 97 NW. U. L. REV. 1315, 1315 (2003))).

44. See Council Directive 2001/18, 2001 O.J. (L 106) 1 (EC); Council Regulation 258/97, 1997 O.J. (L 043) 1 (EC); Heald & Smith, *supra* note 40, at 112; see also *infra* Part IV.A.

45. See Rich, *supra* note 41, at 899.

46. See Altieri, *supra* note 29, at 362; Heald & Smith, *supra* note 40, at 111–13 (describing the growth in the European market for organic foods and noting that the organic market may “serve as a reliable proxy” for the non-GMO market where data on the non-GMO market are difficult to obtain).

47. Endres, *supra* note 29, at 13,536 (“In the absence of legal rules seed and specialty crop producers (including organic producers) have historically borne all of the costs necessary to achieve desired purity standards.”).

48. Drew L. Kershen, *Legal Liability and Agricultural Biotechnology: Ten Questions*, AGRIBIOTECH (Apr. 23, 2009), <http://agribiotech.info/details/KershenFinal%2003%20layout.pdf> (explaining that, as of 2009, there were no farmer-against-farmer suits alleging GMO contamination and describing the four lawsuits brought by farmers against purveyors of GMO technology that ultimately were dismissed or settled out of court); see *In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d 1004 (E.D. Mo. 2009); *Sample v. Monsanto Co.*, 283 F. Supp. 2d 1088 (E.D. Mo. 2003); *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002); *Hoffman v. Monsanto Canada Inc.*, (2005) SKQB 225 (Sask.), *aff’d*, [2007] SKCA 47 (Can.).

sance and trespass.⁴⁹ Non-GMO farmers incur significant costs in preventing GM pollen and seeds from crossing into their fields.⁵⁰ Some farmers contract with contiguous blocks of farmers in a particular region to grow non-GM crops.⁵¹ Others plant rows of crops at the boundaries of their fields to act as buffer zones that absorb wayward pollen.⁵² In California, several counties have passed referendums to establish GM-free zones.⁵³

Current legal measures such as seed stewardship guidelines from seed breeders and regulatory agencies address the development of pest-resistance in GM crops but do not aim to achieve meaningful coexistence between GM and non-GM crops. For example, Monsanto instructs growers of its GM seeds to plant twenty percent of their field with non-GMO cotton in order to slow pest resistance to the *Bt* toxin that the GM plants produce.⁵⁴ Although it would aid coexistence if farmers planted the reserve as a buffer around GM crops, the location of this reserve is left up to the grower, thereby “squandering its value as a coexistence tool.”⁵⁵

C. Consumer Choice and Labeling

Despite consistently strong demand for labeling over the past two decades, the FDA does not mandate disclosure of the presence of GM material in food products.⁵⁶ Furthermore, the FDA originally maintained that voluntary negative labeling — labeling food “GM-free” or

49. See Heald & Smith, *supra* note 40, at 113–136 (discussing potential and actual theories of liability for contamination of conventional farms by GMOs and predicting the strength of each); Stephanie E. Cox, Note, *Genetically Modified Organisms: Who Should Pay the Price for Pollen Drift Contamination?*, 13 DRAKE J. AGRIC. L. 401, 409–12 (2008). See generally Michael Faure & Andri Wibisana, *Liability for Damage Caused by GMOs: An Economic Perspective*, 23 GEO. INT’L ENVTL. L. REV. 1 (2010) (presenting an economic analysis of various theories of liability for harms caused by GMOs).

50. See, e.g., Cox, *supra* note 49, at 414 (“One of the biggest hurdles for coexistence is the economic cost associated with it, especially for smaller producers.”).

51. Endres, *supra* note 29, at 136–38.

52. *Id.*

53. *Id.*; see, e.g., *Agriculture Division, CNTY. OF MENDOCINO, CAL.*, <http://www.co.mendocino.ca.us/agriculture/agriculturedivision.htm> (last visited Dec. 22, 2012).

54. See, e.g., MONSANTO, 2011 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT 1, available at http://thefarmerslife.files.wordpress.com/2012/02/scan_doc0004.pdf; MONSANTO, 2013 INSECT RESISTANCE MANAGEMENT (IRM) GROWER GUIDE FOR GENUITY VT DOUBLE PRO RIB COMPLETE 7–10 (2013), available at <http://www.monsanto.com/SiteCollectionDocuments/IRM-Grower-Guide.pdf>; Endres, *supra* note 29, at 139. The idea behind planting such “refuges” is that “insects with a mutation allowing them to survive exposure to Bt will mate with insects in the refuge and produce offspring without a tolerance for Bt.” *Id.*

55. Endres, *supra* note 29, at 140.

56. See Federici, *supra* note 27, at 518; Marden, *supra* note 7, at 761–62.

“GMO-free” — would be considered misleading under the FFDCA,⁵⁷ though it has since retreated from this position.⁵⁸

Under the FFDCA, food is “misbranded” if “its labeling is false or misleading.”⁵⁹ Labeling is misleading if it “fails to reveal facts material . . . with respect to consequences which may result from the use of the article.”⁶⁰ The FDA originally interpreted this provision to require labeling only where the absence of such labeling would “(1) pose health or environmental risks[,] . . . (2) mislead the consumer in light of other statements on the label[,] . . . or (3) mislead the consumer to assume that because of its similarity to another food, a product has certain specific nutritional characteristics.”⁶¹ The FDA found mandatory labeling inappropriate because, under its product-based approach, it typically considers GMOs to be “substantially similar” to conventionally produced foods.⁶² The FDA also stated in its 1992 policy statement that voluntary negative labeling would be considered misleading under 21 U.S.C. § 343(a)(1),⁶³ because there were no established threshold levels at which a mixed crop is considered GM and no scientific evidence that GMOs posed a greater health and safety risk.⁶⁴

As GMOs became more prevalent in the late 1990s and as consumers became more aware of their presence in the food supply, polls revealed that an unequivocal majority of consumers wanted GM foods labeled.⁶⁵ The FDA’s critics saw the agency’s GMO labeling policy as a paternalistic move to “protect” consumers from their own supposed irrationality.⁶⁶ Typically, when consumers disagree for ethical or socioeconomic reasons with the consumption of a product, they can ex-

57. See *infra* text accompanying notes 61–64.

58. See *infra* text accompanying notes 72–74.

59. 21 U.S.C. § 343(a)(1) (2006 & Supp. V 2011).

60. 21 U.S.C. § 321(n) (2006 & Supp. V 2011).

61. Marden, *supra* note 7, at 759 (citing *Hearing Before the Subcomm. on Health, Education, Labor and Pensions*, 107th Cong. (2000) (statement of Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition)).

62. *Id.* at 759–60; see also Federici, *supra* note 27; Rich, *supra* note 41.

63. Marden, *supra* note 7, at 760 (citing 58 Fed. Reg. 25,837 (Apr. 28, 1993)).

64. See *id.* at 761–62.

65. Denton, *supra* note 35, at 344 (“Studies indicate that consumers overwhelmingly support the labeling of GM food.”). A 1997 survey conducted by Novartis reported that 93% of Americans wanted the FDA to require labeling of GM foods. Marden, *supra* note 7, at 760. A *Time Magazine* poll in 1999 reported that 81% of respondents wanted labeling. *Id.* A 2001 telephone poll by ABC News found that 93% of Americans wanted mandatory labeling. Gary Langer, *Poll: Skepticism of Genetically Modified Food*, ABC NEWS.COM (June 19, 2001), <http://abcnews.go.com/Technology/story?id=97567&page=1#.UKG3JYZBmDk>. A 2002 Center for Food Safety compilation of various polls reported that 75% to 93% of American consumers wanted GM foods labeled. *Compilation and Analysis of Public Opinion Polls on Genetically Engineered (GE) Foods*, CENTER FOR FOOD SAFETY, <http://www.organicconsumers.org/gefood/polls051602.cfm> (last updated Feb. 1, 2002); see also Federici, *supra* note 27, at 530 (“One survey showed that 94% of consumers would like labels to indicate the presence of GM content.”).

66. See, e.g., Rich, *supra* note 41, at 906.

press their disapproval by opting not to buy it.⁶⁷ Labeling food enables the market to decide whether certain types of foods should be sold. It solves the problem of intractably mixed opinions on the social utility of a product or practice. The government, industry, and theorists have all endorsed this approach in some contexts to avoid bureaucracy and misinformed policies.⁶⁸

Moreover, the FDA and USDA permit certain other types of food labels that are unrelated to the nutritional or safety profile of the food. One socially oriented food label that has taken off by storm in recent years is the “fair trade” label.⁶⁹ This label facilitates consumer choice in purchasing imported produce made by workers who were paid fairly for their labor.⁷⁰ The FDA and USDA are not responsible for fair trade certifications — which are usually performed by a variety of international and domestic organizations⁷¹ — but they have not objected to fair trade labels.

In response to mounting criticism and consumer demand, the FDA released draft guidance on voluntary labeling for GM products in 2001.⁷² The FDA reaffirmed its view that food production by bioengineering is not a material fact under section 343(a) of the FFDCFA.⁷³ It recognized, however, that in some circumstances voluntary negative labeling may be permissible.⁷⁴

67. Kysar, *supra* note 3, at 619; see Elizabeth Barham, *Towards a Theory of Values-Based Labeling*, 19 AGRIC. & HUM. VALUES 349, 350 (2002).

68. See, e.g., Barham, *supra* note 67, at 349–58; *Food Irradiation: What You Need to Know*, FDA.GOV, <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm261680.htm> (last updated May 9, 2012); *Products & Partners*, FAIR TRADE USA, <http://www.fairtradeusa.org/products-partners#tabset-tab-2> (last visited Dec. 22, 2012).

69. Kysar, *supra* note 3, at 583 (“Demand for ‘fairly traded’ coffee, chocolate, bananas, and other goods has grown to the point that Fairtrade Labelling Organizations International, a leading certification body, now endorses more than 800,000 producers in forty countries . . . [S]ales of Fairtrade-labeled goods . . . reach[ed] an international total of \$260 million in 2002.”).

70. See Katy McLaughlin, *Is Your Grocery List Politically Correct? Food World’s New Buzzword Is ‘Sustainable’ Products; Fair Trade Certified Mangos*, WALL ST. J. (Feb. 17, 2004), <http://online.wsj.com/article/0,,SB107698348237931093,00.html> (“The labels mean that workers in poor countries received higher-than-usual wages and other benefits.”).

71. See *id.* (“[T]here is no central authority setting definitions for the new claims.”).

72. FDA CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING; DRAFT GUIDANCE (2001), available at <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodlabelingnutrition/ucm059098.htm> [hereinafter CENTER FOR FOOD SAFETY, GUIDANCE FOR INDUSTRY].

73. 21 U.S.C. § 343(a) (2006 & Supp. V 2011); CENTER FOR FOOD SAFETY, GUIDANCE FOR INDUSTRY, *supra* note 72.

74. See CENTER FOR FOOD SAFETY, GUIDANCE FOR INDUSTRY, *supra* note 72. The guidance explains that, for example, a “GMO free” label or label that implies that a product is superior because it is not bioengineered would be misleading and inaccurate. *Id.* In contrast, a label that says, “We do not use ingredients that were produced using biotechnology” would be acceptable. *Id.* The latter does not imply that the product has zero bioengineered material or that it is superior to its bioengineered counterpart. *Id.*

For consumers who do not wish to consume GM food, the FDA's new position is still too limited to enable them to purchase non-GM food reliably. With only voluntary labeling, consumers cannot know with certainty whether a product has particular characteristics in the absence of the label.⁷⁵ Mandatory labeling disseminates information much more reliably because the presence or absence of the labeled characteristic is immediately apparent to a consumer in every case.⁷⁶

Organic labeling initially presents itself as an alternative way to detect GMO presence in food⁷⁷ because one requirement for organic certification is that methods "to genetically modify organisms" are not used to produce the food.⁷⁸ However, "organic" is not a reliable proxy for GMO-free.⁷⁹ Organically labeled foods may nevertheless contain GMOs because there is no mandatory testing for GMO residues,⁸⁰ and there is no EPA threshold tolerance level for the finding of an unacceptable amount of GMO residues in organic food.⁸¹ Organic labels are permitted on GMOs so long as genetic engineering methods were not *intentionally* used.⁸²

In light of strong consumer demand and lack of comparable alternative food labels, mandatory labeling presents an appealing alternative to expanding the scope of the risk factors regulatory agencies may consider. However, there are several reasons it has not been instituted. First, labeling is not compulsory precisely because it would directly reflect consumers' non-scientific concerns. Second, even if labeling were required, it would be an incomplete solution because it is inherently reactive, rather than prophylactic.⁸³ Upstream regulations are better suited to resolving issues of field contamination and moral objections to biotechnology. Third, mandatory labeling could increase

75. See Rich, *supra* note 41, at 906.

76. See *id.* at 1034–35; Steve Keane, *Can a Consumer's Right to Know Survive the WTO?: The Case of Food Labeling*, 16 *TRANSNAT'L L. & CONTEMP. PROBS.* 291, 297 (2006).

77. See Federici, *supra* note 27, at 518.

78. Mandel, *supra* note 9, at 2190 n.96 ("National Organic Program food labeling requirements may create an implicit 'non-genetically modified' label because products labeled 'organic' cannot contain products produced through rDNA technology."). For a brief overview of organic requirements and certification, see Michelle T. Friedland, *You Call That Organic? — The USDA's Misleading Food Regulations*, 13 *N.Y.U. ENVTL. L.J.* 379, 388–90 (2005).

79. See Rich, *supra* note 41, at 911 ("Under the old organic standards, a customer could reasonably believe that the product did not contain genetically modified proteins. That is no longer the case.")

80. Friedland, *supra* note 78, at 392–94 (explaining that NOP regulations merely provide that the state organic program's governing state official or certifying agents "may require" testing of any agricultural input represented as organic).

81. *Id.* at 396–97 ("[R]egulations do not establish any limit whatsoever on contamination by genetically engineered materials.")

82. *Id.* at 397.

83. See Kysar, *supra* note 3, at 639–41.

the cost of non-GMO food for farmers and consumers by forcing non-GMO farmers to bear the expense of testing their crops for GMOs.⁸⁴

D. Patent Litigation and Corporatization of the Food Supply

The patentable status of GMOs has played a crucial role in precipitating a shift in the agriculture industry towards large agribusiness. Increasingly, multinational corporations with little connection to local farmers or consumers control the food supply.⁸⁵ Patents and other intellectual property rights have facilitated this process by enabling companies to control GM seeds and herbicides designed for use with GM crops. In the 1970s, for example, the Plant Variety Protection Act⁸⁶ spurred an important merger and acquisition movement that left a predominant share of intellectual property rights over plants in the hands of a few corporations, including Cargill, Monsanto, Occidental Petroleum, and Shell Oil.⁸⁷

Lay and expert critics alike have pointed to real and potential harms caused by corporatization of the food supply. Some critics fear that if farmers surrender their traditional control over the seed supply,⁸⁸ they may no longer devote the same time and energy to breed-

84. *See id.* California Proposition 37 would have created the first law in the United States to mandate labeling of GMOs or processed food with GM ingredients, but it failed to pass by a vote of 47.2% to 52.8% on November 6, 2012. *See State Ballot Measures — Statewide Results*, SEC’Y OF STATE OF CAL., <http://vote.sos.ca.gov/returns/ballot-measures> (last updated Nov. 20, 2012). For the full text of the proposed change to the California Health and Safety Code, see SEC’Y OF STATE OF CAL., TEXT OF PROPOSED LAWS 32 (2012), available at <http://vig.cdn.sos.ca.gov/2012/general/pdf/text-proposed-laws-v2.pdf#nameddest=prop37>. The reasons for the failure of the proposition to pass, despite studies showing a strong consumer preference for mandatory labeling, are not clear and deserve examination.

85. *See, e.g.*, Inmaculada de Melo-Martin & Zahra Meghani, *Beyond Risk, a More Realistic Risk-Benefit Analysis of Agricultural Biotechnologies*, 9 EUR. MOLECULAR BIOLOGY ORG. REP. 302, 304 (2008) (“[A] handful of seed companies own most of the patents for various GM plants, which means that farmers must purchase their seed stock from them, at prices set by those businesses.”); Rich, *supra* note 41, at 899 (“[T]here is concern that the patenting of genetically modified crops ‘will create a new feudalism in which farmers . . . will be dependent upon a few multinational companies . . .’” (quoting Franz Xaver Perrez, *Taking Consumers Seriously: The Swiss Regulatory Approach to Genetically Modified Food*, 8 N.Y.U. ENVTL. L.J. 585, 588 (2000))). Currently, the top four beef packers control 80% of the market, compared to 1970, when the top five beef packers controlled about 25% of the market. FOOD, INC. (Participant Media 2008).

86. 7 U.S.C. §§ 2321–2583 (2006).

87. Susan E. Gustad, Comment, *Legal Ownership of Plant Genetic Resources — Fewer Options for Farmers*, 18 HAMLINE L. REV. 459, 470–71 (1995) (citing Frederick H. Buttel & Jill Belsky, *Biotechnology, Plant Breeding and Intellectual Property: Social and Ethical Dimensions*, in OWNING SCIENTIFIC AND TECHNICAL INFORMATION, VALUE AND ETHICAL ISSUES 110, 120 (Vivian Weil & John W. Snapper eds., 1989)). In spite of the special protection that the Plant Variety Protection Act provides to plant patent owners, most infringement litigation relating to transgenic plants has involved utility patents. Drew Kershen, *Of Straying Crops and Patent Rights*, 43 WASHBURN L.J. 575, 575–76 (2004).

88. *See* Rich, *supra* note 41, at 898 (“The patented plants are often sold only for one growing season, and farmers must purchase new seed or renew their permits to plant in

ing more robust and higher yielding crops through traditional techniques.⁸⁹ Others warn against the perception that society must accept biotechnology in order to feed the world's growing population and the poor, arguing that society should focus on effecting broader social change to resolve these issues.⁹⁰

Additionally, critics claim that biotechnology raises long-term costs for farmers because farmers must continually buy next generation seeds. Technology licenses prohibit farmers from planting the seeds produced by their GM crops.⁹¹ These licenses were upheld in *Monsanto Co. v. Scruggs*, in which the Federal Circuit held that Monsanto's "no replant" policy did not constitute an illegal anticompetitive practice because patent holders have a right to exclude others from use of their technology and condition its use on contractual limitations.⁹² Moreover, the court held that the first sale doctrine of patent law does not apply to GM seeds produced by GM crops, reaffirming its earlier ruling in *Monsanto v. McFarling*.⁹³ The court reasoned that the patent holder never sold the second generation of seeds, and therefore did not exhaust its patent rights in the second generation.⁹⁴

Still others criticize the practice of filing patent suits against farmers for illegally appropriating GM seeds⁹⁵ even where the presence of GMOs in their fields is accidental or unwanted. For example, in *Monsanto v. Schmeiser*, a Canadian court found a farmer guilty for infringing Monsanto's patents for herbicide-resistant canola, despite

order to continue growing the crops. Traditionally, seed was simply harvested and used again during the next growing season.").

89. See Gustad, *supra* note 87, at 471.

90. Katrin Dauenhauer, *Activists Say U.S. Manipulating Meet to Promote GM Food*, INTER PRESS SERV. (June 24, 2003), <http://www.ipsnews.net/2003/06/science-activists-say-us-manipulating-meet-to-promote-gm-food>.

91. Althouse, *supra* note 14, at 425–26, 429 (stating that GMO manufacturers require producers to sign a Technology Use Agreement, which typically contains express terms prohibiting seed saving and replanting, as well as requirements to comply with a seed stewardship program and to allow the manufacturer to test and sample the crop); see also Carmen G. Gonzalez, *Genetically Modified Organisms and Justice: The International Environmental Justice Implications of Biotechnology*, 19 GEO. INT'L ENVTL. L. REV. 583, 604–05 (2007) (describing the potential for adoption of GM technology to marginalize small farmers); Kershen, *supra* note 87, at 577; Rich, *supra* note 41, at 898.

92. *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1340 (Fed. Cir. 2006).

93. *Id.* at 1336 (citing *Monsanto v. McFarling*, 302 F.3d 1291, 1299 (Fed. Cir. 2002)). Under the first sale doctrine, the first unrestricted sale of a patented article exhausts the patentee's rights. *Id.*

94. *Id.* ("The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology."). The Supreme Court has granted certiorari to reconsider the application of the first sale doctrine to GM seeds in *Monsanto Co. v. Bowman*, 657 F.3d 1341 (Fed. Cir. 2011), *cert. granted*, 133 S.Ct. 420 (2012); see Lynn Li, *Patent Rights for Self-Replicating Technology*, COLUM. SCI. & TECH. L. REV. (Oct. 25, 2012), <http://www.stlr.org/2012/10/patent-rights-for-self-replicating-technology>.

95. Rich, *supra* note 41, at 898 ("Under the terms of most GMO contracts, [collecting seeds from a previous harvest of GM crops and using them again during the next growing season] would now constitute patent infringement, and the biotechnology corporations who own the patents have brought a number of lawsuits against farmers.").

evidence that the GM presence in the farmer's field was adventitious.⁹⁶ The farmer had not used glyphosate, the herbicide Monsanto produced to spray on the GM canola,⁹⁷ and offered evidence that GM seeds contaminated his field after spilling out of a neighbor's seed bag.⁹⁸ Under patent infringement doctrine, however, the farmer's intent was irrelevant; by making and selling the patented invention, he had infringed.⁹⁹

In reaction to these decisions, some scholars have suggested adding an "intent" element to the test for patent infringement in cases of transgenic plants because of the difficulties associated with preventing reproduction.¹⁰⁰ However, adding a barrier to finding infringement could significantly harm incentives for innovation, hinder seed companies from recovering their costs, and encourage the use of gene restriction technologies.¹⁰¹

E. Rise of Monocultures and Effects on Biodiversity in the Food Supply

The planting of GM crops contributes to an industrial farming model that has decreased crop varieties. Intensive farming practices and advances in agricultural technology have caused complex, long-term changes in conventional agriculture; since World War II, an average of 219 farms have shut down each day.¹⁰² Planting GM crops has the potential to reduce biodiversity further by exacerbating this trend.¹⁰³

96. See *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902 (Can.); Faure & Wibisana, *supra* note 49, at 6 n.14.

97. Faure & Wibisana, *supra* note 49, at 6 n.14.

98. Kershen, *supra* note 87, at 601.

99. *Id.* at 585; see *Monsanto Canada*, 1 S.C.R. 902.

100. Kershen, *supra* note 87, at 585.

101. See Jason Savich, *Monsanto v. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology*, 22 BERKELEY TECH. L.J. 115, 126–27 (2007). Genetic Use Restriction Technologies ("GURTs") refer to a specific type of genetic modification not on the market in which GM plants are modified to be sterile so that their seeds cannot be replanted. *Id.* at 132.

102. See CAROLYN DIMITRI, ANNE EFFLAND & NEILSON CONKLIN, USDA ECON. RES. SERV., ECON. INFO. BULL. NO. 3, THE 20TH CENTURY TRANSFORMATION OF U.S. AGRICULTURE AND FARM POLICY 2, 2–6 (2005), http://www.ers.usda.gov/media/259572/eib3_1_.pdf; Altieri, *supra* note 29, at 366; *Trends in U.S. Agriculture: Market Basket*, USDA NAT'L AGRIC. STAT. SERV., http://www.nass.usda.gov/Publications/Trends_in_U.S._Agriculture/Market_Basket/index.asp.

103. Altieri, *supra* note 29, at 363–65; see also Kysar, *supra* note 3, at 556 ("[S]ome believe that GM agriculture exacerbates the trend toward concentrated, monocultural production, thereby threatening national food security and traditional agrarian culture."); Terry Marsden, *Agri-Food Contestations in Rural Space: GM in Its Regulatory Context*, 39 GEOFORUM 191, 193 (2008) ("GM technologies represent a constituent part of the agri-industrial model in that they are used to uphold intensive and large-scale agri-economies and production and supply systems which are inherently unsustainable.").

Farmers of GM crops use pesticides to suppress the insects that the GM transgenes do not control and use broad spectrum herbicides, like Monsanto's Roundup, to eliminate all vegetation in the fields besides the herbicide-tolerant GM crops.¹⁰⁴ Such overreliance on biotechnological fixes can accelerate pest resistance and disturb natural balances in the ecosystem, promoting a cycle that leads to the need for more pesticides and herbicides and ultimately creates monocultures.¹⁰⁵ For example, farmers who rely on Roundup to kill weeds limit themselves to a few varieties of GM-protected plants. Planting only a few types of crops can lead to soil exhaustion¹⁰⁶ and create an environment that is harmful to the natural enemies of pests — such as birds and insects that rely on a variety of weeds, seeds, and microhabitats that are not available in monocultures.¹⁰⁷ Decreases in the number of natural enemies of pests in turn foster the need for more GM products and pesticides.

GM monocultures can also increase the risk of large-scale crop failures.¹⁰⁸ Decreased biodiversity increases the vulnerability of crops to disease and pests, meaning that a single blight or pest could potentially decimate hundreds of thousands of acres of crops.¹⁰⁹ The most obvious example of the potential for disaster is the Irish Potato Famine.¹¹⁰ The same potato blight had much less impact in the Andes because farmers there had cultivated forty-six varieties of potato.¹¹¹

Monocultures could also contribute to poor nutrition by reducing the food choices available to consumers. For example, corn, which in the United States is mostly GM, has permeated just about everything we eat.¹¹² If scientists are correct that our spiking consumption of high fructose corn syrup and uniform diet rich in carbohydrates contribute to obesity and heart disease, then the adoption of GMOs may be hurt-

104. See Altieri, *supra* note 29, at 363–66.

105. See *id.* Monocultures are large areas of farmland on which a single species of crop is grown. Merriam-Webster Online Dictionary, available at <http://www.merriam-webster.com/dictionary/monoculture> (last visited Dec. 22, 2012).

106. Gustad, *supra* note 87, at 471.

107. Altieri, *supra* note 29, at 366.

108. See, e.g., *id.* at 365; Mandel, *supra* note 9, at 2197; Spence, *supra* note 26, at 1020–21 n.75.

109. See Altieri, *supra* note 29, at 365 (“History has repeatedly shown that uniformity characterizing agricultural areas sown to a smaller number of varieties, as in the case of GM crops, is a source of increased risk for farmers as the genetically homogeneous fields tend to be more vulnerable to disease and pest attack.” (citation omitted)).

110. Mandel, *supra* note 9, at 2197 n.147; Holly Saigo, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 GEO. INT'L ENVTL. L. REV. 779, 795–96 (2000).

111. Mandel, *supra* note 9, at 2197 n.147.

112. FOOD, INC. (Participant Media 2008) (“So much of our industrial food turns out to be clever rearrangements of corn.” (quoting Michael Pollan, author of *The Omnivore's Dilemma*)). Such unexpected products as ketchup, cheese, Twinkies, batteries, peanut butter, and tilapia feed contain corn. *Id.*

ing our health even though GMOs are nutritionally identical to conventional crops.¹¹³

III. REASONS FOR INCORPORATING NON-SCIENTIFIC CONCERNS INTO THE REGULATORY PROCESS

Socioeconomic and ethical factors should be incorporated into GMO regulation to improve transparency and increase public trust in regulation. Gary Marchant first articulated these arguments in the context of emerging technologies;¹¹⁴ this Part applies them to GM crop regulation.

A. Non-scientific Considerations Are Already Driving GM Policy Implicitly and Non-transparently, Creating Problems with Accountability and Expertise

The current regulatory scheme creates an impression of impartiality, masking underlying values that favor biotechnology.¹¹⁵ Non-scientific value judgments are embedded within science and technology regulation to a greater extent than we frequently realize.¹¹⁶ For example, “safety” concerns require regulators to look outside of the realm of scientific facts for indicators of acceptability and adequate protection because the degree of acceptable risk is ultimately a non-scientific question of culture, values, and priorities.¹¹⁷

The U.S. regulatory framework is a “subjective performance[] of differing judgments” about which aspects of GMOs are important to

113. For an overview of different studies examining the relationship between high fructose corn syrup and obesity, see Richard A. Forshee et al., *A Critical Examination of the Evidence Relating High Fructose Corn Syrup and Weight Gain*, 47 CRITICAL REV. FOOD SCI. & NUTRITION 561 (2007).

114. See *supra* Part I.

115. See *supra* note 9.

116. See generally Les Levidow & Susan Carr, *How Biotechnology Regulation Sets a Risk/Ethics Boundary*, 14 AGRIC. & HUM. VALUES 29, 29–30, 33 (1997) (commenting on the value-laden nature of biotechnology risk assessment in Britain and the EU).

117. Katy L. Johnson et al., *How Does Scientific Risk Assessment of GM Crops Fit Within the Wider Risk Analysis?*, 12 TRENDS PLANT SCI. 1, 1 (2006) (“[T]he acceptability of a given level of risk cannot be determined scientifically. Scientific assessment of the environmental risks (and benefits) of a technology is not sufficient to set policy and make decisions.”); de Melo-Martin & Meghani, *supra* note 85, at 305 (“[R]isk assessments of GMOs also include crucial ethical assumptions, such as: what counts as a serious risk? What is the relevant time frame for investigating such risks? What are the standards required to judge that unmanageable risks are not present?”); see also Wendy Craig et al., *An Overview of General Features of Risk Assessments of Genetically Modified Crops*, 164 EUPHYTICA 853, 854 (2008); Nicholas P. Guehlstorf, *Understanding the Scope of Farmer Perceptions of Risk: Considering Farmer Opinions on the Use of Genetically Modified (GM) Crops as a Stakeholder Voice in Policy*, 21 J. AGRIC. & ENVTL. ETHICS 541, 545 (2008) [hereinafter Guehlstorf, *Farmer Perceptions of Risk*] (“[R]isk assessment is a contextual or cultural phenomenon that uses science, but considers other social and economic contexts.”).

regulate and which are not.¹¹⁸ With the goal of maintaining the United States' economic position as a leader in the development of biotechnology,¹¹⁹ the Reagan administration and the OSTP made the normative assumption that the process of genetic engineering is not inherently risky and "correspondingly focused on a relatively narrow range of possible effects[.] . . . [largely] questions about toxic and allergenic properties."¹²⁰ As a result, the Framework prioritizes "production, development, and commerce" over potentially countervailing "qualitative factors like equity, welfare, and democracy."¹²¹

The FDA's GMO labeling policy is illustrative. Despite overwhelming support for labeling of GMOs, the regulatory scheme has not — and cannot — integrate these public opinions into policy because GMOs are "substantially similar" to conventional foods under the adopted standard.¹²² The regulatory scheme's reliance on specialized perspectives has prompted the observation that laypeople have been cut out of the debate, despite their stakeholder status.¹²³ The problem lies in the fact that the government has "implicitly or covertly"¹²⁴ adopted a set of normative views, sidestepping the democratic process by using policy documents like the Framework to direct agency regulation.

As long as regulatory agencies can frame their decisions as science-based, agency experts can simply preclude non-experts and non-scientists from participating in government decision-making.¹²⁵ The public cannot hold these scientists accountable for misinformed, under-informed, or biased decisions.¹²⁶ Even well-intentioned scientists are ill-qualified to make determinations about the types and levels of risk acceptable to the public because non-scientific issues lie outside of their training and expertise.¹²⁷

Yet transparency can create other problems. It forces the government to make transparent judgments about whose ethical views to follow. Potentially more troubling, navigating among countless ethical or philosophical views could lead the government to take a middle-of-the-road approach. It is not clear that the morality of a policy decision should be decided by majority vote. Compromise may be inconsistent

118. GUEHLSTORF, *supra* note 23, at 2–3.

119. *See* Bratspies, *supra* note 1, at 405 n.59.

120. JASANOFF, *supra* note 9, at 131.

121. GUEHLSTORF, *supra* note 23, at 3.

122. *See supra* Part II.C.

123. *See* Federici, *supra* note 27, at 530.

124. Marchant et al., *supra* note 2, at 350.

125. de Melo-Martin & Meghani, *supra* note 85, at 302 ("[F]raming the debate as one that involves only technical problems effectively limits who can legitimately participate in the discussion. Presumably, only scientific experts are trained sufficiently to determine the risks or benefits of GMOs, and non-scientists are therefore disqualified from participating in the dialogue.").

126. *See id.* at 305.

127. *Id.*

with some conceptions of ethics. Creating a system that smoothly integrates socioeconomic and ethical views into GMO regulation can be difficult, and neither unfiltered democracy nor a middle-of-the-road approach would satisfy all interested parties.

B. Incorporation of Non-scientific Concerns Would Create Opportunities for Greater Public Participation, Strengthening Public Trust in GMOs and GMO Regulation

The effectiveness of a regulatory framework for biotechnology depends on citizens' acceptance of the technology and trust in the regulatory process.¹²⁸ When stakeholders are dissatisfied with the regulatory system, they may refuse to comply or employ inefficient countermeasures. In the case of GMOs, some counties in California have banned planting GMOs in order to accommodate conventional and organic farming because more precise coexistence measures are not required by law.¹²⁹ Grocery shoppers nationwide have turned to organic produce to reduce their likelihood of consuming GMOs, even though buying organic produce is an imprecise way to avoid GMOs.¹³⁰

Public trust in biotechnology and its regulation is not particularly high,¹³¹ and consumers feel systematically disadvantaged compared to biotechnology purveyors.¹³² For example, the regulatory scheme for GMOs is committed to minimizing the risk of accidental consumption of non-food GM products, such as StarLink Corn, but is not committed to mandatory labeling to ensure consumer certainty in the presence or absence of GMOs for those with certain religious

128. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, PUBLIC SENTIMENT ABOUT GENETICALLY MODIFIED FOOD 8 (2006), available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public_Opinion/Food_and_Biotechnology/2006summary.pdf [hereinafter PEW, PUBLIC SENTIMENT] (noting that 50% of the Pew respondents identified trust in information sources as a very important factor in shaping their attitude towards biotechnology); Bratspies, *supra* note 1, at 395, 397; Montserrat Costa-Font et al., *Consumer Acceptance, Valuation of and Attitudes Towards Genetically Modified Food: Review and Implications for Food Policy*, 33 FOOD POLICY 99, 104 (2008) (“[T]he lack of consumer trust in institutions may seriously hinder the complete acceptance of transgenic technology.” (citation omitted)); Guehlstorf, *Farmer Perceptions of Risk*, *supra* note 117, at 549; see Johnson et al., *supra* note 117, at 3–4.

129. Endres, *supra* note 29, at 137.

130. See *supra* Part II.C.

131. One author has noted that the Pew Initiative on Food and Biotechnology has found that “between 2001 and 2006 the number of respondents expressing outright opposition to GM crops decreased from 58% to 46%, [but] the percentage of Americans supporting the technology remained constant (around 27%).” Bratspies, *supra* note 1, at 396 (citing PEW, PUBLIC SENTIMENT, *supra* note 128). Similarly, in 2006, “34% of respondents characterized GM foods as ‘basically safe,’ while 29% characterized them as basically unsafe,” even though GM foods had been on the market for more than a decade. *Id.* (quoting PEW, PUBLIC SENTIMENT, *supra* note 128).

132. Bratspies, *supra* note 1, at 396.

convictions.¹³³ The regulatory scheme purports to study issues of biodiversity by examining the effects of GM crops on non-target organisms¹³⁴ but ignores the decreased biodiversity and increased risk of massive crop failure that may result from GM-associated farming practices.¹³⁵

In light of these problems, the government should consider strengthening public trust in GMO regulation by broadening the risk factors that agencies consider. Broadening the official dialogue to consider non-scientific factors would create natural opportunities to include affected stakeholders in the regulatory process, incorporating the unique perspectives of different segments of the public.

Directly addressing public perceptions of risk could more effectively control these perceptions.¹³⁶ Public participation in shaping regulations is essential for creating trust in the regulatory process.¹³⁷ Scholarship shows that “institutional transparency, coupled with the integration of public concerns into policy development and implementation, will facilitate the introduction of emerging technologies . . . into society.”¹³⁸ The public more readily accepts government decisions, even those with which it disagrees, when its views are accorded respect and consideration.¹³⁹ Expanding the theory of risk in GMO regulation is consistent with the notion that, in a democratic society, normative policymaking is best left to the public, rather than to scientists.

IV. ARGUMENTS AGAINST INCORPORATION INTO THE REGULATORY PROCESS

It is not necessarily true that all “non-scientific” concerns need be incorporated into the regulatory process. Comprehensive incorporation could conflict with international free trade laws, sacrifice scientific truth for political correctness, and generate significant opportunity costs.

133. See *supra* Part II.

134. *Introduction to Biotechnology Regulation for Pesticides*, EPA.GOV, <http://www.epa.gov/opbpbpd1/biopesticides/regtools/biotech-reg-prod.htm> (last updated May 9, 2012).

135. See *supra* Part II.

136. See Lynn J. Frewer et al., *The Media and Genetically Modified Foods: Evidence in Support of Social Amplification of Risk*, 22 RISK ANALYSIS 701, 710 (2002) [hereinafter Frewer et al., *Social Amplification of Risk*].

137. See Gregory Jaffe, *Regulating Transgenic Crops: A Comparative Analysis of Different Regulatory Processes*, 13 TRANSGENIC RES. 5, 15 (2004).

138. Frewer et al., *Societal Aspects*, *supra* note 25, at 1191.

139. Marchant et al., *supra* note 2, at 350; see Kysar, *supra* note 3, at 605.

A. Incorporation of Socioeconomic and Ethical Concerns into GMO Regulation May Be Incompatible with International Trade Laws

Under the World Trade Organization's ("WTO") philosophy of free trade,¹⁴⁰ no member country may enact protectionist policies to unfairly benefit its domestic industries over exporters.¹⁴¹ In practice, this has meant that laws in member states that limit the commercialization and importation of biotechnology must be science-based.¹⁴² The fear is that an unquantifiable link in the regulatory chain could be used to disguise illegitimate protectionist motives.¹⁴³

1. Agreement on the Application of Sanitary and Phytosanitary Measures

One significant treaty in this vein is the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"),¹⁴⁴ which requires that "WTO members either adopt international health and safety standards or justify deviant measures"¹⁴⁵ supported by "sufficient scientific evidence" and applied "only to the extent necessary to protect human, animal or plant life or health."¹⁴⁶

The resolution of long-standing tensions between the European Union and the United States over biotechnology policy exemplifies the restrictive effect of the SPS Agreement on GMO regulations. European nations are generally adverse to GMOs¹⁴⁷ and have adopted the "precautionary principle," a process-based approach to GMO regulation.¹⁴⁸ In October 1998, a strong consumer backlash against GMOs led the European Union to impose a de facto moratorium on GM field testing and commercialization.¹⁴⁹

140. *The WTO in Brief*, WTO.ORG, http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr00_e.htm (last visited Dec. 22, 2012).

141. See Newell, *supra* note 14, at 487 (referring to the WTO's attempts to "narrow the terms by which countries may restrict the trade in the products of agricultural biotechnology according to principles such as 'sound science' contained in WTO accords," and describing "legal challenges brought through the WTO against countries responding to popular concern about GMOs by putting in place moratoria and other restrictive measures").

142. See *id.*; Laylah Zurek, Comment, *The European Communities Biotech Dispute: How the WTO Fails to Consider Cultural Factors in the Genetically Modified Food Debate*, 42 TEX. INT'L L.J. 345, 361 (2007) ("Allowing only limited restrictions based on food safety premised on scientific assessments, the WTO has favored market access.").

143. Marchant et al., *supra* note 2, at 352.

144. Agreement on the Application of Sanitary and Phytosanitary Measures, MTN/FA II-A1A-4 (Dec. 15, 1993) [hereinafter SPS Agreement].

145. David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 YALE J. INT'L L. 81, 90 (2005).

146. SPS Agreement art. 2.2; see Althouse, *supra* note 14, at 433.

147. See *supra* Part II.B.

148. See Althouse, *supra* note 14, at 427; *supra* Part II.B.

149. Kysar, *supra* note 3, at 563; Marsden, *supra* note 103, at 197; Winickoff et al., *supra* note 145, at 88.

On May 13, 2003, the United States filed a WTO complaint alleging that the moratorium created unfair barriers to trade by failing to meet the SPS Agreement's requirements of "scientific justification" and "risk assessment," and by causing "undue delay" in regulatory decision-making when none of the health and safety harms cited had been proven.¹⁵⁰ The European Commission ("EC") invoked the safe harbor provision outlined in Article 5.7 of the SPS Agreement, which states that "where relevant scientific evidence is insufficient, a Member [state] may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information."¹⁵¹

In 2006, the WTO determined that the European Union's de facto ban was illegal,¹⁵² concluding that the moratorium had caused an "undue delay" in the completion of EC GM approval procedures and that the safe harbor provision in Article 5.7 did not apply because there was "sufficient scientific evidence" for a risk assessment as required by the SPS Agreement.¹⁵³ In light of the WTO's holding, an attempt by the United States to expand the breadth of its regulations on GMOs based on non-scientific considerations would likely run into similar problems.¹⁵⁴

Critics argue that the WTO's sound science standards "move[] too far beyond nondiscrimination in trade" and pose "a serious threat to the democratic system of government of the WTO member states in the areas of health and environmental protection."¹⁵⁵ They believe that the United States has the right and the obligation, as a democratic and sovereign nation, to tailor its regulations according to public concerns and national values, rather than merely to empirical evidence.¹⁵⁶ Multiple scholars have proposed that the WTO allow import limitations as long as they are "based on national values, not protectionist tenden-

150. Winickoff et al., *supra* note 145, at 82–83; see Kysar, *supra* note 3, at 563–64 (citing Request for Consultations by the United States, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/1 (May 20, 2003)).

151. SPS Agreement art. 5.7; see Winickoff et al., *supra* note 145, at 83, 91.

152. Althouse, *supra* note 14, at 427; Federici, *supra* note 27, at 516; Marsden, *supra* note 103, at 197.

153. See Panel Report, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products*, ¶¶ 8.6, 8.9–8.10, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006).

154. Newell, *supra* note 14, at 489 ("Policies and measures that may be popularly desirable, such as labelling, comprehensive and precautionary forms of risk assessment, . . . restrictions on investment in domestic seed markets or even moratoriums on the trade in GMOs, are increasingly difficult to enforce on the basis that they are incompatible with global trade accords.")

155. See Winickoff et al., *supra* note 145, at 92–93 (citations and quotations omitted).

156. See Kysar, *supra* note 3, at 567–68 (asking whether "a ban on GM food [could] be considered similar to a ban on child pornography, justified not by empirical evidence regarding harmful consequences of its distribution but simply by the sovereign will of a nation's citizens"); Winickoff et al., *supra* note 145, at 84–85, 99.

cies.”¹⁵⁷ However, it may be too difficult to distinguish legitimately value-based actions from protectionism.¹⁵⁸

2. Cartagena Protocol on Biosafety

Another source of international governance over GMOs is the Cartagena Protocol on Biosafety (“CPB”).¹⁵⁹ The United States has neither signed nor ratified the Convention on Biological Diversity, the treaty which encompasses the CPB.¹⁶⁰ However, parties trading with non-parties must follow domestic regulations implemented in accordance with the CPB to stay compliant with the Convention on Biological Diversity.¹⁶¹

Unlike the SPS Agreement, the CPB explicitly endorses the “precautionary principle.”¹⁶² In effect, however, it permits the same kind of limited flexibility found in Article 5.7 of the SPS Agreement. First, the CPB provides that “[l]ack of scientific certainty due to insufficient relevant scientific information” shall not preclude a signatory from regulating the import of the GMO.¹⁶³ Second, the broader reach of the CPB only extends to consideration of GM crops’ effects on biosafety and biodiversity in the context of sustainability and conservation.¹⁶⁴ Attempts to raise issues, such as “whether . . . society needs biotechnology, as well as broader social, ethical, moral and religious issues,” have been found to be “off-limits.”¹⁶⁵

Despite their similarities, there is room for conflict between the CPB and the WTO regarding biotechnology.¹⁶⁶ The CPB is slightly more permissive towards international trade restrictions imposed on the basis of socioeconomic justifications. As such, some countries, including members of the European Union, have argued that the CPB

157. Althouse, *supra* note 14, at 427; see Winickoff et al., *supra* note 145, at 85 (“WTO judges charged with interpreting the SPS Agreement should use anti-protectionism as their guiding norm, rather than fall back upon a singular conception of scientific sufficiency.”).

158. Althouse, *supra* note 14, at 427.

159. Cartagena Protocol on Biosafety to the Convention on Biodiversity, Jan. 29, 2000, 39 I.L.M. 1027; Gonzalez, *supra* note 91, at 611.

160. See *Parties to the Protocol and Signature and Ratification of the Supplementary Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://bch.cbd.int/protocol/parties> (last updated Sept. 10, 2012); *United States Country Profile*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://bch.cbd.int/about/countryprofile.shtml?country=us> (last visited Dec. 22, 2012).

161. *Fact Sheet: Cartagena Protocol on Biosafety*, USDA (July 21, 2003), <http://www.fas.usda.gov/info/factsheets/biosafety.asp>.

162. Gonzalez, *supra* note 91, at 613.

163. Cartagena Protocol on Biosafety, *supra* note 159, pmbl., arts. 10.6, 11.8.

164. Gonzalez, *supra* note 91, at 614 (citing Cartagena Protocol on Biosafety, *supra* note 159, art. 26).

165. Newell, *supra* note 14, at 487.

166. José B. Falck-Zepeda, *Socio-economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What Are the Issues and What Is at Stake?*, 12 *AGBIOFORUM* 90, 103–04 (2009), available at <http://agbioforum.org/v12n1/v12n1a09-falckzepeda.pdf>.

should take precedence where the treaties conflict.¹⁶⁷ The United States and other GMO exporters, however, point out that the CPB's preamble indicates that socioeconomic considerations must be consistent with obligations arising from other international agreements.¹⁶⁸ It is not yet clear how these issues will be resolved.

B. Integrating Non-scientific Factors into GMO Regulation Could Adulterate Scientific Determinations in the Pursuit of "Political Correctness"

The government could end up sacrificing truth for legitimacy in an attempt to win public trust. Throughout the development of the debate over GMOs in the United States, the government has painted fears of genetic engineering as irrational, emotionally tainted, and potentially dangerous.¹⁶⁹ In 1993, David Kessler, the Commissioner of the FDA, speculated that "public distrust of GMOs was based on [the public's] envisioning a sci-fi landscape, such as from the movie 'Attack of the Killer Tomatoes,' where mutated tomatoes roll through the streets on a murderous rampage."¹⁷⁰

Given the potential for media sensationalism, concerns that increasing the public's influence on GMO regulation would hinder the commercialization of beneficial products are not unfounded. Empirical evidence suggests that perceptions of risk are socially amplified by the media,¹⁷¹ and even critics of the current regime recognize "issues of [scientific] literacy."¹⁷² Skepticism of the public's ability to accurately assess the risk of GMOs partially explains why the FDA resists mandatory labeling of GM crops.¹⁷³

167. See Fuzhi Cheng, *Biosafety, Trade, and the Cartagena Protocol: The Role of Government in the Global Food System*, in *FOOD POLICY FOR DEVELOPING COUNTRIES: CASE STUDIES*, # 9-6, 6-7 (eds. Per Pinstrup-Andersen & Fuzhi Cheng, 2007), available at <http://cip.cornell.edu/dns.gfs/1200428198>.

168. Falck-Zepeda, *supra* note 166, at 103.

169. See Frewer et al., *Societal Aspects*, *supra* note 25, at 1183 ("Public perceptions of risk have often been dismissed on the basis of 'irrationality,' and have tended to be excluded from policy processes by risk assessors and managers.")

170. Rich, *supra* note 41, at 900; see also Kysar, *supra* note 3, at 564 ("In the words of U.S. Trade Representative Robert B. Zoellick, the United States believes that European caution with respect to GM agriculture is 'Luddite' and 'immoral,' reflecting not only a failure to respect the findings of science but also a failure to appreciate the powerful potential of genetic engineering to boost world food production.")

171. Frewer et al., *Social Amplification of Risk*, *supra* note 136, at 708 (finding that "perceptions of risk . . . associated with genetically modified food increased during the highest levels of reporting about genetically modified foods, but were subsequently reduced as reporting levels diminished")

172. de Melo-Martin & Meghani, *supra* note 85, at 305.

173. See *supra* Part II.C (describing the FDA's original position that negative labeling of non-GMOs is inherently misleading because it implies that GMO crops are scientifically inferior to conventional crops).

Despite some legitimate concerns about mob mentality and irrationality, however, Part II clarified that many socioeconomic and ethical concerns are legitimate. The ease with which the government has adopted the product-versus-process distinction and trivialized a plethora of socioeconomic externalities is just as disturbing as the potential for consumer irrationality.¹⁷⁴ Moreover, there is no inherent reason why scientific and non-scientific risk assessments cannot be adequately separated to prevent the adulteration of scientific data in the overall regulatory scheme.

C. The Opportunity Cost of Integration: The Potential for Depriving Farmers, Consumers, and Biotech Companies of GM Technology

Incorporation of non-scientific concerns could chill the incentives of biotech companies to invest in agricultural innovation. It is not hard to imagine how regulations promoting coexistence, requiring labeling, or curbing patent suits could greatly increase the cost of monitoring, marketing, and segregating biotech products.¹⁷⁵ For example, adding an “intent” requirement to prove patent infringement of GMOs would make it harder for biotech companies to win lawsuits against farmers, decreasing returns on investments¹⁷⁶ and increasing business uncertainty about the success of GM products.¹⁷⁷ Increased costs could have an anticompetitive effect by creating a significant barrier to market entry for smaller companies.¹⁷⁸

However, if we agree as a society to consider socioeconomic and ethical factors in the regulation of GMOs, and the undesirability of certain GM crops to society is borne out by informed and holistic regulation, then decreasing incentives to produce these technologies is precisely the point. Moreover, such regulation would provide incentives to develop technology that promotes coexistence and creates a net social benefit.

Another argument against incorporating non-scientific factors is that farmers with a choice between growing GM and non-GM crops have rapidly adopted GM technology. Many farmers choosing to grow GM crops cite “the potential for higher yields, fewer chemicals,

174. See Kysar, *supra* note 11, at 587, 620.

175. See Sarah Hartley & Grace Skogstad, *Regulating Genetically Modified Crops and Foods in Canada and the United Kingdom: Democratizing Risk Regulation*, 48 CAN. PUB. ADMIN. 305, 311 (2005) (describing the conclusions of a report issued by the Standing Committee on Agriculture and Agri-Food of the Canadian House of Commons showing the increased costs for producers and manufacturers that would result from labeling).

176. See Savich, *supra* note 101, at 116.

177. See Martin Qaim et al., *Economic and Social Considerations in the Adoption of Bt Crops*, in INTEGRATION OF INSECT-RESISTANT GENETICALLY MODIFIED CROPS WITHIN IPM PROGRAMS 329, 348 (Jörg Romeis et al. eds., 2008) (citation omitted).

178. *Id.*

and the fact that most markets accept the crops.”¹⁷⁹ If we assume that farmers are rational economic actors, farmers must be experiencing a net benefit from planting GM crops.¹⁸⁰

Several studies have shown that GM crops reduce pesticide use,¹⁸¹ resulting in net savings for farmers even after considering the technology fee for the seeds.¹⁸² An analysis of forty-nine peer-reviewed publications covering twelve countries, including the United States, revealed that “with few exceptions, . . . GM crops have benefitted farmers [economically] . . . especially in terms of increased yields.”¹⁸³ An older study showed that in 2001, GM crops increased yields in the United States by four billion pounds and saved farmers \$1.2 billion in production costs, resulting in a total net savings of \$1.5 billion.¹⁸⁴ Numbers like these worldwide translate into tens of billions of dollars.¹⁸⁵ A study that attempted to measure the cost of delaying the planting of transgenic crops “found that a two-year delay in the approval of *Bt* cotton in India led to aggregated losses to farmers of over \$100 million.”¹⁸⁶

The fact that GM crops may provide economic benefits to farmers, however, does not resolve all of the issues at stake in GM regulation. First, consumers and farmers may have different attitudes towards GMOs, particularly because the genetic modifications prevalent in the market are traits that are intended primarily to benefit growers rather than consumers.¹⁸⁷ In fact, the evidence shows that many consumers are skeptical of the purported benefits of biotechnology.¹⁸⁸ Second, using rapid adoption of the technology as a gauge for the merits of GM crops ignores the effects of biotechnology on farmers electing *not* to grow GM crops. As explained in Part II, GM crops are contaminating conventional crops through pollen drift or commingling with increasing frequency at great social and economic cost.

179. Denton, *supra* note 35, at 342; *see also* Faure & Wibisana, *supra* note 49, at 2 (“Authors have also argued that the rapid adoption of genetically modified (GM) crops occurs because farmers gain remarkable economic benefits from adopting GM crops, including the reduction of chemical sprays, yields improvement, increased yields, labor savings, and the shifts to a system that requires less tillage.”).

180. Qaim, *supra* note 177, at 330 (“Farmers only adopt new crop technologies when they can realize personal benefits in terms of productivity gains or other advantages.”).

181. *Id.* (“[T]here are numerous studies showing that *Bt* crops allow sizeable insecticide savings and reductions in pest-related crop losses.” (citations omitted)).

182. *Id.* at 335.

183. Janet E. Carpenter, *Peer-Reviewed Surveys Indicate Positive Impact of Commercialized GM Crops*, 28 NATURE BIOTECHNOLOGY 319, 319 (2010).

184. Mandel, *supra* note 9, at 2181.

185. *Id.* at 2182.

186. Qaim, *supra* note 177, at 348.

187. *See* Denton, *supra* note 35, at 343 (“Currently, over ninety-nine percent of the GM crops on the market produce their own pesticides, or are engineered to be immune to herbicides.”). For studies showing greater consumer acceptance of GMOs that are designed to benefit consumers directly, *see* Costa-Font et al., *supra* note 128, at 100.

188. *See supra* Part II.

While the opportunity costs of stronger regulation weigh against incorporating non-scientific factors into GM regulation, the expanded regulatory process proposed in this Note would add new factors for consideration to the existing regulatory scheme, not replace the old considerations.

V. CONCLUSION

The planting of GM crops has skyrocketed since 1996 in response to a favorable U.S. regulatory framework, rapid farmer adoption of the technology, and scientific consensus that GM crops do not pose unique health and safety risks. This Note addresses a number of socio-economic and ethical externalities unique to GMOs that have, nonetheless, been lost in the official portrayal of GM crops. Consideration of these externalities would increase transparency and foster public trust in regulatory decisionmaking. The hope is that moving forward, policymakers will realize that non-scientific issues surrounding GMOs warrant regulatory attention, even if this means simply weighing the pros and cons of incorporating non-scientific factors into the regulatory process. As the current regulatory scheme stands, legitimate concerns that affect all stakeholders have little effect on decisions to commercialize GMOs.