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The Role of Non-Profit Organizations in Shaping Food Law and Corporate Responsibility in the United States

Melissa M. Card*

INTRODUCTION

Disputes between Europe and the United States over real and perceived concerns about food safety demonstrate different perspectives on corporate responsibility and different institutional processes for settling those differences.¹ For example, in the United States, a bill concerning genetically engineered labeling was sponsored and drafted by the Senate Agriculture Committee focusing on industry needs.² However, Europe adopted a labeling approach for genetically engineered products based on input from various non-profit organizations focusing on consumers' concerns.³

Non-governmental organizations ("NGOs") are assumed to be counterweight to capitalism and globalization.⁴ NGOs promote what they perceive to be more ethical and socially

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1. *Compare* *Liebeck v. McDonald's Restaurants, P.T.S., Inc.*, No. CV-93-02419, 1995 WL 360309, at *1 (N.M. Dist. Aug. 18, 1994), *vacated sub nom. Liebeck v. Restaurants* (N.M. Dist. Nov. 28, 1994) (exemplifying the litigious society of the United States, in which consumers hold corporations responsible), *with* DAVID VOGEL, *THE MARKET FOR VIRTUE: THE POTENTIAL AND LIMITS OF CORPORATE SOCIAL RESPONSIBILITY* 8 (2006) (declaring that interest in Corporate Social Responsibility exists on the European continent).

2. Agricultural Marketing Act of 1946 § 202, 7 U.S.C.A. § 1621 (1946).

3. Commission Regulation 1829/2003, 2003 O.J. (L 268) 24 (EU).

4. *See* Jonathan P. Doh & Terrence R. Guay, *Corporate Social Responsibility, Public Policy, and NGO Activism in Europe and the United States: An Institutional-Stakeholder Perspective*, 43 *J. OF MANAGEMENT STUDIES* 47, 47, 51 (2006) (stating that others suggest that NGOS may cause risks of 'privatizing' public policies that deal with environmental, labor, and social issues, thereby leading to a loss in democratic accountability).

responsible business practices.⁵ In addition, NGOs create and institutionalize new norms in society. With the use of social media and dynamic documentaries, non-profit organizations are able to successfully network and influence public opinion about various food safety topics.⁶ But is it advantageous for the United States to adopt an institutional process similar to Europe's, where non-profit organizations provide input on food law and corporate responsibility?

This article will assess whether the United States should adopt an institutional process similar to Europe's by giving non-profit organizations a role in shaping food law and corporate responsibility. Part I provides a comparative analysis of genetically engineered product regulations in the United States and European Union (EU). Part II explains how the institutional processes of the United States and Europe led to the varying regulations, and demonstrates that the United States institutional structure is too different from Europe's to allow NGO's to have a role in shaping food law and corporate responsibility. Finally, Part III asserts that the United States should change its institutional process by allowing public universities and private colleges to influence food law and corporate responsibility. This article concludes that public universities and private colleges afford collaboration from a diverse group of individuals who are likely to have both the industry's needs and consumers' concerns in mind.

I. The Comparative Analysis of the Institutional Processes of the United States and Europe Through the Regulation of Genetically Modified Foods

Genetically engineered ("GE"), more commonly genetically modified, refers to the genetic modification through the use of recombinant deoxyribonucleic acid ("rDNA") techniques to express desired traits.⁷ The food industry often

5. *E.g.*, Cristina Brandão, et al., *Social Responsibility: A New Paradigm of Hospital Governance?*, 21 HEALTH CARE ANAL., 390, 391 (2013) (explaining that a number of organizations embrace a socially responsible conduct, meaning that citizens, and investors, are deeply aware that profit and ethical values are not incompatible).

6. *E.g.*, WHAT THE HEALTH (Vimeo 2017).

7. NEAL D. FORTIN, FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE 277 (Wiley ed., 2d ed. 2017) (asserting that genetically modified, or more precisely genetically engineered, indicates that humans have directly engineered the DNA). *Cf. id.*

creates genetically modified organisms and genetically modified plants to produce a target trait of a nonrelated species.⁸ For example, Calgene, Inc. modified its FLAVR SAVR™ tomatoes to contain lower levels of a naturally occurring enzyme, resulting in ripe fruit remaining firm for an extended period of time and allowing fresh market tomatoes to remain on the vine longer for enhanced flavor.⁹ While the technology concerning GE foods is identical, GE food regulations in the U.S. and EU vary considerably.¹⁰ The United States focuses on the end product, and the EU focuses on the process.¹¹ This section delves into the regulatory and labeling requirements for GE foods in the U.S. and the EU.

(defining conventional plant breeding to mean all breeding methods other than by rDNA techniques). See generally Rachele B. Bailey, *A Tale of Two Systems: A Comparison Between U.S. and Eu Labeling Policies of Genetically Modified Foods*, 15 SAN JOAQUIN AGRIC. L. REV. 193, 197 (2006) (stating that genetically modified organisms have been altered in a way that would not occur naturally, allowing selected genes to be transferred between non-related species).

8. See Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775, 777 (2008) (considering the implications of the precautionary principle, the role of multilateral environmental agreements, the ability of nations to apply safeguard measures, and ultimately the appropriateness of the WTO as a body for determining environmental and food policy). As it relates to food, genetically modified organisms and genetically modified plants are created when the genes of one organism are inserted into the DNA of another organism to produce the target trait in that nonrelated species. *Id.*

9. Agency Summary Memorandum Re: Consultation with Calgene, Inc., Concerning FLAVR SAVR™ Tomatoes, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/IngredientsPackagingLabeling/GEPlants/Submissions/ucm225043.htm#out2> (last updated Oct. 13, 2015). When developing the FLAVR SAVR™ tomatoes, Calgene, Inc., a Californian company, used rDNA techniques to introduce an antisense polygalacturonase (PG) gene. *Id.* The PG gene is ordinarily present in tomatoes. *Id.* The PG gene encodes the enzyme PG, which is associated with the breakdown of pectin. *Id.* The principle underlying the FLAVR SAVR™ tomato was that the antisense PG gene suppresses the production of the PG enzyme. *Id.*

10. See Katharine Gostek, *Genetically Modified Organisms: How the United States' and the European Union's Regulations Affect the Economy*, 24 MICH. ST. INT'L. L. REV. 761, 761-63 (2016) (explaining that the changes to the EU's regulations will not benefit the EU's economy, but changes in U.S. regulations may benefit the U.S. economy); see also FORTIN, *supra* note 7, at 486 (asserting that genetically modified organisms and food derived from genetically engineered organisms have been a contentious matter in international trade).

11. Jessica Lau, *Same Science, Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe*, HARVARD UNIVERSITY: THE GRADUATE SCHOOL OF ARTS AND SCIENCES: SCIENCE IN THE NEWS (Aug. 9, 2015), <http://sitn.hms.harvard.edu/flash/2015/same-science-different-policies/>.

A. GE Food Regulations and Labeling Requirements in United States

Various federal agencies, such as U.S. Food and Drug Administration (“FDA”), the U.S. Environmental Protection Agency (“EPA”), and the U.S. Department of Agriculture (“USDA”), share regulatory oversight of GE products.¹² While various federal agencies have regulatory oversight over GE foods, the FDA ensures that the nation’s foods, including products that have been genetically modified, are safe for consumption.¹³ FDA asserts that conventional foods and GE foods pose the same risks; they can potentially contain allergens, toxins, or anti-nutrients.¹⁴ Due to this assertion, GE foods are regulated in the same manner as conventional foods based on the doctrine of substantial equivalence.¹⁵ In accordance with this doctrine, any GE crop varieties produced using rDNA techniques are considered to be essentially the same as the conventional varieties produced using traditional breeding methods.¹⁶ GE foods are considered to be the same as the conventional varieties because the substances expected to become components of food—as a result of genetic modification of a plant—will be the same as, or substantially similar to, substances commonly found in foods, such as proteins, fats and

12. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302-03 (Jun. 26, 1986) (noting the relevant agencies and their functions in the administration of the Coordinated Framework). The Animal and Plant Health Inspection Service determines whether a genetically modified plant has the potential to harm natural habitats or agriculture. *Id.* The EPA regulates specific genetic modifications that protect plants from insects, bacteria, and viruses, including plants that have been genetically modified to contain a pesticide trait. *See id.* The USDA, along with the APHI, oversees the release of certain categories of plants and the field testing of Genetically Engineered crops. *Id.*

13. *See Statement of FDA Mission*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm298331.pdf> (last visited Sept. 6, 2017). (“FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply cosmetics, and products that emit radiation.”).

14. *See FORTIN*, *supra* note 7, at 279. Anti-nutrients are natural or synthetic compounds that interfere with the absorption of nutrients. *Statement of Policy - Foods Derived from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm> (last updated May 2, 2016) [hereinafter *Statement of Policy*].

15. Maria R. Lee-Muramoto, *Reforming the “Uncoordinated” Framework for Regulation of Biotechnology*, 17 DRAKE J. AGRIC. L. 311, 338 (2012).

16. *Id.*

oils, and carbohydrates.¹⁷ Thus, if the conventional food's traits are considered safe, then a GE food's traits—that are substantially equivalent—would also be considered safe. For example, the FDA stated that the genetic modifications for the FLAVR SAVR™ tomato resulted in nutritional characteristics that were within the range of existing tomatoes; therefore, the FLAVR SAVR™ tomatoes were substantially equivalent to existing tomatoes.¹⁸ Based on federal regulations, conventional foods do not ordinarily require premarket approval.¹⁹ Therefore, the FDA is not required to conduct any independent safety, allergen, or other tests, to differentiate GE foods from their conventional counterparts.²⁰

While GE food products are ordinarily exempt from premarket review and approval, there are instances in which food manufacturers are subject to premarket requirements. If a GE food is not substantially equivalent to the conventional food, then the FDA would require premarket review and approval.²¹ When GE foods require premarket review and approval, the products are treated as a food additive and must go through a food additive review.²² Additionally, the FDA recommends that

17. *Statement of Policy*, *supra* note 14.

18. See Jennifer A. Thelen, *FDA Regulation of Food and Drug Biotechnology*, LEDA AT HARVARD LAW SCHOOL, <https://dash.harvard.edu/bitstream/handle/1/8846761/jthelen.html?sequence=1> (last visited Sept. 6, 2017) (stating that the FDA concluded that FLAVR SAVR™ tomatoes had not been significantly altered when compared to varieties of tomatoes with a history of safe use).

19. *Cf.* 21 U.S.C. 348 (inferring that premarket approval is required for food additives, unless an exemption from the regulations concerning food additives applies).

20. Lee-Muramoto, *supra* note 15, at 338 (2012) (declaring that the FDA does not conduct independent safety or allergen testing, unless the GE food product contains an allergen that people would not generally expect in that particular food).

21. See FORTIN, *supra* note 7, at 283 (stating that if a GE-derived food is significantly different in function or structure, then it is treated as a food additive). To be different from conventional foods, a food must be different from conventional foods in a meaningful way or present any different or greater safety concerns than conventional foods. *Statement of Policy*, *supra* note 14. For example, if a food was genetically engineered to include allergens that the conventional food did not have, then the FDA would not find that the GE food was substantially equivalent to the conventional food. See Lee-Muramoto, *supra* note 15, at 338.

22. FORTIN, *supra* note 7, at 283. Any food additives intended to have a technical effect in food is deemed unsafe unless it either conforms to the terms of a regulation prescribing its use or to an exemption for investigational use. *Guidance for Industry: Questions and Answers About the Petition Process*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm253328.htm#answerA> (last updated July 1, 2016). A petition for a food additive is

food manufacturers communicate with the FDA even if the differences between the GE food and the conventional food are not significant.²³

In the United States, labeling of GE products is shared between various federal agencies.²⁴ Under the Food, Drug, and Cosmetic Act there is no labeling mandate for foods that are genetically modified.²⁵ The FDA stated that “labels would erroneously imply that genetically modified foods differ from conventional foods and that conventional foods are in some way superior.”²⁶ However, if the composition of a GE food differs significantly from its conventional counterpart, that information would require labeling.²⁷ This stems from the misbranding

submitted to request issuance of a regulation allowing new uses of the additive and must contain the necessary supporting data and information. *Id.*

23. *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm> (last updated July 1, 2016) [hereinafter *Guidance for Industry: Voluntary Labeling*].

24. See FORTIN, *supra* note 7, at 293 (stating that the three primary agencies that are involved with regulating GMO safety, are also involved the labeling).

25. The Food, Drug and Cosmetic Act (“Act”) requires labeling because (1) the labeling is expressly required by the Act, or (2) the information is “material”, as used in the Act, and the absence of the information is considered misleading under section 201(n) of the Act. *Id.* On July 29, 2016, President Obama signed the National Bioengineered Food Disclosure Standard into law which, in part, directs USDA to establish a national standard to disclose certain food products or ingredients that are bioengineered. See generally 7 U.S.C.A. § 1639b (West). As a result of the National Bioengineered Food Disclosure Standard, the regulations issued by the USDA will establish labeling of human food derived from biotechnology. See *id.*

26. MARION NESTLE, *SAFE FOOD: THE POLITICS OF FOOD SAFETY* 145-50, 222 (Darra Goldstein ed., 2010) (discussing the alleged benefits of genetically engineered foods).

27. 21 U.S.C. 321(n) (proving that labeling is misleading if, among other things, 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 under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual). The term “material” is actually not defined in the Food, Drug, and Cosmetic Act. Historically, the agency has interpreted the term, within the context of food, to mean information about the attributes of the food itself. *Guidance for Industry: Voluntary Labeling, supra* note 23. For example, FDA has required special labeling in cases where the absence of such “material” information may: (1) pose special health risks; (2) mislead the consumer in light of other statements made on the labeling; 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. *Id.* The FDA does not consider the methods to create GE food to be “material” within the meaning of “misleading” in section 201(n) as used in the Food, Drug, and Cosmetic Act. *Id.*

provision of the Food, Drug, and Cosmetic Act.²⁸ While labeling is generally not required by the Food, Drug, and Cosmetic Act, manufacturers may voluntarily label their GE food products, provided that such labeling is truthful and not misleading.²⁹

In conclusion, the United States determines the safety of a GE food product based on its composition, not the method or process by which it was produced.³⁰ Based on this determination, most GE foods are not subject to premarket review or approval.³¹ In addition, the Food, Drug, and Cosmetic Act does not require a specific labeling scheme if a food has been genetically engineered.³²

B. EU's Regulatory Requirements Concerning GE Foods and Labeling Requirements

Since 2003, the precautionary principle has governed the EU's approach to GE foods.³³ The precautionary principle is risk-adverse; because potential risks of GE foods are not completely known, regulatory decisions require a high burden of proof for product safety.³⁴ Therefore, in the EU, all GE food products go through a premarket approval process.³⁵ Companies of GE food products submit applications for approval to an EU member state; the centralized European Food Safety Authority

28. 21 U.S.C. § 343(a)(1) (stating that a food is misbranded if its labeling is false or misleading in any particular).

29. *Labeling of Foods Derived from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/ingredientspackaginglabeling/geplants/ucm346858.htm> (Jan. 1, 2017). In general, an accurate statement about whether a food was not produced using bioengineering is one that provides information in a context that clearly refers to bioengineering technology. Examples of such statements include: "not bioengineered" or "not genetically modified through the use of modern biotechnology." *Id.*

30. *See* Lee-Muramoto, *supra* note 15, at 338.

31. *Id.* at 334.

32. *Id.*

33. *See* Gostek, *supra* note 10, at 773.

34. Lau, *supra* note 11. Precautionary principle refers to preventing not only known environmental harms and health risks but also to prevent conduct that may be harmful although scientific evidence is unavailable to prove actual harm. *See* FORTIN, *supra* note 7, at 489 (arguing that precautionary principle creates confusion because there is no standard definition, and any uncertainty on safety requires prohibition of a potentially harmful or risky activity until it is proven to be safe).

35. *See* Lau, *supra* note 11 (asserting that all GE foods are regulated because they are made with processes different from those used to produce conventional foods).

(“EFSA”) then conducts scientific risk assessments.³⁶ After the EFSA’s acceptance of safety, the recommendation is forwarded to the European Commission.³⁷ The European Commission Directorate General for Health and Consumer Protection drafts proposals based on the EFSA’s risk assessment; however, it can reject or base its proposal on other considerations beyond the risk assessment.³⁸ A regulatory committee comprised of representatives of member states’ authorities then decides whether to accept the proposal through a weighted voting system.³⁹ If there is disagreement amongst the member states committee failing to reach a majority decision, then the European Commission makes the final decision for approval.⁴⁰

Following the approval, EU regulations mandate that manufacturers inform consumers that products are genetically modified through labeling.⁴¹ Specifically, a product containing more than 0.9% GE material must be labeled as being GE foods.⁴² Under EU regulation, if a food consists of more than one ingredient, the phrases “genetically modified” or “produced from genetically modified (name of the ingredient)” must appear

36. See Sci. Commun. of the Eur. Comm’n, *Risk Assessment*, HEALTH AND FOOD SAFETY: SCIENTIFIC COMMITTEES, available at http://ec.europa.eu/assets/sante/health/scientific_committees/risk_assessment/index_en.htm (last visited Sept. 6, 2017) (stating that the Scientific Committees assess the potential risks before making a legislative proposal, namely the probability and the severity of an adverse effect, in relation to the hazards and to the exposure) [hereinafter *European Risk Assessment*]. Margaret Rosso Grossman, *Traceability and Labeling of Genetically Modified Crops, Food, and Feed in the European Union*, 1 J. FOOD L. & POL’Y 43, 85 (2005) (inferring that even though the EFSA conducts risks assessment for GE food products, EFSA has no authority to approve a product even if the product has been found completely safe). EFSA is an independent European agency funded by the European Union set up in 2002 following a series of food crises in the late 1990s which is responsible for risk assessment for food safety. See *About EFSA*, EFSA: EUROPEAN FOOD SAFETY AUTHORITY, <https://www.efsa.europa.eu/en/aboutefsa> (last visited September 4, 2017).

37. See Lau, *supra* note 11.

38. See *European Risk Assessment*, *supra* note 36 (stating that the European Commission makes a legislative proposal based on the risk assessment, and all other relevant aspects). For example, the European Commission may authorize a substance, prohibit a substance, or define exposure limits for a substance. *Id.*

39. See Lau, *supra* note 11.

40. See *id.*

41. Commission Regulation 1829/2003, 2003 O.J. (L 268) 13 (EC).

42. *Id.* (“This Section shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.”).

in the list of ingredients in parentheses immediately following the applicable ingredient.⁴³ If the ingredients are designated categorically, the phrase “contains genetically modified (name of organism)” or “contains (name of ingredient) produced from genetically modified (name of organism)” must appear in the list of ingredients.⁴⁴ Lastly, if no ingredient list is present, then the phrase “genetically modified” or “produced from genetically modified (name of organism)” must be conspicuously on the labeling.⁴⁵

In conclusion, the EU’s regulations concerning genetically modified foods are among the strictest in the world.⁴⁶ The EU focuses on the method or process of creation when determining the safety of a GE food, and not on the final composition. Due to this determination, all GE foods are subject to premarket review or approval.⁴⁷ In addition, all GE foods that meet a specific threshold are required to meet a specific labeling scheme, disclosing that a food has been genetically engineered.⁴⁸

II. The Institutional Structures of the United States Differs From Europe’s, Which Affects the Role That NGOs Have in Shaping Food Regulations and Corporate Responsibility

The regulations of GE foods are different in the United States and the EU, however, both sides claim that their regulations were created to address public health and environmental safety issues.⁴⁹ Because the purpose behind the

43. *Id.* (indicating that this information may appear in a footnote to the list of ingredients, but must be printed in a font of at least the same size as the list of ingredients). If there is no list of ingredients, then the information shall appear clearly on the labeling. *Id.*

44. *Id.* (indicating that this information may appear in a footnote to the list of ingredients, but must be printed in a font of at least the same size as the list of ingredients). If there is no list of ingredients, then the information shall appear clearly on the labeling. *Id.*

45. *Id.*

46. See *Restrictions on Genetically Modified Organisms: European Union*, LIBR. OF CONG., <https://www.loc.gov/law/help/restrictions-on-gmos/eu.php> (last visited September 4, 2017).

47. *Fact Sheet: Questions and Answers on EU’s Policies on GMOs*, EUROPEAN COMM’N PRESS RELEASE DATABASE (Apr. 22, 2015), http://europa.eu/rapid/press-release_MEMO-15-4778_en.htm.

48. *Id.*

49. See Doh & Guay, *supra* note 4, at 59.

regulations is the same, assessing the institutional processes of the United States and Europe that led to the varying regulations is imperative. This section explains how scientific uncertainties and ethical concerns played out differently in the EU and the United States due to institutional and ideational reasons.⁵⁰ Additionally, this section demonstrates that the United States institutional structure is too different from Europe's to allow NGOs to have a role in shaping food law and corporate responsibility.

A. The Influences Leading to GE Regulations

The original EU regulations concerning GE products were very similar to the rules in the United States.⁵¹ However, food safety scares and the rise of anti-genetically engineered food protests in Europe sent the EU regulations concerning GE foods in a different direction.⁵² NGOs reinforced that the EU regulations should take a different direction.⁵³ Industry tried to counter the NGOs viewpoint and dissipate the food safety fears, but industry actions only strengthened the NGOs' position.⁵⁴ Europe adopted the precautionary principle based on input from various NGOs, which assumed the new genetic foods must be proven safe before introduction into the marketplace.⁵⁵ The

50. M.J. PETERSON, THE EU-US DISPUTE OVER REGULATION OF GENETICALLY MODIFIED ORGANISMS, PLANTS, FEEDS, AND FOODS – CASE SUMMARY, INTERNATIONAL DIMENSIONS OF ETHICS EDUCATION IN SCIENCE AND ENGINEERING CASE STUDY 4 (2010).

51. *Id.* at 6.

52. *Id.* (stating that the food safety scares included: (1) a fear that humans would contract "mad cow disease" from English beef, and (2) the discoveries of toxic materials in Belgian and French animal feedstocks).

53. See, e.g., *Restrictions on Genetically Modified Organisms: European Union*, *supra* note 46 (asserting that NGOs expressed the need to clarify even further that the 0.9% labeling threshold is not a tolerance level but applies only to the adventitious and technically unavoidable presence of GMOs).

54. See PAULETTE KURZER & ALICE COOPER, WHAT'S FOR DINNER? VARIATIONS IN EUROPEAN SUPPORT FOR GENETICALLY MODIFIED FOOD 3 (2005), <http://aei.pitt.edu/3092/1/EUSAKurzerCooper05.pdf> ("In countries with intensely hostile publics, the biotech industry, scientific experts, and government officials are outmaneuvered by anti-GMO voices, who reclaim the debate by introducing new concepts concerning the risks inherent in experimenting with technological innovations to the country's food production regime.").

55. See Lesley K. McAllister, *Judging Gmos: Judicial Application of the Precautionary Principle in Brazil*, 32 *ECOLOGY L.Q.* 149, 150 (2005) (stating that the precautionary principle embraces the idea that full scientific certainty should not be

EU's resistance regarding GE foods related to three environmental risks associated with biotechnology: (1) genetically engineered traits could harm non-target species; (2) cross-pollination could cause relatives of the cultivated crop to inherit the genetically modified trait; and (3) pests targeted by the genetic modification will evolve resistant.⁵⁶

While the EU's regulations were largely influenced by NGOs, the regulations in the United States were largely influenced by the food industry.⁵⁷ US firms developing agricultural applications of GE technologies formed an effective nationwide industry lobby.⁵⁸ The industry based lobbying group successfully influenced how GE products would be regulated.

In 1986, the Reagan administration set the basic parameters of the United States' policy in the Coordinated Framework for the Regulation of Biotechnology,⁵⁹ which ensured the development of biotechnology without burdensome regulations.⁶⁰ Then in 1989, the National Research Council ("NRC") published an influential report regarding the safety of GMOs,⁶¹ concluding that "the product of genetic modification

required before governments take preventative action against potentially serious environmental harms).

56. See, e.g., WORLD HEALTH ORGANIZATION (WHO), MODERN FOOD BIOTECHNOLOGY, HUMAN HEALTH AND DEVELOPMENT AN EVIDENCE-BASED STUDY iii (2005); see generally Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENV'T L. L.J. 297 (2002) (linking Bt corn to pest resistance).

57. PETERSON, *supra* note 50, at 5 (asserting that due to pressures from conservatives and business interests, the United States' regulatory approaches for genetically modified products rely heavily quantifiable estimates of potential harms and benefits used to make cost-benefit analyses).

58. *Id.* at 11 (comparing the United States industry lobbying techniques with European firms; Europe failed to form industry lobbies, particularly at the EU-wide level).

59. See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302-03 (Jun. 26, 1986) (explaining that the Coordinated Framework for the Regulation of Biotechnology encouraged the approach under which the federal agencies in the United States treated genetic modification the same as other forms of breeding).

60. See Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C.L. REV. 733, 738 (2003) (reviewing the development and implementation of the regulatory framework of GE products through FDA, USDA, and EPA).

61. See Gostek, *supra* note 10, at 767. The purpose of the National Research Council is to help improve public policy, understanding, and education in matters of science, technology, and health. See THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, MEDICINE, ARTICLES OF ORGANIZATION OF THE NATIONAL RESEARCH COUNCIL, https://web.archive.org/web/20160519172226/http://www.nationalacademies.org/nrc/na_0

and selection should be the primary focus for making decisions . . . not the process by which the products were obtained.”⁶² In addition, NRC concluded that although information concerning “the process used to produce a genetically modified organism is important in understanding the characteristics of the product . . . the nature of the process is not a useful criterion for determining whether the product requires less or more oversight.”⁶³ Lastly, the NRC report concluded that “[t]he same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods.”⁶⁴ The NRC Report was a large step towards the acceptance of GE products.⁶⁵

In conclusion, regulations concerning GE foods, as well as GE food labeling, differ in the United States as compared to the EU.⁶⁶ The United States focuses on the end product, while the EU focuses on the process.⁶⁷ The varying regulations resulted from scientific uncertainties and ethical concerns playing out differently in the EU and the United States. In addition, the EU’s regulations were influenced by NGOs, and the regulations in the United States were influenced by industry interest groups.

B. Institutional Structures of the United States and Europe

EU NGOs’ influence on GE product regulations was successful; however, NGOs in the United States failed to influence GE regulations.⁶⁸ Due to the varying institutional

70358.html (last visited Sept. 7, 2017) (“The Council of the National Academy of Sciences, under the authority conferred upon the Academy by its charter enacted by Congress and approved by President Lincoln on March 3, 1863.”).

62. See NAT’L RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 14 (1989), <http://www.nap.edu/catalog/1431/field-testing-genetically-modified-organisms-framework-for-decisions>.

63. See *id.* at 14-15.

64. See *id.* at 15.

65. Strauss, *supra* note 8, at 779 (presenting that the US does not segregate from non-GE crops because, in stark contrast to the EU, U.S. law does not require labeling, segregating, or monitoring of these crops).

66. *Id.* at 779-81.

67. Lau, *supra* note 11.

68. See Doh & Guay, *supra* note 4, at 60-61 (asserting that NGOs in the United States had not succeeded in extending these adversarial relationships to biotechnology policy-making). The NGOs in the United States stated their failure to influence GE regulations stemmed from “a lack of news-grabbing biotechnology”, and failure to use the

structures, NGOs play a different role in shaping food law and corporate responsibility in the United States than in Europe.⁶⁹ Institutional variation between the United States and Europe emanates from differences in social, political, economic, historical, and geographic experiences.⁷⁰

The United States focuses on federal and sub-federal institutions.⁷¹ The focus on federalism and the separation of national powers stems from a historical experience, emphasizing a decentralized political structure.⁷² The resulting decentralized political system creates numerous access points for NGOs to influence the government.⁷³ However, NGOs have no formal standing in the public policy process.⁷⁴ Therefore, NGOs fail to successfully lobby in the United States.

While the United States is focused on federal and sub-federal institutions, Europe is focused on EU-wide and national institutions.⁷⁵ This institutional structure affords NGOs success when influencing regulation. In addition, interest groups have a formal place in the policy-making process.⁷⁶ For NGOs, the main access points to influence policy-making are the Commission and Parliament.⁷⁷ The Commission is the initial drafter of legislation and welcomes the opportunity to receive information from lobbyists.⁷⁸ Lastly, multiparty political systems exist in most EU member states, making it easier for

judicial system. *Id.* Note, that NGOs have gained some success in influencing GE labeling regulations. *See generally* 7 U.S.C.A. § 1639b (West).

69. *See id.* at 49 (explaining that the main institutions in Europe and the United States include political, legal, and social).

70. *See generally*, NEW DIMENSIONS IN THE HUMANITIES AND SOCIAL SCIENCES (Harry R. Garvin ed., Bucknell University Press 1977).

71. *See* Cristina Rodriguez, *Negotiating Conflict Through Federalism: Institutional and Popular Perspectives*, 123 YALE L.J., 2094, 2096 (2014) (emphasizing that having many institutions with lawmaking power enables overlapping political communities to work toward national integration, while preserving governing spaces for meaningful disagreement when consensus fractures or proves elusive).

72. *See id.* at 2099-3000.

73. *See* Doh & Guay, *supra* note 4, at 52 (2006) (stating that the access points that were created include the executive, legislative, and judicial branches at the national level, as well as comparable entities at the state and local levels).

74. GLOBALIZATION AND NGOS: TRANSFORMING BUSINESS, GOVERNMENT, AND SOCIETY 25 (Jonathan P. Doh & Hildy Teegan eds., 2003).

75. *See* Doh & Guay, *supra* note 4, at 49.

76. GLOBALIZATION AND NGOS, *supra* note 74, at 25.

77. *See* Doh & Guay, *supra* note 4, at 53.

78. *Id.*

NGOs to form political parties and win seats in the national legislature than do two-party systems, which exist in the USA and the UK.⁷⁹

Institutional variation between the United States and Europe stem from social, political, economic, historical, and geographic experiences.⁸⁰ EU NGOs' influence on food law was successful; however, NGOs' in the United States failed to influence food law. Due to the varying institutional structures, public universities and private colleges, rather than NGOs, should play a role in shaping food law and corporate responsibility in the United States.

III. The United States Should Allow Public Universities and Private Colleges to Shape Food Law and Corporate Responsibility

The United States' institutional structure is too different from Europe's; NGOs cannot successfully shape food law and corporate responsibility. However, some type of institution or organization must serve as the counterweight to capitalism and globalization in the United States. Without that counterweight, the food industry will lobby the governmental systems, producing monetary or other private benefits for industry, or influencing government legislation in ways that undercut any attempts to serve the broader public interests.⁸¹ In addition,

79. PETERSON, *supra* note 50, at 11 (stating that the multiparty political system contributes to higher level of environmental consciousness among European voters than the average US voters).

80. *See generally*, NEW DIMENSIONS IN THE HUMANITIES AND SOCIAL SCIENCES, *supra* note 70.

81. Craig Holmana & William Luneburg, *Lobbying and Transparency: A Comparative Analysis of Regulatory Reform*, 1 INTEREST GROUPS & ADVOCACY, 75, 78 (2012). The food industry lobbying for its own interests, and influencing consumers, is best demonstrated through the Dietary Supplement Health and Education Act (DSHEA). Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325, (codified as amended in scattered sections of 21 U.S.C. §§ 301-399 (2000)). DSHEA worked to prevent the federal government's interference with the supplement industry in four ways. *See generally* Melissa Card & John Abela, *Self-Prescribing a Legal Overdose or Duped into Deficiency? – Should Dietary Supplements Regulations Be Changed to Avoid Health Adversities?* IFIS: FOOD AND HEALTH INFORMATION, (forthcoming fall 2017). The first means was the expansion of the definition of a dietary supplement. Prior to DSHEA, dietary supplements were defined as vitamins and minerals. *Id.* DSHEA expanded the statutory definition to include herbal, botanical, and diet products. *Id.* The second means in which DSHEA prevented federal

NGOs create and institutionalize new norms in society promoting what they perceive to be more ethical and socially responsible business practices.⁸² The issue becomes which institution should serve as a counterweight to capitalism and globalization, and promote ethical and socially responsible business practices in food law? This section concludes that, in the United States, public universities and private colleges should shape food law and corporate responsibilities, rather than NGOs. This section argues that institutional structures in the United States include public universities and private colleges, therefore, public universities and private colleges should have a seat at the table when it comes to policy-making. Additionally, this section emphasizes that public universities and private colleges are the best places for collaboration amongst diverse perspectives to create solutions addressing industry needs, while also counteracting capitalism and globalization.

In part, NGOs are ineffective at influencing United States' law and corporate responsibility because there are too many access points, and NGOs have no formal standing in the public policy process.⁸³ However, universities and colleges have a direct access point to influence food law and corporate responsibility. University and college members comprise the Advisory Committees of the FDA.⁸⁴ The Advisory Committees provide advice to the FDA Commissioner on specific complex

intervention was that manufacturers did not need to prove that their product was safe prior to manufacturing them. *Id.* The third means in which DSHEA prevented federal intervention was that DSHEA grandfathered in the safety of supplements that were marketed in the United States prior to October 15, 1994. *Id.* The last means in which DSHEA prevented federal intervention was that DSHEA allowed supplement manufacturers to label their products with statements of nutritional support. *See also* MARION NESTLE, *FOOD POLITICS: HOW THE FOOD INFLUENCES NUTRITION AND HEALTH* (3rd ed. 2013).

82. *See Jay Aronson, Non-governmental Organizations Lecture*, CARNEGIE MELLON, (Sept. 28, 2017), <https://www.cs.cmu.edu/~iliano/courses/07F-CMU-CS502/lectures/TGD07-L16-NGO.pdf> (stating that the counterweight to the impersonal forces of governmental bureaucracy and globalization is non-governmental organizations).

83. *See Doh & Guay, supra* note 4, at 52.

84. *Roster of the Science Board to the Food and Drug Administration*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm115370.htm> (last updated June 29, 2017).

scientific and technical issues that are important to the FDA.⁸⁵ The Advisory Committees' advice influences the FDA's decisions on various regulations, and provides functions that support the FDA's mission of protecting and promoting public health.⁸⁶

In addition to having access to the FDA, universities and colleges are better suited to influence food law and corporate responsibility because universities and colleges afford collaboration from a diverse group of individuals who are well-educated, and have both industry's and consumers' perspectives in mind. In fact, universities and colleges can serve the FDA even better than current advisory committees because universities and colleges can assess the science, as well as the economic impact, policy considerations, social injustice concerns, and legal issues.⁸⁷ For example, genetic engineering would have benefitted from diverse viewpoints because GE foods require people to reimagine the relationship between science, politics, health, and society.⁸⁸ Therefore, universities contain the various disciplines that are necessary to reach a conclusion regarding science, politics, and society.

IV. Conclusion

Disputes between Europe and the United States over real and perceived concerns about food safety will continue due to different perspectives on corporate responsibility and different institutional processes for settling those differences. While NGOs are the counterweight to capitalism and globalization, the United States' institutional process does not allow for NGOs to have an influence on food law and corporate responsibility. In

85. *Science Board to the Food and Drug Administration*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/default.htm> (last updated May 2017). Additionally, the Science Board will provide advice that supports the FDA in keeping pace with technical and scientific developments, and it will provide expert review of Agency sponsored intramural and extramural scientific research programs. *Id.*

86. *Committees & Meeting Materials*, U.S. FOOD & DRUG ADMIN. <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm> (last updated May 2017).

87. *E.g., Food Law & Policy*, CENTER FOR HEALTH LAW & POLICY INNOVATION, <http://www.chlpi.org/food-law-and-policy/> (last visited Sept. 8, 2017).

88. KELLY CLANCY, *THE POLITICS OF GENETICALLY MODIFIED ORGANISMS IN THE UNITED STATES AND EUROPE* 4 (2016).

the United States, public universities and private colleges should shape food law and corporate responsibilities, rather than NGOs. The institutional structures in the United States include public universities and private colleges, therefore, public universities and private colleges have a seat at the table when it comes to policy-making. Additionally, public universities and private colleges are the best places for collaboration amongst diverse perspectives to create solutions addressing industry's needs, while also acting as a counterweight to capitalism and globalization.