

PLAYING POLITICS WITH FOOD: COMPARING LABELING REGULATIONS OF GENETICALLY ENGINEERED FOODS ACROSS THE NORTH ATLANTIC IN THE UNITED STATES AND EUROPEAN UNION

I. INTRODUCTION

When American families sit down for breakfast every morning, they are likely eating genetically engineered (“GE” or “GMO”) food.¹ The United States is the world’s largest producer of GE crops,² which are typically used as ingredients in processed foods.³ The average American diet consists of many processed foods,⁴ approximately 80% of which currently contains GE ingredients.⁵ Despite the saturated market, there is inconclusive knowledge about the effects of GE foods

¹ See FDA, *FDA’s Role in Regulating Safety of GE Foods*, U.S. FOOD & DRUG ADMIN. CONSUMER UPDATES, 2 (May 14, 2013), <http://www.fda.gov/forconsumers/consumerupdates/ucm352067.htm> (last updated Nov. 15, 2013) [hereinafter *FDA’s Role*]; FDA, *Questions & Answers on Food from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/food/foodscienceresearch/biotechnology/ucm346030.htm> (last updated Apr. 7, 2013) [hereinafter *Questions & Answers*]; see also Renee Sharp, *Americans Eat Their Weight in Genetically Engineered Food*, ENV’L WORKING GROUP (Oct. 15, 2012), <http://www.ewg.org/agmag/2012/10/americans-eat-their-weight-genetically-engineered-food>.

² See *Global Status of Commercialized Biotech/GM Crops: 2012*, INT’L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, <http://www.isaaa.org/resources/publications/briefs/44/executivesummary/> (last visited Dec. 19, 2013).

³ See *FDA’s Role*, *supra* note 1, at 2; *Questions & Answers*, *supra* note 1.

⁴ It is estimated that 75 to 80% of processed foods in supermarkets contain GE ingredients. Elisa Zied, *Calif. to vote on labeling GMO foods, but you may already eat them*, NBC NEWS (Nov. 2, 2013 7:05 AM), <http://www.nbcnews.com/health/calif-vote-labeling-gmo-foods-you-may-already-eat-them-1C6825713>.

⁵ *Id.*; *GMO Facts*, NON-GMO PROJECT, <http://www.nongmoproject.org/learn-more/> (last visited Dec. 30, 2013) (“In the U.S., GMOs are in as much as 80% of conventional processed food.”).

on human health.⁶ Currently, the United States does not require that GE plants or ingredients be labeled in food products.⁷ This has caused problems both domestically and internationally based on perceived risks that are exacerbated by the lack of uniform regulatory practices and a rise of non-scientific rhetoric.⁸

For over two decades based on the consumer's "right to know,"⁹ Americans have increasingly demanded labels that disclose GE ingredients in foods, and now dozens of states are experimenting with GE food labeling laws.¹⁰ Presently, two states—Connecticut and Maine—have passed but not yet enacted mandatory labeling laws.¹¹ Additionally, a federal bill requiring the United States Food and Drug Administration ("FDA") to mandate labeling has been introduced in both chambers of Congress.¹² Meanwhile, in the rest of the world, over sixty countries have some form of labeling regulations for GE foods.¹³ While the United States is the world's largest exporter of GE products, the lack of transparency regarding GE foods threatens its place in the global market.¹⁴

⁶ See generally *Questions & Answers*, *supra* note 1.

⁷ *FDA's Role*, *supra* note 1, at 2.

⁸ See Rick Blizzard, *Genetically Altered Foods: Hazard or Harmless?*, GALLUP (Aug. 12, 2003),

<http://www.gallup.com/poll/9034/genetically-altered-foods-hazard-harmless.aspx> (The American public is increasingly worried about GE foods as they are "a source of worldwide controversy."); see also Colleen Scherer, *Soybean Farmers Support Biotechnology In EU*, AG PROFESSIONAL (July 12, 2012).

⁹ See generally *Right to Know*, JUST LABEL IT!, <http://justlabelit.org/right-to-know/> (last visited Mar. 12, 2014).

¹⁰ Sixty-four countries, including all member nations of the EU, have mandatory GE food labeling policies. The U.S. is not included. *Federal Legislation Introduced To Require The Labeling Of Genetically Engineered Foods*, CTR FOR FOOD SAFETY (Apr. 24, 2013), <http://www.centerforfoodsafety.org/press-releases/2116/federal-legislation-introduced-to-require-the-labeling-of-genetically-engineered-foods> [hereinafter *Federal Legislation Introduced*] ("In the U.S. there is overwhelming public demand—consistently near 95%—for the labeling of GE foods.")

¹¹ See discussion *infra* Part IV.

¹² *Federal Legislation Introduced*, *supra* note 10 ("The Genetically Engineered Food Right-to-Know Act is the first federal GE labeling bill to be introduced in the Senate since 2000."); see also sources cited *infra* note 200, 201.

¹³ *Federal Legislation Introduced*, *supra* note 10.

¹⁴ See *infra* Part III; see also *Countries and Regions: United States*, EUROPA, <http://ec.europa.eu/trade/policy/countries-and-regions/countries/united-states/> (last updated Nov. 19, 2013) (stating that the EU-US trade relationship is the largest bilateral trade relationship).

This Comment will argue that GE food labeling requires federal action: a cohesive national policy is the best way to meet domestic consumer concerns and preserve international trade. The ideal federal solution would be the creation of a national policy through uniform mandatory labeling. This Comment reviews concerns regarding agricultural biotechnology such as GE plants and processed foods derived from GE plants. Part II provides an overview of the GE science and addresses some of the concerns with current studies. Part III compares the United States approach to regulating agricultural biotechnology with the European Union approach. Part IV discusses and analyzes GE food labeling initiatives in four states, specifically in California, Washington, Connecticut and Maine, and the proposed federal Right-To-Know Act. Part V recommends that Congress enact comprehensive, uniform, and risk-based food safety legislation and that the FDA consider commissioning a study of alternative organizational structures for food safety. Federal law would preempt the patchwork of state regulations, provide a consistent approach to informing consumers both within the United States and abroad of GE products and potential risks, and improve consumer awareness by clearly labeling foods that contain GE material.

II. OVERVIEW: CONTROVERSY AND UNCERTAINTY OVER THE POTENTIAL HEALTH IMPACTS OF GENETICALLY ENGINEERED FOODS

The increase in GE food and crop production over the past two decades has resulted in a corresponding increase in consumers' perception of risk.¹⁵ Genetic engineering refers to the process of changing the genetic material of a living organism to produce new characteristics.¹⁶ In the United States, strong coalitions of consumers are wary that GE foods contain new genes that are allergenic or otherwise harmful to human health.¹⁷ The current GE debate concerns GE plants and centers around food safety and consumer choice issues.¹⁸ To date, no GE animals have been approved for human

¹⁵ Blizzard, *supra* note 8.

¹⁶ See *FDA's Role*, *supra* note 1, at 1.

¹⁷ Blizzard, *supra* note 8; *Link or No Link? Controversy Simmers Over Allergies and Genetically Modified Food*, HARVEST PUB. MEDIA (Aug. 22, 2012), <http://harvestpublicmedia.org/article/1390/link-or-no-link-controversy-simmers-over-allergies-and-genetically-modified-food/5> [hereinafter *Link or No Link*].

¹⁸ *Link or No Link*, *supra* note 17.

consumption, although GE salmon is pending FDA approval.¹⁹ The FDA is the federal agency primarily responsible for regulating the safety of GE foods for human consumption.²⁰ The FDA exemplifies the benefits of genetic engineering plants to “enhance the nutritional value of the food crop.”²¹ Indeed, GE plants are promoted on claims that they provide benefits to consumers such as greater nutritional value²² and allow farmers to significantly increase their yields.²³ However, consumers are concerned with the potential human health consequences of GE foods given the currently inconclusive science and lack of long-term studies.²⁴ Despite these consumer concerns, safety testing on GE foods is only voluntary according to the FDA as long as the final GE food product is “substantially equivalent” to its traditional counterpart.²⁵

The most common food safety concern is that GE food production can lead to human health issues.²⁶ Supporters of this theory cite the

¹⁹ As of October 2013, the first GE animal—GE salmon—is still awaiting likely FDA approval. Jon Swaine, *'Frankenfish' coming to a supermarket near you as campaigners warn against GM salmon*, DAILY TELEGRAPH (Oct. 22, 2013 8:00 AM), <http://www.telegraph.co.uk/earth/agriculture/geneticmodification/10391080/Frankenfish-coming-to-a-supermarket-near-you-as-campaigners-warn-against-GM-salmon.html>.

²⁰ See *FDA's Role*, *supra* note 1, at 2.

²¹ *Id.*

²² *Id.* at 1-2.

²³ According to the USDA, “[b]iotechnology provides farmers with tools that can make production cheaper and more manageable.” *Biotechnology Frequently Asked Questions*, USDA., <http://www.usda.gov/wps/portal/usda/usdahome?navid=AGRICULTURE&contentid=BiotechnologyFAQs.xml> (last updated Dec. 30, 2013).

²⁴ *Link or No Link*, *supra* note 17.

²⁵ Safety here refers specifically to health and not environmental concerns. See generally FDA, STATEMENT OF POLICY: FOODS DERIVED FROM NEW PLANT VARIETIES, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992) [hereinafter POLICY: NEW PLANT VARIETIES] (discussing how foods from “new plant varieties,” or GE plants, are being regulated by existing agencies and considered “as safe as” conventionally grown plants as long as the end product is not materially different from traditional plants). Consultation with the FDA is optional. See *U.S. Regulation of Genetically Modified Crops*, FED’N OF AM. SCIENTISTS, <http://www.fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/us-regulation-of-genetically-engineered-crops.html> (last visited March 25, 2014).

²⁶ See generally Brooke Borel, *Can Genetically Engineered Foods Harm You?*, HUFFINGTON POST (Nov. 1, 2012 8:49 AM),

increase in food allergens, potential toxicity, and antibiotic resistance stemming from GE foods.²⁷ However, opponents of this theory cite the American Medical Association's June 2012 study of the impact of GE foods on human health, which concluded that in over twenty years of human consumption of GE foods, "no overt consequences on human health have been reported and/or substantiated,"²⁸ and that "[t]here is no scientific justification for special labeling of genetically modified foods."²⁹ While neither side of the labeling debate can conclusively interpret the limited data that is available, it is settled that unlabeled GE foods may affect consumer confidence domestically and internationally if not properly labeled.

A. Fear of Increased Food Allergies

The risk of allergic reaction may be the strongest safety justification for GE food labeling.³⁰ Scientific studies have proven that food allergens are transferrable through genetic engineering.³¹ When scientists attempted to produce a healthier soybean by adding a gene from the Brazil nut—a known allergenic food—tests verified that the GE soybean contained the known allergen.³² In the face of genuine concerns about the rise in food allergies in the United States,³³ the

http://www.huffingtonpost.com/2012/11/01/genetically-engineered-food-health_n_2041372.html; Blizzard, *supra* note 8.

²⁷ See, e.g., *Link or No Link*, *supra* note 17 (discussing the allergenic aspects of GE foods); see discussion *infra* Part II.B, II.C (discussing fear of potential toxicity and antibiotic resistance from GE foods).

²⁸ REPORT 2 OF THE COUNCIL ON SCI. AND PUB. HEALTH, AM. MED. ASS'N 2012 ANNUAL MEETING, 2, available at <http://www.ama-assn.org/resources/doc/csaph/a12-csaph2-bioengineeredfoods.pdf> [hereinafter REPORT 2].

²⁹ *Id.*

³⁰ See POLICY STATEMENT ON GENETICALLY ENGINEERED FOODS, U.S. FOOD & DRUG ADMIN. (Oct. 19, 1999), <http://www.fda.gov/newsevents/testimony/ucm115032.htm> [hereinafter FDA GE POLICY 1999].

³¹ REPORT 2, *supra* note 28, at 4.

³² *Id.*

³³ *Food Allergy Facts and Statistics for the U.S.*, FOOD ALLERGY RESEARCH & EDUC., <http://www.foodallergy.org/document.doc?id=194> (last visited Dec. 21, 2013). According to a study released in 2013 by the Centers for Disease Control and Prevention, food allergies among children increased approximately 50% between 1997-2011. Kristen D. Jackson et al., *Trends in Allergic Conditions Among*

FDA maintains that GE plants are adequately assessed for potential risks of food allergy prior to market,³⁴ but does not require allergen testing.³⁵

Furthermore, greater fears of allergic reactions have arisen because farmers have widely adopted GE varieties of commonly allergenic plants,³⁶ which are used in many different processed foods.³⁷ Concerns about allergic reactions to GE corn peaked in 2013 when *ELLE*, a popular magazine with a global circulation of approximately 6.6 million readers,³⁸ released an article describing the author's allergic reaction to GE corn.³⁹ While no scientific studies confirmed her claim,⁴⁰ the article drew attention back to a highly publicized food recall when StarLink, a GE corn for animal feed, inadvertently entered the human food supply in 2000.⁴¹ Although some consumers reported adverse allergenic reactions, the link to StarLink corn was not

Children: United States, 1997-2011, NAT'L CTR FOR HEALTH STATISTICS DATA BRIEF (May 2013), <http://www.cdc.gov/nchs/data/databriefs/db121.pdf>.

³⁴ See FDA GE POLICY 1999, *supra* note 30.

³⁵ See *FDA's Role*, *supra* note 1, at 3 (stating that the "FDA encourages developers of GE plants to consult with the agency before marketing their products[] . . . [a]lthough the [safety] consultations is voluntary").

³⁶ See *About Food Allergies*, FOOD ALLERGY RESEARCH & EDUC., <http://www.foodallergy.org/allergens/soy-allergy> (last visited Jan. 21, 2014) (stating that "[s]oybean allergy is one of the more common food allergies" and soybeans are widely used as ingredients in processed foods).

³⁷ Soy-based ingredients used in processed foods are likely products of GE soybeans given that the majority of soybeans plants in the United States are GE. See *Questions & Answers*, *supra* note 1.

³⁸ *ELLE*, <http://www.elleonomics.com.au/contacts/about-us/>.

³⁹ Caitlin Shetterly, *The Bad Seed: The Health Risks Of Genetically Modified Corn*, *ELLE* (July 24, 2013), <http://www.elle.com/beauty/health-fitness/allergy-to-genetically-modified-corn>. Almost 90% of corn grown in the United States is genetically engineered and corn-based ingredients are commonly used in processed foods.

⁴⁰ See Jon Entine, *No, You Shouldn't Fear GMO Corn: How ELLE Botched a Story About Genetically Modified Food*, *SLATE* (Aug. 7, 2013 2:45 PM), http://www.slate.com/articles/health_and_science/science/2013/08/can_gmo_corn_cause_allergies_don_t_believe_elle_s_scary_story.html (disputing the veracity of Shetterly, *supra* note 39).

⁴¹ See *generally StarLink Corn: A Cautionary Tale*, FED'N OF AM. SCIENTISTS, <http://www.fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/starlink-corn.html> (last visited Jan. 16, 2014); ALEJANDRO E. SEGARRA & JEAN M. RAWSON, CONG. RESEARCH SERV., RS20732, STARLINK CORN CONTROVERSY: BACKGROUND (Jan. 10, 2001).

confirmed and allergen tests were inconclusive.⁴² This discovery, however, increased consumer fear of GE foods,⁴³ and disrupted agriculture exports.⁴⁴

B. Fear of Potential Toxicity

Further fear that GE foods may be toxic to humans and cause food poisoning stems from a 2011 toxicological study on animals that revealed a diet of herbicide-resistant GE plants could cause animals to develop liver and kidney tumors.⁴⁵ This study was retracted in November 2013 because it was based on insufficient data, comprised of a poor sample size, and used rats prone to cancer.⁴⁶ Toxicity refers to the potential for GE plants to contain a higher level of toxic chemicals than conventional plants as a result of genetic engineering.⁴⁷ Herbicide-resistant GE plants are modified in laboratories to make GE crops resistant to glyphosate, a chemical herbicide popularly known by its name brand, Round-up Ready.⁴⁸ This allows farmers to douse fields with glyphosate to destroy weeds, not crops.⁴⁹ The retracted study found that rats fed for two years with GE corn developed significantly more tumors and died earlier than rats in the control group.⁵⁰ It also found that the rats developed tumors when glyphosate was added to their drinking water.⁵¹ However, even if animal toxicity studies were conclusive, the information would not provide unequivocal evidence for the effect of GE plants on human health.⁵²

⁴² Andrew Pollack, *Study Raised Doubt About Allergy to Genetic Corn*, N. Y. TIMES (Nov. 10, 2003), <http://www.nytimes.com/2003/11/10/business/study-raises-doubt-about-allergy-to-genetic-corn.html>.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.* (discussing the retraction of the 2012 paper by Gilles-Eric Séralini that concluded that GE corn can be toxic).

⁴⁶ Andrew Pollack, *Paper Tying Rat Cancer to Herbicide Is Retracted*, N. Y. TIMES (Nov. 28, 2013), <http://www.nytimes.com/2013/11/29/health/paper-tying-rat-cancer-to-herbicide-is-retracted.html>.

⁴⁷ REPORT 2, *supra* note 28, at 4.

⁴⁸ *See id.*

⁴⁹ *See id.*

⁵⁰ Pollack, *Tying Rat Cancer to Herbicide*, *supra* note 46.

⁵¹ *Id.*

⁵² *Link or No Link*, *supra* note 17 (quoting a food science and technology professor that animal studies are not predictive of human reactions).

C. Fear of Antibiotic Resistance

Other human health concerns include fear of antibiotic resistance through artificial horizontal gene transfer (“HGT”)—the laboratory process of transferring genetic material between unrelated species.⁵³ HGT deals with whether the consumption of GE foods containing antibiotic-resistant genes can introduce antibiotic-resistant bacteria into the human body and, if so, what the consequences would be.⁵⁴ HGT first became an issue of public concern when scientific studies warned that antibiotic-resistant genes could survive digestion in the human gut, enter the bloodstream and thereby cause unpredictable effects.⁵⁵ Current studies reviewing this claim conclude that while the probability is low, it is plausible that HGT from GE plants can give rise to human health risks.⁵⁶ Because the consequences remain unknown, the risk cannot be ruled out.⁵⁷

D. Fear Affects Consumers’ Risk Perception

The ongoing uncertainty over GE foods due to the lack of long-term studies and their relatively recent entry into the nation’s food supply has increased consumers’ risk perception.⁵⁸ Fear of unknown food allergens, potential toxicity, and antibiotic resistance through consuming GE foods contributes to consumer uncertainty about the safety of GE foods domestically⁵⁹ and internationally.⁶⁰ Consumers demand uniform labeling in order to have full knowledge of their

⁵³ See REPORT 2, *supra* note 28, at 3.

⁵⁴ See *id.*

⁵⁵ See generally Paul Keese, *Risks from GMOs Due to Horizontal Gene Transfer*, 7 ENVIRON BIOSAFETY RES. 123 (2008), available at <http://www.ncbi.nlm.nih.gov/pubmed/18801324> (finding that the occurrence of uptake by gut microbes is too low of a possibility to give rise to a significant human risk and unanticipated HGT from GM crops to humans is expected to be low because HGT is restricted by stringent natural selection pressure).

⁵⁶ See REPORT 2, *supra* note 28, at 3.

⁵⁷ See generally Keese, *supra* note 55.

⁵⁸ See generally REPORT 2, *supra* note 28.

⁵⁹ See generally *National Opinion Poll on Labeling of Genetically Engineered Foods*, CTR FOR SCI. IN THE PUB. INTEREST, http://www.cspinet.org/reports/op_poll_labeling.html (last visited Mar. 20, 2014).

⁶⁰ Michael Lipsky, *Will European Requirements for Labeling GMO Foods Survive New Trade Negotiations?*, HUFFINGTON POST (July 3, 2013 8:15 PM), http://www.huffingtonpost.com/michael-lipsky/will-european-requirement_b_3535795.html.

purchased foods.⁶¹ Thus, while the uncertainty remains, the controversy highlights the need for a uniform national labeling regime to provide a choice for both the domestic and international market and to ameliorate consumer concerns.⁶²

III. CURRENT GE FOODS LABELING REGULATIONS AND POLICIES IN THE UNITED STATES AND EUROPEAN UNION – COMPARING A SCIENCE-BASED APPROACH TO A RISK-BASED APPROACH

A. Overview: European Union's Precautionary Approach to Regulating GE Products

In the face of inconclusive safety concerns, the EU—a major trading partner with the United States⁶³—takes a more precautionary approach to regulating biotechnology.⁶⁴ The EU regulates the distribution of, and requires labeling for, GE ingredients used in the production process and the final product,⁶⁵ whereas current United States policy does not.⁶⁶ The United States does not view biotechnology as posing special risks,⁶⁷ and thus GE foods have only been regulated within existing laws.⁶⁸ In contrast, the EU views biotechnology as a novel

⁶¹ *Id.*

⁶² *Id.*

⁶³ COUNTRIES AND REGIONS, *supra* note 14.

⁶⁴ Lipsky, *supra* note 60; *see also* David Jukes, *Novel Food Legislation in the European Union*, FOOD LAW, <http://www.foodlaw.rdg.ac.uk/novel.htm> (last updated Mar. 31, 2011).

⁶⁵ Council Regulation 1829/2003, On Genetically Modified Food and Feed, 2003 O.J. (L 268) 1, 1; Council Regulation 1830/2003, Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced From Genetically Modified Organisms and Amending Directive 2001/18/EC, 2003 O.J. (L 268) 24, 24 (2) (finding that a harmonized framework for tracing and labeling GE materials “should contribute to the effective functioning of the internal market”); *see also* Michael T. Roberts, *International Legal Issues Concerning Animal Cloning and Nanotechnology – More of the Same Or Are ‘The Times They Are A-Changin’?*, ARK. L. NOTES, at 12 (Nov. 2008), *available at* http://nationalaglawcenter.org/wp-content/uploads/assets/articles/roberts_cloning.pdf [hereinafter Roberts].

⁶⁶ *FDA's Role*, *supra* note 1, at 2 (discussing the FDA's policy of encouraging, but not requiring, developers of GE plants to consult with the agency before marketing food and food ingredients derived from GE plants).

⁶⁷ *See id.*

⁶⁸ *See id.*

process that requires new regulations.⁶⁹ These differences carry trade implications that negatively impact the American export market for GE crops.⁷⁰

Divergent regulatory approaches contribute to trade imbalances because the EU has one of the world's strictest regulatory systems for GE foods.⁷¹ EU legislation takes a risk-based approach that requires more regulation, which can even lead to prohibition.⁷² Prior to market entry, the EU requires that GE products undergo a high level of scientific assessment.⁷³ Under this approach, GE products require a distinct regulatory regime because they are deemed inherently different from their conventional counterparts.⁷⁴ The EU's GE food policy "pursues the global objective of ensuring a high level of protection of human life and health and welfare, environment and consumer interests while ensuring that the internal market works effectively."⁷⁵ There are two main regulations in the EU that cover the farming process and final product.⁷⁶ Regulation 1829/2003 regulates the final product and requires labels for all GE food and animal feed as long as it was derived from a GE plant, even if there is no GE material in the final product.⁷⁷ Exceptions include enzymes and animals that

⁶⁹ See 2003 O.J. (L268) 1, *supra* note 65 (stating: "(5) An authorisation [sic] procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. . . . (9) The new authorisation [sic] procedures for genetically modified food and feed should include the new principles . . . should also make use of the new framework for risk assessment in matters of food safety . . . Thus, genetically modified food and feed should only be authorized for placing on the Community market after a scientific evaluation of the highest possible standards, [. . .], of any risks which they present for human and animal health."); see also Roberts, *supra* note 65, at 13.

⁷⁰ See Roberts, *supra* note 65 at 12. One ban on GE foods reportedly cost corn growers \$300 million in exports. See also WTO RULES EU BAN ILLEGAL, *infra* note 122.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ EUROPA, RULES ON GMOs IN THE EU – INTRODUCTION, EUROPEAN COMMISSION http://ec.europa.eu/food/food/biotechnology/gmo_intro_en.htm (last visited Jan. 12, 2014).

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*; GM Labelling, FOOD STANDARDS AGENCY, http://www.food.gov.uk/policy-advice/gm/gm_labelling#.Utlfu_ShR2CZ (last updated Jan. 30, 2013).

consumed GE animal feed.⁷⁸ The purpose of this regulation is to identify GE ingredients throughout the supply chain.⁷⁹ Regulation 1830/2003 regulates each stage of the production process and requires labels for any product that “contains or consists” of an ingredient derived from a GE plant.⁸⁰ The purpose of this regulation is to provide information about the product’s origin and ensure GE foods are properly labeled at all times before reaching the consumer.⁸¹

B. Overview: United States’ Substantially Equivalent Approach to Regulating GE Products

In contrast to the EU’s stringent precautionary approach to biotechnology,⁸² the United States takes a science-based approach that considers GE crops substantially equivalent to traditionally bred crops and therefore regulates GE foods no differently from other foods.⁸³ However, the United States has not created new regulatory bodies to control the use or production of GE crops and foods, and existing agencies regulate based on laws that predate biotechnology. The United States does not trace the GE production processes, does not require premarket approval, and does not require disclosure to the consumer.

Under the United States Coordinated Framework for Regulation of Biotechnology of 1986, there are three federal agencies primarily

⁷⁸ *GM Labelling*, *supra* note 77.

⁷⁹ GUIDANCE NOTES FROM FOOD STANDARDS AGENCY & DEP’T FOR ENV’T, FOOD & RURAL AFFAIRS (Apr. 7, 2004), <http://www.food.gov.uk/multimedia/pdfs/gmguidancent.pdf> [hereinafter GUIDANCE NOTES].

⁸⁰ 2003 O.J. (L 268) 24, *supra* note 65.

⁸¹ GUIDANCE NOTES, *supra* note 79; *see* EUROPA, RULES ON GMOs IN THE EU, *supra* note 74.

⁸² *Compare* EUROPA, RULES ON GMOs IN THE EU, *supra* note 74 *with* POLICY: NEW PLANT VARIETIES, *supra* note 25, at 22,988; FDA GE POLICY 1999, *supra* note 30 (discussing how Congress determined that GE foods do not require a formal premarket review by the FDA and thus the FDA policy is to regulate GE foods like their conventional counterparts without establishing regulations specific to GE foods).

⁸³ FDA, TESTIMONY ON GENETICALLY ENGINEERED FOODS, U.S. FOOD & DRUG ADMIN. (Aug. 6, 1999), <http://www.fda.gov/newsevents/testimony/ucm115032.htm> [hereinafter FDA TESTIMONY] (discussing the FDA’s legal authority over GE foods under the Federal Food, Drug, and Cosmetic Act). This is true from the FDA perspective, but does not address USDA/EPA regulations based on environmental risk.

responsible for the regulation of biotechnology.⁸⁴ The Environmental Protection Agency (“EPA”) manages the production process by regulating pesticide residue in foods.⁸⁵ The United States Department of Agriculture (“USDA”) regulates the use of biotechnology for agriculture and examines plant pests and weeds.⁸⁶ The FDA has primary authority over the food safety and labeling of GE foods.⁸⁷ These agencies apply existing food safety laws and evaluated GE foods based on the properties of the final *product*,⁸⁸ and not on the *process*.⁸⁹ The FDA does not require premarket approval for GE products⁹⁰ due to its determination that the biotechnology process is immaterial to the final product, and thus, GE foods should be regulated like their conventional counterparts.⁹¹ Instead, the FDA relies on food companies to voluntarily conduct a premarket food safety assessment.⁹²

⁸⁴ Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (June 26, 1986).

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.* § 23302 (stating: “Existing statutes provide a basic network of agency jurisdiction over both research and products” . . . “These laws are product specific because they regulate certain product uses, such as foods or pesticides. This approach provides the opportunity for similar products to be treated similarly by particular regulatory agencies.”); *see also* *FDA’s Role*, *supra* note 1, at 3.

⁸⁹ *Id.* (stating that manufacture of GE products “will be reviewed by FDA, USDA and EPA in essentially the same manner for safety and efficacy as *products* obtained by other techniques” and omitting to review the process of manufacturing) (emphasis added); *see also* FDA GE POLICY 1999, *supra* note 30 (stating that the FDA evaluates only the final food product and not the policy. The FDA stated: “the policy focuses on the traits and characteristics of the foods, and applies to all new varieties of food crops, no matter which techniques are used to develop them.”).

⁹⁰ *See generally* 21 U.S.C.A. § 342 (a)(1) (West 1994) (stating the conditions for when a food is “deemed to be adulterated” but failing to require pre-market testing of conventional and genetically engineered foods); *see also* POLICY: NEW PLANT VARIETIES, *supra* note 25, at 22,988 (stating, “Foods derived for new plant varieties are not routinely subject to scientific tests for safety. . .”).

⁹¹ *See* FDA GE POLICY 1999, *supra* note 30.

⁹² POLICY: NEW PLANT VARIETIES, *supra* note 25, at 22,989 (“Producers *should* consult informally with FDA [. . .] FDA will work with the producer on a case-by-case basis to address requirements such as labeling [. . .] FDA will determine on a case-by-case basis whether it will review the food additive status of these proteins.”) (emphasis added).

Furthermore, the FDA reviews GE products under health and safety laws written prior to the development of modern biotechnology.⁹³ For example, the FDA evaluates the safety of both GE and conventional foods under the Federal Food, Drug, and Cosmetic Act (“FDCA”) passed in 1938.⁹⁴ This 70-year-old law requires the FDA to prevent consumer deception by clarifying that a food label is misleading if it omits significant “material” information.⁹⁵ According to its 1992 policy, the FDA limits the scope of “material” to the “traits and characteristics” of the food itself (i.e., nutritional quality, taste, etc.) and excludes the techniques used to develop it thereby omitting GE foods.⁹⁶ As of November 2013, the FDA has not issued any new regulations for GE products.⁹⁷

The FDA does not require GE food labeling because science has yet to prove that GE foods are materially different from conventional foods.⁹⁸ In 2001, after consumer concern and the EU moratorium on United States crops,⁹⁹ the FDA issued draft guidance reaffirming its position and has not, as of 2013, changed its original stance.¹⁰⁰ Under the 2001 draft guidance, the FDA evaluates whole foods and

⁹³ *Id.* (“Section 402(a)(1) of the act was signed into law in 1938 and has its origins in a similar provision in the Federal Food and Drugs Act of 1906.”)

⁹⁴ *Id.* at 22,988 (“FDA has relied almost exclusively on section 402(a)(1) of the act to ensure the safety of whole foods.”).

⁹⁵ *Id.* at 22,991.

⁹⁶ *Id.* (stating that the “established practices” of observing the “quality, wholesomeness, agronomic characteristics” have historically been reliable for ensuring food safety and this knowledge coupled with a “record of safe development of new varieties of plants” allows FDA to find it not necessary to conduct pre-marketing safety reviews of whole foods derived from GE plants); *see also* FDA TESTIMONY, *supra* note 83 (stating, “To date, FDA has not considered the methods used in the development of a new plant variety [] to be material information”); *FDA’s Role*, *supra* note 1, at 3 (defining “material” facts as “information that is material in light of statements made or suggested on the label, or material with respect to consequences that may result from the use of the food”).

⁹⁷ *FDA’s Role*, *supra* note 1, at 3.

⁹⁸ *See id.*

⁹⁹ *GM Crops: Regulation Detailed Timeline*, GENE WATCH, www.GeneWatch.org/sub-555283 (last visited Dec 20, 2013).

¹⁰⁰ FDA, DRAFT GUIDANCE: GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING, U.S. FOOD & DRUG ADMIN. (Jan. 2001), <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm059098.htm> [hereinafter DRAFT GUIDANCE].

ingredients derived from GE plants based on an equivalency test.¹⁰¹ GE foods are compared to foods derived from traditionally bred plants and assessed under the same safety requirements.¹⁰² Nutritional assessments of GE foods are held to an “as nutritious as” standard.¹⁰³ Allergen and toxicity tests evaluate whether GE foods are “more likely” to cause an allergic or toxic reaction.¹⁰⁴ Furthermore, the FDA relies on developers of GE products to perform allergen and toxicity tests.¹⁰⁵ Because the FDA has found that foods derived from GE plants are generally “as nutritious as” and “no more likely to cause allergic or toxic reactions” than traditionally bred plants, the FDA does not require GE foods to be specifically labeled.¹⁰⁶

C. Practical Effects of Divergent Regulatory Approaches

Differing regulatory regimes for GE food in the United States and EU cause issues in international commerce for the United States that would be ameliorated by a uniform mandatory labeling law.¹⁰⁷ Because the EU views GE foods with skepticism, some member states have restricted imports from the United States and banned cultivation of GE crops.¹⁰⁸ Trade losses are estimated at millions of dollars annually.¹⁰⁹ United States-approved GE crops are restricted from entering the EU market until the crop passes pre-market approval,¹¹⁰ which can take over six years to be completed in the EU.¹¹¹

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Questions & Answers*, *supra* note 1.

¹⁰⁷ See generally U.S. v. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD, PEW (Dec. 2005), available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Biotech_USEU1205.pdf [hereinafter PEW US v. EU]; see also Roberts, *supra* note 65, at 7.

¹⁰⁸ See PEW US v. EU, *supra* note 107, at 10, 15; see also Roberts, *supra* note 5, at 11.

¹⁰⁹ See PEW US v. EU, *supra* note 107, at 22; see also Roberts, *supra* note 65, at 12.

¹¹⁰ See PEW US v. EU, *supra* note 107, at 10.

¹¹¹ *Id.*; see generally *Applications Under Regulation (EC) N. 258/97 of the European Parliament and of the Council*, available at http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf (last accessed Jan. 12, 2014) (For example, Roundup Ready was submitted to be considered for approval in 1998 and not approved until 2006).

Furthermore, the EU has continued to strengthen its proposals for strict labeling and tracing of all food and feed produced from GE crops.¹¹² Current EU legislation expands existing labeling regulation by including “traceability” requirements to track a GE product from the farm through the manufacturing process.¹¹³ Some perceive these as protectionist policies because there are virtually no GE foods producers in the EU, and thus, apply only to foreign competition.¹¹⁴ Compliance has been costly for United States food manufacturers.¹¹⁵

While the EU has one of the world’s strictest regulatory systems for GE products, the EU is also the world’s biggest importer of agricultural commodities,¹¹⁶ and many of these imports are GE foods and feed from the United States.¹¹⁷ Despite its import dependency,¹¹⁸ the EU regulatory approach creates barriers for the United States that have already resulted in trade disruptions over key agricultural commodities.¹¹⁹ An early example is from 1998 when a number of EU member states vowed to block imports of GE crops until the EU

¹¹² See PEW US v. EU, *supra* note 107, at 10, 13.

¹¹³ *Id.* at 13.

¹¹⁴ *Id.* at 18; Marjorie Olster, *GMO Foods: Key Points in the Genetically Modified Debate*, HUFFINGTON POST (Aug. 2, 2013, 12:08 AM), http://www.huffingtonpost.com/2013/08/02/gmo-foods_n_3693246.html?view=print&comm_ref=false.

¹¹⁵ PEW US v. EU, *supra* note 107, at 17 (developing traceability and labeling systems to ensure compliance with EU labeling and traceability requirements has been challenging and costly for United States food manufacturers and exporters).

¹¹⁶ *Commission Report on Bilateral Agricultural Trade Relations*, EUROPEAN COMMISSION, DIRECTORATE-GENERAL FOR AGRIC. & RURAL DEV. (July 2012), http://ec.europa.eu/agriculture/bilateral-relations/eu-trade_en.pdf (last visited Jan. 12, 2014) [hereinafter *EU Commission Report*]; see also Roberts, *supra* note 71, at 11.

¹¹⁷ PEW US v. EU, *supra* note 107, at 2.

¹¹⁸ See Jane Byrne, *EU project aims for non-GMO alternative to soy for feed and food*, FEED NAVIGATOR (Mar. 7, 2014), <http://www.feednavigator.com/content/view/print/891057> (discussing “Europe’s dependence on imports for its feed needs” and stating that “[t]he EU imports 70% of its requirements in protein-rich products used for feeds – 20 to 25 million tons (Mt) of meals and 15MT of soybean seeds”); see also PEW US v. EU, *supra* note 107, at 3, 5, 17 (stating that “there is still active demand for [GE] feed in the EU. While [GE] feed itself must be labeled, meat, milk and eggs derived from animals fed with [GE] feed are not required to be labeled. As a result, some U.S. exports, such as soy and corn gluten intended for feed uses, do not need to be segregated since there continues to be an active EU market for [GE]-labeled feed. (Feed intended to be marketed as [GE]-free would, of course, need to be segregated.)”).

¹¹⁹ *Id.* at 10, 17.

further tightened labeling regulations.¹²⁰ As a result, no new GE foods could be imported from 1998 through 2004 while the EU was developing new legislation.¹²¹ The United States filed a complaint with the World Trade Organization (“WTO”) challenging the *de facto* ban as an impediment to trade.¹²² The WTO ruled that EU’s moratorium on GE products contravened trade rules and the EU lifted the ban.¹²³ However, certain member states still ban the cultivation of GE corn in their territories.¹²⁴

Furthermore, the EU prohibits cultivation of certain types of GE crops, even though the exact same GE products can be imported from other countries.¹²⁵ Thus, the EU has become a net importer of GE crops grown almost exclusively in countries outside Europe where farmers have the choice between conventional and GE varieties.¹²⁶ However, over the last decade as EU imports of GE soybean products have rapidly risen,¹²⁷ intense competition from soybean processors in other countries has cut into the United States’ share of foreign markets for GE products.¹²⁸ These other countries that have increased their trade with the EU have established policies on labeling GE foods.¹²⁹

IV. STATE GE LABELING LAWS: ULTIMATELY INSUFFICIENT PATCHWORK APPROACH

¹²⁰ *Id.* at 10.

¹²¹ *Id.* at 10, 31 (discussing the EU moratorium on GE imports from the United States).

¹²² *Id.* at 11, 31; *European Communities—Approval and Marketing of Biotech Products*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds291sum_e.pdf (last visited Jan. 12, 2014); *see also* *WTO Rules EU Import Ban Illegal*, N.Y. TIMES (Feb. 7, 2006), http://www.nytimes.com/2006/02/07/business/worldbusiness/07iht-gmo.html?_r=0&pagewanted=print.

¹²³ *European Communities—Approval and Marketing of Biotech Products*, *supra* note 122.

¹²⁴ PEW US v. EU, *supra* note 107, at 15, 53.

¹²⁵ EU *Commission Report*, *supra* note 116.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ ECONOMIC RESEARCH SERVICE, USDA SOYBEAN BASELINE, 2010-19, <http://www.ers.usda.gov/topics/crops/soybeans-oil-crops/market-outlook/usda-soybean-baseline,-2010-19.aspx#.UtMrr2RDt3o> (last updated Dec. 24, 2013); *see also* *Global Status of Commercialized Biotech/GM Crops: 2012*, *supra* note 2 (discussing tremendous biotech crop production in Spain, Brazil, and China).

¹²⁹ *Labeling Around The World*, JUST LABEL IT!, <http://justlabelit.org/right-to-know/labeling-around-the-world/> (last visited Jan. 12, 2014); *see generally* PEW US v. EU, *supra* note 107.

A. Overview: State GE Labeling Initiatives – California, Washington, Connecticut, and Maine

1. Failed State GE Labeling Initiatives – California and Washington

While international trade barriers present a national issue, the most prominent United States trends in GE food labeling have occurred at the state level.¹³⁰ However, a review of the four most recent state labeling initiatives shows that having different state requirements would be counterproductive and would not serve consumers or international trade issues. As of March 2014, twenty-one states have considered legislation or ballot initiatives that would require producers and manufacturers to label GE products.¹³¹ While only two of these state initiatives have passed, and none have taken effect to date (Connecticut's and Maine's laws have not been triggered into action), these state labeling initiatives represent an attempt to respond to consumer demands for their "right-to-know."¹³² Although state initiatives are not sufficient to ease international trade tensions with partners such as the EU,¹³³ certain features of state bills provide useful models for the ultimate solution: national, uniform GE food labeling laws.

The largest state-level GE labeling initiative was in California. Proposition 37 would have required all foods containing GE ingredients to be labeled "genetically engineered" or "partially produced with genetic engineering" and would have precluded the use of the term "natural" for all GE foods.¹³⁴ While it provided exemptions for animal products, alcohol, enzymes, medicine, and ingredients under 0.5%, it would have required manufacturers to document the absence of GE ingredients through either supplier or independent

¹³⁰ Ronnie Cummins, *GMO and the 'Natural' Food Fight: The Treacherous Terrain of Food Labeling*, GLOBAL RESEARCH (Jan. 4, 2014), <http://www.globalresearch.ca/gmo-and-the-natural-food-fight-the-treacherous-terrain-of-food-labeling/5363798>.

¹³¹ *Id.*; see also *State Initiatives*, JUST LABEL IT!, <http://justlabelit.org/state-initiatives/> (last visited Mar. 30, 2014).

¹³² See Maggie Caldwell, *Maine Is Second State to Pass GMO Labeling Law*, MOTHER JONES (June 14, 2013 2:05 AM), <http://www.motherjones.com/blue-marble/2013/06/maine-gmo-labeling>; see also *Right to Know*, *supra* note 9.

¹³³ See *infra* Part IV.C.

¹³⁴ *California Right to Know Genetically Engineered Food Act*, PROPOSITION 37 (Nov. 2, 2012), <http://vig.cdn.sos.ca.gov/2012/general/pdf/text-proposed-laws-v2.pdf#nameddest=prop37> (last visited Mar. 10, 2014) [hereinafter PROP 37].

third-party certifications.¹³⁵ Additionally, it contained a “bounty hunter” provision to allow private citizens to sue for violations of labeling requirements and recover attorney’s fees.¹³⁶ Proponents positioned the initiative as a consumer choice issue.¹³⁷ They argued that American consumers, like their EU counterparts, should have an opportunity to see all relevant information on a label so that they can make educated purchasing decisions based on their own views about its perceived safety.¹³⁸ Opponents responded by asserting that mandatory labeling is misleading because it suggests that products that do not contain GE ingredients are in some fashion better, a proposition that they assert is contrary to established science.¹³⁹

While Proposition 37 was defeated by a narrow majority in November 2012,¹⁴⁰ it led the way for other state labeling initiatives. Indeed, one-year later, Washington led the second largest state labeling initiative.¹⁴¹ The proposed ballot initiative to label GE foods

¹³⁵ *Id.* § 110809.2 (e) (stating that processed food would have to be labeled GE “solely because it includes one or more genetically engineered ingredients” after July 1, 2019, as long as: “(1) no single such ingredient accounts for more than one-half of one percent of the total weight of such processed food; and (2) the processed food does not contain more than 10 such ingredients”).

¹³⁶ *Id.* § 111910 (a) states, “any person may bring an action in superior court pursuant to this section.”

¹³⁷ California General Election, OFFICIAL VOTER INFORMATION GUIDE, <http://voterguide.sos.ca.gov/propositions/37/arguments-rebuttals.htm> (last visited Jan. 12, 2014).

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ Karl Haro Von Mogel, *Why Did Proposition 37 Fail?*, FOOD SAFETY NEWS (Nov. 19, 2012), <http://www.foodsafetynews.com/2012/11/why-did-proposition-37-fail/#.UtNDOChR2CY>. Despite the 2012 defeat of ballot initiative Proposition 37, California is not giving up. See CALIFORNIA SENATE BILL 1381, S.B. 1381, 2013-2014 Reg. Sess. (Cal. 2014), available at http://www.leginfo.ca.gov/pub/13-14/bill/sen/sb_1351-1400/sb_1381_bill_20140221_introduced.pdf. On February 21, 2014 Senator Noreen Evans introduced California Senate Bill 1381 to require GE food labeling. In comparison to the ballot initiative, the Bill is simply written and provides justifications such as consumer protection from unintended allergens. Compare *id.* with PROP 37, *supra* note 134. The Bill passed the Senate Health Committee by a vote of 5 to 2 on March 26, 2014. *California Senate Health Committee Passes Bill to Label Genetically Engineered Foods*, CTR FOR FOOD SAFETY (Mar. 26, 2014), <http://www.centerforfoodsafety.org/press-releases/3018/california-senate-health-committee-passes-bill-to-label-genetically-engineered-foods>.

¹⁴¹ WASHINGTON STATE BILL REQ. # 1-2570.1/12, INITIATIVE MEASURE NO. 522, Title 70 RCW, (filed June 29, 2012) (rejected Nov. 5, 2013),

in Washington, I-522, was also narrowly defeated.¹⁴² I-522 required manufacturers to “clearly and conspicuously”¹⁴³ label any seed or food offered for retail sale in Washington as “genetically engineered” and document the absence of GE through an affidavit.¹⁴⁴ It also included the same “bounty hunter” provision and exemptions for animals fed GE feed, alcohol, enzymes, medicine, restaurants, and processed foods with less than 0.9% GE ingredients.¹⁴⁵

2. Successful State GE Labeling Initiatives – Connecticut and Maine

In the summer of 2013, Connecticut and Maine became the first two states to pass bills requiring labels on all foods made from GMOs.¹⁴⁶ Connecticut was the first state to pass a GE food-labeling bill, and Maine soon followed.¹⁴⁷ However, both bills contain a trigger provision that requires other states to pass similar bills before it becomes law.¹⁴⁸ The provision is designed to protect each state from

http://sos.wa.gov/_assets/elections/initiatives/FinalText_285.pdf (last visited Jan. 12, 2014) [hereinafter I-522]. The rejection is interesting given that Washington has been progressive on controversial issues, such as same-sex marriage and the legalization of marijuana. Isolde Raftery, *Legalized pot, gay marriage: Are we all Washington now?* NBC NEWS (Dec. 31, 2012),

http://usnews.nbcnews.com/_news/2012/12/31/15879444-legalized-pot-gay-marriage-are-we-all-washington-now (discussing Washington’s libertarian streak).

¹⁴² Margaret Badore, *GMO Labeling Law Defeated in Washington State*, TREE HUGGER (Nov. 14, 2013), <http://www.treehugger.com/environmental-policy/gmo-labeling-law-defeated-washington-state.html>.

¹⁴³ I-522, *supra* note 141 § 3(2)(a)-(c) (stating “genetically engineered” is not required before each GE ingredient).

¹⁴⁴ *Id.* § 3(2)(b).

¹⁴⁵ *Id.* § 3(2)(a), (c)-(e).

¹⁴⁶ Caldwell, *supra* note 132.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* To be enacted, Connecticut’s GE Act requires that four other states enact similar labeling laws, at least one of those four states must border Connecticut, and the combined population of all five states must exceed twenty million. *See Conn.*, PA No. 13-183, “An Act Concerning Genetically-Engineered Food” <http://www.cga.ct.gov/2013/act/pa/pdf/2013PA-00183-R00HB-06527-PA.pdf> [hereinafter Connecticut GE Act]. Like Connecticut’s Act, Maine’s Act does not take effect until at least five other states or any state or states with a total population of at least twenty million adopt “substantially similar” legislation. *See Maine*, HP 490/LD 718 126th Session, “An Act To Protect Maine Food Consumers’ Right To Know about Genetically Engineered Food and Seed Stock” <http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP0490&item=1&sum=126> [hereinafter Maine GE Act].

being the only state in the region with a GE food policy and to promote consistency in policy with neighboring states.¹⁴⁹ In contrast with Connecticut's and Maine's bills, California's and Washington's labeling initiatives did not include triggers.¹⁵⁰ Thus had the ballot initiatives passed in California and Washington, the law would have been enacted.¹⁵¹ As a result, biotechnology interest groups spent millions to oppose the labeling initiatives in California and Washington.¹⁵²

i. Specific Disclosure Statement Required

Both Connecticut's and Maine's GE labeling bills require specific disclosure statements for any GE seed, ingredient, or food sold for human consumption, not for animal feed.¹⁵³ Connecticut's GE Act specifies that the GE label must contain "*the clear and conspicuous*

¹⁴⁹ See generally Connecticut GE Act (for the proposition that Connecticut's trigger was designed to ensure that Connecticut's food industry would not be isolated to its neighbors); Maine GE Act (for the proposition that Maine's farmers support the legislation because it creates transparency in the marketplace and increasing demand for Maine products).

¹⁵⁰ See generally PROP 37, *supra* note 134 (requiring no triggers); I-522, *supra* note 141 (same).

¹⁵¹ For more information on state ballot initiatives, see STATE BALLOT MEASURES, EASY VOTER GUIDE, available at <http://www.easyvoterguide.org/wp-content/pdf/FastFacts-BallotMeasures.pdf> (last visited March 17, 2014) ("With the initiative process, voters can change the [California] State Constitution if just over 50% agree. . . . It also is more difficult to 'undo' an initiative than a law passed by the legislature."). Furthermore under California's Constitution, an initiative that is approved by a majority vote takes effect the day after the election, unless the initiative measure provides otherwise. Cal. Const., art. II § 10(a).

¹⁵² See Greg Giroux, *Grocers' Group Spends Record Lobbying Amid Food-Label Fights*, BLOOMBERG (Dec. 2, 2013 11 PM), <http://www.bloomberg.com/news/2013-12-03/grocers-group-spends-record-lobbying-amid-food-labeling-fights.html>.

¹⁵³ See Connecticut GE Act §3 (stating: "(A) food intended for human consumption, and (B) seed or seed stock that is intended to produce food for human consumption, that is entirely or partially genetically-engineered, except a processed food subject to the provisions of this section solely because one or more processing aids or enzymes were produced or derived from genetically engineering, shall be labeled as follows: . . ."); Maine GE Act § 2592 (1) (stating, "Beginning 18 months after the effective date of this section, any food or seed stock offered for retail sale that is genetically engineered must be accompanied by a conspicuous disclosure that states 'Produced with Genetic Engineering.' This statement must be located on the package for all packaged food or seed stock or, in the case of unpackaged food or seed stock, on a card or label on the store shelf or bin in which the food or seed stock is displayed.").

words: ‘Produced with Genetic Engineering’” on the package, on the receipt, or on the retail store display,¹⁵⁴ and the label must be in the “same size and font as the ingredients in the nutritional facts panel on the food label.”¹⁵⁵ Similarly, Maine’s GE Act requires a “*conspicuous disclosure that states ‘Produced with Genetic Engineering’*”¹⁵⁶ on the package or on the store display for “any [GE] food or seed stock offered for retail sale.”¹⁵⁷ Both labeling initiatives have the stated purpose of providing consumers with information to make informed decisions in the marketplace.¹⁵⁸ All four state initiatives would have prohibited the use of the word “natural” for GE foods or seeds in order to prevent confusion between naturally grown food and GE food.¹⁵⁹ However unlike Washington’s I-522 and California’s Proposition 37, Maine’s law eliminated “bounty hunter” provisions.¹⁶⁰ Perhaps because the dominant consumer-initiated civil class action complaint filings concern “natural” claims on food labels.¹⁶¹

ii. Exemptions

Both Connecticut’s and Maine’s GE Acts state that any GE food or seed that does not display the required disclosure statement is deemed misbranded but provides exemptions for certain retailers and products.¹⁶² Both state GE labeling initiatives exempt foods produced without knowledge that the seed, food, or ingredients used in production were GE; animal products even if the animal was fed GE

¹⁵⁴ See Connecticut GE Act § 3 (requiring a specific disclosure statement for raw and processed foods sold wholesale and retail, and for seeds).

¹⁵⁵ *Id.*

¹⁵⁶ See Maine GE Act § 2592.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* (requiring manufacturers to label foods containing GE ingredients at the point of sale in order to provide consumers with information to make informed decisions in the marketplace).

¹⁵⁹ *Id.* § 2592 (2); see Connecticut GE Act § 1(17).

¹⁶⁰ See Maine GE Act § 2594 (stating that there is no private right to enforce the law).

¹⁶¹ Heather S. Goldman & David A. Zetoon, *Managing Legal Risks: Trends in Advertising Class Action Litigation*, BRYAN CAVE (Oct. 2013), [http://www.bryancave.com/files/Publication/4036b5ea-395e-4bfc-b532-a32a223dfd3f/Presentation/PublicationAttachment/a9d63125-0b91-4875-9227-c49563743981/Trends%20in%20Advertising%20Class%20Actions%20Q3%202013-v2%20\(2\).pdf](http://www.bryancave.com/files/Publication/4036b5ea-395e-4bfc-b532-a32a223dfd3f/Presentation/PublicationAttachment/a9d63125-0b91-4875-9227-c49563743981/Trends%20in%20Advertising%20Class%20Actions%20Q3%202013-v2%20(2).pdf).

¹⁶² See Connecticut GE Act § 2593 (2)(3); Maine GE Act § 4 (a)(1), (a)(12).

feed; and products with no more than 0.9% of the total content produced by GE.¹⁶³ Both initiatives provide that the disclosure requirements do not apply to food produced with GE enzymes, foods served at restaurants, medical foods, and alcohol.¹⁶⁴ Furthermore, both protect distributors and retailers and shift the burden of labeling onto suppliers.¹⁶⁵ Connecticut's GE Act stipulates that "a retailer shall not be penalized or otherwise held liable for the failure to label pursuant to this section unless . . . the retailer's failure to label was knowing and wilful."¹⁶⁶ Furthermore, "it shall be a defense that such retailer reasonably relied on (A) any disclosure . . . provided by the wholesaler or distributor . . . , or (B) the lack of any such disclosure."¹⁶⁷ Maine's GE Act provides protection for a distributor or a retailer who "sells or advertises [GE] food or seed stock" if the distributor or retailer relied on the producer or grower's affidavit that certifies that the food or seed stock being sold or shipped is not subject to the disclosure requirements.¹⁶⁸

B. Analysis: Features of State GE Labeling Initiatives

1. Location of the Specific Disclosure Statement Required

Connecticut's and Maine's labeling initiatives require GE foods to be specifically labeled, "Produced with Genetic Engineering" anywhere on the package.¹⁶⁹ For example, Connecticut's labeling initiative would allow the four-word statement to be displayed anywhere on the package as long as the font is not smaller than the font used to list ingredients on the nutritional facts panel on the food label,¹⁷⁰ and Maine's would require "conspicuous disclosure" in any size and font.¹⁷¹ In effect, Connecticut's labeling initiative could be more lenient because the minimum font size could easily be lost in a

¹⁶³ See generally sources cited *supra* note 148.

¹⁶⁴ See generally sources cited *supra* note 148.

¹⁶⁵ Connecticut GE Act § 2592 (3)(A)(1)(2013) (protecting products produced without knowledge that the ingredients were GE); Maine GE Act § 3(f).

¹⁶⁶ See Connecticut GE Act § 3(f).

¹⁶⁷ See generally Connecticut GE Act.

¹⁶⁸ See Maine GE Act § 2592.

¹⁶⁹ See generally sources cited *supra* note 148.

¹⁷⁰ Connecticut GE Act § 3 (stating that the "clear and conspicuous words: 'Produced with Genetic Engineering' . . . shall be displayed in the same size and font as the ingredients in the nutritional facts panel on the food label").

¹⁷¹ Maine GE Act § 2592.

product's packaging while still being "clear and conspicuous words."¹⁷² Meanwhile the lack of specificity as to the size and font required in Maine's labeling initiative could have allowed similar-sized font; however, it may also lead to more litigation as to the statutory interpretation of "conspicuous disclosure."¹⁷³

In contrast to Connecticut's and Maine's labeling initiatives, Washington's I-522 would have required the specific words "genetically engineered" to be stated "clearly and conspicuously" on the front of the package or in the store at the point of sale.¹⁷⁴ For processed foods that contain GE ingredients, the bill required the words "partially produced with genetic engineering" on the front or "may be partially produced with genetic engineering," stated "clearly and conspicuously."¹⁷⁵ For seeds, the bill required the words "genetically engineered" on the container or receipt, or "produced with genetic engineering" stated "clearly and conspicuously."¹⁷⁶ Opponents of front package labeling argued that forcing producers and retailers to prominently display such a label without justification would mislead consumers to perceive GE foods as unsafe or less nutritious.¹⁷⁷ Proponents for front packaging labeling state that existing labels for nutritional content are consistently overlooked or ignored by consumers.¹⁷⁸ However, each side has the same goal of providing American consumers with information in "a practical and common sense way."¹⁷⁹ If the label is on the front or in the ingredients list, GE labels can include a caveat to indicate that no significant difference has been found between the GE and conventionally produced food in order to prevent a perception that GE foods are unsafe or less nutritious.¹⁸⁰

2. Exemptions

¹⁷² See *supra* note 170 and accompanying text.

¹⁷³ Maine GE Act § 2592 (1).

¹⁷⁴ I-522, *supra* note 141.

¹⁷⁵ I-522, *supra* note 141.

¹⁷⁶ I-522, *supra* note 141.

¹⁷⁷ Bill Price, *Analysis of Washington State GMO Labeling Initiative I-522*, BIOFORTIFIED BLOG (Feb. 15, 2013), www.biofortified.org/2013/02/analysis-of-washington-state-gmo-labeling-initiative-i-522/.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*; see generally Cummins, *supra* note 130.

¹⁸⁰ DRAFT GUIDANCE, *supra* note 100.

Exemptions enable regulations to avoid negatively intruding on the business of economically important sections of the agricultural community and staple foods.¹⁸¹ For example, all four state labeling initiatives would exempt GE foods served in restaurants, meat from animals fed with GE feed, medicine, and alcohol and therefore would avoid opposition from each industry's respective associations.¹⁸² Furthermore, the labeling initiatives exempt enzymes, which are often manufactured through GE technologies.¹⁸³ Enzymes are used in wine production, dairy products such as cheese and yogurt, and bakery products such as bread.¹⁸⁴

These labeling initiatives do not state why certain exemptions are being granted for certain foods.¹⁸⁵ Connecticut's exemption for small farm businesses is the only exemption accompanied by a stated purpose within the initiative.¹⁸⁶ Connecticut's labeling initiative would

¹⁸¹ See generally Cummins, *supra* note 130; *Proposition 37 Would Prohibit Marketing of Processed Foods as "Natural"*, NO ON 37, <http://www.noprop37.com/files/no-on-37-grocers-and-retailers-oppose-fact-sheet.pdf> (last accessed Jan. 13, 2014) (discussing the list of exemptions that apply to GE food labeling requirement).

¹⁸² See generally Cummins, *supra* note 130 (discussing how industry groups "pretend[ed] to take the side of consumers" by opposing exemptions within state labeling initiatives, but subsequently supported a "watered-down" federal GE labeling law with similar exemptions in order to preempt stricter state GE labeling laws).

¹⁸³ *FDA's Role*, *supra* note 1, at 2 (stating that the first GE food product was an enzyme used to produce cheese and most GE crops are used as human food ingredients and for animal feed).

¹⁸⁴ See *GM Labelling*, *supra* note 77 (providing cheese as an example of a product produced with GE enzymes that does not have to be labeled as such even in the EU); Borel, *supra* note 26 (discussing how GE enzymes are used to make some cheeses and ferment some wines). I-522 would have exempt alcohol, which is a 3 billion dollar industry in Washington State—the second largest producer of premium wines in the United States.

¹⁸⁵ See, e.g., *PROP 37*, *supra* note 134 (providing exemptions without a stated purposes for foods that are: certified organic, unintentionally produced with GE material, made from animals fed or ejected with GE material, processed with or containing less than 0.9% GE ingredients, medical, sold to restaurants, and alcoholic beverages); I-522, *supra* note 141 (same); Connecticut GE Act § 3 (b)(1)-(4) (providing exemptions without a stated purposes for foods that are: alcoholic beverages, sold to restaurants, made from animals fed or ejected with GE material, processed with or containing less than 0.9% GE ingredients, and unintentionally produced with GE material); Maine GE Act § 2593 (2)(3) (same).

¹⁸⁶ Connecticut GE Act § 3 (b)(3) (providing an exemption that would protect small farm businesses from a non-compliance penalty of \$1,000 per day).

include a protection for small businesses in addition to the same exemptions contained in the other three labeling initiatives,¹⁸⁷ and thus would protect small farmers from the opposition of powerful interest groups.¹⁸⁸

*C. Conclusion: State GE Labeling Initiatives Do Not Help
International Trade Issues*

A review of the four most recent state labeling initiatives shows that arbitrary exemptions would be counterproductive and “bounty hunter” provisions would lead to the unnecessary use of scarce judicial resources to debate issues that do not serve producers or consumers.¹⁸⁹ Furthermore, a patchwork approach could lead to legal challenges regarding the constitutionality of the measures.¹⁹⁰ The legal issues raised by state enacted mandatory labeling laws include federal preemption,¹⁹¹ First Amendment protections of commercial speech,¹⁹² and dormant commerce clause.¹⁹³ In addition, it is unlikely that state level regulations will influence international trade because the state laws only govern the final product’s label and international exports

¹⁸⁷ See, e.g., Cummins, *supra* note 130 (discussing California’s and Washington’s ballot initiatives).

¹⁸⁸ See *Proposition 37 Would Prohibit Marketing of Processed Foods as “Natural”*, *supra* note 181 (“Major funding by Monsanto Company, E.I. DuPont de Nemours & Co., Grocery Manufacturers Association and more than 40 food company members.”).

¹⁸⁹ *Special Report, Initiative 522: Costly, Flawed and Ill-Conceived*, WASHINGTON RESEARCH COUNCIL, 1, 3 (2013), <http://cahnrs-cms.wsu.edu/ses/people/tozer/Documents/Readings/Initiative522fullfinal.pdf> (exemplifying initiatives against mandatory labeling law funded by biotechnology companies).

¹⁹⁰ See, e.g., Sally Noxon Vecchiarelli, Comment, *Mandatory Labeling of Genetically Engineered Food: Constitutionality, You Do Not Have a Right to Know*, 22 SAN JOAQUIN AGRIC. L. REV. 215, 216 (2013) (discussing the First Amendment implications of mandatory GE labels).

¹⁹¹ David Benton, *The Impact of Mandatory Recalls on Negligence and Product Liability Litigation under the Food Safety Modernization Act*, 22 SAN JOAQUIN AGRIC. L. REV. 27, 50 (2013).

¹⁹² Vecchiarelli, *supra* note 190.

¹⁹³ See, e.g., *Hunt v. Washington State Apple Adver. Comm’n*, 432 U.S. 333 (1977) (finding that even non-protectionist state laws could be found to violate the commerce clause if they interfere with interstate commerce).

concern the traceability of process too.¹⁹⁴ These initiatives are intended to benefit intrastate commerce for the state's citizens and do not protect international markets or the United States economy.¹⁹⁵ Consideration of federal law promoting a uniform standard is warranted in order to avoid separate standards for GE food labeling at the state level.¹⁹⁶ A national uniform standard is the most cost-effective and least-confusing way to provide consumers with information and promote American agriculture products abroad.¹⁹⁷

D. Federal GE Labeling Bill – The Genetically Engineered Food Right-To-Know Act

Congress has been increasingly pressured by advocates to pass a mandatory GE labeling law,¹⁹⁸ and has introduced multiple GE-related bills including the Genetically Engineered Food Right-To-Know Act.¹⁹⁹ At the federal level, the Right-To-Know Act was reintroduced in the Senate as Senate Bill 809²⁰⁰ and in the House as House Resolution 1699²⁰¹ (collectively, the “Federal GE Bill”) in April 2013. The Federal GE Bill would amend the Food, Drug, and Cosmetic Act

¹⁹⁴ See generally *Special Report, Initiative 522: Costly, Flawed and Ill-Conceived*, *supra* note 189 (discussing how states must consider international trade implications since their agricultural products are exported).

¹⁹⁵ See generally sources cited *supra* note 148 (failing to state any health or non-local purposes for Connecticut's and Maine's GE labeling initiatives); see *Price supra*, note 177 (stating “it is unlikely that the multi-million dollar agriculture export industry will require or depend on a state level labeling law that does not require product testing” and state level labeling is not critical to preserving economic value).

¹⁹⁶ See Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 431 (2002) (discussing how the extent of the effectiveness of current federal regulation “may lead to the enactment of a patchwork of conflicting and burdensome state regulations”).

¹⁹⁷ See *In U.S., Less Than Half Look at Restaurant Nutrition Facts*, GALLUP (Aug. 9, 2013), <http://www.gallup.com/poll/163904/less-half-look-restaurant-nutrition-facts.aspx> (While fewer Americans pay attention to nutrition labels in restaurants, “most Americans do pay attention to nutrition labels on packaged foods.”); see also Ashley Arther, *Combating Obesity: Our Country's Need For A National Standard to Replace The Growing Patchwork of Local Menu Labeling Laws*, 7 IND. HEALTH L. REV. 305 (2010) (advocating for national standard for menu labeling).

¹⁹⁸ See TADLOCK COWAN, CONG. RESEARCH SERV., R 32809, AGRICULTURAL BIOTECHNOLOGY: BACKGROUND AND RECENT ISSUES (2010) (discussing multiple GE-related bills that were introduced into recent legislation).

¹⁹⁹ *Id.*

²⁰⁰ See S. 809, 113th Cong. (2013) (identical text as H.R. 1699).

²⁰¹ See H.R. 1699, 113th Cong. (2013) (identical text as S. 809).

to require the clear disclosure of a whole or processed food that is GE or contains a GE ingredient.²⁰² Failure to comply would deem the food misbranded.²⁰³ Food manufacturers may shield themselves from penalties for misbranding violations by relying on suppliers' guarantees that "the food is not genetically engineered or does not contain a genetically engineered ingredient."²⁰⁴ The stated purpose of the Federal GE Bill is "to establish a consistent and enforceable standard for labeling of foods produced using genetic engineering" and to provide "consumers with knowledge of how their food is produced."²⁰⁵ As stated in the Federal GE Bill, Congress found, in part, that "[m]andatory identification of foods produced with GE can be a critical method of preserving the economic value of exports or domestically sensitive products."²⁰⁶ The Federal GE Bill expressly exempts food served in restaurants, food produced without GE ingredients other than a GE processing aid/enzyme including yeast, and medicine.²⁰⁷

The last federal GE bill was introduced in 2000 as Senate Bill 2080 and House Resolution 3377.²⁰⁸ The law would have required GE foods be labeled with the statement "THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL."²⁰⁹ In contrast, the Federal GE Bill does not require a specific statement and rather allow producers and manufacturers to choose the way in which to disclose whether foods are genetically engineered or contain genetically engineered ingredients.²¹⁰

²⁰² *Id.* at 3.

²⁰³ *Id.* at 3.

²⁰⁴ *Id.* at 6.

²⁰⁵ *Id.* at 2.

²⁰⁶ *Id.* at 3.

²⁰⁷ *See id.* at 3-4. The Federal GE Bill exempts food that "(A) is served in restaurants or other similar eating establishments, such as cafeterias and carry-outs; (B) is a medical food; (C) was produced using a genetically engineered vaccine; or (D) is a food or processed food that would be subject [] solely because it includes the use of a genetically engineered processing aid (including yeast) or enzyme." *Id.*

²⁰⁸ BILL, S. 2080, 106th Congress (2000) GENETICALLY ENGINEERED FOOD RIGHT-TO-KNOW ACT, available at <http://www.gpo.gov/fdsys/pkg/BILLS-106s2080is/pdf/BILLS-106s2080is.pdf> (last visited Jan. 13, 2014).

²⁰⁹ *Id.*

²¹⁰ *Id.*; *Federal Legislation Introduced*, *supra* note 10 ("The Genetically Engineered Food Right-to-Know Act is the first federal GE labeling bill to be introduced in the Senate since 2000.").

E. Voluntary Non-GMO labeling and Market Forces

While the absence of mandatory GE labeling does not solve the issue of international trade barriers, it has led to a growing trend to market products as “non-GMO,” which means the food does not contain any GE ingredient.²¹¹ Voluntary non-GMO labeling may ease labeling tensions and pave the way for a federal solution as food manufacturers voluntarily decrease their reliance on GE products.²¹² Indeed, the United States recognized that some form of labeling would be required for GE products in order to defend its competitive position in the export trade of GE foods.²¹³ Furthermore, consumers do not need to wait for a legislative solution. Consumers have the authority to impact food labeling through litigation and the use of purchasing power to convince industry to adopt certain practices.²¹⁴ Consumers in past have filed lawsuits against food manufacturers under state consumer protection laws and consumer market preferences have resulted in the industry adopting certain labeling practices.²¹⁵

²¹¹ See generally NON-GMO PROJECT BLOG, <http://www.nongmoproject.org/press/blog/>.

²¹² See, e.g., *FDA Moves to Finalize Guidance on Voluntary GMO Labeling*, NON-GMO PROJECT BLOG (Dec. 18, 2013), <http://www.nongmoproject.org/2013/12/18/fda-moves-to-finalize-guidance-on-voluntary-gmo-labeling/>.

²¹³ See generally DONNA U. VOGT & MICKEY PARISH, CONG. RESEARCH SERV., R30198, *FOOD BIOTECHNOLOGY IN THE U.S.: SCIENCE, REGULATION, AND ISSUES* (2001).

²¹⁴ For a study of the factors that influence rBST use among U.S. Dairy Farmers in six states, see BRADFORD L. BARHAM ET AL., *RBST USE AMONG U.S. DAIRY FARMERS: A COMPARATIVE ANALYSIS FROM 6 STATES* (July 2002), available at <http://ageconsearch.umn.edu/bitstream/19598/1/os02ba02.pdf>. For use of pressure on industry through litigation, see Goldman & Zetoon *supra*, note 161.

²¹⁵ For example, in March of 2013, Whole Food Markets announced that by 2018 all of its suppliers would be required to either certify that their product does not contain genetically modified organisms (GMOs) or label products that do contain GMOs. *Whole Foods Market Commits to Full GMO Transparency*, WHOLE FOODS, <http://media.wholefoodsmarket.com/news/whole-foods-market-commits-to-full-gmo-transparency> (last visited Mar. 27, 2014) [hereinafter *GMO Transparency*]. Frito-Lay announced in 2000 that it would no longer use oil from GE plants and GE corn. Ironically in 2011, Frito-Lay was sued for using “all natural” when their product indeed contained GE ingredients. Rady Ananada, *Frito-Lay Sued for labeling its GMO-filled snacks as ‘All Natural’*, GLOBAL RESEARCH (Dec. 23, 2013), http://www.globalresearch.ca/frito-lay-sued-for-labeling-its-gmo-filled-snacks-as-all-natural/28331_

An example of consumer authority is seen in the dairy labeling industry, when public opinion led most manufacturers and retailers to market only milk that is “rBST-free.”²¹⁶ Recombinant bovine somatotropin (“rBST,” also known as “rBGH,”) is the genetically engineered version of a naturally occurring hormone that is administered to dairy cows to increase their milk production.²¹⁷ Use of rBST was controversial because treated dairy cows were more prone to infections than untreated cows even though the science was unsettled regarding potential health effects on consumers.²¹⁸ Consumer concerns that originally revolved around health and safety devolved into a debate about the right to information.²¹⁹ Labels stating “rBST-free” were initially banned based on the arguments that “rBST-free” is misleading because there is no hormone-free milk since BST occurs naturally in cows and implies that rBST treated milk is less desirable. As a result, labels stating rBST-free were allowed only if they included the caveat, “no significant difference has been shown between milk from treated and untreated cows.”²²⁰ The purpose of the disclosure was to ensure that consumers were informed that the FDA has determined that the milk from treated and untreated cows is substantially equivalent.²²¹ As a result, even though the FDA approved milk from rBST-treated cows for human consumption, many producers have voluntarily stopped using rBST.²²²

The growing trend to market products as non-GMO makes it clear that consumer and retail pressure will likely lead to increased demands

²¹⁶ Libby Moulton, *Labeling Milk from Cows Not Treated with rBST: Legal in all 50 States as of September 29, 2010*, COLUM. SCI. & TECH. L. REV. (Oct. 28, 2010), <http://www.stlr.org/2010/10/labeling-milk-from-cows-not-treated-with-rbst-legal-in-all-50-states-as-of-september-29th-2010/>; see also Jeff Simmons, *More Food, Less Resources*, DAIRY FARMERS OF AM. (Apr. 5, 2011),

<http://www.dfamilk.com/newsroom/dfa-leader-magazine/more-food-less-resources>.

²¹⁷ FDA, REPORT OF THE FDA’S REVIEW OF THE SAFETY OF RECOMBINANT BOVINE SOMATOTROPIN, U.S. FOOD & DRUG ADMIN. (Apr. 22, 2009), <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm130321.htm>.

²¹⁸ *Id.*

²¹⁹ Moulton, *supra* note 216.

²²⁰ Moulton, *supra* note 216.

²²¹ FDA, INTERIM GUIDANCE ON THE VOLUNTARY LABELING OF MILK AND MILK PRODUCTS FROM COWS THAT HAVE NOT BEEN TREATED WITH RECOMBINANT BOVINE SOMATOTROPIN, U.S. FOOD & DRUG ADMIN. (Feb. 7, 1994), <http://www.idfa.org/files/fdarbstpolicy.pdf> (last visited Jan. 15, 2014).

²²² Simmons, *supra* note 216.

for suppliers to provide information about the production process to manufacturers and retailers.²²³ This may lead to companies wishing to cater to a growing consumer segment through labeling products as “GMO free” to demand uniform federal labels to maintain competitiveness in a market that is overflowing with labels.²²⁴ For example, in June 2013, the USDA (the agency responsible for labeling meat and poultry products) approved, after prior rejections, non-GMO labeling for certain meat and egg products that are produced from animals that never ate feed containing GE ingredients like corn, soy, and alfalfa.²²⁵ The producer must have demonstrated certifications to substantiate the claims.²²⁶ The USDA’s decision may cause more meat and poultry processors to seek the non-GMO Project verification and therefore lead to an industry-wide initiative to decrease their use of GE feed.²²⁷

Another example of the food industry’s response to consumer concerns and activist pressure is seen through changes food producers have made voluntarily. The changes include purchasing non-GE ingredients, demanding their suppliers segregate fields, grain bins, and storage elevators,²²⁸ and phasing out GE ingredients in human food.²²⁹

²²³ Stephanie Strom, *U.S. Approves a Label for Meat From Animals Fed a Diet Free of Gene-Modified Products*, N.Y. TIMES (June 20, 2013), <http://www.nytimes.com/2013/06/21/business/us-approves-a-label-for-meat-from-animals-fed-a-diet-free-of-gene-modified-products.html?pagewanted=print>.

²²⁴ *Id.*

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ See, e.g., A.C. Gallo, *GMO Labeling Update*, WHOLE FOODS (Sept. 18, 2013), <http://www.wholefoodsmarket.com/blog/gmo-labeling-update> (stating, “Now that Non-GMO claims for feed are being allowed by the appropriate government agencies, there is an incentive for producers to switch to Non-GMO feed and get verified.”); Stephanie Strom, *Genetic Changes to Food May Get Uniform Labeling*, N.Y. TIMES (Jan. 31, 2013), http://www.nytimes.com/2013/02/01/business/food-companies-meet-to-weigh-federal-label-for-gene-engineered-ingredients.html?pagewanted=all&_r=0&pagewanted=print (providing examples of companies that have decreased their use of GE ingredients based solely on the influential impact of proposed legislation to label GE products); see also discussion *supra* note 215.

²²⁸ Alexander G. Haslberger, *Monitoring and Labeling for Genetically Modified Products*, 287 SCI. 431, 432 (2000), http://openwetware.org/images/5/53/Policy_Forum.pdf (last visited Jan. 15, 2014).

²²⁹ See Bruce Horovitz, *Cheerios drops genetically modified ingredients*, USA TODAY (Jan. 2, 2014),

Furthermore, some food manufacturers have begun to source non-GE corn, oil, and ingredients,²³⁰ and some food distributors have pledged to stop carrying GE products by 2018 or include labels for all GE products.²³¹ While producers of GE crops have embraced the technology,²³² producers do not decide who their clients are.²³³ Instead, the farmers will be compelled to produce what the manufacturers and distributors desire.²³⁴ In turn, market forces can influence producers, manufacturers, and distributors to respond to consumers by requiring the disclosure of GE. As the market moves away from GE foods for human consumption, a national uniform standard would best serve consumers and producers.

V. RECOMMENDATIONS

A. Legislative Reform: Improve the FDA Regulation of Genetically Engineered Foods

As the agency tasked with overseeing the labeling of GE foods, the FDA must consider the various technicalities and implications of potential labeling.²³⁵ In order to restore consumer confidence in the United States food supply and its regulatory system, the FDA should require GE labeling. Currently, the FDA treats GE foods as substantially the same as foods created through the traditional process.²³⁶ While the FDA takes a science-based approach to conclude

<http://www.usatoday.com/story/money/business/2014/01/02/cheerios-gmos-cereals/4295739/>.

²³⁰ Ariana Eunjung Cha, *New twist on GMO debate: Are they 'natural'?*, WASH. POST (Oct. 21, 2013), <http://www.concordmonitor.com/news/8989862-95/debate-over-genetically-modified-food-heats-up-with-chipotle-video?print=true>.

²³¹ *GMO Transparency*, *supra* note 215.

²³² See Colleen Scherer, *Soybean farmers support biotechnology*, AG PROFESSIONAL (July 17, 2012), <http://www.agprofessional.com/news/Soybean-farmers-support-biotechnology-in-EU-162790066.html>.

²³³ *Id.*

²³⁴ See generally Horovitz, *supra* note 229.

²³⁵ *FDA's Role*, *supra* note 1, at 2; see also FOODS DERIVED FROM GENETICALLY ENGINEERED PLANTS, *supra* note 25, at 22985, 22991 (describing, paradoxically, the FDA's "ample authority" to regulate GE foods, conduct "premarket safety review," and require food labels despite its longstanding policy to not require disclosure of foods derived by "new methods" of plant breeding (e.g., GE plants) since they are used to "achieve the same goals as pursued with traditional plant breeding").

²³⁶ *FDA's Role*, *supra* note 1, at 2 (providing the FDA's consumer update as of Nov. 15, 2014).

that GE foods are “as safe as” conventional foods, there are consumer advocates who adhere to the EU’s precautionary stance and say that GE products are not sufficiently tested for safety, may carry allergy risks, and should be labeled.²³⁷ As the scientific community continues to analyze the safety implications associated with GE foods, the creation of a uniform national policy similar to international norms would preserve the position of American agricultural goods in the world market.

In determining the requisite labeling, the FDA must evaluate the potential impact of mandatory GE food labeling in the United States. Because GE crops would need to be stored separately from conventionally bred crops and labeled at each stage in the production process like in the EU,²³⁸ some food producers may face greater initial costs. However, producers who routinely export to markets where product segregation and GE product labeling is already required may face lower costs.²³⁹ Labeling may also decrease the risk of liability from lawsuits.²⁴⁰ Currently, the litigation model dominates the GE food labeling debate as seen by the increased number of class action lawsuits over food labels.²⁴¹ The industry has been moving on its own to address public concerns, with some success.²⁴² In recent years, food companies have voluntarily reduced GE ingredients through non-GE alternatives and independent certifying agencies such as the Non-GMO Project have become leaders in the movement for “food transparency” through non-GE labeling.²⁴³

When examining the regulatory options, the FDA should examine international norms in order to facilitate trade.²⁴⁴ To be effective for

²³⁷ See, e.g., *Right to Know*, *supra* note 9 (providing an overview of the “many reasons why Americans want labeling” including “health, safety or environmental concerns”); see also discussion *infra* Parts II, III.

²³⁸ REPORT 2, *supra* note 28, at 7.

²³⁹ Press Release, Oregon State University, OSU Economist Estimates Cost of GM Food Labels (Oct. 23, 2000), available at http://www.biotech-info.net/label_cost.html.

²⁴⁰ For a general discussion of liability issues, see Tana N. Vollendorf, Comment, *Genetically Modified Organisms: Someone is in the Kitchen with DNA—Who is Responsible When Someone Gets Burned?*, 21 MISS. C.L. REV. 43 (2001).

²⁴¹ Goldman & Zetoony, *supra* note 161.

²⁴² See *GMO Transparency*, *supra* note 215.

²⁴³ See, e.g., *id.*; see also *Mandatory Labeling Efforts*, NON-GMO PROJECT, <http://www.nongmoproject.org/take-action/mandatory-labeling/> (last visited Apr. 2, 2014).

²⁴⁴ See PEW US v. EU, *supra* note 107, at 8-9, 17.

American consumers and international trading partners, the label should indicate the presence of GE ingredients like the EU.²⁴⁵ The current voluntary labeling of the absence of GE ingredients is not adequate as indicated by near-unanimity in public opinion polls for mandatory labeling laws.²⁴⁶ Food manufacturers and producers that have benefited from using GE ingredients should bear the initial costs of labeling.²⁴⁷ While costs will eventually be passed on to the consumer, the vast majority of American consumers support labeling GE foods.²⁴⁸ Furthermore, because the food industry is highly competitive and constantly regulated, food companies have developed robust marketing systems that are constantly evolving and adapting to regulatory intervention.²⁴⁹ Thus, food companies will quickly develop marketing strategies to promote the benefits of its products while complying with labeling policies. Rather than being reactive, the food industry needs to become vigilant and proactive. Anti-science and anti-industry views often become the template from which consumers make decisions—but also by regulators who often respond not to the facts but to their constituents.²⁵⁰ Through a targeted education campaign that informs consumers, the food industry can get in front of questions about its credibility and labeling transparency.²⁵¹ Additionally, the FDA can develop a national performance plan that includes mechanisms to monitor progress and address any shortfalls.

B. Legislative Reform: Strengthen the Federal Genetically Engineered Food Act

The Federal GE Bill as written is ineffective and does not serve its stated purpose. Its scope is inappropriately large, it does not explicitly preempt similar state laws, and the exemptions are unjustified.²⁵² The Federal GE Bill requires that all foods that contain or are produced

²⁴⁵ For a list of countries with mandatory GE food labeling laws, see *Labeling Around The World*, *supra* note 129.

²⁴⁶ See *generally Right to Know*, *supra* note 9.

²⁴⁷ REPORT 2, *supra* note 28, at 7.

²⁴⁸ See *generally Right to Know*, *supra* note 9.

²⁴⁹ For example, the processed food industry adopted trans fats labeling requirements and voluntarily reduced its use of trans fats in products. Ashley Hayes, *Put down that doughnut: FDA takes on trans fats*, CNN (Nov. 13, 2013), <http://www.cnn.com/2013/11/07/health/fda-trans-fats/>.

²⁵⁰ See S. 809 (identical text as H.R. 1699).

²⁵¹ See *GMO Transparency*, *supra* note 215.

²⁵² See S. 809 (identical text to H.R. 1699).

with at least one GE organism must be labeled unless it falls into one of four exemptions.²⁵³ This would mean foods *containing* GE ingredients such as soy or corn would have to be labeled the same as foods *produced* with genetically engineered material such as milk from a cow injected with GE hormones: rBST.²⁵⁴ The Federal GE Bill does not, as it did in 2000, specify the form of the disclosure and thus leaves an inappropriate amount of discretion to the retailer.²⁵⁵ This could mislead consumers and nullify the Federal GE Bill's very purpose: "to establish a consistent and enforceable standard for labeling of foods produced using genetic engineering, including fish, thereby providing consumers with knowledge of how their food is produced."²⁵⁶

The Federal GE Bill as written does not preempt similar state laws, which it should in order to avoid a multitude of disparate laws. Expressly preempting similar state laws would strengthen the law and allow manufacturers to comply with one comprehensive national standard thereby serving the purpose of the law: to establish a consistent standard for labeling. The Federal GE Bill includes exemptions, but it does not state why these exemptions are granted and how the exemptions further its stated purpose.²⁵⁷ While the Federal GE Bill is ineffective as written, it has already gained the support of both chambers of Congress and thus should be amended to serve its stated purpose.²⁵⁸

C. Legislative Reform: Serve the Purpose of the Federal Genetically Engineered Food Act

The ultimate goal of the Federal GE Bill is to establish a uniform labeling regime for GE products in the United States.²⁵⁹ In order to serve the purpose of the law and establish a consistent national standard for labeling GE products, the Federal GE Bill must be limited in scope, preempt similar state laws, and justify its exemptions. An appropriate scope would be to require mandatory labeling for only certain highly prominent genetically engineered crops, such as corn,

²⁵³ *Id.*

²⁵⁴ *See id.*

²⁵⁵ *Id.*

²⁵⁶ *See id.*

²⁵⁷ *Id.*

²⁵⁸ *See id.*

²⁵⁹ *Id.*

soybean, canola, cotton, sugar beets, and include guidance for voluntary labeling for less commonly genetically modified crops. Preempting similar state laws would strengthen the law and allow manufacturers to comply with one comprehensive national standard thereby serving the purpose of the law: to establish a consistent standard for labeling. Some consumers' perception of GE foods vary, thus exemptions must be justified to prevent the legislation from dividing manufacturers and restaurants into opposing camps comprised of those who make "good food" versus others who trade in "bad foods."²⁶⁰ Additionally, an effective labeling system would include options for affirmatively indicating the presence of GE ingredients as well as voluntarily labeling its absence. A dual, mandatory and voluntary label scheme was the effective model used for trans fats, and assisted the food industry phase out trans fats in anticipation for scientific studies that resolved health concerns.²⁶¹ As consumer preferences shape market forces, food producers can offset any costs associated with labeling through price variation.²⁶²

More critically, the Federal GE Bill must be accompanied by a focused education campaign to educate consumers about the process

²⁶⁰ See Marcelo Gleiser, *Genetically Modified Organisms: To Eat Or Not To Eat?*, NPR (July 31, 2013, 8:01 AM), <http://www.npr.org/blogs/13.7/2013/07/31/206969863/genetically-modified-organisms-to-eat-or-not-to-eat>.

²⁶¹ Compare FDA, *Guidance for Industry: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, Health Claims; Small Entity Compliance Guide*, U.S. FOOD & DRUG ADMIN. (Aug. 2003), www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm053479.htm with *Questions & Answers*, *supra* note 1 (For the proposition that until recently, FDA considered trans fats safe for human consumption and only required that companies label trans fats in nutrition labels for consumers interested in limiting their intake. However, one decade later, FDA announced its preliminary determination that trans fats are no longer recognized as safe.). The required "contains trans fats" and voluntary "no trans fats" labeling scheme encouraged companies to voluntarily reduce trans fats in the production process to avoid the required label. See Fadar O. Otite et al., *Trends in Trans Fatty Acids Reformulations of US Supermarket and Brand-Name Foods From 2007 Through 2011*, CTR. FOR DISEASE CONTROL & PREVENTION (May 23, 2013), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670643/pdf/PCD-10-E85.pdf>.

²⁶² McDonalds stopped cooking with trans fats more than ten years ago, and stated that it will absorb the costs. Janet Adamy, *McDonald's Loses Its Trans Fats*, WALL ST. J. (May 23, 2008 11:59 PM EST), <http://online.wsj.com/news/articles/SB121151133018416567>.

and production of GE foods.²⁶³ An education and collaborative research campaign fund can be created through a voluntary program or mandatory tax because it would impact industry at each stage of food production—from the seed company and the farmers to the manufacturers and retailers.²⁶⁴ Collective funds have been implemented in other agriculture industries such as the milk and beef industries to require producers to contribute towards collective advertising funds.²⁶⁵ Convincing the public about the inconclusiveness of studies regarding GE food safety and the importance of GE crop exports in international trade is critical to the regulation's longevity.²⁶⁶

1. Location of the Specific Disclosure Statement Required: Front Panel or Ingredient List

Unlike the state bills, the Federal GE Bill does not specify the location where the statement disclosing the presence of a GE product must be.²⁶⁷ Instead, the Federal GE Bill preserves the manufacturers' discretion in where and how to provide the disclosure.²⁶⁸ Thus, the exact phrase required *and* the placement on the product would be left to the manufacturer's discretion. The state initiatives require that the information is displayed on a processed food package's front or side

²⁶³ See, e.g., *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 336-37 (1977) (creating a state agency to promote and protect Washington State's apple industry through advertising, research, and public education instead of relying on polarized interest groups to conduct research and present educational material).

²⁶⁴ See GM-FREE SCHOOLS, GE ACTION, <http://www.geaction.org/chapter7.pdf> (last visited Jan. 15, 2014).

²⁶⁵ See, e.g., *Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550 (2005) (holding that the USDA did not violate the First Amendment rights of beef producers and ranchers by requiring them to contribute funds to support genetic advertisements for beef); *Johanns v. Cochran*, 544 U.S. 1058 (2005), remanded to 2005 WL 2755711 (3d Cir. Sept. 15, 2005) (holding that the federal Dairy Promotion Stabilization Act, which compelled all dairy producers to subsidize "got milk?" advertisements, is not unconstitutional and the government can compel traditional dairy farmers to support dairy advertisements that allegedly benefit the whole industry).

²⁶⁶ See, e.g., Daniel Stokes, CONSUMERS AND FAIR TRADE: LESSONS FROM A DECADE OF DRAMATIC GROWTH AND GROWING IMPACT, http://www.gwu.edu/~iiep/assets/docs/fair_trade_stokes.pdf (last visited Jan. 15, 2014) (discussing the importance of consumer education in sustainable international trade).

²⁶⁷ See S. 809 (identical text as H.R. 1699).

²⁶⁸ *Id.*

panel, and require that a tagged shelf or bin provide information about raw GE foods.²⁶⁹

The Federal Bill, likewise, should contain more detailed guidelines and the Federal GE Bill should ask the FDA to update its 2001 GE guidelines that provide ample information but are currently outdated given the recent developments in biotechnology. The amendment to the Federal GE Bill should require that the disclosure convey whether the product *contains* a genetically engineered ingredient or was *produced* from a GE plant. The information could be placed on the front of the package or in the ingredients list as long as it is not smaller than the nutritional facts label.²⁷⁰ Merely stating that a food was genetically engineered without providing more information would not be an acceptable solution for biotechnology companies or to consumers demanding their “right to know.” Instead, a potential compromise would be to provide more information about the benefits of GE farming.²⁷¹ Some methods of providing information are through a QR code or using a symbol to avoid stigmatizing the product with a “warning label.” A label could also include the name of the certifying agent so consumers can seek more information.²⁷² Regardless of the form, all labels must abide by the FDA’s FDCA and therefore must be truthful and not misleading.²⁷³

2. Exemptions

Like the state bills, the Federal GE Bill includes exemptions. Unlike the state bills that include a greater number of exemptions to protect local interests,²⁷⁴ the federal bill contains four to protect restaurants, animal meat, healthcare providers, and alcohol.

The Federal GE Bill should be amended to not exempt restaurants. Americans are estimated to eat their weight in GE food annually

²⁶⁹ See *supra* Part IV.

²⁷⁰ *Consumers Don’t Pay as Much Attention to Nutrition Facts Labels as They Think, Eye-Tracking Study Finds*, SCIENCE DAILY (Oct. 24, 2011), <http://www.sciencedaily.com/releases/2011/10/111024084634.htm>.

²⁷¹ Sudhir Burgaard, *The Labeling of Genetically Modified Foods Debate*, Summer 2013, AM. BAR ASSOC., http://www.americanbar.org/publications/natural_resources_environment/2013-14/summer-2013/the_labeling_genetically_modified_foods_debate.html.

²⁷² *Id.*

²⁷³ DRAFT GUIDANCE, *supra* note 100.

²⁷⁴ See discussion *supra* Part IV.B.2.ii.

through commonly processed foods containing GE ingredients such as salad dressing.²⁷⁵ An exemption for restaurants, which would include fast food chains, may cause GE food producers to target sales to food establishments, in order to avoid new labeling regulations.²⁷⁶ Fast food chains cannot be exempt from the labeling requirements especially because of their large market presence.²⁷⁷

In labeling the presence of GE ingredients, standards consistent with the EU would be beneficial for trade. Thus, it is important to determine a minimum threshold level so that a reasonably low percentage of accidental GE presence—whether through drift, storage or processing—may be exempted.²⁷⁸ This practical approach, which is set to 0.9%, is reflected in EU Directives and the four state labeling initiatives.²⁷⁹ Furthermore, a federal labeling law over the final product would naturally require the FDA to step up its regulation of GE content during the production process.²⁸⁰

3. *Private Right of Action through a “Bounty Hunter” Provision*

The Federal GE Bill does not include a private right to sue, whereas both failed initiatives in California and Washington did.²⁸¹ While there is controversy over whether citizens—and most likely plaintiff’s attorneys—should have the right to sue, the ideal regulation should not include a bounty hunter provision. The purpose of a uniform national labeling standard in the United States is to increase transparency and stabilize international trade.²⁸² Allowing private citizens to enforce compliance on producers through a “bounty hunter” provision would not be an efficient method for providing information and would not

²⁷⁵ Sharp, *supra* note 1.

²⁷⁶ See Adamy, *supra* note 262.

²⁷⁷ See *id.*

²⁷⁸ See *Initiative 522: Costly, Flawed and Ill-Conceived*, *supra* note 189. While a minimum threshold is reasonable, I-522 would set a 0% threshold for labeling in 2019 and no existing data is available for the costs of complying with a threshold that low. *Id.*

²⁷⁹ See discussion *supra* Part III.

²⁸⁰ Lauren Zeichner, *Product vs. Process: Two Labeling Regimes For Genetically Engineered Foods and How They Relate to Consumer Preferences*, 27 ENVIRONS ENV'T'L L. & POL'Y J. 467, 472 (2004).

²⁸¹ See discussion *supra* Part IV; see also Price, *supra* note 177.

²⁸² See Segarra & Rawson, *supra* note 41, at 1.

parallel other country's GE regulations. Instead, a private right of action would create more liability than benefit for at least two reasons.

First, private lawsuits would impose significant defense costs on food processors and could open the floodgates for frivolous lawsuits. In recent years, civil class action complaints concerning "natural" claims on food labels have been increasingly litigated.²⁸³ Processed food companies have been forced to defend their products labeled natural against consumers who allege misleading representation because the product cannot be natural if it contains ingredients, such as oil, that were derived from a GE crop.²⁸⁴ If the Federal GE Bill were to contain a bounty hunter provision such as the one included in California's Proposition 37, plaintiffs would not need proof of a violation or damages before bringing a lawsuit. Therefore, plaintiff attorneys could target unlabeled foods that commonly contain GE ingredients and allege that they are mislabeled with a minimal burden of discovery. The defendant producer would therefore bear the burden of proving the unlabeled food does not intentionally contain GE ingredients. The stigma associated with the bounty hunter provision would potentially result in the failure to pass an otherwise reasonable labeling requirement just as it did in California. Potential exposure to consumer class action complaints may also influence industry to increase their lobbying effects against a Federal GE Bill.²⁸⁵

²⁸³ Cha, *supra* note 230; Goldman & Zetoony, *supra* note 161.

²⁸⁴ Elaine Watson, *Goldfish Crackers targeted in 'natural' lawsuit over genetically engineered soy as Prop 37 supporters launch 'GMO inside' initiative*, FOOD NAVIGATOR USA (Nov. 12, 2012) <http://www.foodnavigator-usa.com/Regulation/Goldfish-Crackers-targeted-in-natural-lawsuit-over-genetically-engineered-soy-as-Prop-37-supporters-launch-GMO-inside-initiative>. For example, Goldfish Crackers were targeted in a class action lawsuit alleging that Pepperidge Farm "mistakenly or misleadingly represented" that its crackers are "natural" when in fact, they are not, because they contain GE ingredients in the form of soy and soy derivatives. Another example is when Frito-Lay's was sanctioned for misleading use of "all natural" labeling on products that contain GE corn. The federal judge reviewing the Frito-Lay's case rejected the defense lawyers' argument that consumer claims should be barred by the "primary jurisdiction doctrine," which says that courts must wait for federal agencies to apply their regulatory expertise before hearing claims in litigation. In rejecting the defense argument, the federal judge stated, in dicta, that there is no guarantee that the FDA would clarify its position especially because the "FDA has assiduously avoided a hard-and-fast definition" since 1992 when the agency first issued a statement on GE food. *Id.*

²⁸⁵ See Strom, *supra* note 227 (discussing lobby efforts).

The second reason is that the increased risks of lawsuits are not justified in the absence of conclusive scientific studies.²⁸⁶ There is global consensus that GE foods do not present an imminent risk to human health and long-term studies are required.²⁸⁷ Those in favor of the bounty hunter provision state that consumers who perceive a risk should be able to sue instead of waiting for the FDA to inspect, and the companies who benefit from using GE products should bear the burden of proving that their labels are not untruthful and not misleading.²⁸⁸ However, a private right of action may interfere with the FDA's ability to react and inspect a product while the safety implications associated with GE foods remain inconclusive.

VI. CONCLUSION

As newer applications of GE foods emerge, existing United States policies are not able to address growing consumer concerns and increasing trade issues about the adequacy of oversight for GE organisms. American consumers are finding it increasingly difficult to navigate supermarkets saturated with GE products.²⁸⁹ Currently, the science remains inconclusive regarding whether GE foods are "as safe as" conventionally produced foods.²⁹⁰ Some believe the increase in food allergies and food recalls is linked with the GE process.²⁹¹ The FDA, however, holds that GE foods are no more likely to cause allergic reactions.²⁹² The FDA therefore takes the position that GE products can be adequately regulated under the existing framework that oversees conventionally grown foods.²⁹³

The EU, on the other hand, takes a more precautionary approach to the potential health consequences of GE foods and regulates both the biotechnology process and the final GE product.²⁹⁴ The more risk-based EU legislation requires accountability at every stage of production and ensures transparency of the final GE product.²⁹⁵ The

²⁸⁶ See discussion *supra* Part II.

²⁸⁷ See, e.g., *Initiative 522: Costly, Flawed and Ill-Conceived*, *supra* note 189, at 1.

²⁸⁸ See Von Mogel, *supra* note 140.

²⁸⁹ See discussion *supra* Part I.

²⁹⁰ See discussion *supra* Part II.

²⁹¹ See discussion *supra* Part II.

²⁹² See discussion *supra* Part III.

²⁹³ See discussion *supra* Part III.

²⁹⁴ See discussion *supra* Part III.

²⁹⁵ See discussion *supra* Part III.

EU's policies extend to international exporters—and the United States is the EU's largest trading partner.²⁹⁶ However, the dearth of cohesive legislation in the United States has led to increased agricultural trade imbalances as other GE-producing countries threaten to displace United States GE exports.²⁹⁷ The lack of mandatory federal regulations that distinguish GE foods from other foods has led to state initiatives to label GE products.²⁹⁸ Yet the piecemeal state initiatives do not address the actual issue, which is to ensure transparency in the GE food production system.

To overcome the regulatory challenge, the United States should enact uniform risk-based GE labeling legislation consistent with the EU's precautionary principle given the inconclusive science and international trade concerns. An amended Federal GE Bill will turn out to be a step in the right direction for consumer safety concerns and American agricultural foods in the world market. Mandatory labeling legislation may mitigate consumer risk perceptions as it did for rBST milk. After litigating over rBST milk labeling and non-rBST milk was labeled, companies voluntarily stopped using the GE version of the hormone even though no studies showed negative health effects for humans. Labeling actually increased consumer confidence and trade.²⁹⁹

Adopting a precautionary approach and enacting federal labeling laws for GE foods in the United States would reduce international trade obstacles and increase consumer confidence in the government. Uniform labeling laws would streamline the approval process for GE crop exports. The ideal regulation would be modeled on an approach that ensures consumers receive information and increases the confidence of international trading partners in the American food production and regulatory system. Legislation that requires labeling would be more proactive and effective than a *laissez-faire* approach. It would minimize harm to international trade while also responding to consumer concerns. Federal law should preempt state laws and prevent patchwork legislation that would not serve state, federal, or consumer interests. In sum, a mandatory federal labeling law in the United States

²⁹⁶ See discussion *supra* Part III.

²⁹⁷ See discussion *supra* Part IV.

²⁹⁸ See discussion *supra* Part IV.

²⁹⁹ See discussion *supra* Part IV.

is a reasonable public policy for consumers on both sides of the Atlantic.

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