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”So Close, Yet So Far”: The United States Follows the Lead of the European Union in Mandating GMO Labeling. But Did It Go Far Enough?

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NOTE

"SO CLOSE, YET SO FAR": THE UNITED STATES FOLLOWS THE LEAD OF THE EUROPEAN UNION IN MANDATING GMO LABELING. BUT DID IT GO FAR ENOUGH?

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INTRODUCTION

The footage aftermath of the 7.0 magnitude earthquake that devastated Haiti on January 12, 2010 touched the hearts of millions as they saw buildings flattened to the ground, leaving victims without homes and suffering without basic necessities.[1] The earthquake

1. *See* Olivier Laurent, *Haiti Earthquake: Five Years After*, TIME (Jan. 12, 2015), http://time.com/3662225/haiti-earthquake-five-year-after/ (describing the 2010 earthquake in Haiti); *Haiti Earthquake Fast Facts*, CNN (Dec. 13, 2015, 4:01 PM), http://www.cnn.com/2013/12/12/world/haiti-earthquake-fast-facts/ (discussing the devastation of the 2010 earthquake).

resulted in over 200,000 deaths, 300,000 injuries, and 1.5 million people being initially displaced from their homes.[2] In the wake of the earthquake, relief came from governments and private citizens alike, with US$13.34 billion allocated by international agencies and US$4 billion from the US Government.[3] As part of this relief effort, the agricultural biotechnology corporation Monsanto donated 60,000 seed sacks, equivalent to 475 tons, of hybrid corn seeds and vegetable seeds.[4] Despite the dire situation in Haiti at the time, many Haitian farmers so vehemently opposed the donation that they vowed to burn the donated seeds.[5] In fact, the farmers considered the donation to be so catastrophic that they called it "a new earthquake" and characterized it as a strong attack on small agriculture, biodiversity, Creole seeds, farmers, and what was left of the environment in Haiti.[6] The reason for this seemingly odd response? GMOs.[7]

Prior to 1994, no food sold in US stores contained genetically modified organisms ("GMOs"), which are defined as "organisms (i.e. plants, animals or microorganisms) in which the genetic material ("DNA") has been altered in a way that does not occur naturally by mating and/or natural recombination."[8] In 2015, over seventy percent

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2. *See Haiti Earthquake Fast Facts*, *supra* note 1 (giving statistics on the earthquake in Haiti in 2010); Richard Pallardy, *Haiti Earthquake of 2010,* ENCYCLOPEDIA BRITANNICA, http://www.britannica.com/event/Haiti-earthquake-of-2010 (giving information about the 2010 earthquake).

3. *See Haiti Earthquake Fast Facts*, *supra* note 1 (providing information on the amount of relief contributed to the country of Haiti after the earthquake); *Haiti Earthquake of 2010*, *supra* note 2 (discussing relief efforts).

4. *See* Beverly Bell, *Haitian Farmers Commit to Burning Monsanto Hybrid Seeds*, HUFFINGTON POST (Mar. 17, 2010, 12:44 PM), http://www.huffingtonpost.com/beverly-bell/haitian-farmers-commit-to_b_578807.html (discussing the Monsanto donation); Michelle Greenhalgh, *Haitian Farmers Reject Monsanto Donation*, FOOD SAFETY NEWS (June 7, 2010), http://www.foodsafetynews.com/2010/06/haitian-farmers-burn-monsanto-hybrid-seeds/ (explaining Monsanto's donation of 60,000 seed sacks).

5. Bell, *supra* note 4 (highlighting the vow of the Haitian farmers to burn the Monsanto seeds); Greenhalgh, *supra* note 4 (detailing this pledge).

6. Greenhalgh, *supra* note 4 (stating why the Haitian farmers so strongly opposed the donation); Bell, *supra* note 4 (describing the reasoning behind the farmers' dissent).

7. *See* Bell, *supra* note 4 (discussing the anti-GMO sentiments of the Haitian farmers); Greenhalgh, *supra* note 4 (explaining the views of the farmers with respect to GMOs and the Monsanto donation).

8. *Frequently asked questions on genetically modified foods*, WHO http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/ (defining genetically modified organisms (GMOs)); Elizabeth Weise, *Genetically engineered*

of items sold in US food stores contained GMOs.[9] Yet, until July 2016, the United States resisted joining more than sixty nations that require GMO labeling and instead regulated GMOs using a voluntary labeling system, since the Food and Drug Administration ("FDA") does not distinguish foods containing GMOs from those that do not.[10] While the FDA has not required labeling because of this policy, at least ninety-two percent of US citizens desire GMOs to be labeled.[11] Furthermore, despite the fact that more than sixty percent of US citizens believe that "natural" signifies that a food product contains no GMOs, the FDA has never issued a formal definition of the word "natural," and therefore has allowed companies to advertise their products that contain GMOs or were made using genetic engineering

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foods Q & A, USA TODAY (Dec. 30, 2015), http://www.usatoday.com/story/news/nation/2012/10/28/gmo-questions/1658225/ (identifying 1994 as the first year a GMO product was brought to the US market); *GMO Timeline – A History of Genetically Modified Foods*, GMO AWARENESS (Dec. 30, 2015), http://gmo-awareness.com/all-about-gmos/gmo-timeline-a-history-of-genetically-modified-foods/ (listing important dates in the development of GMOs, including 1994 as the first year a GMO product was on the US market).

9. *See* Travis Nunziato, *"You Say Tomato, I Say Solanum Lycopersicum Containing Beta-ionone and Phenylacetaldehyde": An Analysis of Connecticut's GMO Labeling Legislation*, 69 FOOD & DRUG L.J. 471, 472 (2014) (assessing the percentage of products sold in the United States that contain GMOs to be seventy percent); *see also* Michael Potter, *Give Americans what they want and deserve: Label GMO Foods*, MICH. LIVE (Dec. 30, 2015), http://www.mlive.com/opinion/index.ssf/2015/09/give_americans_what_they_want.html (explaining that seventy percent of food on the shelves of grocery stores contain GMOs).

10. *See* Christina Sarich, *The 64 Countries That Require GMO Labeling – U.S. Buckles Under Biotech Pressure*, NAT. SOC'Y (Oct. 13, 2014), http://naturalsociety.com/64-countries-require-gmo-labeling-not-united-states/ (stating that during 2014, the United States was not one of the sixty-four countries that require GMO labeling); Carey Gillam, *House Passes Anti-GMO Labeling Law*, REUTERS (July 23, 2015, 4:52 PM), http://www.reuters.com/article/us-usa-gmo-labeling-idUSKCN0PX17920150723 (stating that sixty-four countries required GMO labeling in 2015).

11. *See* Julie M. Muller, *Naturally Misleading: FDA's Unwillingness To Define "Natural" and the Quest for GMO Transparency Through State Mandatory Labeling Initiatives*, 48 SUFFOLK U. L. REV. 511, 523 (2015) (stating that despite its stated intention to formally define "natural," the FDA has never issued a formal definition for the term); *US Polls on GE Food Labeling*, CTR. FOOD SAFETY, http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling (citing numerous reports that report over ninety-two percent of US citizens want the federal government to require GMO labeling); Gary Langer, *Poll: Skepticism of Genetically Modified Foods*, ABC NEWS (June 19, 2015), http://abcnews.go.com/Technology/story?id=97567&page=1 (describing a poll in which ninety-three percent of US citizens believe that the federal government should require labels on food saying whether it's been genetically modified or "bio-engineered").

("GE") as "natural."[12] Since the FDA has not changed its policy on GMOs since 1992, it continues to maintain a bare minimum standard of review for foods containing GMOs.[13] The FDA relies solely on voluntary information provided by food manufacturers to ensure safety and compliance with its standards.[14]

This regulatory framework departs both from US public opinion and global standards.[15] Perhaps one of the most comprehensive GMO regulatory systems is that of the European Union, which is rooted in a fundamental policy known as the precautionary principle.[16] In sharp contrast with the United States, which assumes that GMOs are not materially different from traditional foods and are safe for human consumption, the European Union has designed its entire GMO regulatory system on the precautionary principle and assumes that genetically modified foods are not safe until proven otherwise by

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12. *See* Andrea Rock, *Where GMOs hide in your food*, CONSUMER REP. (Oct. 2014) http://www.consumerreports.org/cro/2014/10/where-gmos-hide-in-your-food/index.htm (describing a Consumer Reports National Survey in which over sixty percent of people said they believed "natural" means "no GMOs"); Muller, *supra* note 11 (citing a survey in which over sixty percent of people said that "natural" means that a product contained no GMOs).

13. *See infra* notes 85-89 and accompanying text.

14. *See Food From Genetically Engineered Plants,* FDA, http://www.fda.gov/Food/FoodScienceResearch/GEPlants/ (last updated Nov. 19, 2015) (detailing the FDA policy on food from genetically engineered plants and the agency's biotechnology policy)*; U.S. Regulation Of Genetically Modified Crops*, FED'N AM. SCIENTISTS, http://fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/us-regulation-of-genetically-engineered-crops.html (last visited Jan. 7, 2016) (explaining how the FDA regulates GMOs and describing the agency's voluntary consultation process with manufacturers).

15. *See GMO foods: What you need to know*, CONSUMER REP. (Feb. 26, 2015, 3:20 PM), http://www.consumerreports.org/cro/magazine/2015/02/gmo-foods-what-you-need-to-know/index.htm (discussing that GMO labeling is mandatory in more than sixty countries, which did not include the United States during 2015); Tom McKay, *64 Countries That Have GMO Labeling Laws*, GENETIC LITERACY PROJECT (May 14, 2014), https://www.geneticliteracyproject.org/2014/05/14/64-countries-that-have-gmo-labeling-laws/ (distinguishing the United States from the sixty-four countries that mandated GMO labeling through 2014).

16. *See* Harrison Joss, *The Rise Of Frankenbeer: A Holistic Analysis On International Labeling And Beverage Laws Through The Lens Of This Ongoing Controversy Of Genetically Modified Organisms*, 21 ILSA J. INT'L & COMP. L. 131, 147 (2014) (commenting on how the precautionary principle in the European Union has created the "strictest and broadest regulations"); Mystery Bridgers, *Genetically Modified Organisms And The Precautionary Principle: How The GMO Dispute Before The World Trade Organization Could Decide The Fate Of International GMO Regulation*, 22 TEMP. ENV'T L. & TECH. J. 171, 184 (2004) (explaining how the European Union used the precautionary principle to design its GMO regulations).

reliable scientific research.[17] In accordance with the precautionary principle, the European Union requires companies to indicate if their products contain any amount of GMOs past a threshold level.[18] This requirement allows consumers to choose whether or not to consume food containing GMOs.[19] Unlike the US structure, the EU regulatory system operates in a way that reflects public opinion, which is quite distrustful of genetic engineering and is strongly anti-GMO.[20] Since the European Union presumes foods containing GMOs to be harmful unless proven otherwise under the precautionary principle, companies seeking approval of genetically modified products are required to submit detailed application materials and undergo a rigorous approval process based on independent assessments.[21]

While the United States has regulated GMOs from a position that greatly contrasts with that of the European Union for over two

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17. *See* Emily Marden, *Risk And Regulation: U.S. Regulatory Policy On Genetically Modified Food And Agriculture*, 44 B.C. L. REV. 733, 735 (2003) (explaining how the United States has taken an approach that stands in contrast with the precautionary principle, upon which the European Union has based its GMO regulatory system); Bridgers, *supra* note 16, at 184 (stating how the European Union designed its GMO regulatory system using the precautionary principle).

18. *See infra* Section I.B and accompanying text (providing an overview for the EU GMO regulatory system and its foundation in the precautionary principle).

19. *See* Katherine Wilinska, *Aquadvantage Is Not Real Advantage: European Biotechnology Regulations and the United States' September 2010 FDA Review of Genetically Modified Salmon*, 21 MINN. J. INT'L L. 145, 156 (2012) (describing how the precautionary principle has influenced the EU GMO regulatory system and how the European Union errs on the side of caution even without any demonstrable risk); Stephanie Amaru, *A Natural Compromise: A Moderate Solution to the GMO and "Natural" Labeling Disputes*, 69 FOOD & DRUG L.J. 575, 600 (2014) (explaining how, as opposed to the US system under the FDA's policy, the European Union has determined a threshold level for GMOs and labeling requirements according to that level).

20. *See* Nathan W. Eckley, *Reaping The Benefits Of Agricultural Biotechnology Through Uniform Regulation*, 35 J. MARSHALL L. REV. 433, 442 (2002) (explaining that the motivation behind the strict approach of the European Union is public distrust of GMOs); Wilinska, *supra* note 19, at 155-56 (explaining how European consumers are deeply skeptical about the small environmental impact of GM foods and do not trust the food safety regulations of the European Union).

21. *See* Javier Guillem Carrau, *Lack Of Sherpas For a GMO Escape Route In The EU*, 10 GERMAN L.J. 1169, 1180 (2009) ("[The European Union] regulates a 'case by case' authorization process, applying the precautionary principle, in order to make decisions on the basis of risk assessment, scientific criteria, the introduction of emergency and surveillance programmes, and so on."); Wilinska, *supra* note 19, at 157 (explaining how under the precautionary principle, the European Union assumes that new technology is not safe until proven otherwise by extensive scientific research conducted by a separate designated agency).

decades, this stark polarity has suddenly lessened, as the United States reversed its long-held policy on GMO labeling by enacting federal GMO labeling requirements under S. 764 in 2016.[22] The complete reversal in US policy occurred as a result of the state movement that pushed for GMO labeling requirements and brought about much dispute among those in federal government, the food industry, and state government.[23] From 2014 to 2016, consumer demand for GMO labeling reached an all time high in the United States, as individual states such as Vermont and Connecticut enacted their own legislation mandating the labeling of GMOs.[24] While the FDA has refused to require such labeling since 1992 in contrast with growing public opposition, these states listened to the concerns of their citizens and acted in defiance of the FDA's policy.[25] It is this consumer opposition and state action that prompted the US Congress to quickly implement S. 764, which mandates GMO labeling of bioengineered foods, as a solution to the GMO labeling crisis.[26] S. 764 signaled both triumph and defeat on both sides of the GMO debate, as those advocating state GMO labeling measures witnessed the revolutionary laws of Vermont, Connecticut, and Maine become federally preempted, while others who vehemently opposed GMO labeling watched it become a

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22. *See infra* Section II.A (highlighting this sudden shift to mandatory GMO labeling under S. 764).

23. *See infra* Section II.A. (explaining the impact of the state movement toward mandatory GMO labeling on the US federal government and the conflict associated with such state measures).

24. *See* Dana Ford & Lorenzo Ferrigno, *Vermont Governor Signs GMO Food Labeling Into Law*, CNN (May 8, 2014, 9:17 PM), http://www.cnn.com/2014/05/08/health/vermont-gmo-labeling/ (announcing that Vermont passed the first state GMO labeling law without a requirement that other states enact similar laws in order for it to go into effect); Stephanie Strom, *Connecticut Approves Labeling Genetically Modified Foods*, NY TIMES (June 3, 2013), http://www.nytimes.com/2013/06/04/business/connecticut-approves-qualified-genetic-labeling.html?r=0 (stating that Connecticut became the first state to pass a GMO labeling law and explaining the conditions that had to be met for the law to go into effect).

25. *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984-01 (May 29, 1992) [hereinafter *1992 FDA Statement of Policy*] (not requiring GMO labeling); Clare Leschin-Hoar, *Vermont Takes On Genetically Modified Foods With New Labeling Law*, GUARDIAN (May 8, 2014, 10:38 PM), http://www.theguardian.com/sustainable-business/vermont-gmo-labeling-law-genetically-modified-foods-lawsuits (describing some of the arguments surrounding the states' actions to require GMO labeling when the FDA does not).

26. *See infra* Section II.A.

federal requirement.[27] While S. 764 has been met with both great praise and disdain, it is undeniable that the federal measure will significantly change the way in which GMOs are regulated at the federal level, which used to be governed solely by the 1992 FDA Statement of Policy and the agency's strict opposition to GMO labeling requirements.[28]

Therefore, as shown by this brief overview, the regulatory systems of the European Union and United States that govern GMOs radically differ due to the contrasting principles upon which they are based.[29] The US regulatory system is based on the substantial equivalence doctrine, which assumes that GMOs are substantially equivalent to their traditional counterparts and therefore present no new risks beyond those of conventional organisms.[30] In contrast to the United States, the European Union formed an entirely new regulatory system based on the precautionary principle, which allows governments to take preventative action to avoid potentially serious environmental dangers even if the causal connection has not been scientifically confirmed.[31] Accordingly, the two regulatory systems are unlikely to ever completely mirror one another.[32] However, the

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27. *See infra* Section II.A.10.

28. *See infra* Sections I.A, II.A.10.

29. *See generally* Rebecca M. Bratspies, *Is Anyone Regulating? The Curious State Of GMO Governance In The United States*, 37 VT. L. REV. 923, 929-39 (2013) (explaining how the substantial equivalence doctrine, which asserts that genetically engineered products are equivalent to their unmodified counterparts, formed the basis of the US GMO regulatory system); Wilinksa, *supra* note 19, at 156-57 (detailing how the precautionary principle, which serves as the foundation of the EU GMO regulatory system, presumes genetically engineered products to be unsafe until proven otherwise).

30. *See* Bratspies, *supra* note 29, at 929 (defining the substantial equivalence doctrine); Nunziato, *supra* note 9, at 479 (stating that the FDA treats GMOs as substantially equivalent to their non-GMO counterparts).

31. *See* Wilinska, *supra* note 19, at 156 (describing how the European Union, even without evidence of risk, errs on the side of caution); Bridgers, *supra* note 16, at 184 (articulating how a lack of scientific certainty concerning the cause of risks should not be an obstacle to preventative action being taken).

32. *See The EU-US Dispute over GMOs: Risk Perceptions and the Quest for Regulatory Dominance*, EU CTR. N.C. (May 2007), http://europe.unc.edu/wp-content/uploads/2013/08/Brief0705-GMOs.pdf (highlighting the many differences between the two regulatory systems and commenting on how the transatlantic differences have not been settled); Jessica Lau, *Same Science, Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe,* SCI. IN NEWS (Aug. 2015), http://sitn.hms.harvard.edu/flash/2015/same-science-different-policies/ (comparing the two regulatory systems and explaining how the United

United States has followed the example of the European Union and implemented a mandatory labeling regime under S. 764 in order to avoid a patchwork system of GMO labeling requirements and calm public unrest.[33] While mandatory GMO labeling is now a reality in the United States, there still exists a preferable solution that better aligns with public opinion and will result in true GMO transparency based on the Consumer Right to Know Policy.[34]

Part I of this Note will discuss the US and EU regulatory systems and will introduce the debate over GMO labeling in the United States. Part II will discuss the state GMO labeling laws that prompted Congress to pass S. 764 and will include a discussion of the Consumer Right to Know Policy. Part II will also detail how the demand for mandatory GMO labeling led to a crisis in the European Union in 1997, when several Member States banned an approved GMO product because it was not required to be labeled as a GMO. Finally, this Part will discuss how the opposition from the Member States was only resolved through the implementation of stricter labeling requirements under the *Traceability and Labeling Regulation*. Part III will offer a solution to the current US debate over mandatory GMO labeling. In Part III, this Note will argue that while the United States successfully followed the example of the European Union by implementing a mandatory GMO labeling regime, it failed to achieve GMO transparency. Part III will show how the United States Congress should replace S. 764 with a system based on the Consumer Right to Know Policy that requires labeling based on the process of genetic engineering. By implementing such a system at the federal level, the United States will answer the public demand for the ability to make informed decisions and adhere to the 1992 FDA Statement of Policy.

States focuses on the end product while the European Union emphasizes the processes used to develop the end product).

33. *See infra* Part II.

34. *See infra* Part III.

I. THE US AND EU GMO REGULATORY SYSTEMS

This Part gives an overview of both the US and EU GMO regulatory systems, including their foundational principles and how they were developed. Section I.A explains the Coordinated Framework and the 1992 FDA Statement of Policy, which led to the decision not to mandate GMO labeling in the United States. Section I.B details the many changes sustained by the EU GMO regulatory system and further discusses the series of Directives and Regulations that have formed the European Union's current regulatory system. Through these discussions, Section I.A shows how the United States has based its GMO regulatory system on the substantial equivalence doctrine, while Section I.B stresses the importance of the precautionary principle as the foundation of the EU GMO regulatory system. Finally, Section I.B also includes a comparison of the EU and US GMO regulatory systems.

A. US Regulation of Genetically Modified Organisms

This Section details how the United States regulates GMOs through existing laws within three federal agencies under a system known as the Coordinated Framework. Section I.A.1 examines the regulation of GMOs under the Coordinated Framework, while Section I.A.2 explains how the FDA regulates GMOs through existing law under the Federal Food and Drug Cosmetic Act ("FDCA.") Section I.A.3 provides an analysis of the 1992 FDA Statement of Policy concerning GMOs and the substantial equivalence doctrine. Section I.A.4 explains the lack of mandatory labeling for GMOs, while Sections I.A.5 and I.A.6 provide the FDA position on defining "natural" and labeling products that do not contain GMOs. Finally, Section I.A.7 shows how the 1992 FDA Statement of Policy has been upheld by the courts.

1. The Roles, Benefits, and Concerns of GMOs

Genetic modification is a process of biotechnology whereby genetic material of an organism is manipulated to deliberately modify

the organism's characteristics to create new variations of life.[35] This technology has been greatly beneficial in agriculture and pharmaceuticals.[36] For example, the first human insulin was created using methods of genetic modification.[37] Because of GMOs, farmers are able to plant herbicide-resistant plants and plants that are more resistant to diseases, droughts, and pesticides.[38] This has also led to increased crop productivity, longer shelf life, lower use of chemical pesticides, and lower average levels of fungal toxins on produce.[39]

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35. *See* Nunziato, *supra* note 9, at 474 (giving a definition for genetic modification); *Definition of biotechnology*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/biotechnology (last visited Jan. 6, 2016) ("Definition of biotechnology: the manipulation (as through genetic engineering) of living organisms or their components to produce useful usually commercial products (as pest resistant crops, new bacterial strains, or novel pharmaceuticals)"). To create these new variations of life, scientists first extract DNA from the designed organism and isolate a particular gene of interest. After a particular section of DNA has been extracted and isolated, scientists can manipulate the gene to work in the new organism and finally combine it with another segment of DNA from another cell to create a "new" organism. As a result, the organism is able to express the trait encoded by that gene, usually to the organism's benefit. *See* Amy Glasscock, *How America Can Move Closer Toward Mandated Labeling for Genetically Modified Foods and Remain 1st Amendment Compliant*, 14 HOUS. J. HEALTH L. & POL'Y 223, 226 (2014) (detailing the process involved in genetic engineering and how original organisms are modified to result in a new transformation); Charlotte Davis, *A Right to Know about GMOs: What American Meat Institute v. USDA Means for Vermont's Food Labeling Law,* 16 N.C. J.L. & TECH. ON. EDITION 32, 36 (2015) (describing the results of this process); Nunziato, *supra* note 9, at 474-75 (describing how a GMO is developed and explaining that the new organism can express the new trait that is encoded by the gene).

36. *See Benefits of Genetic Engineering*, XAMPLIFIED, http://www.chemistrylearning.com/benefits-of-genetic-engineering/ (last visited Jan. 7, 2016) (describing many of the benefits of genetic engineering in the field of science); Nunziato, *supra* note 9, at 475 (explaining how genetic modification has brought about many benefits in the areas of agriculture and pharmaceuticals).

37. *See* Nunziato, *supra* note 9, at 475 (describing how the first human insulin was created using genetic modification methods)*; Benefits of Genetic Engineering, supra* note 36 (describing how genetic engineering was used to develop human insulin).

38. *See* George A. Kimbrell & Aurora L. Paulsen, *The Constitutionality of State-Mandated Labeling For Genetically Engineered Foods: A Definitive Defense*, 39 VT. L. REV. 341, 355 (2014) (stating that genetically engineered crops are agricultural biotechnology's major research and development focus); *Benefits of Genetic Engineering*, *supra* note 36 (giving an overview of many of the agricultural benefits of genetic engineering).

39. *See* Valery Federici, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Law*, 35 BROOKLYN J. INT'L L. 515, 524 (2010) (putting forth many of the positive impacts of GMOs); Kyndra A. Lundquist, Note, *Unapproved Genetically Modified Corn: It's What's for Dinner*, 100 IOWA L. REV. 825, 830 (2015) (detailing some of the agricultural advances made with genetic engineering); Nunziato, *supra* note 9, at 475-76 (explaining some of the benefits of GMOs).

The popularity of such biotechnology is not to be underestimated.[40] As of 2014, genetically engineered crops made up ninety-three percent of US corn acreage, ninety-four percent of US soybean acreage, and ninety-six percent of US cotton acreage.[41] Worldwide, the number of acres planted with genetically engineered crops grew from 167 million acres in 2004 to 448 million acres in 2014.[42]

GMO proponents argue that in addition to the benefits previously described, other positive impacts include lower food prices, reduction in greenhouse gases, increased production of biofuels, decrease in soil erosion, and social benefits like reduction in hunger in developing countries.[43] On the opposite side of the debate, there are many concerns over the safety of GMOs with respect to human health and the environment.[44] Part of these concerns stem from what is unknown about GMOs, specifically how genetically modified genes interact with other genes and the environment.[45] Health concerns include increased allergenicity, compromised immune

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40. *See* JUSTICE MING W. CHIN ET AL., FORENSIC DNA EVIDENCE: SCIENCE AND THE LAW § 13:16, 1 (showing the impressive impact of biotechnology); *Biotech industry – Statistics & Facts,* STATISTA, http://www.statista.com/topics/1634/biotechnology-industry/ (last visited Jan. 7, 2017) (stating that the United States generates US$90 billion in biotech revenue and that globally, US$160 billion were spent on biopharmaceuticals in 2011).

41. *See* CHIN ET AL., *supra* note 40, at 1 (giving statistics for genetically engineered crops); *Adoption of Genetically Engineered Crops in the U.S.: Recent Trends*, US DEP'T AGRIC. ECON. RES. SERV., http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx (showing statistics concerning GE soy and corn crops).

42. *See* CHIN ET AL., *supra* note 40, at 1 (describing how the number of acres grown worldwide has multiplied); *Global Status of Commercialized Biotech/GM Crops in 2014*, INT'L SERV. ACQUISITION AGRI-BIOTECH APPLICATIONS, http://www.isaaa.org/resources/publications/pocketk/16/ (showing this jump in GE crops).

43. *See* CHIN ET AL., *supra* note 40, at 1 (setting forth these benefits by GMO proponents); Maria Gabriela Balboa, *Legal Framework To Secure The Benefits While Controlling The Risks Of Genetically Modified Foods: A Comparison Of The Cartagena Protocol And Three National Approaches*, 31 TEMP. J. SCI. TECH. & ENV'T L. 255, 258-59 (2012) (discussing these and other benefits claimed by GMO advocates).

44. *See* Balboa, *supra* note 43, at 259 (contrasting the listed benefits with the common fears surrounding GMOs); Nunziato, *supra* note 9, at 476 (discussing many of the fears surrounding GMOs).

45. *See generally* Balboa, *supra* note 43, at 259-61 (explaining many of the concerns surrounding the unknown effects of GMOs); Nunziato, *supra* note 9, at 476 (analyzing many of the arguments against GMOs based on what is not known about them).

function, antibiotic resistance, and increased toxicity.[46] With respect to agriculture, the biggest benefits of GMOs are also seen by some as the biggest negatives of genetic engineering.[47] While genetic engineering is used for its ability to make crops more herbicide-resistant, environmentalists are concerned that this may lead to increased human consumption of dangerous toxins and may jeopardize seed diversity.[48] While most scientific research supports the argument that GMOs are safe for human health, many individuals around the world demand either a ban on the use of GMOs or labeling laws that require GMO information on food labels.[49]

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46. *See* Balboa, *supra* note 43, at 259 (discussing these concerns); Nunziato, *supra* note 9, at 476 (analyzing some of the concerns regarding GMOs).

47. *See Herbicide Resistant Crops*, GMO COMPASS (Dec. 11, 2006), http://www.gmo-compass.org/eng/agri_biotechnology/breeding_aims/146.herbicide_resistant_crops.html (explaining the position of critics who claim that the use of herbicide resistant crops can lead to an increase in herbicide use and damage biodiversity); Rachel Rettner, *New GMO Controversy: Are The Herbicides Dangerous*, LIVE SCI. (Aug. 19, 2015, 5:08 PM), http://www.livescience.com/51917-gmo-herbicides-health.html (explaining the argument that herbicide resistant GM crops have caused an increase in the use of herbicide).

48. *See* Beth Hoffman, *GMO Crops Mean More Herbicide, Not Less*, FORBES (July 2, 2013, 11:39 AM), http://www.forbes.com/sites/bethhoffman/2013/07/02/gmo-crops-mean-more-herbicide-not-less/#35c065faa371 (stating that despite the main argument that genetically engineered crops will allow farmers to use less herbicide and pesticide, USDA and EPA data shows that the use of genetically engineered crops has actually increased the use of herbicide in the United States); *Herbicide Tolerant Crops*, BEYOND PESTICIDES, http://www.beyondpesticides.org/programs/genetic-engineering/herbicide-tolerance (citing a USDA report that found that herbicide use on GE corn rose from 1.5 pounds per planted acre in 2001 to more than 2.0 pounds in 2010).

49. *See* Jon Entine, *The Debate About GMO Safety Is Over, Thanks To A New Trillion-Meal Study*, FORBES (Sept. 17, 2014), http://www.forbes.com/sites/jonentine/2014/09/17/the-debate-about-gmo-safety-is-over-thanks-to-a-new-trillion-meal-study/#4eb692b7ca93 (explaining how many major studies have found that GMOs are as safe or safer than conventional or organic foods and that biotechnology does not pose an unusual risk to human health); Stefaan Blancke, *Why People Oppose GMOs Even Though Science Says They Are Safe*, SCI. AM. (Aug. 18, 2015), http://www.scientificamerican.com/article/why-people-oppose-gmos-even-though-science-says-they-are-safe/ (analyzing why so many individuals oppose GMOs and believe that they are harmful to human health and the environment despite "overwhelming evidence that proves GMOs are safe to eat, and that they bring environmental benefits by making agriculture more sustainable"); McKay, *supra* note 15 (explaining that even though GMO foods are generally considered safe for human consumption, 64 countries required GMO labeling in 2014).

2. United States: The Food and Drug Administration and Other Agencies

In 1986, the White House Office of Science and Technology ("OST") began regulating biotechnology by issuing the Coordinated Framework for Regulation of Biotechnology ("Coordinated Framework").[50] Intended to be the comprehensive federal policy that would assure safety in biotechnology, the Coordinated Framework was based upon two principal policy views.[51] The first policy element was that existing law was sufficient to deal with the regulatory needs of genetically modified products, which signaled the administration's refusal to promulgate GMO-specific rules.[52] The second policy factor, known as the "substantial equivalence doctrine," maintains that products containing GMOs present no new risks as opposed to traditional products that are not genetically modified.[53] Although the Coordinated Framework was not enacted into law, it would later become clear that its principles were to be the foundation of the US GMO regulatory system.[54] The Coordinated Framework was mirrored by the 1992 FDA Statement of Policy, which brought about the GMO regulatory process that the United States has used for over twenty years.[55]

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50. *See* Nunziato, *supra* note 9, at 477 (detailing the Coordinated Framework); Lundquist, *supra* note 39, at 831 (explaining the Coordinated Framework).

51. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986); Lundquist, *supra* note 39, at 831 (quoting the Coordinated Framework and describing its stated purpose); Nunziato, *supra* note 9, at 477 (detailing the fundamental purpose of the Coordinated Framework).

52. *See* Lundquist, *supra* note 39, at 831 (acknowledging the idea under the Coordinated Framework that existing law is sufficient to regulate GMOs); Nunziato, *supra* note 9, at 477 (stating the stance that no new legislation was required under the Framework to regulate GMO products).

53. *See* Lundquist, *supra* note 39, at 831 (explaining the substantial equivalence doctrine); Sheryl Lawrence, *What Would You Do With a Fluorescent Green Pig? How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 ECOLOGY L.Q. 201, 219 (2007) (describing this second policy factor).

54. *See* Lundquist, *supra* note 39, at 831 (demonstrating how the GMO regulatory system is guided by the Coordinated Framework); Bratspies, *supra* note 29, at 929-30 (" . . . with virtually no modifications in the intervening decades, this Coordinated Framework continues to govern regulatory decisions about agricultural biotechnology.").

55. *See* Bratspies, *supra* note 29, at 938 (explaining how the FDA built upon the substantial equivalence mindset of the Coordinated Framework); Nunziato, *supra* note 9, at

While this policy did not implement any new measures specifically crafted for GMOs, it placed the regulation of foods, medical devices, drugs, biologics, and pesticides developed through modern biotechnology within the same existing statutory system that regulates similar products developed using traditional methods, such as traditionally bred foods.[56] Traditional breeding usually involves the hybridization between varieties of the same species and, therefore, can only introduce traits that are found in close relatives.[57] Thus, corn that has been produced using genetic modification is treated the same as corn that has been produced without the use of such methods.[58] Hence, products that are derived from traditional methods, like traditional crossbreeding, are to be regulated under the same rules and standards as products derived from genetic engineering methods, including gene insertion.[59] Under this framework, GMOs are regulated by the FDA under two sections of the FDCA.[60] The first component of this framework is the General Safety Clause of FDCA Section 402(a)(1), which considers food that contains any poisonous or dangerous substance that makes it injurious to health as adulterated and subject to seizure.[61] The second component is the Food Additives Amendment of FDCA Section 409, which provides the procedures for approval of food additives and divides substances that are added to food into two categories: food additives and substances generally

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478 (describing how the Coordinated Framework is still the same basic organizing principle for GMO regulation in the United States).

56. *See* Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 265-66 (2000) (detailing what is regulated within the existing law); Nunziato, *supra* note 9, at 477-78 (explaining that no new laws would be enacted to regulate biotechnology).

57. *See 1992 FDA Statement of Policy, supra* note 25, at 22986 (discussing traditional breeding).

58. *See generally id.;* Nunziato, *supra* note 9, at 479 (giving the corn example).

59. *See* Francer, *supra* note 56, at 265-66 (demonstrating how such products would be regulated under the same rules). *See generally* Bratspies, *supra* note 29, at 929-30 (detailing the principles of the Coordinated Framework).

60. *See* Bratspies, *supra* note 29, at 937-38 (detailing the regulatory power of the FDA and the FDCA); Francer, *supra* note 56, at 267-70 (giving an overview of the statutory framework of the FDA regulatory system).

61. 21 U.S.C. § 341(a)(1) (1994); *see* Francer, *supra* note 56, at 268 (quoting section 402(a)(1) of the FDCA and describing the power of the FDA under the General Safety Clause).

recognized as safe ("GRAS").[62] This section allows the FDA to subject manufacturers to premarket approval unless their food product is recognized as safe.[63] In order to be deemed safe under the FDCA, competent scientists must be reasonably certain that a substance is not harmful under the intended conditions of the use.[64] A food additive that does not fit this definition is considered "unsafe," and the food containing the additive is deemed adulterated.[65] If the substance is determined to be "safe," it is not considered a food additive and thus no prior FDA approval is necessary.[66]

The Coordinated Framework resulted in a three-part regulatory system that delegates genetic engineering regulation to three government agencies: the FDA, the Environmental Protection Agency ("EPA"), and the United States Department of Agriculture ("USDA").[67] Under the Coordinated Framework, the FDA has authority to regulate food, feed, veterinary drugs, and food additives developed by biotechnology as delegated by the FDCA.[68] As a second part of the Coordinated Framework, the EPA is responsible for regulating the manufacture and release into the environment of microbial products of biotechnology and pesticides manufactured through biotechnology through the Toxic Substances Control Act

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62. *See* Francer, *supra* note 56, at 267 (discussing section 409 of the FDCA); Bratspies, *supra* note 29, at 937 (explaining that substances added to food fall into either of these two categories).

63. *See* Bratspies, *supra* note 29, at 937 (discussing how the FDA can mandate premarket approval with respect to food additives); Francer, *supra* note 56, at 269 (describing the application of premarket approval to food additives depending on their safety status).

64. 21 C.F.R. § 170.30(i) (2016); *see* Bratspies, *supra* note 29, at 937 (describing how the FDA defines "safe" with respect to premarket approval for food additives).

65. 21 U.S.C. §§ 331(a), 342(a)(1), (2)(C) (2015); *see* Bratspies, *supra* note 29, at 937 (stating that the FDA will deem a food containing an additive that is unsafe as "adulterated").

66. *See* Bratspies, *supra* note 29, at 937 (explaining that if a substance added to food is "generally recognized as safe," it is not deemed to be a food additive and therefore prior FDA approval is not required); Francer, *supra* note 56, at 269 (stating that the FDA is allowed to require food manufacturers to apply for premarket approval of food that has a substance added to it unless the food is "generally recognized as safe").

67. *See* Lundquist, *supra* note 39, at 831-32 (detailing the three-part system under the Coordinated Framework and how responsibilities are divided among the agencies); Francer, *supra* note 56, at 66 (explaining how the different agencies work within the framework); Muller, *supra* note 11, at 519 (describing how the regulation of biotechnology is divided among the three agencies under the Coordinated Framework).

68. *See* Nunziato, *supra* note 9, at 478 (establishing the FDA's responsibilities); Francer, *supra* note 56, at 266 (articulating the FDA regulation of GMOs through the FDCA).

("TSCA") and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").[69] Finally, as the third part of this Framework, the USDA is charged with regulating the use of genetically modified plants, animals, and microorganisms in agriculture as part of the Federal Plant Protection Act.[70]

The regulation carried out by these three agencies is firmly rooted in the Coordinated Framework's two principles, as well as the conclusion of the National Research Council ("NRC") that because the same physical and biological laws govern genetically modified and non-modified organisms, genetically modified organisms do not present a greater risk to human health than unmodified organisms.[71] As a result, the FDA, EPA, and USDA all regulate the genetically modified items within their jurisdiction through their traditional procedures.[72] Through this application of the Coordinated Framework and substantial equivalence doctrine, products subject to FDA regulation must comply with the same safety standards as their natural counterparts (i.e., unmodified organisms).[73] For example, as previously discussed, corn that is produced by using genetic modification is regulated the same way as corn that has been produced without the use of genetic modification.[74] While the

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69. *See* Nunziato, *supra* note 9, at 474 (describing the EPA's responsibilities under the Coordinated Framework); Francer, *supra* note 56, at 266 (citing the TSCA and FIFRA and describing the EPA's duties with respect to biotechnology).

70. *See* Lundquist, *supra* note 39, at 835 (describing the USDA's role within the Coordinated Framework through the Federal Plant Protection Act); Nunziato, *supra* note 9, at 478 (commenting on the USDA's responsibilities under the Coordinated Framework).

71. *See* Francer, *supra* note 56, at 266 (commenting on how the NRC's conclusion that products developed through biotechnology do not entail greater risk "per se" compared to unmodified products served as the basis for the Coordinated Framework's policy); *see also* Alison Peck, *Leveling the Playing Field in GMO Risk Assessment: Importers, Exporters and the Limits of Science*, 28 B.U. INT'L L.J. 241, 257 (2010) (describing some findings of the NRC with respect to GMOs).

72. *See* Francer, *supra* note 56, at 267 (explaining how the three agencies regulate GMOs). *See generally* Lundquist, *supra* note 39, at 832 (discussing how the agencies operate when regulating GMOs or GE products).

73. *See* Nunziato, *supra* note 9, at 479 (detailing how the FDA treats GMOs the same as their conventional counterparts). *See generally* Federici, *supra* note 39, at 537 (describing how GMOs are evaluated under the same laws as their conventionally produced counterparts by the FDA).

74. *See generally 1992 FDA Statement of Policy*, *supra* note 25; Nunziato, *supra* note 9, at 479 (explaining how unmodified corn and genetically modified corn are treated as substantially equivalent to one another by the FDA, which generally recognizes both as safe).

substantial equivalence doctrine has its roots in the 1986 findings of the NRC, it was further solidified and incorporated into US regulation through the 1992 FDA Statement of Policy.[75]

3. The 1992 FDA Statement of Policy

The 1992 FDA Statement of Policy has had a major impact upon the regulation of GMOs in the United States.[76] It has steered the regulatory system in a way that greatly lessened the burden on manufacturers to get GMO products approved for sale.[77] Instead of regulating GMOs within the much stricter approach of FDCA Section 409, the FDA announced that it would continue to mainly rely on Section 402(a)(1)—which only deals with substances that may be injurious to health—for the safety of whole foods and those derived from plants genetically modified by new techniques.[78] Furthermore, the FDA decided that it was the responsibility of the producer of a new food to evaluate the safety of that food and to ensure that the safety requirements under Section 402(a)(1) are met.[79] The FDA also stated that it encouraged producers to informally consult FDA scientists to ensure that safety concerns are resolved and that the producers are legally responsible for satisfying Section 402(a)(1) of

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75. *See generally* Nunziato, *supra* note 9, at 479 (explaining how the FDA treats GMOs as substantially equivalent to their non-GMO counterparts); Bratspies, *supra* note 29, at 929 (explaining how substantial equivalence was the central assumption guiding the Coordinated Framework).

76. *See generally supra* Section I.A (demonstrating how the 1992 FDA Statement of Policy has shaped the US GMO regulatory system, specifically with respect to labeling).

77. *See generally* Rebecca Jesada, *Buyer Beware: An Exploration Of Health Risks And Legal Policies In Favor Of A Labeling Requirement For Genetically Modified Organisms*, 14 J. HEALTH CARE L. & POL'Y APPENDIX S-30, S-38-39 (2011) (explaining the voluntary consultation process for GMO approval with the FDA); Francer, *supra* note 56, at 269 (stating that the FDA allows manufacturers to determine whether genetically modified foods are GRAS).

78. *See 1992 FDA Statement of Policy*, *supra* note 25, at 22990 (announcing that GMOs would be regulated under section 402(a)(1) of the FDCA); Francer, *supra* note 56, at 270 (describing how the FDA relies on section 402(a)(1) of the FDCA to regulate genetically modified foods).

79. *See 1992 FDA Statement of Policy*, *supra* note 25, at 22990 (showing that the FDA would not be relying on its own independent research, but rather on the food producers to evaluate the safety of the food and to make sure their foods meet the safety standards under section 402(a)(1)).

the act.[80] With respect to Section 409, the FDA stated that it would not require genetically engineered foods to be regulated as food additives under this section.[81] This, the FDA reasoned, was because GMOs are presumptively GRAS and therefore not subject to Section 409, including the food additive approval process.[82] The FDA further noted that it did not anticipate any serious questions about the GRAS status of transferred genetic material and therefore did not expect such transferred genetic material to be subject to food additive regulation.[83] It was from this viewpoint that the FDA put forth a policy that presumes that added genetic material from substances already in the food supply is GRAS.[84]

This FDA policy has greatly affected the process of GMO regulation, as leading producers such as Monsanto are not required to submit their GMO products for FDA approval.[85] As these products are protected by a presumption of safety, GMOs are not subject to FDA independent research, but are only regulated based upon information that such companies voluntarily give to the FDA.[86]

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80. *See id*. (identifying the agency's role in the GMO approval process).

81. *See id*. (explaining the FDA's reasoning behind its decision to not regulate GMOs under section 409 and its continued position that such materials are presumed to be GRAS).

82. *See id*. (describing the FDA's presumption that GMOs are GRAS and therefore not subject to regulation as food additives).

83. *See id*. (asserting the FDA's position that it does not anticipate that transferred genetic material would itself be subject to food additive regulation).

84. *See* Francer, *supra* note 56, at 270 (summarizing the FDA's viewpoint concerning added genetic material from substances that already exist in the food supply); *see also 1992 FDA Statement of Policy*, *supra* note 25, at 22990 ("When the substance present in the food is one that is already at generally comparable or greater levels in currently consumed foods, there is unlikely to be a safety question sufficient to call into question the presumed GRAS status of such naturally occurring substances and thus warrant formal premarket review and approval by FDA.").

85. *See* Bratspies, *supra* note 29, at 938 (assessing how companies such as Monsanto are allowed to voluntarily consult with the FDA before marketing a new GE food product and how they are responsible for ensuring that the product is safe but are not required to prove safety to the FDA); Francer, *supra* note 56, at 269 (noting that consultation with the FDA regarding an ingredient's regulatory status is not legally required).

86. *See* Bratspies, *supra* note 29, at 938-39 (detailing how this "developer-driven consultation" process "imposes no obligation on the developer to share all its data, including negative or inconclusive results with the agency" and also explaining that the FDA does not conduct any independent testing of the GMO food products); *see also* Tiffany B. Wong, Comment, *Playing Politics With Food: Comparing Labeling Regulations Of Genetically Engineered Foods Across The North Atlantic In The United States And The European Union*,

Furthermore, since genetically engineered traits can be classified as "novel proteins," companies are allowed to withhold all information about the properties of the proteins and are therefore not compelled to disclose this information to the FDA regardless of their potential harm to humans or animals.[87] Before such GMO products are approved, the FDA does not conduct any independent testing.[88] It therefore approves GMO products by relying solely on the information voluntarily provided to it by the companies seeking approval.[89]

4. The Labeling of GMO Products in the United States

In addition to its dramatic effect on the GMO approval process, the 1992 FDA Statement of Policy significantly influenced the way GMO products have been labeled for over twenty years in the United States.[90] It is important to note that while the following information concerning GMO labeling has been accurate from 1992 to 2016, it is no longer the standard for GMO labeling in the United States as S. 764 now mandates GMO labeling for products that are classified as "bioengineered food."[91] Even though GMO labeling is now mandatory under S. 764, the information below provides a crucial

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23 SAN JOAQUIN AGRIC. L. REV. 243, 254 (2013-2014) (indicating that the FDA relies on food companies "to voluntarily conduct a premarket food safety assessment").

87. *See* Glasscock, *supra* note 35, at 236 (specifying how the "novel proteins" classification of genetically engineered traits permits biotech companies to withhold all information about the properties of the protein, "even their general nature, including potential toxicity to humans or other wildlife"); Bratspies, *supra* note 29, at 938 (detailing how companies are not obligated to share all their data with the FDA and how the FDA only reviews the information submitted by companies voluntarily).

88. *See* Muller, *supra* note 11, at 520 (discussing this lack of independent testing); Francer, *supra* note 56, at 270 (describing the FDA's guidance framework for manufacturers).

89. *See* Muller, *supra* note 11, at 520 (indicating that the FDA does not conduct a safety assessment on genetically modified foods and shifts the responsibility to the producers who create the genetically modified crops to voluntarily disclose any studies that have been conducted on the product). *See generally* Francer, *supra* note 56, at 270 (giving an overview of the FDA's guidance framework for manufacturers in which the agency suggests, but does not require, consultation as well as the included flowchart that is meant to help manufacturers to determine if they should engage in a formal consultation with the FDA).

90. *See* Francer, *supra* note 56, at 272 (stating that the 1992 FDA Statement of Policy declined to mandate labeling of genetically modified foods); Muller, *supra* note 11, at 518-20 (detailing how the 1992 FDA Statement of Policy has impacted the agency's stance on GMO labeling).

91. *See infra* notes 459-66 and accompanying text (discussing the mandates for products that are classified as "bioengineered food" under S. 764).

overview of the FDA policy that governed GMO labeling in the United States for over twenty years and which gave rise to the state movement for GMO labeling and the enactment of S. 764 as a compromise to calm public unrest.[92]

Under FDCA Section 403(I), a producer of a food product is required to describe the product by its common name or appropriately descriptive term if there is no common name.[93] Furthermore, the producer is required to reveal all facts that are material to the labeling of the products or the consequences that might result from the use of its product.[94] If a food that is derived from a new plant variety differs from its traditional counterpart so much that the common name no longer applies to the food, consumers must be informed by appropriate labeling.[95] Consumers must also be informed by such labeling if there is a safety issue that they must be made aware of.[96]

In its 1992 Statement of Policy, the FDA used the example of a tomato, which had a peanut protein introduced into it, to illustrate its positioning on the labeling of GMOs.[97] The FDA stated that it would require a label declaration for these tomatoes in order to alert peanut-allergic consumers if there was not sufficient evidence to show that the introduced peanut protein could not cause an allergic reaction in a susceptible population.[98] This is because the information is a material fact "whose omission may make the label of the tomato misleading under section 403(a) of the act."[99] In light of its findings, the FDA ruled that it had not considered the methods used in developing a new plant variety to be "material information" within FDCA Section

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92. *See infra* notes 455-89 and accompanying text (analyzing S. 764 and the circumstances surrounding it).

93. *See* 21 U.S.C. § 343(i) (2010) (stating the requirements for describing food either with its common name or an appropriately descriptive term); *1992 FDA Statement of Policy*, *supra* note 25, at 22991 (detailing how foods must be described under section 403(i) of the FDCA).

94. *See 1992 FDA Statement of Policy, supra* note 25, at 22991.

95. *Id.*

96. *See id.* (explaining these requirements under the Policy).

97. *Id.* (using the example of a tomato that had a peanut protein introduced into it to explain its stance on GMO labeling).

98. *See id.* (detailing how the FDA would require labeling of a tomato with peanut protein introduced into it since this would be a material fact whose omission would make the tomato label misleading under 403(a) of the FDCA).

99. *Id*. (giving the FDA's reasoning).

201(n).[100] The FDA also noted that it was not aware of any information demonstrating that foods derived by such new methods differ from other foods in any meaningful or uniform way or that "as a class, food developed by the new techniques present any different or greater safety concerns than foods developed by traditional plant breeding."[101] Thus, the FDA did not believe that the method of development of a new plant variety, including those using recombinant DNA techniques, is material information within the meaning of the act and therefore did not require the information to be disclosed in the food label.[102] Since the FDA has not modified its stance on GMOs or reinvestigated the issue, the 1992 FDA Statement of Policy has been the governing policy on GMO labeling until the enactment of S. 764 and is the reason why the United States has not required labeling of GMO products until 2016.[103]

5. The FDA's Decision Not to Define "Natural"

In addition to its decision to not mandate GMO labeling, the FDA has also refused in the past to issue a formal definition of the word "natural."[104] While "natural" is the most widely used food label on US food products, the term has only been informally defined by the FDA.[105] The Third Circuit held that the definition does not have the force of law.[106] In *Holk v. Snapple Beverage Corp.*, the US Court

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100. *Id.* (describing the agency's findings).

101. *Id*. (stating the agency's position on the method of genetic engineering with respect to labeling the final product).

102. *Id.* (providing the FDA's decision not to mandate GMO labeling based on methods of production).

103. *See* Nunziato, *supra* note 9, at 479 (stating that the FDA has not changed its policy on GMOs since 1992). *See generally* Lundquist, *supra* note 39, at 831-34 (describing the GMO regulatory framework through 2015).

104. *See* Muller, *supra* note 11, at 523 (stating that the FDA has never issued a formal definition of "natural"); April L. Farris, *The "Natural" Aversion: The FDA's Reluctance To Define A Leading Food-Industry Marketing Claim, And The Pressing Need For A Workable Rule,* 65 FOOD & DRUG L.J. 403, 404-07 (2010) (describing the history behind the FDA's informal policy on defining "natural" and the agency's refusal to formally define the term).

105. *See* Muller, *supra* note 11, at 523 (explaining that while "natural" is the most widely used food label on US food products, the FDA has declined to formally define the term); Farris, *supra* note 104, at 403-08 (discussing the popularity of "natural" on food products and the history of the FDA's stance on defining "natural").

106. *See* Holk v. Snapple Beverage Corp., 575 F.3d 329, 342 (3d Cir. 2009) (stating the court's belief that the 1992 FDA Statement of Policy regarding the use of the term "natural"

of Appeals for the Third Circuit ruled that the definition was not binding and therefore could not be imposed on manufacturers because the FDA stated its intention not to create a formal definition and because the FDA promulgated the informal definition without public notice and comment.[107]

As a result of the FDA's decision not to formally define "natural," many consumers have sued companies for using the term "natural" on food products that contain GMOs or genetically modified based ingredients.[108] By refusing to craft a formal definition of "natural," the FDA has not decided whether foods containing genetically bioengineered ingredients can be labeled as "natural," "all natural," or "100% natural," essentially leaving this issue to the federal courts.[109] However, as the courts do not necessarily possess the requisite expertise to answer these questions, many have stayed the litigation pending FDA answers.[110] During 2014, when two cases were pending in the district courts of California and one case was pending in New Jersey, the FDA wrote a letter to the three district court judges hearing the cases, stating that this issue would not be appropriate to decide in litigation since it is complex and concerns

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does not have the force of law)*;* Muller, *supra* note 11, at 523 (citing *Holk*, in which the Third Circuit held that the FDA's informal definition of "natural" does not have the force of law).

107. *See Holk*, 575 F.3d at 341-42 (detailing the court's reasoning in its decision to rule that the 1992 FDA Statement of Policy regarding the use of "natural" did not have the force of law required to preempt conflicting state law).

108. *See* Muller, *supra* note 11, at 524 (stating that many consumers have filed lawsuits against companies who are labeling their products as "natural" despite using GMOs and giving a general overview of some of the complications from this development); *see also* Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, BROOKINGS INST. 1 (June 2014), https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf (commenting that between 2011 and June 2014, more than 150 food labeling class action lawsuits had been filed against food and beverage companies by consumer advocacy groups and plaintiffs).

109. *See* Muller, *supra* note 11, at 524-25 (discussing the way in which the FDA's refusal to formally define "natural" has resulted in dispute at the litigation level); Stephanie Jill Fogel, *FDA declines to define "Natural"*, DLA PIPER (Jan. 8, 2014), https://www.dlapiper.com/en/us/insights/publications/2014/01/fda-declines-to-define-natural/ (explaining the significant cases in which the FDA's informal definition is a source of contention).

110. *See* Muller, *supra* note 11, at 524-25 (describing how the courts do not have the necessary expertise in this area); Fogel, *supra* note 109 (discussing the courts' belief that the "natural" claims require FDA expertise).

myriad interests.[111] FDA Assistant Commissioner for Policy Leslie Kux explained that a discussion of using "natural" on GMO products would be better suited to a public proceeding, including an issuance of a regulation or formal guidance.[112]

The FDA has responded to these lawsuits and the public outcry for labeling reform with respect to the use of "natural."[113] On November 10, 2015, the agency announced its request for public comments on the use of the term "natural" on food labeling.[114] From November 12, 2015 until May 10, 2016, the FDA allowed the public to provide information and public comment on three questions: (1) whether it is appropriate to define the term "natural," (2) if so, how the agency should define "natural," and (3) how the agency should determine the appropriate use of the term on food labels.[115] Specifically, the FDA noted that it was taking this step in response to three Citizens Petitions that asked the agency to define "natural" for use in food labeling and one Citizen Petition that requested it to prevent parties from using "natural" on food labels.[116] Additionally, the FDA indicated that it received requests for administrative determinations from some federal courts that had ongoing litigation between private parties regarding whether food products containing ingredients using genetic engineering or foods containing high fructose corn syrup can be labeled as "natural."[117]

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111. *See* Josh Long, *FDA: Courts on Their Own in GMO "All Natural" Lawsuits*, NAT. PRODUCTS INSIDER (Jan. 8, 2014), http://www.naturalproductsinsider.com/news/2014/01/fda-courts-on-their-own-in-gmo-all-natural-lawsui.aspx (describing the FDA letter to the three district court judges in which the FDA declined to decide on the issue in the litigation setting); Fogel, *supra* note 109 (examining the FDA letter and response to the lawsuits).

112. *See* Long, *supra* note 111 (analyzing the FDA's refusal to resolve this issue in the context of a lawsuit); Fogel, *supra* note 109 (highlighting the FDA's statement that it declined to determine when a food may be labeled "natural" in the private litigation setting and that it would do so through formal administrative processes).

113. *See infra* notes 114-21 and accompanying text (describing the agency's response).

114. *See "Natural" on Food Labeling*, FDA, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm (last visited Jan. 9, 2016) [hereinafter *FDA Request*].

115. *See id.* (setting forth the questions that the agency is asking the public to comment on).

116. *See id.* (putting forth some of the main motivation behind the FDA's request).

117. *See id.* (explaining how the FDA is reacting to the requests from federal courts that are dealing with lawsuits concerning the use of "natural" on food products with respect to GMOs).

In its request, the FDA acknowledged that while it has never issued a formal definition for natural, it has maintained a longstanding policy concerning the use of this term in human food labeling in which "natural" means "nothing artificial or synthetic (including all color additives regardless of sources) has been included in, or has been added to, a food that would not normally be expected to be in that food."[118] More importantly, the FDA stated that this policy was not meant to address food production methods or manufacturing methods.[119] This is clearly aligned with the Coordinated Framework, in which the Reagan administration argued that GMO food products were not to be analyzed by the processes by which they were made, but rather by the product's safety with respect to human health.[120] In its request, the FDA also stated that it did not consider whether the term "natural" should describe "any nutritional or other health benefit."[121]

6. The FDA's Position On Labels Indicating A Product's Non-GMO Status

While the use of the word "natural" on products containing GMOs has been allowed for the last two decades, terms such as "GMO free" or "not genetically modified" have not been so greatly accepted by the FDA.[122] Until 2016, producers wishing to advertise that their products were GMO free were required to comply with the regulations that the FDA had imposed on the labeling of non-GMO foods.[123] According to the FDA, claims such as "GMO free" and "not genetically modified" are misleading and thus the food producer or

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118. *See id.* (describing the informal definition that the agency has used in place of a formal definition).

119. *See id.* (stating what the policy does not apply to).

120. *See id.*; *see also supra* notes 39-44 (discussing the Coordinated Framework).

121. *FDA Request*, *supra* note 114 (giving limitations to the request).

122. *See* Neil D. Hamilton, *Forced Feeding: New Legal Issues In The Biotechnology Policy Debate,* 17 WASH. U. J.L. & POL'Y 37, 44 (2005) (discussing the FDA's negative view of such claims and stating that the FDA has ruled that using the terms "GM" or "GMO Free" is misleading); Glasscock, *supra* note 35, at 237 (explaining how the FDA has imposed "strict" limitations on the voluntary labeling of non-GM foods in the past).

123. *See* Glasscock, *supra* note 35, at 237 (highlighting the difficulty of labeling non-GM foods as such under the current FDA requirements); Hamilton, *supra* note 122, at 44 (discussing the burden of proof placed upon manufacturers by the FDA concerning claims of GMO free).

manufacturer must substantiate such voluntary claims.[124] Prior to S. 764, it followed that while producers and manufacturers who wished to use the label "GMO free" or "not genetically modified" had to bear the cost to take the steps to substantiate such labels, producers or manufacturers were free to use the label "natural," "all natural," or "100% natural" on GMO products, despite the fact that most US consumers believe that such terms also mean "non-GMO."[125]

7. The 1992 FDA Statement of Policy Upheld by the Courts

While the 1992 FDA Statement of Policy has not been altered since 1992, it has been challenged in court.[126] In the *District of Columbia in Alliance for Bio-Integrity v. Shalala*, a non-profit organization brought an action against the FDA for its labeling guidelines.[127] Ultimately, the court upheld the 1992 FDA Statement of Policy since the decision to not mandate GMO labeling was not arbitrary or capricious.[128] In this suit**,** plaintiffs argued that (1) the statement was not properly subjected to notice-and-comment procedures and (2) both the FDA's presumption that genetically modified foods were GRAS and its decision not to require labeling was arbitrary and capricious, and therefore should be set aside by the court.[129] The FDA argued that since its statement was a policy statement or an interpretive rule, it was not subject to formal notice and comment requirements.[130] The United State District Court for the District of Columbia ruled that as evidenced by the name and plain

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124. *See* Hamilton, *supra* note 122, at 44 (explaining how the FDA determined that using "GMO free" and "GM" is misleading); Glasscock, *supra* note 35, at 237 (stating that under the 1992 FDA Statement of Policy, manufacturers had to substantiate voluntary claims of "non-genetically modified" and "GMO free").

125. *See* Glasscock, *supra* note 35, at 237 (describing how the requirement prior to S. 764 that manufacturers and producers substantiate claims of "not genetically modified" or "GMO free" could be cost prohibitive); Farris, *supra* note 104, at 405-06 (explaining the informal definition of "natural" by the FDA).

126. *See* Nunziato, *supra* note 9, at 479 (stating that the FDA has not changed its position since 1992); Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d 166 (D.D.C. 2000) (where the plaintiffs challenged the FDA's stance on GMO labeling).

127. *See Shalala*, 116 F.Supp.2d 166.

128. *Id.* at 177 (explaining the court's holding that the 1992 FDA Statement of Policy was not arbitrary or capricious).

129. *Id* at 173 (explaining plaintiffs' claims).

130. *Id*. (detailing the FDA's arguments).

language of the statement, the 1992 Statement of Policy creates a rebuttable presumption of GRAS and exists as a policy statement.[131] Thus, the court ruled, the FDA did not err in implementing its 1992 Statement of Policy without formal notice and comment.[132]

In deciding whether or not the agency acted arbitrarily and capriciously in presuming that GMOs were GRAS and deciding not to label such products, the court used the *Chevron* analysis, which is a legislation and regulation tool that courts use to analyze agency action in a lawsuit against the agency.[133] In performing this analysis, the court examined the Food Additives Amendment to the FDCA and found that though the 1958 Congress could not conceive of GMOs at the time the amendment was made, the statute exempts substances that are "generally recognized . . . to be safe under the conditions of its intended use" from regulations as additives.[134] The court highlighted the fact that the plaintiffs were not disputing the FDA's claim that nucleic acid proteins are generally recognized to be safe, but rather that the FDA presumed GMOs as GRAS in light of "significant disagreement" among scientists as to whether nucleic proteins are generally recognized as safe when used to alter organisms genetically.[135] The court noted that it had to proceed with particular caution in order to avoid directing the agency in a choice between rational alternatives.[136] Furthermore, the court ruled that in analyzing the agency's determination of GRAS, its review is confined to the

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131. *Id.* (explaining the court's basis for determining the status of the statement).

132. *Id*. (discussing the court's ruling concerning the legality of the FDA's administrative process in implementing its Statement of Policy).

133. *Id* at 176 (describing how the court's examination of the FDA's interpretation is "framed by" the case Chevron, U.S.A. v. Natural Resources Def. Council, 467 U.S. 837 (1984)).

134. 21 U.S.C. § 321(s) (2009); *see Shalala*, 116 F.Supp.2d at 177 (quoting 21 U.S.C. § 321(s) to describe the FDA's inability to regulate substances that are recognized as GRAS as additives under the FDCA).

135. *See Shalala*, 116 F.Supp.2d at 177 (explaining that the plaintiffs' argument concerning disagreement among experts concerning the GRAS status of nucleic acid proteins was not the same as disputing the FDA's claim that nucleic acid proteins are GRAS, which plaintiffs did not do).

136. *Id.* (quoting Int'l Fabricare Inst. v. U.S.E.P.A., 972 F.2d 384, 389 (D.C. Cir. 1992) to describe the justification behind deferring to an agency when it is evaluating scientific data that is within its technical expertise, and Env't Def. Fund, Inc. v. Costle, 578 F.2d 337, 339 (D.C. Cir. 1978) to explain how the court is supposed to judge the matter cautiously as to not direct the agency when a choice is made between rational alternatives).

record before the agency at the time it made its decision, and that while unanimity among scientists is not necessary, "a severe conflict among experts . . . precludes a finding of general recognition."[137] In light of all of these considerations, the court found that the plaintiffs did not show that the GRAS determination was inconsistent with the statutory requirements, and therefore it was not arbitrary and capricious.[138]

Through this analysis, the court found that the FDA's decision not to include consumer interests in the factors used to determine whether a change is "material" constituted a reasonable interpretation of the statute.[139] The court reasoned that because the FDA found that rDNA modification does not "materially" alter food, the agency does not have a basis for legally requiring labeling, despite a level of consumer demand for it.[140] Also, the court deferred to the FDA's determination that foods produced with rDNA modification techniques do not present any different or greater safety concerns than foods that come from traditional plant breeding, and that mandatory labeling is not warranted.[141] Since the court did not find this decision to be irrational, it ruled that the FDA's decision not to require GMO labeling was not arbitrary and capricious and upheld the agency action.[142]

Since the FDA has not reexamined the issue of requiring GMO labeling since 1992, the 1992 Statement of Policy that was upheld by

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137. *See* Substances Generally Recognized as Safe, 62 Fed. Reg. 18938-01 (Apr. 17, 1997); *Shalala*, 116 F.Supp.2d at 177 (quoting *Substances Generally Recognized as Safe* to describe how a GRAS finding is not permitted if there is a severe conflict among experts and also explaining how the court must only review the record before the FDA at the time it made its decision).

138. *See Shalala*, 116 F.Supp.2d at 177 (stating that the court's finding that the GRAS presumption is not inconsistent with the statutory requirements).

139. *See id*. (explaining that the FDA's interpretation of the statute with respect to excluding consumer choice as a factor that determines whether a change is "material" was reasonable).

140. *See id*. (asserting that the FDA cannot legally require labeling without finding that rDNA modification materially alters food).

141. *See id*. (explaining that the FDA's determination that rDNA derived foods do not present any different or greater safety concern than foods developed by traditional plant breeding is entitled to deference unless it is irrational).

142. *See id*. (setting forth the court's ruling).

the *Shalala* court is still in effect.[143] While the FDA's position on GMOs has not substantially changed in over twenty years, the US attitude towards GMOs has dramatically shifted from neutrality towards skepticism.[144] Three states, including Connecticut and Vermont, enacted their own labeling laws that essentially circumvented the FDA's stance on GMO labeling laws.[145] It appeared that this inconsistent dichotomy would continue in the absence of federal action, as more states looked to enact their own GMO labeling laws in opposition to the FDA's position under its 1992 Statement of Policy.[146] However, as discussed in Part II of this Note, the implementation of federal GMO labeling requirements under S. 764 has resolved this conflict and avoided a patchwork system of state GMO labeling laws.[147] While the 1992 Statement of Policy is still valid, the federal government has placed the regulation of GMO labeling in the hands of the USDA despite objection by the FDA.[148] It is not clear how this system under S. 764 will exist in the shadow of the 1992 Statement of Policy, as the very requirement of GMO

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143. *See* Nunziato, *supra* note 9, at 479 (stating that the FDA has not changed its position since 1992); Marden, *supra* note 17, at 756 (detailing how the decision ". . . made it clear that critics of the FDA's policy had very little legal ground on which to stand").

144. *See* Kate Galbraith, *Attitudes on Crops Are Modifying*, NY TIMES (July 10, 2013), http://www.nytimes.com/2013/07/11/business/energy-environment/11iht-green11.html?_r=0 (discussing the rise in consumer interest in food and dietary issues in recent years, which has led to the labeling initiatives). *See generally* Cary Funk & Lee Rainie, *Chapter 6: Public Opinion About Food*, PEW RES. CTR. (July 1, 2015), http://www.pewinternet.org/2015/07/01/chapter-6-public-opinion-about-food/ (providing a Pew Research survey on public perception of GMOs in the United States).

145. *See* Philip Brasher, *FDA Refuses To Require GMO Labeling,* AGRI-PULSE (Nov. 19, 2015), http://www.agri-pulse.com/FDA-refuses-to-require-GMO-labeling-11192015.asp (explaining how the FDA still refuses to mandate GMO labeling); Mary Clare Jalonick, *A Senate Committee Is Moving Forward On Legislation That Would Prevent States From Requiring Labels On Genetically Modified Foods*, US NEWS & WORLD REP. (Feb. 19, 2016, 7:26 PM), http://www.usnews.com/news/business/articles/2016-02-19/senate-bill-would-block-mandatory-labeling-of-gmos (discussing the measures taken by these three states).

146. *See infra* Section II.A (providing an overview of this state movement).

147. *See infra* Section II.A.9 (discussing how S. 764 eliminated the patchwork system of GMO labeling laws by prohibiting state GMO labeling laws and preempting the laws of Connecticut, Maine, and Vermont).

148. *See infra* Sections II.A.9 and II.A.10 (explaining how S. 764 places the GMO labeling system within the power of the USDA and the criticism facing this assignment).

labeling under the law conflicts with the FDA's long held policy that GMOs should not be labeled due to their GRAS status.[149]

B. EU Regulation of GMOs: Product, Labeling, and Marketing

This Section explains EU regulation of GMOs and its foundation in the precautionary principle. Section I.B.1 explains the precautionary principle and EU environmental policy, while Section I.B.2 examines the fundamental ideas of the precautionary principle. Section I.B.3 examines how the Commission applies the precautionary principle and Sections I.B.4 and I.B.5 discuss two crucial cases that elaborate on the precautionary principle. Section I.B.7 details the regulatory system prior to 2001 through the *1990 Deliberate Release Directive* and the problems associated with the Directive, including a de facto moratorium on GMOs in the European Union in 1998 and the public's intense demand for mandatory GMO labeling.[150] Sections I.B.8 and I.B.9 describe EU GMO regulation after 2001 under the *2001 Deliberate Release Directive* and the *Genetically Modified Food and Feed Regulation*, while Section I.B.10 sets out the GMO labeling requirements under the *Traceability and Labeling Regulation*.[151] Finally, Section I.B.11 summarizes and compares the GMO regulatory systems of the United States and the European Union.

Citizens of the European Union have been wary of the effects of GMOs on human health and the environment since the agricultural product industry began genetically engineering food.[152] Despite

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149. *See supra* Section I.A.3 (explaining the FDA position).

150. *See* Council Directive 90/220//EEC on the Deliberate Release into the Environment of Genetically Modified Organisms, 1990 O.J. L 117/15 [hereinafter *1990 Deliberate Release Directive*].

151. *See* Council Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EC, 2001 O.J. L 106/1 [hereinafter *2001 Deliberate Release Directive*]; Council Regulation 1829/2003/EC on Genetically Modified Food and Feed, 2003 O. J. L 268/1 [hereinafter *Genetically Modified Food and Feed Regulation*]; Council Regulation 1830/2003/EC on the Traceability and Labeling 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. 18/10/2003 [hereinafter *Traceability and Labeling Regulation*].

152. *See The EU-US Dispute over GMOs: Risk Perceptions and the Quest for Regulatory Dominance, supra* note 32 (describing the negative opinion of the EU public

having the second largest amount of arable land in the world, the European Union grows less than one percent of the world's genetically modified crops.[153] The EU GMO regulatory system has been described as among the strictest in the world and is known for providing a high level of scientific assessment, while simultaneously safeguarding the consumer's right to choose.[154]

1. The Precautionary Principle & EU Environmental Policy

In sharp contrast to the United States' decision to regulate GMOs within existing statutory systems under the Coordinated Framework, the European Union's GMO regulatory system is based upon several specific legislative measures that monitor and restrict the growth, cultivation, and marketing of GMOs.[155] As opposed to the US system that is based on the substantial equivalence doctrine, the EU regulatory system is founded upon the precautionary principle.[156] The precautionary principle presumes that if an activity may have environmentally harmful consequences, it is better to take action before it is too late instead of waiting until complete scientific

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regarding GMOs and genetic engineering); Wilinska, *supra* note 19, at 155-56 (highlighting the skepticism of EU consumers and their distrust in government food safety regulations).

153. *See* Laura Moore Smith, *Divided We Fall: The Shortcomings of the European Union's Proposal for Independent Member States to Regulate the Cultivation of Genetically Modified Organisms,* 33 U. PA. J. INT'L L. 841, 841 (2011-2012) (stating the fact that the European Union grows less than one percent of the world's genetically modified crops despite having the second largest amount of arable land in the world); Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775, 778 (2008) (giving the statistics of the EU land and GMO cultivation as of 2008).

154. *See* Rachele Berglund Bailey, *A Tale of Two Systems: A Comparison Between US and EU Labeling Policies of Genetically Modified Foods*, 15 SAN JOAQUIN AGRIC. L. REV. 193, 205 (2012) (highlighting this dichotomy of stringent scientific requirements and the protection of the consumer right to choose); *see also* Joss, *supra* note 16, at 147 (describing the strictness of the EU GMO regulatory system).

155. *See generally 2001 Deliberate Release Directive*, *supra* note 151; *Genetically Modified Food and Feed Regulation*, *supra* note 151; *Traceability and Labeling Regulation*, *supra* note 151.

156. *See* Elizabeth G. Hill, *Nature's Harvest Or Man's Profit: Environmental Shortcuts In The Deregulation Of Genetically Modified Crops*, 44 TEX. TECH. L. REV. 353, 360 (2012) (stating that the European Union adopted an approach to GMOs based on the precautionary principle); Marden, *supra* note 17, at 735 (explaining how the European Commission has taken a precautionary approach towards the technology of genetically modified foods).

evidence can indisputably prove the causal connection.[157] The major difference in policy provides the explanation for the stark differences between the two regulatory systems and explains why the European Union has such strict labeling requirements for GMOs.[158]

On July 1, 1987, the Single European Act ("SEA") became effective and amended the European Economic Community Treaty ("EEC"), which established the European Economic Community in 1957.[159] Among the amendments found in the SEA, Article 130r provided the basis for environmental action taken by the Community.[160] According to Article 130r, the objectives of Community action relating to the environment were to preserve, protect, and improve the quality of the environment, as well as contribute towards protecting human health and ensure a prudent and rational utilization of natural resources.[161] Specifically, Community action relating to the environment was to be based on the principles that preventive action should be taken, environmental damages should be rectified at the source, and that the polluter should pay.[162] In order to achieve these goals, the Community had to take into account four pieces of information, some of which included available scientific data and the potential benefits and costs of action or lack of action.[163]

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157. *See* JAN H. JANS & HANS H.B. VEDDER, EUROPEAN ENVIRONMENTAL LAW AFTER LISBON 41 (4th ed. 2012) (describing the presumption of the precautionary principle that taking preventative action and avoiding damage is better than not taking such action in order to wait until complete scientific evidence becomes available that demonstrates the causal connection); ALBERTO ALEMANNO, TRADE IN FOOD: REGULATORY AND JUDICIAL APPROACHES IN THE EC AND THE WTO 106 (2007) (claiming that under the precautionary principle, it is preferable to not wait for a risk to materialize before examining and withdrawing a product whose safety is uncertain from the market).

158. *See* Debra M. Strauss, *Genetically Modified Organisms in Food: A Model with Positive Implications for International Trade*, 40 INT'L L. 95, 115 (2006) (noting the contrasting approaches to GMO regulation of the United States and European Union); *see also* Bailey, *supra* note 154, at 208-09 (analyzing the differences between the US and EU regulatory systems, specifically in approaches to labeling requirements, and the reasons behind such differences).

159. *See* Single European Act, 1987 O.J. L 169/1, [hereinafter SEA] (amending Treaty Establishing the European Economic Community, March 25, 1957, 298 U.N.T.S. 11 [hereinafter EEC Treaty]).

160. *Id.* art. 130r.

161. *Id.* at 1.

162. *Id.* at 2.

163. *Id.* at 3.

Under the Treaty of Maastricht, which was effective on November 1, 1993, the EEC Treaty was revised and renamed the European Community Treaty ("ECT").[164] Expanding upon the SEA requirements for environment action, the new provisions provided that Community policy on the environment shall be based on the precautionary principle, in addition to the previous policies that were provided in Article 130r of the SEA.[165] Article 130r of the Treaty of Maastricht also provided that environmental protection requirements were to be integrated into other Community policies' definition and implementation.[166] Finally, it stated that in this context, harmonization procedures with respect to these requirements needed to include a safeguard clause that allowed the Member States to take provisional measures for non-economic environmental reasons where appropriate.[167] These measures were also required to be subject to a Community inspection procedure.[168]

The next major revision of the basic treaties occurred on November 1, 2009, when the Lisbon Treaty on European Union came into effect, which modified the Maastricht Treaty.[169] The EEC Treaty was renamed the Treaty on the Functioning of European the Union ("TFEU") and all references to the European Community were replaced with the "European Union."[170] It is under Article 191 of the TFEU that the current instructions for EU policy on the precautionary principle are found.[171] According to Article 191, EU policy on the environment shall be based upon the precautionary principle, in addition to the principles of prevention, that environmental damage should be rectified at the source, and that the polluter should pay.[172]

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164. *See* Treaty on European Union (Maastricht text), July 29, 1992, 1992 O.J. C 191/1 [hereinafter Maastricht TEU].

165. *Id.* art. 130r, at 2 (requiring Community environmental policy to be based on the precautionary principle).

166. *Id.*

167. *Id.*

168. *Id.*

169. *See generally* Consolidated Version of the Treaty on the Functioning of the European Union, 2008 O.J. C 115/47 [hereinafter TFEU].

170. *See generally id.*

171. *Id.* art. 191.

172. *Id*. at 2.

2. The Fundamentals Of The Precautionary Principle

The idea behind the precautionary principle is that governments should be able to take preventative action in order to prevent potentially serious environmental harms when the scientific findings concerning a possible causal connection are not completely certain.[173] The precautionary principle presumes that if there is a strong suspicion that an activity may be environmentally harmful, it is better to take action before it is too late instead of waiting to act for scientific evidence to become available that shows a causal connection.[174] While a causal link has not been clearly formed based on available scientific evidence, an action that is taken in order to prevent damage in this instance can be supported by the precautionary principle.[175]

Risk assessment is the key to the precautionary principle.[176] In view of risk assessment, not all preventative actions are completely justified by the precautionary principle.[177] Instead, the precautionary

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173. *See* JANS & VEDDER, *supra* note 157, at 43 (articulating the precautionary principle and what it requires of government with respect to preventing environmental harms in the face of uncertain scientific findings); ALEMANNO, *supra* note 157, at 105 (characterizing the precautionary principle as allowing the adoption of protective measures in circumstances where there is scientific uncertainty).

174. *See* JANS & VEDDER, *supra* note 157, at 43 (describing the presumption of the precautionary principle that taking preventative action and avoiding damage is better than not taking such action in order to wait until complete scientific evidence becomes available that demonstrates the causal connection); ALEMANNO, *supra* note 157, at 106 (claiming that under the precautionary principle, it is preferable to not wait for a risk to materialize before examining and withdrawing a product from the market whose safety is uncertain).

175. *See* JANS & VEDDER, *supra* note 157, at 43 (showing a possible justification under the precautionary principle for taking action without scientific certainty concerning a causal connection); ALEMANNO, *supra* note 157, at 106 (" . . . recourse to the precautionary principle presupposes that scientific evaluation does not allow the risk to be determined with sufficient certainty.").

176. *See* JANS & VEDDER, *supra* note 157, at 43 (specifying that the Commission guidelines indicate that the precautionary principle is all about risk management); Joss, *supra* note 16, at 147 (stating that the precautionary principle "necessitates" that risk assessment be conducted when introducing biotechnology).

177. *See* Council Regulation 178/2002/EC on Laying Down The General Principles And Requirements Of Food Law, Establishing The European Food Safety Authority and Laying Down Procedures In Matters Of Food Safety, 2002 O.J. L 31/1, art. 7, at 2 [hereinafter *General Principles and Requirements of Food Law Regulation*] (explaining the boundaries of the precautionary principle); JANS & VEDDER, *supra* note 157, at 43 (discussing how the precautionary principle justifies actions taken).

principle calls for proportion between the measures taken and the chosen level of protection that is determined when action is deemed necessary.[178]

Because the precautionary principle is applied when scientific uncertainty exists, a proper risk assessment is paramount and must be performed as part of a correct application of the principle.[179] A correct application of the precautionary principle requires, first, that the potentially negative health consequences of a proposed use of the substance be identified and that a comprehensive risk assessment based on the most reliable scientific data be conducted.[180] Under the precautionary principle, a hypothetical risk will not be an adequate basis for action.[181] Rather, action is only justified if it is deemed necessary in order to ensure that there is no danger for the environment and human health as shown by a prior complete risk assessment.[182]

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178. *See General Principles and Requirements of Food Law Regulation, supra* note 177, art. 7, at 2 (stating that measures adopted on the basis of the precautionary principle that are necessary to ensure the high level of health protection ". . . shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration"); JANS & VEDDER, *supra* note 157, at 43 (detailing how measures taken under the precautionary principle should be proportional to the chosen level of protection).

179. *See* Joss, *supra* note 16, at 147 (explaining how risk assessment is necessary under the precautionary principle); *General Principles and Requirements of Food Law Regulation, supra* note 177, art. 6 (describing the necessity of risk assessment).

180. *See* JANS & VEDDER, *supra* note 157, at 44 (detailing the viewpoint of the Court of Justice of what constitutes a correct application of the precautionary principle); *see also infra* Section II.B.3 (setting forth the parameters for the precautionary principle as set forth by the Commission).

181. *See* Ruby R. Fernandez, *Monsanto And The Requirement For Real Risks In GM Food Regulation*, 28 LOY. L.A. INT'L & COMP. L. REV. 335, 338 (2006) (detailing how risk assessments must be conducted on real, perceived risks and not hypothetical risks); JANS & VEDDER, *supra* note 157, at 44 (highlighting the need for risk assessment to be conducted on real risks as opposed to hypothetical risks).

182. *See* JANS & VEDDER, *supra* note 157, at 45 (explaining the prohibition of justifying action based on a hypothetical risk); Fernandez, *supra* note 181, at 345 (discussing the requirements of the precautionary principle); Claudio Mereu, *Schizophrenic Stakes of GMO Regulation in the European Union,* 3 EUR. J. RISK REG. 202, 207 (2012) (explaining how a complete risk assessment must be conducted before a Member State can impose a ban).

3. The Precautionary Principle As Explained By The Commission

As discussed by the Commission of the European Communities in its Communication on the Precautionary Principle, the issue on when and how to use the precautionary principle is a contentious topic and has led to some mixed views concerning the principle.[183] Through the Commission Communication, the Commission outlined its approach to using the precautionary principle and established guidelines for its application.[184] The Commission desired to craft a common understanding on how to manage risks that have not been fully evaluated by science and to avoid the use of the principle as a disguised form of protectionism.[185] Within this approach, the precautionary principle should be considered within a structured approach to risk analysis, which is made up of risk assessment, risk management, and risk communication.[186] The precautionary principle is specifically relevant to the management of risk.[187] In this risk analysis, the precautionary principle should be resorted to when potentially dangerous effects of a phenomenon, process, or product have been identified and the risk cannot be determined with sufficient certainty under a scientific evaluation.[188] Specifically, the precautionary principle is only relevant in the situation of a potential risk, even if the risk is not fully demonstrable because of insufficient or inclusive scientific data.[189] In order to determine if measures are necessary to protect human, animal, or plant health, as well as the environment, an evaluation of the potential negative effects using available data is required.[190] The Commission Communication gives guidance on how to perform this evaluation.[191] Determining what is an acceptable level of risk for society and what an appropriate

183. Commission of the European Communities, Communication from the Commission on the Precautionary Principle, COM (2000) 1 Final [hereinafter Commission Communication].

184. *Id.* at 2, ¶ 1.

185. *Id.*

186. *Id.* at 2, ¶ 4.

187. *Id.*

188. *Id.* at 3, ¶ 4.

189. *Id*. at 13, ¶ 5.1.

190. *Id.* at 13, ¶ 5.1.2.

191. *Id*. at 13-15.

response might be are both political determinations.[192] Those making these political determinations may either adopt measures to respond or decide to do nothing in response and leave things status quo.[193]

According to the Commission Communication, once action is deemed necessary, measures taken based on the precautionary principle should be (1) proportional to the chosen level of protection, (2) non-discriminatory in their application, (3) consistent with similar measures already taken, (4) based on an examination of the potential benefits and costs of action or lack of action, (5) subject to review in light of new scientific data, and (6) capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.[194] Particularly important is the proportionality requirement, as a total ban of something may be the only possible response to a certain risk, but also may not be proportional to a potential risk in every case.[195]

4. The Precautionary Principle & *Monsanto*

In *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, the European Court of Justice ("Court of Justice") closely examined the application of the precautionary principle and how the principle can be used to justify Member State actions.[196] At the time of this case, genetically modified foods and food derived from GMOs were regulated as novel foods and had to be authorized under the *Novel Foods Regulation* (described in more detail later in this Note).[197] Under the second recital of the *Novel Foods Regulation*, a simplified procedure existed for the authorization of foodstuffs that were produced from GMOs but did not contain them in the final product.[198] All that was required under this simplified procedure was

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192. *Id*. at 15, ¶ 5.2.1.

193. *Id*.

194. *Id*. at 3, ¶ 5.

195. *Id*.

196. Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others v. Presidenza del Consiglio dei Ministi and Others, Case C-236/01 [2003] E.C.R. I-8166.

197. *See* Council Regulation No 258/97/EC Of the European Parliament and of the Council of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients, 1997 O.J. L 43/1 [hereinafter *Novel Foods Regulation*].

198. *Id.* recital 2.

notification to the Commission.[199] This procedure could be used when the products were substantially equivalent to similar conventional foods with regard to their intended use, composition, nutritional value, and the level of undesirable substances contained within them.[200]

Between December 1997 and October 1998, Monsanto and other companies submitted three notifications to the Commission under the simplified procedure for food produced from different genetically modified maize lines on the market.[201] Along with the notifications was an opinion of the UK scientific assessment body that found that the products at issue were substantially equivalent to traditional maize and safe for use in food, such as corn flour.[202] Italy objected several times about the use of the simplified procedure to the Commission, arguing that the products were not substantially equivalent to their traditional counterparts.[203] Despite the correspondence with the Commission, Italy adopted a Decree based on the safeguard clause of the *Novel Foods Regulation* that suspended the trading and use of certain transgenic products within its national territory.[204] Under this safeguard clause, a Member State could temporarily restrict or suspend the trade in and use of a food or food ingredient in question in its territory if it had detailed grounds for considering it to endanger human health or the environment based on new information or a reassessment of existing information.[205] The Commission responded by consulting with the Scientific Committee on Food in accordance with Article 11 of the *Novel Foods Regulation* to inspect the opinions submitted by Italy when it objected to the simplified procedure.[206] The Scientific Committee on Food found that Italy's information did not provide specific scientific grounds for considering that the use of the novel foods in question endangered human health.[207] While the

199. *Id.* art. 3, at 4 (setting forth the simplified procedure).
200. *Id.*
201. *Monsanto, supra* note 196, at ¶ 18.
202. *Id.* ¶ 19.
203. *Id.* ¶ 32-33.
204. *Id.* ¶ 31.
205. *Id.; Novel Foods Regulation*, *supra* note 197, art. 12, at 1 (providing the safeguard clause).
206. *Monsanto, supra* note 196, ¶ 34.
207. *Id.* ¶ 35.

Commission presented a draft decision contesting the Italian decree to the Standing Committee on Foodstuffs, the Commission did not go to a formal vote (largely because of the de facto moratorium on GMOs that was ongoing in the European Union).[208] Companies such as Monsanto challenged the Italian Decree before the *Tribunale amministrativo regionale del Lazio* ("TAR").[209] They claimed that it violated Community law and that Italy inadequately relied on the safeguard clause under Article 12 of the *Novel Foods Regulation.*[210] The TAR stayed its proceedings and referred questions to the Court of Justice for a preliminary ruling concerning the invoking of the safeguard clause, the validity of the simplified procedure, and whether a GMO-derived novel food could be regulated by the simplified procedure as substantially equivalent.[211]

The court held that under Article 12 of the *Novel Foods Regulation*, Member States could not submit a general risk assessment.[212] Rather, a Member State could only meet the burden of proof if it relied on the evidence that showed the existence of a specific risk of the novel food at question.[213] Additionally, the safeguard clause was interpreted as giving specific expression to the precautionary principle and, as such, the application of the clause was required to have "due regard to this principle."[214] Under the precautionary principle, when there is uncertainty about the existence or amount or risk to human health, protective measures can be taken without having to wait for the reality and seriousness of such risks to become fully apparent.[215] Thus, under Article 12 of the *Novel Foods Regulation* and the precautionary principle, protective measures could be taken even if it was impossible to carry out a full risk assessment with respect to a specific food because of the inadequate nature of the available scientific data.[216] However, the court specifically held that

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208. *Id.* ¶¶ 35-37

209. *Id.* ¶¶ 40, 48 (explaining the procedural history and giving the questions posed by TAR).

210. *Id.* ¶¶ 44-49.

211. *Id.*

212. *Id.* ¶ 108.

213. *Id.* ¶ 109.

214. *Id.* ¶ 110.

215. *Id.* ¶ 111.

216. *Id.* ¶ 112.

under the safeguard clause, protective measures could not be adopted based on a purely hypothetical approach to risk.[217] Under the clause, a Member State had to perform a risk assessment that was complete as possible and find that the implementation of such measures was necessary to ensure that novel foods did not present a danger to the consumer.[218]

Ultimately, the court rejected Italy's argument that the simplified procedure resulted in a relaxation of the safety requirements for novel foods that had been justified as substantially equivalent.[219] This, the court reasoned, was because there were many other procedures within Community law to ensure the safety of novel foods, such as the Safeguard Clause and re-assessment of the status of a GMO product at the Community level.[220] The court also found that the simplified procedure complied with the idea of proportionality.[221]

5. The Precautionary Principle & *Commission v. Denmark*

The fundamental ideas behind the precautionary principle were demonstrated by the Court of Justice in *Commission v. Denmark*, when Denmark partly relied on the principle to support its administrative practice that only allowed enriched foodstuffs lawfully produced or marketed in other Member States to be marketed in Denmark if it was shown that the nutritional enrichment met a need in the Danish population.[222] The Court of Justice found that the Danish administrative practice violated Article 28 EC, which prohibits any quantitative restrictions on imports between Member States and all measures having equivalent effect.[223] The court addressed whether the administrative practice could be justified on the basis of Article 30 EC, which allowed for a trade restriction if this would protect human

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217. *Id.* ¶ 106.

218. *Id.* ¶ 114. The court also addressed whether the novel foods at issue could be considered substantially equivalent to their traditional counterparts and what precludes a finding of substantial equivalence. However, this discussion will not be addressed by this Note.

219. *Id.* ¶ 80.

220. *See generally id.* ¶ 130-32.

221. *Id.*

222. *See* Commission v. Denmark, Case C-192/01, [2003] E.C.R. I-9724, ¶ 1 (describing the factual background of the actions that led to the case).

223. *Id*. ¶ 39, 41.

health.[224] The Court of Justice held that depending on any uncertainties in modern scientific research, it is up to the Member States to decide their level of protection for human health and life.[225] Furthermore, it is up to the Member State's discretion as to require prior authorization for the marketing of foodstuffs, subject to considering the requirements of free movement of goods within the Community.[226] The Court of Justice determined that within this discretion, Member States have to comply with the principle of proportionality.[227] This means that the methods chosen by such a Member State have to be restricted to what is actually necessary to protect public health and also that such protection cannot be attained by means less restrictive of Community trade.[228] Under the strict exception under Article 30 EC to the rule of free movement of goods within the Community, a Member State is required to show that its rules are necessary and that the marketing of the product is a risk to public health, in light of national nutritional habits and international scientific research.[229] The Court of Justice stated that the decision to prohibit marketing can only be adopted if the most current scientific data sufficiently established the real risk.[230]

In examining Denmark's administrative action, the Court of Justice clearly stated that " . . . a proper application of the precautionary principle presupposes, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive risk assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research."[231] The Court of Justice went further and addressed the permissible justification of action based on the precautionary principle and ruled that "where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness, or imprecision of the

224. *Id.* ¶ 42.
225. *Id.*
226. *Id*.
227. *Id.* ¶ 45.
228. *Id*.
229. *Id*. ¶ 46.
230. *Id.* ¶ 48.
231. *Id.* ¶ 51.

results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures."[232] The Court of Justice also added that such measures are not allowed unless they are objective and non-discriminatory.[233] Ultimately, the Court of Justice found that the Danish administrative practice was disproportionate since it prohibited the marketing of foodstuffs with added vitamins and minerals without distinguishing among different vitamins and minerals added or according to the level of risk that their addition may pose to public health.[234]

6. The 1990 Deliberate Release Directive

As previously discussed, provisions for Community policy on the environment were provided in Article 130r of the SEA in 1987.[235] As these measures were in effect until 1993, the Council adopted the *1990 Deliberate Release Directive* consistent with these provisions as well the precautionary principle.[236] As a Directive, the *1990 Deliberate Release Directive* was binding on all Member States.[237] But Member States had the ability to choose the forms and methods used to implement the Directive.[238] Applicable to all GMOs, this Directive pertained to then-modern biotechnology techniques, such as microinjection of foreign genetic material and cell fusion that does

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232. *Id.* ¶ 52.

233. *Id.* ¶ 53.

234. *Id.* ¶ 55.

235. *See supra* notes 158-63 and accompanying text (discussing the environmental policy under SEA).

236. *See* Ruth MacKenzie & Silvia Francescon, *The Regulation of Genetically Modified Foods In The European Union: An Overview*, 8 N.Y.U. ENV'T L.J. 530, 533 (1999-2000) (arguing that while the 1990 Deliberate Release Directive does not specifically mention the precautionary principle, the approach taken in the Directive " . . . is consistent with a precautionary approach insofar as the Directive as a whole addresses the uncertain nature and the extent of risks to the environment and human health associated with the use and release of GMOs."); Mereu, *supra* note 182, at 205 (articulating that the 1990 Deliberate Release Directive was based on the precautionary principle).

237. *See 1990 Deliberate Release Directive*, *supra* note 150, art. 23, at 1 (requiring Member States to bring laws, regulations, and administrative provisions necessary to comply with the Directive into force before October 23, 1991).

238. *See 1990 Deliberate Release Directive*, *supra* note 150; *see also* Francer, *supra* note 56, at 278 (stating that the 1990 Deliberate Release Directive was binding on all Member States as a directive).

not occur from natural processes.[239] In order to comply with the *1990 Deliberate Release Directive*, Member States were required to pass conforming legislation within eighteen months.[240] The first part of this Directive was a premarket notification, in which a manufacturer wishing to place a food containing a GMO into the market was required to submit a notification to the "competent authority" of the Member State where the GMO would be released.[241] It required the manufacturer to include in its notification information that was necessary to evaluate any immediate or delayed foreseeable risks that the GMO may have posed to human health or the environment.[242] Thus, while the FDA relies on manufacturers of GMO products to ensure that their products comply with the agency's safety standards, the European Union required that the manufacturer provide the information necessary for a proper third-party risk assessment.[243] Some of the required notification data included methods used for modification, allergencity, antibiotic resistance, and potential for genetic transfer and exchange with other organisms.[244]

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239. *See 1990 Deliberate Release Directive*, *supra* note 150, art. 2, at 2 (defining "genetically modified organism (GMO)"); Francer, *supra* note 56, at 279 (detailing the broad scope of the 1990 Deliberate Release Directive).

240. *See 1990 Deliberate Release Directive, supra* note 150, art. 23 (setting forth the time span in which the Member States had to pass legislation in order to conform with the Directive as eighteen months); Francer, *supra* note 56, at 279 (stating the eighteen-month deadline for Member States under the 1990 Deliberate Release Directive).

241. *See 1990 Deliberate Release Directive*, *supra* note 150, art. 5, at 1 (mandating the notification for manufacturers to be submitted to the competent authority of the Member State where the GMO would be released); Francer, *supra* note 56, at 280 (introducing the premarket notification under the 1990 Deliberate Release Directive).

242. *See 1990 Deliberate Release Directive*, *supra* note 150, art. 5, at 2(a) (setting forth the requirements of the notification with respect to risk assessment); Francer, *supra* note 56, at 279-80 (setting forth the requirements of the notification with respect to risk assessment).

243. *See* Francer, *supra* note 56, at 279-80 (describing the independent risk assessment conducted by the competent authority of the Member State that received the notification); *see also 1990 Deliberate Release Directive*, *supra* note 150, annex II (some of the required notification data included methods used for modification, allergencity, antibiotic resistance, and potential for genetic transfer and exchange with other organisms). *See generally* Terrence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243 (1999) (giving an overview of the foundation of the EU regulatory system).

244. *See 1990 Deliberate Release Directive*, *supra* note 150, annex II; Francer, *supra* note 56, at 280 (discussing the required notification data).

The second part of this Directive required review by the competent authority in the Member State.[245] After the competent authority of a Member State received a GMO notification, it had to submit a summary of the notification to the European Commission, which was responsible for immediately giving the summary to the competent authorities of each Member State.[246] Within ninety days, the Member State that received the notification from the manufacturer could either approve or reject the notification.[247] As part of this review, the competent authority in the Member State was required to determine if the notification fulfilled the requirements under the *1990 Deliberate Release Directive*, while giving particular attention to the environmental risk assessment.[248] If the competent authority found that introducing the GMO into the environment was too high of a risk to human health and the environment, it was allowed to reject the application for use in the European Union.[249] However, if it found that the release of the GMO into the environment would be safe to human health and the environment, it was required to send the dossier of notification and its recommendation to the Commission and other Member States.[250]

Under the *1990 Deliberate Release Directive*, GMO labeling was not required.[251] While Article 11.1 stated that the notifying party must include a proposal for labeling or packaging a product approved for the market, it also clearly indicated that the party could also choose not to comply with one or more of the labeling rules.[252]

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245. *See 1990 Deliberate Release Directive*, *supra* note 150, art. 5, at 1 (setting forth the notification procedure); Francer, *supra* note 56, at 280 (explaining that manufacturers needed to provide the competent authority in the Member State where the GMO would be released).

246. *See 1990 Deliberate Release Directive, supra* note 150, art. 9, at 1-2 (requiring the creation and distribution of the summary).

247. *See id*. art. 6, at 2 (stating what the Member State that received the notification could do).

248. *See id.* art. 12, at 1 (describing what the Member State had to do with respect to the notification).

249. *See id*. art. 12 (explaining how a competent authority could reject the application for use in the European Union).

250. *See id.*

251. *See id.* art. 11, at 1 (detailing the procedure for labeling GMOs); Stewart & Johanson, *supra* note 243, at 258 (stating that GMO labeling was not mandated under the 1990 Deliberate Release Directive).

252. *See 1990 Deliberate Release Directive, supra* note 150, art. 11, at 1 (explaining how applicants could propose not to comply with the labeling requirements in Annex III.B);

According to the *1990 Deliberate Release Directive*, after approval of a GMO notification, other Member States had sixty days to object to the GMO being introduced into the environment.[253] If no such objection was made, then the Member State that reviewed the notification would give written consent to the use of the GMO.[254] If a Member State did object within the sixty days and the competent authorities of the two Member States could not reach an agreement, the Commission was responsible for deciding whether to consent to the use of the GMO through a procedure under Article 21.[255]

The Commission was then required to draft and submit a proposal to a Committee made up of representatives from the Member States for review.[256] If the measures were in accordance with the opinion of the Committee, then the Commission would adopt the measures.[257] However, the Commission had to forward the proposal to the Council if they were not in accordance with the opinion of the Committee or if the Committee did not give an opinion.[258] The Council would then vote on the measures, either rejecting them unanimously or endorsing them by a qualified majority.[259] The Commission had to adopt the proposed measures if the Council failed to vote upon the proposal within three months.[260] If the Commission adopted the proposed measures, then the Member State that initially received the notification was required to consent to the placing of the

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see also Stewart & Johanson, *supra* note 243, at 258 (explaining the labeling aspects of the 1990 Deliberate Release Directive).

253. *See 1990 Deliberate Release Directive*, *supra* note 150, art. 13, at 2 (giving instructions if no Member States objected within sixty days).

254. *See id.* (explaining how written consent was given if no Member States objected); Francer, *supra* note 56, at 280-81 (explaining the procedure if no Member States objected within sixty days).

255. *See 1990 Deliberate Release Directive, supra* note 150, art. 13, at 3 (explaining the role of the Commission in this situation)*; see also* Stewart & Johanson, *supra* note 243 (describing the protocol under the Directive when the competent authorities of two Member States could not come to an agreement).

256. *See 1990 Deliberate Release Directive, supra* note 150, art. 21 (describing the responsibility of the Commission).

257. *See id.* (setting forth the action to be taken if the measures were in accordance with the opinion of the Committee).

258. *See id.* (explaining what the Commission was required to do in this situation).

259. *See id.* (putting forward the voting requirements).

260. *See id*. (describing what the Commission would do if the Council did not vote within three months).

GMO onto the market in writing and to notify other Member States of its consent.[261] After the initial Member State consented to the marketing of the GMO, it may have been used in the European Union without any further notification required and Member States could not "restrict or impede" the placing on the market of products containing or consisting of GMOs that comply with the *1990 Deliberate Release Directive*.[262]

While Member States could not prevent an approved GMO from being placed on the market, Article 16 of the Directive provided an important exception to this rule that proved to be a problem in 1997.[263] Even if a product has been approved for the market under the *1990 Deliberate Release Directive*, a Member State could provisionally restrict the product from its borders if it had justifiable reasons to believe that the GMO posed risks to human health or the environment.[264] If a Member State chose to restrict the product under Article 16, it was required to notify the Commission and the other Member States.[265] Within three months, the Commission was required to make a decision concerning the State's action under procedures set out in Article 21.[266] This created a significant loophole for the Member States to restrict approved GMOs in their territories.[267] This proved to be a significant international problem in 1998, when a de facto moratorium on GMOs occurred in the European Union and significant reform was undertaken that resulted in the current GMO regulatory system of the European Union.[268]

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261. *See id.* art. 20 (explaining the notification process once the Commission adopted the proposed measures).

262. *See id.* (detailing the conditions of the use of the approved GMO).

263. *See id.* art. 16, at 1 (providing the Safeguard Clause of the Directive).

264. *Id.* (explaining under what conditions a Member State could restrict an approved GMO from its territory).

265. *Id.*

266. *See id.* art. 16, at 2 (giving the procedures for the Commission to follow).

267. *See* Mereu, *supra* note 182, at 206 (explaining how several Member States relied on the Safeguard Clause under Article 16 in order to refuse the implementation of the authorization of a particular GMO); MacKenzie & Franceson, *supra* note 236, at 538-39 (detailing Article 16 and how it was used by several Member States in 1997).

268. *See* Stewart & Johanson, *supra* note 243, at 261-62 (discussing the crisis in the European Union when certain Member States used this loophole to ban approved Bt-maize from their territories in 1997); Mereu, *supra* note 182, at 206 (explaining this part of the 1990 Deliberate Release Directive).

In the years following the *1990 Deliberate Release Directive*, the Commission indicated that the European Union was lagging in biotechnology advancements and progress in the 1992 White Paper on Growth, Competiveness, and Employment and the 1994 Communication on Biotechnology.[269] In 1996, a review conducted by the Commission called for reform to the EU regulatory system, including more streamlined approval procedures for GMOs that posed a lower or nonexistent risk and a possible reform to the labeling requirements under the *1990 Deliberate Release Directive*.[270] In 1996, the President of the Commission expressed concerns over a lack of competition in the European Union and the trend of European companies that were seeking to invest in places outside of the European Union.[271] In fact, much of these remarks included comparisons of the European Union to the United States and concerns over the United States' advantage in the field of biotechnology.[272]

In 1997, France sent a favorable opinion on the approval of a GMO product named Bt-maize to the Commission, which then received objections from Austria, Belgium, Germany, Denmark, Italy, and Sweden after it forwarded the notification to the other Member

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269. *See* Stewart & Johanson, *supra* note 243, at 263-64 (analyzing the viewpoint of the Commission that greatly contrasted public opinion at the time concerning the need for more involvement in the advancement of biotechnology); *see also* DAVID BISSONNETTE, IT'S ALL ABOUT NUTRITION: SAVING THE HEALTH OF AMERICANS 162 (2013) (explaining the hostile public opinion towards genetic engineering during 1997); MacKenzie & Francescon, *supra* note 236, at 530-31 (discussing the unpopular views of the Commission that biotechnology was a key for future competitive development and the expressed concern of the Commission regarding the European Union's lack of involvement in the field).

270. *See* Commission Press Release, IP 96/1148 (Dec. 10, 1996); Stewart & Johanson, *supra* note 243, at 263-64 (discussing the Commission's position on the EU GMO regulatory system in 1996).

271. *See* Stewart & Johanson, *supra* note 243, at 264 (quoting the President of the Commission's statement concerning the position of the European Union in the biotechnology sector and the trend of European companies investing outside of the European Union). *See generally* MacKenzie & Francescon, *supra* note 236, at 530-31 (discussing the general concerns about the negative impacts of EU avoidance of biotechnology).

272. *See* Stewart & Johanson, *supra* note 243, at 264-65 (describing some of the comparisons made with respect to biotechnology). *See generally* MacKenzie & Francescon, *supra* note 236, at 530-31 (highlighting the concerns of the Commission that involvement in biotechnology would determine if Community industries would remain world leaders in developing products that were innovative).

States.[273] Under the *1990 Deliberate Release Directive*, the Commission sought the opinion of the Regulatory Committee on the Commission's draft decision, which wanted consent to put the product on the market for all uses.[274] Many Member States that opposed the drafted proposal were concerned with the fact that the proposal did not include labeling the product as a GMO.[275] They were also worried about the long-term environmental risks that the GMO product might cause.[276] After the Regulatory Committee did not approve the draft decision due to the lack of a qualified majority, it sent a proposal to the Council under Article 21 of the *1990 Deliberate Release Directive* for it to decide whether the GMO maize would be allowed on the market.[277] According to this proposal, no label would be required if the GMO was not a threat to humans or the environment.[278]

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273. *See* Stewart & Johanson, *supra* note 243, at 260-61 (explaining the favorable opinion sent by France to the Commission and listing the Member States who had objected to the proposal). *See generally* Association Greenpeace France and Others v. Ministère de l'Agriculture et de la Pêche and Others, Case C-9/99 [2000] E.C.R. I-1676 (providing a summary of these developments); Commission Decision No. 97/98/EC (*Zea mays L.*), 1997 O.J. L 31/69 (giving a history).

274. *See* Stewart & Johanson, *supra* note 243, at 261 (detailing how the Commission sought the opinion of the Regulatory Committee); EXPLORING CENTRAL AND EASTERN EUROPE'S BIOTECHNOLOGY LANDSCAPE 189 (Peter T. Robbins & Farah Huzair eds., 2011) (discussing this Committee and its role).

275. *See* Stewart & Johanson, *supra* note 243, at 261-62 (explaining the expressed concerns of the Member States); MARIA LEE, EU REGULATION OF GMOS: LAW AND DECISION MAKING FOR A NEW TECHNOLOGY 2 (Han Somsen ed., 2008) (discussing these attitudes).

276. *See* Stewart & Johanson, *supra* note 243, at 261-62 (detailing the environmental concerns of several Member States); Lee, *supra* note 275, at 2 (highlighting the Member States' arguments concerning the environment).

277. *See* Stewart & Johanson, *supra* note 243 (detailing the actions of the Commission); EXPLORING CENTRAL AND EASTERN EUROPE'S BIOTECHNOLOGY LANDSCAPE, *supra* note 274, at 189 (explaining that after the Article 21 committee of representatives of the Member States failed to reach a majority opinion, the Commission took the decision to the European Environment Council).

278. *See* Stewart & Johanson, *supra* note 243 (describing the proposal); EXPLORING CENTRAL AND EASTERN EUROPE'S BIOTECHNOLOGY LANDSCAPE, *supra* note 274, at 189 (explaining that after the Article 21 committee of representatives of the Member States failed to reach a majority opinion, the Commission took the decision to the European Environment Council).

Before the three-month deadline ended, Austria brought new information concerning the safety of the Bt-maize.[279] A month before the deadline, the Commission decided to have three scientific committees review the new information.[280] Upon review, all three committees gave favorable opinions concerning the proposal that denied the presence of risk to humans, the environment, or animals.[281] After the favorable opinions were released, the Commission adopted Commission Decision 97/98/EC and France was allowed to place the GMO on the market without requiring labeling of the product as genetically modified.[282]

The beginning of this movement towards further approval of GMOs was not accepted well by the public in 1997, as public opposition to GMOs remained significantly high.[283] Additionally, not all bodies of the European Union were in agreement with the approval decision, as the Parliament issued a resolution that heavily opposed the Commission for not considering new scientific evidence on the risks posed by the GMO and for acting in the face of disapproval of most Member States and the Parliament.[284] Specifically, the Parliament demanded that the authorization procedure be reopened and that the procedures to authorize GMOs be revised in order to

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279. *See* Commission Press Release, IP/98/358 (Apr. 16, 1998) (discussing the information submitted by Austria concerning the safety of this GMO); Stewart & Johanson, *supra* note 243 (explaining Austria's actions).

280. *See* Commission Press Release, IP/98/358 (Apr. 16, 1998) (explaining how the Commission responded to the actions of Austria by requesting the opinion of the three Scientific Committees); Stewart & Johanson, *supra* note 243 (detailing this development).

281. *See* Stewart & Johanson, *supra* note 243 (discussing the opinions regarding the proposal); *Zea mays L.*, 1997 O.J. 31/69 (explaining the conclusions of the Commission that there was no reason to believe that the maize would adversely affect human health or the environment).

282. *See* Stewart & Johanson, *supra* note 243, at 263 (discussing the approval of the Bt-maize in 1997); THE YEAR IN TRADE (1997): OPERATION OF THE TRADE AGREEMENTS PROGRAM, 49TH REPORT 104 (Arona Butcher ed., 1997) (stating that in 1996, the Commission authorized the sale of a particular strain of corn that was genetically modified).

283. *See* Stewart & Johanson, *supra* note 243, at 263-71 (discussing the contentious response to the Commission's actions and the belief that the European Union should take a larger role in the advancement of biotechnology); *see also* BISSONNETTE, *supra* note 269, at 162 (stating that during 1997, there was an uneasiness among Europeans and that public opinion in the European Union rose against GM crops with protests becoming more common).

284. *See* Stewart & Johanson, *supra* note 243, at 265-66 (detailing the Parliament's scathing reaction to the Commission); Lee, *supra* note 275, at 2 (stating that the Commission authorized the product despite a European Parliament resolution against authorization).

mirror the clear opinions of the Member States and the Parliament.[285] Instead of responding to the Parliament's resolution, the Commission's spokesman dismissed the thought of suspending the Bt-maize from the market unless new scientific evidence was presented on the product's dangers and stated that the Parliament's resolution was based on factual errors.[286]

Because Member States were allowed to object to the placement of approved GMOs on the market under the *1990 Deliberate Release Directive*, a crisis erupted when several Member States refused to implement the authorization.[287] Under Article 16 of the Directive, Austria issued a decree that prohibited the marketing of Bt-maize in its borders because it believed research that showed that an antibiotic-resistant gene named ampicillin could be passed to animals and humans through the Bt-maize.[288] Citing the same reasons, Luxembourg also banned the GMO product shortly after.[289] In an attempt to solve this issue, the Commission proposed a "fast-track" procedure to require labeling by amending the *1990 Deliberate Release Directive*. The *1997 Adapting Directive* altered Annex III of the *1990 Deliberate Release Directive* to require labeling of products that contained GMOs.[290] The Directive also stated that if GMO

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285. *See* Stewart & Johanson, *supra* note 243, at 265-66 (quoting the Parliament's resolution); Lee, *supra* note 275, at 2 (summarizing the reaction of the Parliament).

286. *See* Stewart & Johanson, *supra* note 243, at 266 (explaining how the Commission did not change its trajectory in response to the Parliament's resolution). *See generally* Lee, *supra* note 275, at 2 (describing how the Commission continued with the authorization despite the Parliament resolution against authorization).

287. *See* Stewart & Johanson, *supra* note 243, at 266 (analyzing the response of several Member States to prohibit the marketing of Bt-maize in their territories); THE YEAR IN TRADE, *supra* note 282 (explaining how Austria, France, Italy, and Luxembourg announced bans on the planting and use of genetically modified corn and how some Member States eventually lifted their bans in the fall of 1997).

288. *See* Stewart & Johanson, *supra* note 243, at 266 (outlining Austria's response to the authorization of Bt-maize); THE YEAR IN TRADE, *supra* note 282, at 104 n.180 (stating that Austria banned Bt-maize after it was authorized).

289. *See* Stewart & Johanson, *supra* note 243, at 267 (explaining how Luxembourg similarly reacted to the approval of Bt-maize); THE YEAR IN TRADE, *supra* note 282, at 104 n.180 (stating that Luxembourg was one of the Member States that banned Bt-maize).

290. *See* Commission Directive 97/35/EC Adapting to Technical Progress For the Second Time Council Directive 90/220/EEC On The Deliberate Release Into The Environment Of Genetically Modified Organisms, 1997 O.J. L 169/72 (hereinafter *1997 Adapting Directive*); Stewart & Johanson, *supra* note 243, at 270-71 (describing the adoption and content of the *1997 Adapting Directive*).

products placed in the market were mixed with non-GMO products, it was sufficient to state the possibility that GMOs may be present in such products.[291]

Despite attempts to change the authorization procedure, a de facto moratorium occurred in the European Union, as no new GMOs were authorized in the European Union and no new GMOs were placed on the market until 2004.[292] When the United States, Canada, and Argentina brought cases against the European Union in the World Trade Organization ("WTO"), the WTO panel declared that the European Union unacceptably delayed processing GMO applications by the members and that the moratorium could not continue because it conflicted with the European Union's international commitments.[293] In the midst of these upheavals, the European Union formed the three-part GMO regulatory system still used today, made up of the *2001 Deliberate Release Directive*, the *Genetically Modified Food and Feed Regulation,* and the *Traceability and Labeling Regulation*.[294]

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291. *See 1997 Adapting Directive*, *supra* note 290, Annex III(C) (explaining how to deal with this possible mix); Stewart & Johanson, *supra* note 243, at 269-70 (explaining the requirements under the 1997 Adapting Directive*)*.

292. *See* BALANCING BETWEEN TRADE AND RISK 109 (Marjolrin B.A. van Asslet, Esther Versluis, & Ellen Vos eds., 2013) (explaining how the Member States suspended all authorizations of GMOs and imposed a de facto moratorium ". . . until the framework could be reformed in such a way as to apply stricter rules, in particular on the labeling and traceability of GMOs"); Mereu, *supra* note 182, at 207 (explaining how the de facto moratorium ensued in 1998, leading there to be no new GMOs placed on the market again until 2004).

293. *See generally* Panel Report, *European Communities–Measures Affecting the Approval and Marketing of Biotech Products,* WTO Doc. WT/DS291/R (adopted Sept. 9, 2006); Meureu, *supra* note 143, at 206-07 (detailing how the WTO found that the de facto moratorium was not compatible with the international commitments of the European Union); Andrea L. Stephenson, *Germany's Ban Of Monsanto's Genetically Modified Maize (MON810): A Violation Of International Law,* 2 TRADE L. & DEV. 292, 300 (2010) (analyzing how the WTO dispute panel decided that the European Union breached its legal obligations under the WTO with its unacceptable delay of processing GMO applications by the Members).

294. *See* David E. Sella-Villa, *Gently Modified Operations: How Environmental Concerns Addressed Through Customs Procedures Can Successfully Resolve the US-EU GMO* Dispute, 33 WM. & MARY ENV'T L. & POL'Y REV. 971, 982-83 (2008-2009) (summarizing the current regulatory system in the European Union made up of these measures); Carrau, *supra* note 21, at 1185-86 (outlining the European Union's GMO regulatory system).

7. The 2001 Deliberate Release Directive

After realizing many problems associated with the *1990 Deliberate Release Directive*, the European Parliament and the Council of the European Union repealed it and replaced it with the *2001 Deliberate Release Directive*.[295] This Directive applies to all attempts to grow or sell GMOs in the European Union, except those with a strict scientific purpose, and thus covers placing GMO products or products containing GMOs on the market within the European Union.[296] The precautionary principle is heavily emphasized throughout the document.[297]

The Directive states that in order to protect human health and environmental demands, a state regulatory agency must control risks that may come from deliberately releasing GMOs into the environment, especially because their effects may irreversibly and adversely affect the environment of neighboring Member States.[298] In Article 1, the Directive states that in accordance with the precautionary principle, the objective of the Directive is to approximate the laws and regulations of the Member States and to protect human health and the environment.[299] Prior to a deliberate release of a GMO into the environment, a "case-by-case" environmental risk assessment must always be conducted that considers the potential cumulative long-term effects of the interaction of the GMO with the environment.[300] More importantly, this environmental risk assessment is to be made based on independent

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295. *See generally 2001 Deliberate Release Directive, supra* note 151; Fernandez, *supra* note 181, at 339 (stating that the 1990 Deliberate Release Directive was amended in 2001 and renamed Directive 2001/18/EC).

296. *See 2001 Deliberate Release Directive*, *supra* note 151, art. 2, at 4 (defining "placing on the market" and listing the three operations that were not to be regarded as "placing on the market"); Sella-Villa, *supra* note 294, at 986 (explaining the scope of the 2001 Deliberate Release Directive).

297. *See 2001 Deliberate Release Directive, supra* note 151, recital 8 (stating that the precautionary principle was taken into account when the Directive was being drafted and must be taken into account when implementing it).

298. *See id.* recital 4 (noting the possibly irreversible effects of GMOs).

299. *See id.* art. 1 (detailing the objective of the Directive).

300. *See id.* art. 19 (setting out the idea that a case-by-case environmental risk assessment should always be carried out before a release and how this assessment should appropriately consider the potential cumulative long-term effects associated with the interactions with other GMOs and the environment).

scientific advice through a common methodology, rather than the patchwork system consisting of independent Member State actions that had been created under the *1990 Deliberate Release Directive*.[301]

Part B of this Directive applies to the deliberate release of GMOs for any other purpose than for placing on the market, while Part C covers the placing on the market of GMOs as or in products.[302] Because this Directive applies to both the release and the placing on the market of products containing GMOs, this Directive applies to both the farming of GMOs and the importation of such products.[303] Furthermore, independent researchers should be given access to all relevant material when the Commission is considering a GMO for approval.[304] The Directive also indicates that a step-by-step system must be applied to the GMO approval process, in which a specific GMO becomes systematically less contained when evaluations show that its release does not threaten human health and the environment.[305] Furthermore, the Directive asserts that every GMO being considered for placement on the market must have undergone satisfactory field testing in the ecosystems that could be affected by its release.[306] For purposes of this Note, Part C will be discussed to demonstrate the approval process for GMOs for the purpose of placing them on the market.[307]

While the Directive does not apply to organisms that have been obtained through certain GE techniques that have conventionally been used and have a long safety record, it does set out a very specific

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301. *See id*. recital 20 (describing the necessity of having a common methodology for the environmental risk assessment, which is based on independent scientific advice).

302. *See id*. Parts B-C; Margaret Rosso Grossman, *Traceability and Labeling Of Genetically Modified Crops, Food, and Feed In The European Union*, 1 J. FOOD L. & POL'Y 43, 56 (2005) (explaining what is governed by Parts B and C of the 2001 Deliberate Release Directive).

303. *See 2001 Deliberate Release Directive, supra* note 151, art. 1 (describing how the Directive applies to both).

304. *See id*. (stating that while the Commission is considering a GMO for approval, independent researchers should have access to all relevant material).

305. *Id*. recital 24 (detailing the step-by-step process).

306. *Id*. recital 25 (describing how no GMOs may be considered for placing on the market without having gone through a satisfactory field testing at the stage of research and development in ecosystems that can be affected by their use).

307. *See infra* notes 308-21 and accompanying text (detailing Part C of the 2001 Deliberate Release Directive).

procedure for approving all remaining GMOs.[308] As part of this case-by-case analysis, an applicant wishing to place a GMO on the market must first submit a notification to the national competent authority that contains a technical dossier of information that includes a full environmental risk assessment and appropriate safety and emergency responses.[309] As part of this assessment, applicants are required to evaluate potential risks to human health and the environment associated with the release of the GMOs in question.[310] The assessment is broad, as it applies to risks that are direct or indirect and immediate or delayed.[311] Applicants are required to include in their application a plan for monitoring the effects and impact of the GMO release under Article 13.[312]

After the applicant submits the application to the competent authority in a Member State, the authority evaluates the notification for compliance with the Directive and then makes an independent assessment.[313] Within sixty days from the date of the circulation of the assessment report, a competent authority or the Commission may make comments, present reasoned objections to the placing on the market of the GMO, and ask for further information.[314] The Member State's competent authority that received the notification can either reject the application or approve the GMO for entry into the

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308. *See 2001 Deliberate Release Directive, supra* note 151, recital 17 (excluding organisms that have been obtained through certain genetic modification techniques that have been conventionally used in a number of applications and that have a long safety record from the Directive).

309. *Id*. recitals 32-33 (stating the requirements under the Directive for the notification); *id.* art. 13 (setting forth the specific procedure for this notification).

310. *Id*. art. 2, at 8 (defining "environmental risk assessment" and what is required to be addressed under this evaluation).

311. *Id*.; Paula Rey Garcia, *Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs: An Overview and the Main Provisions for Placing on the Market*, 3 J. EUR. ENV'T & PLAN. L. 3, 8 (2006) (explaining the types of risks to be examined during this analysis).

312. *See 2001 Deliberate Release Directive*, *supra* note 151, art. 13, at 2(e) (stating the requirement that applicants include a plan for monitoring the effects and impact of the GMO release).

313. *See id.* art. 14 (detailing the process for the competent authority once it receives the application).

314. *Id.* art. 15, at 1 (describing the ability of competent authorities to submit comments or reasoned objections, which are circulated to all competent authorities by the Commission).

market.[315] Under Article 15, if the competent authority approves the GMO and there is no reasoned objection from another Member State or the Commission within sixty days of the date of circulation of the assessment report or if outstanding issues are resolved within the 105 day period referred to in Paragraph 1, the competent authority is required to give written consent and transmit it to the applicant, the Member States, and the Commission within thirty days.[316] This approval for the introduction into the EU market lasts for ten years, starting on the date the consent was given.[317] The Directive also gives specific procedures for the renewal of consent, which include the applicant filing an abbreviated notice packet to the competent authority of the Member State.[318] The competent authority has to complete another assessment of the GMO to determine if it should remain on the market and must consider the well-reasoned objections from other Member States and the Commission.[319] Perhaps the most important part of this segment of the Directive is the Safeguard Provisions, under which any Member State can ban a GMO in its territory.[320] A Member State can only act under this provision if it has new or additional scientific knowledge with detailed grounds for believing that an approved GMO constitutes a risk to human health or the environment.[321]

8. The Genetically Modified Food and Feed Regulation

Under the "one door, one key" principle, applicants can a file a single application to be authorized for placement on the market as a food or feed under the *Genetically Modified Food and Feed*

315. *See id.* art. 15, at 2-3 (stating that if the competent authority decides that the GMO should not be placed on the market, the notification shall be rejected, and giving the procedure for approval by the Member State's competent authority).

316. *See id*. art. 15, at 3 (providing instructions for the competent authority which has approved a GMO and has not received a reasoned objection from other Member States or the Commission within sixty days after the date of circulation of the assessment report referred to in Article 14).

317. *See id*. art. 15, at 4 (establishing the ten-year limit on the authorization of a GMO).

318. *See id.* art. 17 (detailing the procedure for renewal of consent).

319. *See id*. (stating these requirements under the renewal procedure).

320. *See id.* art. 23 (providing the Safeguard Clause, which allows Member States to refuse to allow future circulation of a GMO in their borders).

321. *See id.* at 1 (detailing the only way a Member State can invoke the Safeguard Clause).

Regulation and for release into the environment under the *2001 Deliberate Release Directive*.[322] Relying on the principles of the *2001 Deliberate Release Directive*, the *Genetically Modified Food and Feed Regulation* further refined the application process.[323] Under Article 3, these requirements apply to (a) GMOs for food use, (b) food containing or consisting of GMOs, and (c) food produced from or containing ingredients produced from GMOs.[324]

According to Article 4 of the *Genetically Modified Food and Feed Regulation*, no person can place any of the products described in Article 3 on the market unless the specific product has been authorized under the Section and the relevant conditions of the authorization are satisfied.[325] While applicants are still required to submit detailed applications to the competent Member State authority, this authority is now required to work with other Member States and the European Food Safety Authority ("EFSA"), a body established by the *General Principles and Requirements of Food Law Regulation*.[326] The Member State that has received an application forwards it to the EFSA.[327] This specialized body reviews each application and sends

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322. While the *Genetically Modified Food and Feed Regulation* applies to both food and foodstuffs, this Note will only be addressing the food authorization requirements governed by Chapter II of the Regulation. *See* Bernd van der Meulen, *The EU Regulatory Approach to GM* Foods, 16 KAN. J.L. & PUB. POL'Y 286, 307 (2007) (stating that under the "one door one key" principle, a single application can be filed to obtain authorization under the 2001 Deliberate Release Directive for release into the environment and authorization for placement on the market as a food or feed under the *Genetically Modified Food and Feed Regulation*); Garcia, *supra* note 311, at 11 (explaining how these applications can be filed under either the 2001 Deliberate Release Directive and the *Genetically Modified Food and Feed Regulation*).

323. *See Genetically Modified Food and Feed Regulation, supra* note 151, recital 9 (stating that the new authorization procedures for genetically modified food and feed should include the principles introduced in the 2001 Deliberate Release Directive); Grossman, *supra* note 295, at 61 (explaining how the Genetically Modified Food and Feed Regulation incorporates the principles introduced in the 2001 Deliberate Release Directive).

324. *See Genetically Modified Food and Feed Regulation, supra* note 151, art. 3, at 1 (explaining what the Section applies to).

325. *See id.* art. 4, at 2 (setting forth this requirement).

326. *See id.* arts. 3-7 (highlighting the more significant part of the ESFA in the regulation of GMOs); Sella-Villa, *supra* note 294, at 988 (discussing the increased role of the EFSA in the EU regulatory system).

327. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 5, at 2 (setting forth the requirements for the competent authority that receives an application under this Regulation).

the dossier to the other Member States, which are allowed to make their own evaluations and give their opinions to the EFSA.[328]

It is important to note that the EFSA is not a regulatory authority with its own powers, but rather serves as an "independent source of advice."[329] As a specialized body, the EFSA is required to make a scientific risk assessment that addresses both environmental risks and risks to human and animal health safety, which it can do itself or assign to a national food assessment body.[330] According to the Regulation, the EFSA is also required to submit the elements necessary to test and validate the method of detection and identification of the GMO proposed by the applicant to the Community Reference Laboratory, which is aided by the European Network of GMO laboratories.[331] The Community Reference Laboratory is responsible for validating the applicant's methods for detecting and identifying the transformation event in the GMO food, as well as the applicant's data concerning sampling and detection.[332] After receiving a full evaluation report from the Community Reference Laboratory, the EFSA publishes the opinion to the public within six months of receiving the original application from the Member State and sends this opinion to the Commission.[333] At this time, the public is also allowed to submit opinions to the EFSA on the

328. *See id.* art. 4, at 2(b) (charging the ESFA with the responsibility of informing the Commission and the other Member States about the application).

329. *See* Vesco Paskalev, *Can Science Tame Politics: The Collapse of the New GMO Regime in the EU*, 3 EUR. J. RISK REG. 190, 193 (2012) (detailing the function of the ESFA); van der Meulen, *supra* note 322, at 301 (explaining how the EFSA is an independent entity that provides scientific advice and technical support for the Community's legislation and policies).

330. *See Genetically Modified Food and Feed Regulation, supra* note 151, art. 6, at 3(b) (stating that the EFSA may ask the appropriate food assessment body of a Member State to carry out a food safety assessment); van der Meulen, *supra* note 322, at 308 (detailing the responsibilities of the EFSA with respect to human health and the environment).

331. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 6, at 3(d) (stating what the EFSA must submit to the Community Reference Laboratory).

332. *See id.* art. 6, at 3(d) (explaining that the Community Reference Laboratory must test and validate the method of detection and identification that the applicant has proposed); *see also* van der Meulen, *supra* note 322, at 308 (describing the role of the Community Reference Laboratory).

333. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 6, at 7 (giving the requirements for the opinion of the ESFA); van der Meulen, *supra* note 322, at 308-09 (giving the procedure that the ESFA must undergo once it has received an evaluation report from the Community Reference Laboratory).

pending GMO application within thirty days from the publication.[334] The opinion must include a scientific assessment conducted by a committee of independent scientific experts that checks and evaluates data from the safety research that the applicant has presented.[335]

Within three months of receiving the EFSA's opinion, the Commission must draft and submit a proposal for granting or refusing authorization to the Standing Committee on the Food Chain and Animal Health, which is comprised of representatives of the Member States.[336] These representatives have expertise in areas including GMOs, food supply safety, and animal health, and are nominated by Member States.[337] If the decision is different from the EFSA's opinion, it must explain the difference in detail.[338] If the Committee approves the proposal by a qualified majority, then the Commission adopts the Decision.[339] If the Committee does not give a favorable

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334. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 6, at 7 (explaining the public's opportunity to submit opinions); CAOIMHIN MACMAOLAIN, EU FOOD LAW 248 (2007) (providing the specific requirements concerning the publication of the EFSA's opinion and the public's opportunity to respond).

335. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 6, at 7 (requiring the ESFA to make its opinion public and allowing the public to make comments within thirty days); van der Meulen, *supra* note 322, 308-09 (discussing this requirement); MACMAOLAIN, *supra* note 334, at 249 (stating that the ESFA must give an opinion on the merits of the application within six months of receiving it).

336. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 7, at 1 (requiring the Commission to submit a proposal for granting or refusing authorization to the Standing Committee on the Food Chain and Animal Health within three months of receiving the EFSA's opinion); *see also* van der Meulen, *supra* note 322, at 309 (explaining what the Commission must do in response to the EFSA's opinion and describing the makeup of the Standing Committee on the Food Chain and Animal Health).

337. *See General Principles and Requirements of Food Law Regulation, supra* note 177, art. 58, at 1 (describing and establishing the Standing Committee on the Food Chain and Animal Health); Sella-Villa, *supra* note 294, at 988 (describing the expertise and nomination of those on the Standing Committee on the Food Chain and Animal Health).

338. The Commission's decision must be based on the opinion of the Authority, relevant provisions of Community Law, and any other relevant factors. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 7, at 1 (stating that the Commission must explain any differences when the draft decision is not in accordance with the opinion of the ESFA); MACMAOLAIN, *supra* note 334, at 249 (explaining how the Commission must note any differences when its decision diverges from the ESFA's opinion).

339. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 35 (describing the Committee Procedure); van der Meulen, *supra* note 322, at 309 (describing how the Commission adopts the Decision if the Committee approves the proposal by a qualified majority).

opinion, the draft Decision is then sent to the Council of Ministers, who can adopt or reject it by a qualified majority.[340] Finally, the Commission must adopt the decision if the Council fails to act within three months.[341]

If a GM food is authorized, the decision is addressed to the applicant and therefore only the applicant is permitted to bring it into the market in any and all of the Member States.[342] The market authorization of a GM food is valid for ten years throughout the European Union.[343] Specific details about the decision are published in the Official Journal of the European Union and the product is entered into a public register of GM food and feed.[344]

9. The Labeling of GMOs in the European Union Under the *Traceability and Labeling Regulation*

In sharp contrast to the previous labeling system under the FDA Statement of Policy, the European Union requires that Member States take steps to ensure traceability and labeling of authorized GMOs at all stages of their placing on the market under the *2001 Deliberate Release Directive*.[345] According to the *Traceability and Labeling Regulation*, which serves as the foundation of the current EU GMO labeling system, traceability requirements for GMOs should facilitate the withdrawal of products whose unforeseen adverse effects on

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340. *See* van der Meulen, *supra* note 322, at 309 (explaining how the Council of Ministers can either adopt or reject the draft Decision by a qualified majority if the Committee has not given a favorable opinion); *see also Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 7 (giving instructions for this process).

341. *See* van der Meulen, *supra* note 322, at 309 (stating that if the Council does not act within three months, the Commission must adopt the decision); *see also Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 7 (setting the parameters of this process).

342. *See generally Genetically Modified Food and Feed Regulation, supra* note 151, art. 7, at 1-5 (detailing the procedure once a GMO is authorized); van der Meulen, *supra* note 322, at 309 (outlining the process after a GMO is approved in relation to the applicant).

343. *See Genetically Modified Food and Feed Regulation*, *supra* note 151, art. 7, at 5 (limiting the approval of a GMO to ten years).

344. *See* van der Meulen, *supra* note 322, at 309 (detailing the notification process); *see also* MACMAOLAIN, *supra* note 334, at 249 (explaining how applicants are notified).

345. *Traceability and Labeling Regulation*, *supra* note 151, recital 1 (detailing the requirements with respect to traceability of authorized GMOs).

human health, the environment, or animal health become apparent.[346] More importantly, the Regulation states that traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.[347] The Regulation also puts emphasis on consumers, as it states that traceability requirements for food produced from GMOs are implemented to ensure that accurate information is available to operators and consumers to enable them to use their freedom of choice in an effective manner.[348] It further states that it is necessary to ensure that consumers are completely and reliably informed about GMOs.[349]

In the *Traceability and Labeling Regulation*, the Parliament and the Council of the European Union set a GMO threshold "de minimis" amount of 0.9% of the ingredients, which gives some leniency to manufacturers and producers for certain traces of GMOs that may be technically unavoidable.[350] If an operator wishes to place a product on the market that contains an amount of GMOs over the threshold of 0.9%, he or she is required to indicate in writing (1) each food ingredient that is produced with GMOs, (2) each of the feed materials or additives that are produced from GMOs, and (3) that the product is produced from GMOs on products where there is no list of ingredients.[351]

10. Comparison of GMO Regulation Between the United States and the European Union

As demonstrated throughout Part I of this Note, the US and EU GMO regulatory systems differ greatly.[352] The source of the

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346. *Id.* recital 3 (explaining how the traceability requirements under the *Traceability and Labeling Regulation* should improve the removal of such products from the market).

347. *Id*. (emphasizing the continuing importance of the precautionary principle in EU regulation of GMOs).

348. *Id*. at 4 (highlighting the European Union's recognition of consumers' ability to freely choose what they consume and the important role that traceability and labeling requirements play in this ability).

349. *Id*. art. 1, at 11 (emphasizing the importance of informed consumer choice).

350. *Id*. art. 1, at 10 (setting forth the threshold level that triggers the requirements of GMO labeling under this regulation).

351. *See id*. art. 5, at 1 (describing the requirements for operators who want to sell products containing GMO levels over the threshold in the European Union).

352. *See generally supra* Part I (discussing the regulatory systems of both).

difference is the opposite nature of these systems, namely the United States' substantial equivalence doctrine and the European Union's precautionary principle.[353] Because the FDA views GMOs as GRAS, it does not require that companies submit specific information concerning the safety of their GMO products, as the European Union does.[354] While the FDA does not conduct independent research for each GMO seeking approval, the European Union requires an independent body to do its own research for each application.[355] And finally, since the FDA presumes GMOs are safe under the substantial equivalence doctrine, it has not required any labeling of GMOs, as it does not consider GMOs to be materially different from their traditional counterparts.[356] In contrast, the European Union requires traceability at every step for approved GMOs under the precautionary principle, as future risks may become visible at some point.[357]

II. THE PRESSURE FOR MANDATORY GMO LABELING MEASURES IN THE UNITED STATES AND THE EUROPEAN UNION

This Part will introduce the current status of the GMO labeling debate in the United States and will examine a similar debate that occurred in the European Union that led to a crisis in 1997. Section II.A explains the now preempted GMO labeling laws of Connecticut, Maine, and Vermont and compares the requirements of each. Section II.A also discusses the response to these state labeling laws, including legal action against the state of Vermont and the US House of Representatives' opposition to the laws through H.R. 1599. Finally, Section II.A also examines the federal compromise of S. 764, which

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353. *See generally supra* Part I (showing how the substantial equivalence doctrine serves as the basis of the US GMO regulatory system, while the precautionary principle is the foundation of the EU GMO regulatory system).

354. *See generally supra* Part I (explaining the contrasting requirements of the US and EU GMO regulatory systems).

355. *See generally supra* Part I (providing an overview of the different application procedures for the United States and the European Union).

356. *See generally supra* Section I.A (discussing the view of the FDA under the 1992 FDA Statement of Policy and the Coordinated Framework).

357. *See generally supra* Section I.B.10 (discussing the traceability requirements and their justifications).

established national GMO labeling requirements in the United States and preempted the state GMO labeling laws. Section II.B details how the European Union faced similar opposition from its public over the lack of mandatory GMO labeling requirements in 1997 and how it resolved the crisis by mandating GMO labeling based on threshold amounts to allay public fears.

A. The Current US Debate Over Mandatory GMO Labeling

Section II.A.1 introduces the current US debate over mandatory GMO labeling while Sections II.A.2 and II.A.3 discuss the Consumer Right to Know Policy. Sections II.A.4, II.A.5, and II.A.6 explain and contrast the now preempted GMO labeling laws of Connecticut, Maine, and Vermont while Section II.A.7 highlights some of the backlash to these state laws from companies opposing mandatory GMO labeling. Section II.A.8 describes the initial federal reaction to these state laws through H.R. 1599, while Section II.A.9 explains S. 764, which nationalized GMO labeling requirements based on the presence of bioengineered substance in final food products. Section II.A.10 presents an overview of the reaction to S. 764. Section II.B explains how the critical dispute between the Member States and the European Union Commission over the approval of Bt-maize in 1997 was resolved through the adoption of stricter mandatory labeling requirements under the current *Traceability and Labeling Regulation*. Section II.B also explains what is required under the *Traceability and Labeling Regulation* for approved GMOs in the European Union.

While the overwhelming majority of US citizens desire mandatory GMO labeling, the United States long resisted requiring labeling for GMOs and consistently refused to address the concerns of such individuals.[358] This incongruence led several states to take action and respond to their citizens' dissent by taking steps to require GMO labeling within their own borders.[359] As this movement spread across the United States at a fast pace, it prompted the US Congress to quickly respond and eventually led to the implementation of national

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358. *See generally supra* Section I.A (explaining the US federal policy on GMOs under the Coordinated Framework and the 1992 FDA Statement of Policy).

359. *See infra* Sections II.A.3-4, 6 (describing the actions of the states of Connecticut, Maine, and Vermont).

GMO labeling requirements under S. 764 that brought about the demise of the state GMO labeling laws of Connecticut, Maine, and Vermont.[360] However, before examining this revolutionary movement and federal reaction, it is important to understand why so many individuals desire GMO transparency.[361] The Consumer Right to Know Policy contains many of the justifications for mandatory GMO labeling and presents a consistent platform for individuals who argue for GMO labeling generally and for those who continue to argue for stricter measures than those provided for in S. 764.[362]

1. The Consumer Right to Know Policy

As previously discussed, the FDA considers GMOs to be GRAS and does not require independent testing of such products before placement on the market.[363] However, many argue for labeling of GMOs despite the FDA's determination based on the Consumer Right to Know Policy, which supports GMO labeling laws based on the rights of consumers to be able to choose whether or not they purchase and consume food products containing GMOs.[364] The right does not depend on whether or not fears concerning GMOs have scientific foundation or if the FDA finds a material difference between GMO foods and their traditional counterparts.[365] It instead addresses the

360. *See infra* Sections II.A.8-9 (giving an overview of the federal response).

361. *See infra* Section II.A.1 (providing arguments for GMO transparency under the Consumer Right to Know Policy).

362. *See infra* Section II.A.1 (describing these justifications, which are used by many GMO labeling proponents).

363. *See supra* Section I.A.3 (detailing the FDA's policy on these issues).

364. *See* Gary Hirshberg, *Mandatory GMO Labeling—It's Your Right to Know,* HUFFINGTON POST (July 21, 2015, 11:30 AM), http://www.huffingtonpost.com/gary-hirshberg/mandatory-gmo-labeling—i_b_7841144.html (detailing some of the motivations behind the Consumer Right To Know policy, including inadequate research on the long-term effects of GMOs, increased herbicide use, and religious and ethical views); Jon Entine, *Anti-GMO 'Big Lie': Is Labeling Really About Our "Right to Know?"*, GENETIC LITERACY PROJECT (Oct. 16, 2015), https://www.geneticliteracyproject.org/2015/10/16/anti-gmo-big-lie-labeling-really-right-know/ (citing the many national and international organizations that have concluded that genetically engineered crops are as safe as any other and that they pose no special risks to the environment or humans).

365. *See generally* James Hamblin, *No One Is Denying A 'Right To Know What's In My Food'"*, ATLANTIC (July 24, 2015), http://www.theatlantic.com/health/archive/2015/07/no-one-is-denying-a-right-to-know-whats-in-my-food/399536/ (articulating that the majority of Americans currently believe that any and all genetically modified foods are "inherently

concerns of a majority of the US public who desire GMO labeling and allows citizens to make informed decisions as to whether they wish to consume foods containing GMOs and those produced through genetic engineering.[366]

There are a myriad of reasons why consumers do not want to consume GMOs or foods made using genetic engineering, including religious and ethical reasons, that are independent of human safety concerns.[367] For example, a Jewish person observing religious dietary laws might be primarily concerned with avoiding foods made with certain meats or animal products in order to keep his or her strict Kosher diet.[368] Furthermore, many believe that genetic engineering allows corporations to "play God," which violates their religious beliefs.[369] Other reasons might be that people may choose to avoid certain foods for ethical reasons, while others may want to eat an "all natural" diet without consuming any food that has been modified or

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unhealthful" in spite of the "assurances to the contrary" from bodies such as the FDA, The World Health Organization and the American Medical Association); Steve Keane, *Can a Consumer's Right To Know Survive The WTO?: The Case of Food Labeling*, 16 TRANSNAT'L L. & CONTEMP. PROBS. 291, 302 (2006) (stating that the concept of the Consumer Right to Know is not always grounded in health and safety concerns).

366. *See* David Alan Nauheim, *Food Labeling and the Consumer Right to Know: Give the People What They Want*, 4 LIBERTY U. L. REV. 97, 103-04 (2009) (describing many of the reasons for consumer alarm regarding GMOs and stating that thirty-seven percent object to GMOs on religious grounds); Keane, *supra* note 365, at 302 (describing some of the justifications under the Consumer Right To Know policy, including religious or ethical dietary restrictions, environmental concerns, or opposition to production methods).

367. *See* Sarah L. Kirby, *Genetically Modified Foods: More Reasons To Label Than Not*, 6 DRAKE J. AGRIC. L. 351, 357 (2001) (giving the example of Jewish individuals who might violate their religious beliefs by consuming certain GMOs); Emmanuel B. Omobowale, Peter A. Singer, & Abdullah S. Daar, *The Three Main Monotheistic Religions and GM Food Technology: An Overview Of Perspectives,* BIOMED CENTRAL (Aug. 22, 2009), http://bmcinthealthhumrights.biomedcentral.com/articles/10.1186/1472-698X-9-18 (providing for some of the concerns specific to Jewish individuals with respect to consuming GMOs).

368. *See* Omobowale, Singer, & Daar, *supra* note 367 (describing many of the religious arguments concerning GMOs). *See generally* Nauheim, *supra* note 366, at 103 (explaining some of the concerns about GMOs with respect to Judaism).

369. *See* Nauheim, *supra* note 366, at 103 (explaining these religious arguments under the Consumer Right To Know policy); Omobowale, Singer, & Daar, *supra* note 367 (analyzing the religious concerns of those who believe that biotechnology interferes with God's role as the Creator). *See generally* Amaru, *supra* note 19, at 580 (stating that there might be religious reasons why individuals wish to avoid GMOs).

altered by scientific technology.[370] Another group of individuals who might wish to avoid GMOs are individuals with allergies who need to avoid certain allergens that might be present in genetically modified foods.[371] To all of these groups, the potential safety concerns might be secondary to their commitment to eating food that has not been genetically modified or contains GMOs.[372]

2. The Consumer Right to Know Policy & The Courts

In *Alliance for Bio-Integrity v. Shalala*, the court found that the Consumer Right to Know Policy was not a sufficient basis for a food labeling law on its own when the FDA did not find a material difference between GE foods and their traditional counterparts.[373] The court also held that a consumer's right to know could only be considered once a material difference was found between GMO and non-GMO products.[374] Since the Consumer Right to Know Policy was not an adequate basis for mandating GMO labeling, the court dismissed the case.[375]

The Consumer Right to Know Policy was also rejected in *International Dairy Food Association v. Amestoy* as a sufficient basis for a Vermont statute that mandated labeling for milk products containing rBST, a genetically modified hormone.[376] The US Court of Appeals for the Second Circuit ruled that because the FDA found that dairy products derived from cows treated by rBST were

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370. *See* Keane, *supra* note 365, at 302 (stating some of the ethical and moral reasons for consumer demand to know the GMO status of the food they are consuming); Amaru, *supra* note 19, at 580 (noting that many people might have ethical or moral objections to genetic engineering that are not dependent on whether or not GMOs have been proven safe); Kirby, *supra* note 367, at 357 (providing examples of those who morally and ethically oppose GMOs).

371. *See* Kirby, *supra* note 367, at 357 (discussing concerns that genetically modified foods may set off allergies); Strauss, *supra* note 158, at 109 (explaining that allergies are a major concern with genetically modified foods).

372. *See* Kirby, *supra* note 367, at 357 (describing some of the interests at issue as much deeper than mere consumer concern); Amaru, *supra* note 19, at 580 (citing many examples of individuals who wish to avoid GMOs despite how safe they have been proven to be).

373. *See* Alliance for Bio-Integrity v. Shalala, 116 F.Supp.2d at 179.

374. *Id.* (finding that the FDA could consider consumer demand once materiality has been established).

375. *Id.*

376. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

"indistinguishable" from products from untreated herds, the Vermont consumers' desire to know if the product contains rBST was insufficient to allow Vermont to force dairy manufacturers to speak against their will.[377] Specifically, the court stated that it knew of no case where consumer interest by itself was enough to justify requiring a product's manufacturers to make public a statement about a production method that has no discernable impact on a final product.[378]

While these cases do not involve the GMO regulations that are discussed in this Note, they are important to consider with respect to mandating GMO labeling based on the Consumer Right to Know Policy.[379] As will be discussed below, three states passed GMO labeling laws based on this Policy, as state legislatures listened to the demands of their citizens for greater GMO transparency.[380] While these state laws would later be preempted by the new federal national standard under S. 764, the Consumer Right to Know Policy continues to be a strong argument for those arguing for stricter labeling requirements and those who oppose the new federal national standard under S. 764 for various reasons.[381]

3. Connecticut's GMO Labeling Law

In June 2013, Connecticut passed the nation's first state GMO labeling law, which began the state movement towards mandatory labeling for GMOs.[382] Connecticut General Statutes §21a-92c state

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377. *Id.* at 74 (detailing the court's rationale for ruling that the consumers' desire to know about the GMO status of their food was not sufficient to overcome the First Amendment rights of the manufacturers); *see also* Nauheim, *supra* note 366, at 122 (discussing the court's finding that consumer interest was not sufficient and that the Vermont legislature did not satisfy the second prong of the *Central Hudson* test by having a substantial interest in regulating the commercial speech at issue).

378. *See Amestoy*, 92 F.3d at 74 (discussing the non-existence of such a case).

379. *See supra* Section II.A.1 (explaining the Consumer Right to Know Policy).

380. *See infra* Sections II.A.3-4, 6 (describing how the states of Connecticut, Maine, and Vermont enacted laws mandating GMO labeling in response to high public demand for such legislation).

381. *See infra* Section II.A.9 (stating that S. 764 preempts these state laws).

382. *See* 2013 Conn. Acts 777 (Reg. Sess.) (codified at scattered sections of Conn. Gen. Stat. Ann. §21a); *Connecticut passes first GMO labeling law in US*, RT (June 5, 2013, 3:46 AM), https://www.rt.com/usa/connecticut-first-gmo-labeling-law-241/ (describing how Connecticut was the first state to pass a mandatory GMO labeling law); *see also* Michele

that seed or seed stock intended to produce food for human consumption and food intended for human consumption that was introduced or delivered for introduction into commerce in the state of Connecticut that was entirely or partially genetically engineered had to be labeled.[383] Particularly, items contained in a package for retail sale were to be labeled with the clear and conspicuous words "Produced with Genetic Engineering."[384] In addition to requiring such labeling, the state of Connecticut circumvented the FDA and defined "natural food" in General Statutes Ann. §21a-92(17) as food "(A) that has not been treated with preservatives, antibiotics, synthetics additives, artificial flavoring or artificial coloring; and (B) that has not been processed in a manner that makes such food significantly less nutritive; and (C) . . . that has not been genetically engineered."[385] Thus, the Connecticut legislature agreed with the public's view that food that has been genetically engineered should not be labeled as "natural" and should instead be labeled as genetically engineered.[386]

The burden of compliance with the law rested on the party that was selling, offering for sale, or distributing any product in Connecticut that was required to be labeled under the law.[387] Genetically engineered products exempted from the law included processed food intended for immediate consumption, food sold in a restaurant or similar food facility, alcoholic beverages, farm products sold at a pick-your-own farm stand, and food consisting of or derived from an animal that was injected with or fed any genetically engineered food or drugs.[388] Furthermore, it is important to note

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Simon, *Connecticut Makes History as First State to Pass GMO Food Labeling Law*, FOOD DEMOCRACY NOW (June 4, 2013, 3:45 PM), http://www.fooddemocracynow.org/blog/2013/jun/4/connecticut_1st_state_2_pass_gmo_labeling_bill (assessing how Connecticut became the first state to pass a GMO labeling law). *See generally* Muller, *supra* note 11, at 526-27 (discussing Connecticut's GMO labeling law).

383. *See* Conn. Gen. Stat. Ann. § 21a-92c (2015) (describing what items the law applied to); Nunziato, *supra* note 9, at 484 (discussing this part of the statute).

384. *See* Conn. Gen. Stat. Ann. §21a-92c(a)(ii) (setting forth the labeling requirements for items on the market in a package for retail sale).

385. Conn. Gen. Stat. Ann. §21a-92(17) (defining "natural").

386. *See supra* Section I.A (discussing the public attitude in the United States towards GMO labeling and the use of "natural" on products that have been genetically engineered).

387. *See* Conn. Gen. Stat. Ann. § 21a-92c(c) (explaining who had the burden to ensure compliance with the law).

388. *See* Conn. Gen. Stat. Ann. § 21a-92c(b) (exempting certain products from the Act).

Connecticut's choice of label.[389] Instead of looking at only the end product and whether it contained a threshold amount of GMOs—as the European Union does—the Connecticut Act focused more on the procedure used to produce the food and used a label that indicated the method with which the food was produced (instead of a specific breakdown of any GMO components).[390]

4. Maine's GMO Labeling Law

Less than six months after Connecticut passed its labeling law, Maine enacted its own bill titled "An Act To Protect Maine Food Consumers' Right To Know about Genetically Engineered Food and Seed Stock."[391] The Maine law also required genetically engineered food and seed stock to be conspicuously labeled as "[p]roduced with Genetic Engineering."[392] While Maine's law did not define "natural" as Connecticut's law did, the law prohibited foods that were subject to the labeling requirements from being described as "natural" or with a similar identification.[393] Among the foods exempted from the law were products that had been produced without knowledge that the products or ingredients used were genetically engineered and animal products derived from an animal that was not genetically engineered but was fed genetically engineered food.[394]

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389. *See* Conn. Gen. Stat. Ann. § 21a-92c (requiring labeling for products made through genetic engineering, not based on a threshold amount of GMO in the final product).

390. *See* Conn. Gen. Stat. Ann. § 21a-92c (mandating labeling of products made through genetic engineering).

391. *See* Me. Rev. Stat. Ann. tit. 22, § 2591 (2013); Muller, *supra* note 11, at 527 (introducing the Maine bill mandating GMO labeling); Ross H. Pifer, *Mandatory Labeling Laws: What Do Recent State Enactments Portend for the Future of GMOs?*, 118 PENN ST. L. REV. 789, 804 (2013-2014) (explaining the Maine bill).

392. *See* Me. Rev. Stat. Ann. tit. 22, § 2593; Muller, *supra* note 11, at 527 (noting the similarities between the two laws and describing Maine's labeling requirements); Pifer, *supra* note 391, at 804 (describing how food offered for retail sale that was genetically engineered had to be labeled).

393. *See* Conn. Gen. Stat. Ann. §21a-92(17) (defining "natural"); Me. Rev. Stat. Ann. tit. 22, § 2593; Muller, *supra* note 11, at 528 (noting that while the Connecticut law defined "natural," the Maine bill did not).

394. *See generally* Me. Rev. Stat. Ann. tit. 22, § 2593 (listing the exemptions).

5. Connecticut and Maine's Trigger Clauses

While Connecticut and Maine were the first two states to pass GMO labeling laws, the laws did not have a set date to go into effect because of trigger clauses that constrained both acts.[395] The Connecticut Act had three requirements.[396] The first requirement was that four states (not including Connecticut) enact a mandatory labeling law for GE foods similar to its own.[397] For this requirement, the list of states that could have fulfilled this requirement was Maine, New York, Rhode Island, New Jersey, Massachusetts, Vermont, and Pennsylvania.[398] Secondly, one of the states that passed similar legislation had to border Connecticut.[399] Third, the aggregate population of such states located in the northeast region of the United States that enacted a mandatory GMO labeling law had to be more than twenty million based on the 2010 census.[400] Under the Maine trigger clause, substantially similar legislation had to be adopted in at least four contiguous states.[401] If this requirement was not fulfilled before January 1, 2018, the act would have been repealed.[402] These trigger clauses were incorporated into the Connecticut and Maine GMO labeling laws as a means of protection.[403] Specifically, they

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395. *See* Nunziato, *supra* note 9, at 485-86 (discussing the similar trigger clauses of Connecticut and Maine); Muller, *supra* note 11, at 527-28 (explaining how both laws did not go into effect due to their trigger clauses).

396. *See* Muller, *supra* note 11, at 527 (detailing the requirements under the Connecticut trigger clause); Nunziato, *supra* note 9, at 485-86 (analyzing the trigger clause for the Connecticut law).

397. *See* Nunziato, *supra* note 9, at 526-27 (detailing the first requirement under the Connecticut trigger); Muller, *supra* note 11, at 527 (setting forth what was first required).

398. *See* Nunziato, *supra* note 9, at 485-86 (listing the states that could have fulfilled the first requirement). *See generally* Muller, *supra* note 11 (explaining the geographic specifications of this requirement).

399. *See* Muller, *supra* note 11, at 527 (putting forth the requirement that one of the states must border Connecticut); Nunziato, *supra* note 9, at 485-86 (explaining this second requirement).

400. *See* Muller, *supra* note 11, at 527 (noting the second requirement under the trigger clause); Nunziato, *supra* note 9, at 485-86 (discussing the aggregate population requirement).

401. *See* Me. Rev. Stat. Ann. tit. 22, § 2595 (2013) (explaining the circumstances surrounding the trigger clause).

402. *Id*. (setting this deadline).

403. *See infra* note 404 and accompanying text (discussing the justifications for the trigger clauses).

were meant to ensure that no single state would be targeted if a state's GMO labeling law became the center of a lawsuit.[404]

6. Vermont's Labeling Law

The most recent state GMO labeling law to be enacted was the Vermont Labeling Act, known as Act 120, which was signed on May 8, 2014.[405] Similar to the laws of Connecticut and Maine, Act 120 required that food offered for sale by a retailer to be labeled as produced entirely or in part from genetic engineering if it was a product (1) offered for retail sale in Vermont and (2) entirely or partially produced with genetic engineering.[406] When the product was a packaged raw agricultural commodity, the manufacturer would have to label the package that was offered for retail sale with the clear and conspicuous words "produced with genetic engineering."[407] If the product was a raw agricultural commodity that was not separately packaged, the retailer would be required to post a label on the retail store shelf or bin where the commodity was displayed for sale with the clear and conspicuous words "produced with genetic engineering."[408] And finally, if a processed food contained a product or products of genetic engineering, the manufacturer would need to label the package with the words "partially produced with genetic engineering," "may be produced with genetic engineering," or "produced with genetic engineering."[409]

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404. *See* Amaru, *supra* note 19, at 592 (explaining that the trigger clauses were intended to ensure that no single state would be targeted if the legislation was the subject of a lawsuit); Muller, *supra* note 11, at 527 (explaining that the stipulations were "put in place in order to protect small businesses and farmers from suffering at the hands of out-of-state competitors" who were not required to label food products that were genetically engineered).

405. *See* No. 120. An Act Relating To The Labeling Of Food Produced With Genetic Engineering, 2014 Vt. Acts & Resolves No. 120 [hereinafter Act 120], *available at* http://www.leg.state.vt.us/docs/2014/Acts/ACT120.pdf.

406. *See* Act 120, *supra* note 405, §3043(a) (mandating when a food be labeled as produced with genetic engineering).

407. *Id*. §3043(b)(1) (setting forth requirements for packaged raw agricultural commodities).

408. *Id*. §3043(b)(2) (giving instructions for raw agricultural commodities that are not separately packaged).

409. *Id.* §3043(b)(3) (stating the requirements for processed foods that contain a product or products of genetic engineering).

While Act 120 was similar to the Connecticut law in many ways, it differed in one important aspect.[410] Like the Maine law, Act 120 did not define the term "natural" in the text of the Act.[411] Act 120 clearly forbade manufacturers of foods produced entirely or in part from genetic engineering from labeling their products as "natural," "naturally made," "naturally grown," "all natural," or "any word of similar import" that would have a tendency to mislead a consumer.[412] Act 120 also specifically stated that the law should not be construed to require a list or identification of any ingredient or ingredients that were genetically engineered or the placement of the term "genetically engineered" immediately preceding any common name or primary product descriptor of a food.[413]

The purpose of Act 120 was to establish a system by which people make informed decisions regarding the potential health effects of the food they purchase and consume.[414] The Statute was also intended to inform the purchasing decisions of consumers who are concerned about the potential effects on the environment of GE foods.[415] The Act was also meant to reduce consumer confusion and deception by prohibiting the labeling of GE products as "natural."[416] In addition to promoting the disclosure of factual information on food labels, the Act was meant to provide data to consumers in order to make informed decisions for religious reasons, such as keeping Kosher for observant Jewish individuals.[417]

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410. *See* Muller, *supra* note 11, at 526-28 (describing Connecticut's GMO law); Davis, *supra* note 35, at 46-48 (detailing the requirements of Act 120).

411. *See* Muller, *supra* note 11, at 527-28 (stating that unlike the Connecticut law, Maine's law did not define "natural").

412. *See* Act 120, *supra* note 405, §3043(c) (setting forth the restrictions on the use of "natural" with respect to foods produced using genetic engineering in Vermont); Davis, *supra* note 35, at 47-48 (explaining that products manufactured with GMOs could not be labeled as "natural" under Act 120).

413. *See* Act 120, *supra* note 405, §§3041(1-2) (explaining how neither of these labels are required under the Act).

414. *See id.* §3041(1) (setting forth the Act's Legislative Purpose).

415. *See id.* § 3041(2) (stating this statutory purpose).

416. *See id.* §§3041(1-3) (recognizing consumer choice in the Act's Legislative Purpose).

417. *See id.* §3041(4) (addressing the religious concerns of people who wish to avoid GMOs).

Perhaps the most crucial part of Act 120 that distinguished it from the labeling laws of Connecticut and Maine was that it did not contain a trigger clause.[418] The ramifications of excluding a trigger clause became costly when the Grocery Manufacturer's Association ("GMA") sued the state of Vermont a month after the bill was signed, claiming that the law violated its right to free speech and would cost too much to comply with.[419] Despite this immediate backlash, Vermont Governor Peter Shumlin signed the bill to go into effect in July of 2016.[420] While Vermont's law counted toward fulfilling the trigger requirements of the Connecticut and Maine laws, it was not constrained by any state requirement or population requirement in order to go into effect.[421] Furthermore, as opposed to the Connecticut and Maine laws, the Vermont Law was not subject to repeal if other states in the Northeast United States failed to enact similar laws.[422] As

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418. *See* James J. Gormley, *GMO-Labeling Laws: Why The Trigger Clause?*, NUTRITIONAL OUTLOOK (Apr. 4, 2014), http://www.nutritionaloutlook.com/articles/gmo-labeling-laws-why-trigger-clause (stating that unlike Maine and Connecticut, Vermont's GMO labeling law did not contain a trigger clause); Dan Flynn, *State Legislatures Pass On Adopting GMO-Labeling Policies This Year*, FOOD SAFETY NEWS (June 24, 2015), http://www.foodsafetynews.com/2015/06/states-pass-on-opportunities-to-jump-ahead-of-feds-on-gmo-labeling-policy/#.Vrve18ac8UV (stating that while Act 120 was to go into effect in July 2016, Maine and Connecticut's laws are contingent upon the actions of bordering states).

419. *See* Grocery Mfrs. Ass'n v. Sorrell, 102 F.Supp.3d 583 (D. Vt. 2015).

420. *See Vermont Governor Signs First In US GMO-Labeling Law To Go Into Effect*, RT (May 8, 2014, 7:14 PM), https://www.rt.com/usa/157744-vermont-gmo-labeling-signed/ (announcing that despite threats from Monsanto legal action against the state, Vermont's Governor signed the bill into law to go into effect in July 2016); Dave Gram, *After Vermont Passes GMO Labeling Law, Food Industry Announces Plans To Sue*, CORNUCOPIA INST. (May 9, 2014), https://www.cornucopia.org/2014/05/vermont-passes-gmo-labeling-law-food-industry-announces-plans-sue/ (discussing the action taken by GMA shortly after Governor Shumlin signed the bill into law).

421. *See* Nunziato, *supra* note 9, at 485-86 (stating that Vermont was one of the states that was included in the trigger clauses of the Connecticut and Maine GMO labeling laws); Jeff Daniels, *GMOs: Congress May Block States From Requiring Labeling*, CNBC (July 22, 2015, 12:31 PM), http://www.cnbc.com/2015/07/22/gmos-congress-may-block-states.html (explaining how Act 120 was to go into effect in 2016 while Connecticut and Maine's laws would only go into effect when the conditions of their trigger clauses were met); Cathy Siegner, *Vermont Senate Approves GMO Labeling Bill, Sends It Back To House For Final Vote*, FOOD SAFETY NEWS (Apr. 17, 2014), http://www.foodsafetynews.com/2014/04/vermont-senate-approves-gmo-labeling-bill-sends-it-back-to-house/#.Vrv4I8ac8UU (distinguishing Vermont's Law as not having a trigger clause as opposed to those of Connecticut and Maine).

422. *See* Nunziato, *supra* note 9, at 485-86 (discussing how the laws of Connecticut and Maine were to be repealed if their trigger clauses were not fulfilled); *see also* Gormley, *supra*

will be demonstrated in Section II.A.9, Act 120 was a substantial factor in the passing of S. 764 and thus played a large role in the nationalization of GMO labeling requirements in the United States.[423]

7. Backlash to State Labeling Laws

While many anti-GMO and pro-labeling groups praised the passing of these labeling measures, these state laws were faced with immense opposition and were questioned by many as to their constitutionality, practicality, and legality.[424] While Connecticut was able to enact GMO legislation in 2013, there was discussion that legislators were getting cold feet after Monsanto threatened to sue the state.[425] Since many legislators believed that Monsanto would win this legal battle, there was much hesitation surrounding the Connecticut labeling law.[426] After Monsanto similarly threatened to sue Vermont when Act 120 was being drafted, the Grocery Manufacturers Association sued the state.[427] In this suit, GMA argued

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note 418 (distinguishing Act 120 from the GMO laws of Maine and Connecticut, which have trigger clauses).

423. *See infra* Section II.A.9 (demonstrating the importance of Act 120 and its impact on mandating federal GMO labeling under S. 764).

424. *See* Liza Baertlein, *U.S. Food Makers Sue to Stop Vermont's GMO Labeling Law*, REUTERS (June 12, 2014, 6:44 PM), http://www.reuters.com/article/vermont-gmo-idUSL2N0OT20620140612 (announcing that GMA, the Snack Food Association, the International Foods Association, and the National Association of Manufacturers were opposing the Vermont GMO labeling law through a lawsuit); *Vermont's Landmark GMO-Labeling Law Target of Lawsuit By Food Trade Groups*, RT (June 13, 2014, 11:57 PM), https://www.rt.com/usa/165860-vermont-gmo-labeling-lawsuit/ (discussing the claims of the national trade organizations suing the state of Vermont).

425. *See* Mat McDermott, *Connecticut Fears Monsanto - Bill To Label GM Ingredients Dead Due To Lawsuit Worries,* TREEHUGGER (May 8, 2012), http://www.treehugger.com/environmental-policy/connecticut-fears-monsanto-bill-label-genetically-modified-ingredients-dead-lawsuit-worries.html (describing how legislators were getting cold feet in light of Monsanto lawsuit concerns); Analiese Paik, *Connecticut's GE Foods Bill Eviscerated By Lawyers*, FAIRFIELD GREEN FOOD GUIDE (May 5, 2012, 10:06 AM), http://fairfieldgreenfoodguide.com/2012/05/05/connecticuts-ge-foods-bill/ (explaining how legislators feared mandating labeling due to fears of a Monsanto lawsuit).

426. *See* McDermott, *supra* note 425 (explaining the cause behind this hesitation); Paik, *supra* note 425 (discussing the effect of this threat from Monsanto).

427. *See* Christina Sarich, *Groups File Lawsuit Over Vermont's New GMO Labeling Law*, NAT. SOC'Y (June 18, 2014), http://naturalsociety.com/4-gma-groups-file-federal-lawsuit-vermonts-new-gmo-labeling-law/ (giving an overview of the lawsuit); Nancy Remsen, *Trade Groups Sue VT Over GMO Labeling Law*, BURLINGTON FREE PRESS (June 13, 2014,

that the state's GMO labeling law violated the First Amendment protection of commercial speech as well as the dormant Commerce Clause.[428] It is important to note that many other large and influential companies belong to this Association, including Monsanto, The Coco-Cola Company, Del Monte Foods Company, General Mills, Inc., Kraft Foods Group, The Proctor & Gamble Company, and S.C. Johnson & Son, Inc.[429] While these companies have not individually sued any states or were named plaintiffs in any case, they do belong to the same GMA that sued the state of Vermont, demonstrating the strong resistance to such state laws.[430]

Companies that oppose GMO labeling laws have also allocated their resources to defeat state labeling laws when such measures came to a vote.[431] For example, California's Proposition 37, which would have required labeling on raw or processed foods if they were made from plants or animals with genetic material changed in specific ways, was defeated by the "Vote No" campaign, which raised US$46

7:00 AM), http://www.burlingtonfreepress.com/story/news/politics/2014/06/12/gma-sues-vt-gmo-law/10389209/ (detailing the lawsuit filed by GMA, the Snack Food Association, the International Dairy Foods Association, and the National Association of Manufacturers against the state of Vermont).

428. *See GMA Files Lawsuit To Overturn Vermont's Unconstitutional Mandatory GMO Labeling Law*, GMAO ONLINE (June 13, 2014), http://www.gmaonline.org/news-events/newsroom/gma-files-lawsuit-to-overturn-vermonts-unconstitutional-mandatory-gmo-label/ (explaining the grounds for the lawsuit); Sarich, *supra* note 427 (explaining the arguments of GMA).

429. *See GMA Board of Directors*, GMA ONLINE, http://www.gmaonline.org/forms/committee/CommitteeFormPublic/viewExecCommittee?id=16E3DD0000014F (listing the Board of Directors, many of which belong to these companies); Ronnie Cummins, *The Great Boycott: Monsanto And The GMA*, ORGANIC CONSUMERS ASS'N (May 14, 2014), https://www.organicconsumers.org/essays/great-boycott-monsanto-and-gma (stating that members of the GMA include Monsanto, Coca-Cola, and General Mills).

430. *See* Cummins, *supra* note 429 (listing the members of GMA); *GMA Files Lawsuit to Overturn Vermont's Unconstitutional Mandatory GMO Labeling Law*, GMA ONLINE (June 13, 2014), http://www.gmaonline.org/news-events/newsroom/gma-files-lawsuit-to-overturn-vermonts-unconstitutional-mandatory-gmo-label/ (providing the news release from GMA announcing its lawsuit against Vermont).

431. *See* Kimbrell & Paulsen, *supra* note 38, at 345 ("[Lobbying disclosures] show expenditures specifically for opposing GE good labeling (as opposed to more general, related topics) of over US$80 million between 2012 and the first quarter of 2014 . . . ."); Libby Foley, *Corporate Spending to Fight GMO Labeling Skyrockets*, ENV'T WORKING GROUP (Apr. 23, 2015), http://www.ewg.org/research/anti-label-lobby (explaining that in 2014, food and biotechnology companies that oppose mandatory GMO labeling have disclosed expenditures of US$63.6 million to lobby for legislation that reference to GMO labeling).

million from some of the biggest businesses in the industry, as opposed to supporters of the proposition that raised US$8 million.[432] This pattern occurred in states such as Washington and Oregon, where companies such as Monsanto were able to greatly outspend proponents of the GMO labeling bills and the voters rejected the initiatives.[433] It is clear that in the states where the GMO labeling issue was brought to the voters, companies such as Monsanto and organizations such as the GMA put a great amount of money and effort into convincing voters not to support GMO labeling laws.[434]

8. H.R. 1599 & The Federal Reaction to State GMO Labeling Laws

Members of the US House of Representatives took action to oppose the state GMO labeling laws in July 2015 when the House passed H.R. 1599.[435] Titled the "Safe and Accurate Food Labeling Act," H.R. 1599 would have prohibited any state from enacting laws requiring the labeling of GMOs or GE foods.[436] According to H.R.

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432. *See California Proposition 37, Mandatory Labeling of Genetically Engineered Food (2012)*, BALLOTPEDIA, https://ballotpedia.org/ California_ Proposition_37,_Mandatory_ Labeling_of_Genetically_Engineered_Food_(2012) (last visited Jan. 9, 2016) (discussing generally California Proposition 37, including donors for the measure and donors against it); *Organic Consumers Association Calls for Boycott of Organic Brand Parent Companies That Helped Defeat Prop 37,* ORGANIC CONSUMERS ASS'N (Nov. 15, 2012), https://www.organic consumers.org/press/organic-consumers-association-calls-boycott-organic-brand-parent-companies-helped-defeat-prop (listing companies who donated to the NO on 37 campaign).

433. *See* Jeff Mapes, *Grocery Manufacturers Disclose Big Donors in GMO Labeling Campaign in Washington*, OREGON LIVE (Oct. 18, 2013, 5:29 PM), http://www.oregonlive. com/mapes/index.ssf/2013/10/grocery_manufacturers_disclose.html (indicating that GMA revealed that PepsiCo, Nestle USA, and Coca-Cola each gave US$1 million to the campaign against the Washington initiative in hidden donations); *Oregon Mandatory Labeling of GMOs Initiative, Measure 92 (2014),* BALLOTPEDIA, https://ballotpedia.org/ Oregon_Mandatory_ Labeling_of_GMOs_Initiative,_Measure_92_ (2014) (last visited Feb. 7, 2016) (generally discussing the Oregon Mandatory Labeling of GMOs Initiative and the donors who supported the measure as well as those who opposed it).

434. *See* Mapes, *supra* note 433 (discussing the efforts of several large companies to stop GMO labeling efforts at the state level); Kimbrell & Paulsen, *supra* note 38, at 345 (discussing the amount of money spent on lobbying against GMO labeling measures).

435. *See* Safe and Accurate Food Labeling Act of 2015, H.R. 1599, 114th Cong. (1st Sess. 2015) [hereinafter H.R. 1599] (dating the passage of H.R. 1599 as July 24, 2015).

436. *Id*. § 113 (prohibiting all states from directly or indirectly establishing as to any food in interstate commerce "any requirement with respect to the sale of offering for sale in interstate commerce of a genetically engineered plant for use or application in food that is not identical to the requirement of section 461 of the Plan Protection Act (as added by section 111 of this Act)").

1599, the fact that genetic engineering took place during the production of a food does not "by itself" serve as material information when assessing any possible differences between a food that is produced from, contains, or consists of a GE plant and one that does not.[437] According to the bill, GMO labeling could only be required if there is a material difference in functional, nutritional, or compositional characteristics, allergenicity, or other attributes between the GMO and non-GMO foods.[438] Furthermore, the disclosure of such a material difference would have to be necessary to protect public health or safety or to prevent the labeling of the food from being false or misleading.[439] Thus, under the law, no GMO labeling laws could have been established until the US government changed its twenty-three year stance on GMOs and found that GMO foods present a material difference in the above listed categories.[440] This requirement reflected the ruling in *District of Columbia in Alliance for Bio-Integrity v. Shalala*, where the court ruled that the FDA would have to find a material difference between GMO and non-GMO food in order to require such labeling under the FDCA.[441] Furthermore, this law would have meant that even if the FDA found that there was a material difference between GMO foods and non-GMO foods, GMO labeling would still not be possible unless it was shown that such labeling would be necessary to prevent consumer confusion or falsity or harm to the public.[442]

According to the Committee on Agriculture's report, one of the biggest motivations behind the Bill was the concern over the possible "patchwork" system of GMO labeling that would result in the United

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437. *See id*. § 101 (amending Chapter IV of the FDCA by adding section 424 titled "Food Derived from New Plant Varieties").

438. *See id*. § 101(2)(A) (asserting that there must be a material difference in one of these attributes in order to require labeling for GMO products).

439. *See id*. § 101(2)(B) (requiring that the disclosure of this material difference be necessary to protect public health and safety or to prevent the label of the food from being false or misleading).

440. *See generally id*. §§ 101(2)(A-B) (clearly indicating that without these two conditions met, products containing GMOs or derived from genetic engineering cannot be labeled as such).

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

442. *See generally* H.R. 1599, *supra* note 435, at § 101(2)(A-B) (explaining that in order for the Secretary to be able to require GMO labeling, both (A) and (B) must be fulfilled).

States if states were permitted to enact their own labeling laws.[443] The Committee also focused heavily on the immense burden these state laws would impose upon producers and companies, including an estimate from a food industry association that claimed the strict liability scheme of Vermont's Act 120 could result in fines as much as US$10 million per day due to inevitable slips in the system that would cause mislabeled GMO products to be put on the shelves.[444] According to the Committee, the solution was the Safe and Accurate Food Labeling Act, which would continue to administer the voluntary consultation process established by the 1992 FDA Statement of Policy.[445] Specifically, the Committee intended H.R. 1599 to recognize the FDA 1992 Statement of Policy.[446] With respect to consumers' desire to know if they are purchasing foods made using genetic engineering, the bill provided for a voluntary genetically engineered certification program within the USDA that would nationally govern label claims regarding the use or non-use of genetic engineering in food production or processing.[447]

In the report, the Committee asserted that it intended for this program to provide the sole standard by which all food producers, handlers, and processors may make claims regarding the use of genetic engineering in the production and processing of food.[448] This would have included claims for foods that were within the definition of raw or processed agricultural products and for foods that were not, as well as for seeds.[449] The legislation also required the Secretary of

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443. *See* H.R. Rep. No. 114-208, at 11 (2015) ("[The Act will] ensure national uniformity regarding labeling of foods derived from genetically engineered plants by preventing a patchwork of conflicting State or local labeling laws which inherently interfere with interstate and foreign commerce.").

444. *See id.* at 12 (detailing a letter written to Vermont Governor Peter Shumlin from a food industry trade association explaining the massive potential costs of Act 120).

445. *See id*. at 14 (describing the Committee's intent to continue the voluntary consultation process established by the 1992 FDA Statement of Policy).

446. *See id*. (asserting that the Committee intended to recognize the FDA 1992 Statement of Policy and to reinforce its purpose to provide everyone with the assurance that foods regulated under the Policy are "as safe to eat as non-genetically engineered foods").

447. *See id*. at 17 (outlining the Committee's solution to the desires of some consumers to know, via food product labeling, whether they are buying or eating food produced with genetic engineering).

448. *Id.* at 18 (stating the Committee's intent for this solution to be the single standard for food claims concerning genetic engineering).

449. *Id*. at 18 (setting forth what types of claims were included in this framework).

Agriculture to establish national standards for labeling non-GE foods.[450] Very specific procedures to apply for non-GMO and GMO certification were also listed in the bill.[451]

As previously mentioned, this bill was passed in the House in July of 2015 in direct response to the state labeling laws passed in Maine, Vermont, and Connecticut, and would therefore have made such laws illegal as preempted by federal law.[452] In addition to prohibiting state laws requiring GMO labeling, this bill clearly solidified the 1992 FDA Statement of Policy.[453] This would have given the findings of the FDA much more legal power and deference than they currently have as a policy statement.[454]

9. S. 764 and the Nationalization of GMO Labeling Requirements in the United States

When President Obama did not pass H.R. 1599 as part of a spending bill at the beginning of 2016, many GMO labeling advocates celebrated as the state laws of Vermont, Maine, and Connecticut survived federal preemption.[455] However, this celebration would be short-lived, as President Obama signed S.764 into law on

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450. *Id*.

451. *See generally id*. at 20 (describing AMA Sec. 291C. which sets forth national standards for labeling genetically engineered food).

452. *See supra* notes at 437-40 and accompanying text (explaining how no state GMO labeling laws could be established unless the government departed from the 1992 FDA Statement of Policy and found that GMOs present a material difference from their traditional counterparts); Jenny Hopkinson, *GMO Labeling Bill Would Trump States,* POLITICO (Apr. 9, 2014, 4:57 PM), http://www.politico.com/story/2014/04/gmo-labeling-bill-105548 (explaining how H.R. 1599 affects state efforts to label GMOs).

453. *See supra* notes 445-46 and accompanying text (upholding the 1992 FDA Statement of Policy).

454. *See supra* notes 445-46 and accompanying text (examining how H.R. 1599 is meant to recognize and uphold the 1992 FDA Statement of Policy).

455. *See Congress Keeps Anti-GMO Labeling Rider Out of Spending Bill*, ECOWATCH (Dec. 16, 2015, 10:59 AM), http://www.ecowatch.com/congress-keeps-anti-gmo-labeling-rider-out-of-spending-bill-1882130060.html (discussing how the Senate Congress did not include H.R. 1599 in the spending bill at the end of 2015, preventing the preemption of state GMO labeling laws); Karlene Lukovitz, *GMO Labeling Rider Left Out Of Omnibus Spending Bill*, MEDIADAILY (Dec. 16, 2015, 7:21 PM), http://www.mediapost.com/ publications/article/ 264945/gmo-labeling-rider-left-out-of-omnibus-spending-bi.html (highlighting discussing two statements in the reaction to the failure of some to get H.R. 1599 not being included in the spending bill).

July 29, 2016 and implemented a federal GMO labeling system that eliminated any state law that mandated GMO labeling, including those discussed in this Note.[456] The reaction to this federal legislation was mixed, as many praised the federal legislation for implementing the first mandatory GMO labeling system in the United States, while others highlighted defects that supposedly allow companies to avoid clearly labeling their food as genetically modified.[457] Despite the diverse opinions about this federal regulation, it is clear that the state labeling laws of Connecticut, Maine, and Vermont and the general state movement towards GMO labeling laws made a severe impact on the US Congress and President, as these measures prompted the federal government to shift from a voluntary GMO labeling framework under H.R. 1599 to a mandatory GMO labeling regime that responded to public outcry for greater transparency about genetic engineering.[458]

Known as S. 764, the new federal regulation establishes a national disclosure standard for bioengineered foods.[459] Bio-engineering is defined as food that "contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques" and "for which modification could not otherwise be obtained through conventional breeding or found in nature."[460] The

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456. *See* Mary Clare Jalonick, *Obama Signs Bill Requiring Labeling of GMO Foods*, AP (July 29, 2016, 6:07 PM), http://bigstory.ap.org/article/65c61c63e3df4 b74bb90a 2187122d744/obama-signs-bill-requiring-labeling-gmo-foods (reporting that President Obama signed a bill into law requiring genetically modified ingredients to be labeled for the first time); Jason J. Kim & Andrew J. Peterson, *President Obama Signs Bill That Will Establish Federal GMO Labeling Standards*, LEXOLOGY (Aug. 4, 2016), http://www. lexology.com/library/detail.aspx?g=bb672dd0-b232-45c4-a876-e163ee66a849 (describing how the federal GMO labeling standards stating that the law preempts state laws that "mandate the disclosure of GMO ingredients on product packaging").

457. *See* Agri-Pulse Communications, *Obama Signs Historic GMO Labeling Bill*, AGRICULTURE.COM (July 29, 2016), http://www.agriculture.com/news/crops/obama-signs-historic-gmo-labeling-bill (discussing the opinions of those who supporters of the federal law); Stephen Dinan, *Obama Signs Bill Overturning Vermont's GMO Labeling Law*, WASH. TIMES (Aug. 2, 2016), http://www.washingtontimes.com/news/2016/aug/2/obama-signs-bill-over turning-vermonts-gmo-labeling/ (explaining the extreme opposition towards the new federal legislation).

458. *See supra* Sections II.A.3-4, 6, 8 (giving an overview of the state movement and the response of the US federal government).

459. *See generally* 7 U.S.C. § 1639 (2016).

460. *See id.* §§ 1639(1)(A-B).

bill charges the Secretary of Agriculture to establish a national mandatory bioengineered food disclosure standard governing any bioengineered food and any food that may be bioengineered.[461] It further instructs the Secretary of Agriculture to establish requirements and procedures that the Secretary deems necessary to carry out that standard within two years of the date of enactment.[462] As part of this charge, the Secretary must determine "the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food."[463] Furthermore, a bioengineered food will not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because that food is bioengineered or is produced or developed using bioengineering, so long as the food has successfully finished the premarket federal regulatory review process.[464] Thus, the federal regulation of bioengineered foods will depend on the end product, and not solely on the process of genetic engineering used in production of the food.[465] The bill also prevents food derived from animals from being considered bioengineered food solely because the animals consumed feed that was produced from, contained, or consisted of a bioengineered substance.[466] Finally, the bill excludes very small food manufacturers and food served in a restaurant or similar retail food establishment.[467]

The bill also gives specific requirements for the labeling of such bioengineered foods and provides three options for compliance.[468] Food manufacturers may use text, a symbol, or an electronic or digital link to disclose the bioengineered status of their food.[469] On-package language must accompany an electronic or digital link disclosure that demonstrates that the link will provide access to the information by stating "scan here for more food information" or other language that

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461. *See id.* § 1639(a).
462. *See id.* §§ 1639(a)(1-2).
463. *See id.* § 1639(b)(2)(B).
464. *See id.* § 1639(b)(3).
465. *See id.*
466. *See id.* § 1639(b)(2)(A).
467. *See id.* § 1639(b)(2)(G).
468. *See id.* § 1639(b)(2)(D).
469. *See id.*

only reflects technological changes.[470] A telephone number that provides access to the disclosure must also be included with the electronic or digital link disclosure and such electronic or digital link disclosure must be of sufficient size to be effectively and easily read or scanned by a digital device.[471] Furthermore, the electronic or digital link cannot have marketing or promotional information and must provide the disclosure on the first product information page that appears for the product on a mobile device, website, or other landing page.[472] Consumer privacy is protected, as the electronic or digital link disclosure may not analyze, sell, or collect any personally identifiable information about consumers or their devices.[473] If such information is necessary to comply with the regulation, it may not be used for any other purposes and must be deleted immediately.[474]

The Secretary must provide alternative reasonable disclosure options for food contained in small or very small packages.[475] Small manufacturers will have the option of choosing from additional on-package options, which are a telephone number "accompanied by appropriate language to indicate that the phone number provides access to additional information" and a website that is maintained by the manufacturer in a manner consistent with section (d) as appropriate.[476] Any telephone number disclosure must only state "call for more food information."[477]

There is a record-keeping requirement under S. 764, as each person that is subject to the mandatory disclosure requirement must maintain any records that the Secretary determines to be customary or reasonable in the food industry to establish compliance with the law.[478] These records must also be available to the Secretary upon

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470. *See id.* § 1639(d)(1)(A).
471. *See id.* §§ 1639(d)(4-5).
472. *See id.* § 1639(d)(2).
473. *See id.* § 1639(d)(3)(A).
474. *See id.* § 1639(d)(3)(B).
475. *See id.* § 1639(b)(2)(E).
476. *See id.* § 1639(b)(2)(F)(ii).
477. *See id.* § 1639(d)(1)(B).
478. *See id.* § 1639(g)(2).

request.[479] The Secretary is also empowered to conduct an audit, examination, or similar activity to review any required records.[480]

According to S. 764, the Secretary must conduct a study to identify possible technological challenges that may impact consumers accessing the bioengineering disclosure through digital or electronic methods under the regulation.[481] As part of this study, the Secretary must consider public comments and certain factors on consumer access, including the availability of wireless Internet or cellular networks, challenges facing smaller retailers and rural retailers, and the costs and benefits of installing electronic or digital link scanners or other evolving technology that provide bioengineering disclosure information in retail stores.[482] If the Secretary finds through this study that consumers would not have sufficient access to the bioengineering information through electronic or digital methods while shopping, the Secretary must consult with food manufacturers and retailers before providing additional and comparable options to access the bioengineering disclosure.[483]

This federal regulation is meant to be the sole source of GMO labeling requirements, as shown by the explicit prohibition of state GMO labeling laws.[484] According to the law, no state may establish or continue in effect any requirement relating to the labeling or disclosure of whether any food involved in interstate commerce is bioengineered, developed, or produced using bioengineering for a food that is subject of the national bioengineered food disclosure unless such requirement is identical to the mandatory disclosure requirement under S. 764.[485] Under the heading of federal preemption, states are prohibited from establishing any requirement for food or seed in interstate commerce relating to the labeling of "whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of

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479. *See id.*
480. *See id.* § 1639(g)(3)(A).
481. *See id.* § 1639(c)(1).
482. *See id.* §§ 1639(c)(2-3).
483. *See id.* § 1639(c)(4).
484. *See id.* § 1639(e).
485. *Id*.

Agriculture) or was developed or produced using genetic engineering," which includes any requirements for claims that "a food or seed is or contains an ingredient that was developed or produced using genetic engineering."[486]

Finally, the law also provides information about food that is considered non-GMO.[487] If a food is certified under the national organic program established by the Organic Foods Production Act, the food manufacturer may make claims regarding the absence of bioengineering in the food, including "non-bioengineered" or "non-GMO."[488] However, a food may not be regarded as "non-bioengineered" or "non-GMO" only because the food is not required to have a disclosure that the food is bioengineered under this law.[489]

10. Reaction to S.764

As previously discussed, the reaction to the new national federal labeling standard has been mixed and much controversy surrounds the question of whether the law actually requires GMO labeling.[490] Much of the food industry supported S. 764 and several food organizations voiced their opinions in the wake of the new law.[491] According to the GMA, which vehemently opposed state GMO labeling laws, the legislation will "'open a new era for transparency in ingredient information for consumers . . .'" and is a consistent national standard that is superior to a "'costly and confusing patchwork of different state labeling,'" which has allegedly left consumers in the state of Vermont with fewer products available for purchase and

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486. *See id.* § 1639(i)(b).

487. *See* 7 U.S.C. § 6524 (2016).

488. *Id.*

489. *See* 7 U.S.C. § 1639(c).

490. *See supra* note 457 and accompanying text (highlighting some of these opinions and controversy).

491. *See Congress Passes GMO Food Labeling Bill*, NBC NEWS (July 14, 2016, 4:40 PM), http://www.nbcnews.com/health/health-news/congress-passes-gmo-food-labeling-bill-n609571 (stating that the food industry supports the legislation); Dan Flynn, *Compromise Bill On GMO Labeling Lands On President's Desk*, FOOD SAFETY NEWS (July 14, 2016), http://www.foodsafetynews.com/2016/07/compromise-bill-on-gmo-labeling-lands-on-presidents-desk/#.V-sYu8ac8UU (explaining that over 1,000 food and agricultural organizations were in favor of S. 764 and that many of these issued press statements following the vote).

raised compliance costs for small businesses.[492] According to the Organic Trade Organization, while the measure has its flaws and the organization plans to advocate for further changes, the bill goes a long way to increase consumer clarification and covers thousands of more products than Vermont's Act 120 did.[493]

Despite the swelling support of the food industry, many organizations and commentators have strictly opposed the new law and have pointed out deficiencies that some argue allow companies to be less forthcoming about GMOs.[494] A petition urging a veto with the 100,000 signatures necessary to earn an official response was filed with the White House.[495] However, the White House responded after President Obama signed the bill by discussing the bipartisan effort in Congress to pass the legislation.[496] It is important to note that about half of the House Democrats and half of the Senate Democratic Caucus voted against the measure, as well as a small minority of the GOP in both the Senate and House of Representatives.[497]

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492. *See* Agri-Pulse Communications, *supra* note 457; Flynn, *supra* note 491 (discussing the statements made by the GMA).

493. Letter from Leadership: GMO Labeling, Organic Trade Organization (Sept. 16, 2016), https://www.ota.com/advocacy/gmos/gmo-labeling/letters-leadership-gmo-labeling; *Organic Trade Organization: Lobby Group Under Activist Fire For Supporting Federal GMO Labeling*, GENETIC LITERACY PROJECT (Oct. 12, 2016), https://www.geneticliteracyproject.org/glp-facts/organic-trade-association-lobby-group-activist-fire-supporting-federal-gmo-labeling/ (providing an analysis of the Organic Trade Association's reaction to S. 764).

494. *See* Dan Charles, *Congress Just Passed A GMO Labeling Bill. Nobody's Super Happy About It*, NPR (July 14, 2016, 5:34 PM), http://www.npr.org/sections/thesalt/2016/07/14/486060866/congress-just-passed-a-gmo-labeling-bill-nobodys-super-happy-about-it (analyzing the broad criticism of S. 764); Brenna Houck, *President Obama Signs Controversial Bill Requiring GMO Labels*, EATER (July 31, 2016, 2:17 PM), http://www.eater.com/2016/7/31/12337356/us-passes-law-gmo-labels (explaining how critics claim that the law does not go far enough).

495. *See Veto the Dark Act (S. 764)*, WHITE HOUSE (July 9, 2016), https://petitions.whitehouse.gov/petition/veto-dark-act-s764*;* Dinan, *supra* note 457 (discussing this petition).

496. *See Veto the Dark Act (S. 764)*, *supra* note 495*;* Dinan, *supra* note 457 (examining the response of the White House).

497. *See* Dinan, *supra* note 457 (giving the breakdown of the vote); Dianne Lugo, *U.S. Senate Passes GM Food Labeling Bill*, SCIENCEINSIDER (July 8, 2016, 3:45 PM), http://www.sciencemag.org/news/2016/07/us-senate-passes-gm-food-labeling-bill (stating that half of Senate Democrats voted against S. 764).

Many have also criticized the legislative process behind the bill, or rather the supposed lack thereof.[498] After H.R. 1599 did not pass in the Senate in March 2016, S. 764 was introduced to the Senate on June 23, 2016.[499] The Senate passed the bill on July 7, 2016 and the House of Representatives passed it on July 14, 2016.[500] Unlike Vermont's Act 120, which had fifty hearings and two years of debate, the federal bill had less than a week of debate and no hearings.[501] This lack of traditional legislative process has led some to criticize the motives of those behind the bill and characterize legislators as pandering to corporations, which increasingly pushed for federal legislative action in the wake of Vermont's Act 120 that went into effect on July 1, 2016.[502]

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498. *See* Andrew Kimbrell, *Why The GMO 'Labeling' Bill That Obama Just Signed Into Law Is A Sham- And A National Embarrassment*, HUFFINGTON POST (Aug. 5, 2016, 6:13 PM), http://www.huffingtonpost.com/andrew-kimbrell/why-the-gmo-labeling-bill_b_11335918.html (criticizing the bill's lack of hearings and expert testimony); Chris Morran, *Congress Passes Bill Outlawing Vermont's GMO Labels, Replacing Them With Barcodes*, CONSUMERIST (July 14, 2016), https://consumerist.com/2016/07/14/congress-passes-bill-outlawing-vermonts-gmo-labels-replacing-them-with-barcodes/ (stating that the bill did no undergo the usual process of hearings, debate, and amending and marking up in committee). Morran also explains that the bill was fast tracked by Senate Majority Leader Mitch McConnell "by simply copy/pasting its text into the empty shell of a bill that had already passed by the Senate, but not enacted into law."

499. *See* S. 764, 114th Cong. (2015-2016), https://www.congress.gov/bill/114th-congress/senate-bill/764 [hereinafter S. 764 Timeline]*;* Tom Philpott, *Congress Just Passed a Bill to Nix GMO Labeling*, MOTHER JONES (June 27, 2016, 5:22 PM), http://www.motherjones.com/environment/2016/06/senate-deal-would-crush-vermonts-gmo-labeling-law (explaining how S. 764 was introduced after H.R. 1599 failed to pass the Senate in March 2016).

500. *See* S. 764 Timeline*, supra* note 499; Philpott, *supra* note 499 (providing a timeline of S. 764).

501. *See* Jerry Hagstrom, *Senate Passes GMO Label Bill*, PROGRESSIVE FARMER (July 8, 2016, 6:27 AM), https://www.dtnpf.com/agriculture/web/ag/perspectives/blogs/ag-policy-blog/blog-post/2016/07/08/senate-passes-gmo-label-bill (stating that Vermont's Law had fifty hearings, 130 witnesses, and two years of debate while the Senate bill had zero hearings and less than a week of debate time); Kimbrell, *supra* note 498 (stating the no hearings were conducted regarding S. 764).

502. *See* Hagstrom, *supra* note 501 ("[A]gricultural lobbies had come together to create the Coalition for Safe Affordable Food specifically to preempt the Vermont Labeling law."). Hagstrom also noted that this group praised the action of the Senate and characterized S. 764 as a "'common sense bipartisan legislation' that will provide a consistent, disclosure framework." *See also* Kimbrell, *supra* note 498 (characterizing the measure as a product of campaign corruption and organic industry "sellout").

Some also argue that by allowing food manufacturers to use a bar code to disclose GMO information of the food they sell, the regulation allows companies to hide this information and makes it more difficult for consumers to find out information about GMO ingredients.[503] According to Food & Water Watch Executive Director Wenonah Hauter, the options of QR codes, bar codes, or 1-800 numbers are not transparent GMO labeling methods, but are instead "cumbersome, and elitist and above all—a giant hassle."[504] In addition to the supposed inconvenience of these options, many argue they disadvantage certain groups that do not have access to smartphones or the internet, including financially disadvantaged, elderly, and rural consumers who cannot access the information easily or at all.[505] Another major argument against the law is that it provides no penalties for companies that fail to comply with the labeling requirements.[506] The law also does not give any authority to recall products that are not correctly labeled, which has led many to question the law's actual effect on companies.[507]

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503. *See* Dinan, *supra* note 457 (highlighting these arguments); Kimbrell, *supra* note 498 (stating that the use of 800 numbers and websites is another way to masquerade non-labeling).

504. *See President Obama Capitulates to Big Food, Signs DARK Act Into Law*, FOOD CONSUMER (July 29, 2016), http://www.foodconsumer.org/newsite/Politics/32/signsdark_act_into_law_0729160901.html.

505. *See* Emily Monaco, *5 Major Fails of the New GMO Labeling Law*, ORGANIC AUTHORITY (Aug. 18, 2016), http://www.organicauthority.com/5-major-fails-of-the-new-gmo-labeling-law-and-5-ways-its-not-so-bad/ (discussing this argument); Michael Addady, *President Obama Signed This GMO Labeling Bill*, FORTUNE (July 31, 2016, 4:49 PM), http://fortune.com/2016/07/31/gmo-labeling-bill/ (setting forth these concerns); Richard Fama, *The New GMO Labeling Law: A Matter of Perspective*, FOOD SAFETY NEWS (Sept. 8, 2016), http://www.foodsafetynews.com/2016/09/the-new-gmo-labeling-law-a-matter-of-perspective/#.V-diRsac8UU; Kimbrell, *supra* note 498 (highlighting these issues).

506. *See* Phil Lempert, *Sorry Food Industry, The Historic GMO Food Labeling Bill is Anything But*, FORBES (Aug. 1, 2016, 1:24 PM), http://www.forbes.com/sites/phillempert/2016/08/01/sorry-food-industry-the-historic-gmo-food-labeling-bill-is-anything-but/#2beb2db85e39 (detailing this objection); *The Latest: Sanders Says GMO Bill In Congress Has Loopholes*, ASSOCIATED PRESS (July 1, 2016, 1:47 PM), http://bigstory.ap.org/article/cf1e9f6cc9a543bea10f9aaadbcbd266/latest-governor-urges-tweets-vermont-gmo-label-law (explaining Senator Sander's opposition to S. 764 and the lack of penalties for companies who violate the law).

507. *See* Lempert, *supra* note 506 (highlighting this inability); Riette van Laack & Ricardo Carvajal, *GMO Labeling Bill Is A Pen Stroke Away From Becoming Law: What Comes Next?*, FDA LAW BLOG (July 19, 2016), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2016/07/gmo-labeling-bill-is-a-pen-stroke-away-from-becoming-law-

Many also criticize the law as failing to establish measures as strong as the standard under Vermont's Act 120, which went into effect on July 1, 2016.[508] Others also oppose the federal preemption of state GMO labeling laws.[509] While there was question of whether Vermont would sue the federal government if the law was passed, the Vermont Attorney General announced on August 2, 2016 that it would no longer enforce Act 120.[510] As part of this announcement, the Vermont Attorney General's office also stated its intention to "take an active role advocating for the federal regulations to give consumers the same access to information, in plain English, that they had under Vermont's law."[511]

Perhaps one of the most interesting responses to the federal standard comes from the FDA, which has questioned the law's scope and has flagged potential conflicts with the agency's own regulations.[512] In its comments to provide technical assistance on the draft bill, the FDA stated that the bill would give the USDA authority over food labeling that is "otherwise under FDA's sole regulatory jurisdiction."[513] The FDA reiterated its "long-held policy position" on the safety concerns of GMOs and how it has previously not wanted to

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what-comes-next.html (stating that the bill makes it evident that there is no authority for the USDA to recall a food that does not bear a required disclosure).

508. *See Sanders Vows to Defend Vermont's GMO Labeling Law*, SANDERS, http://www.sanders.senate.gov/newsroom/press-releases/sanders-vows-to-defend-vermonts-gmo-labeling-law (last visited Jan. 13, 2017) (providing Senator Sander's opposition to the federal legislation); Lempert, *supra* note 506 (stating that Vermont's law contained much stricter labeling requirements than S. 764 does).

509. *See* Emily Monaco, *New GMO Labeling Bill May Preempt Vermont's More Stringent Law*, ORGANIC AUTHORITY (June 29, 2016), http://www.organicauthority.com/new-gmo-labeling-bill-preempt-vermonts-law (discussing this criticism of S. 764). *See generally* Brad Plumer, *The Controversial GMO Labeling Bill That Just Passed Congress, Explained*, VOX (July 14, 2016, 3:08 PM), http://www.vox.com/2016/7/7/12111346/gmo-labeling-bill-congress (discussing the role of Vermont's state law in the implementation of S. 764).

510. *As of August 2, 2016, Attorney General No Longer Enforcing Act 120,* OFF. ATT'Y GENERAL, http://ago.vermont.gov/hot-topics/ge-food-litigation.php (setting forth the decision of Vermont's Attorney General).

511. *Id*.

512. *See FDA/HHS Technical Assistance on Senate Agriculture Committee Draft Legislation To Establish A National Disclosure Standard For Bioengineered Foods (EDW16734)* (June 27, 2016), *available at* http://src.bna.com/gnD [hereinafter *FDA Comments On S. 764*].

513. *See FDA Comments On S. 764, supra* note 512 (discussing the agency's disagreement with this assignment).

be responsible for a regulatory program governing labeling of foods as bioengineered, as the public might consider it to be a reflection on the safety of such foods.[514] The FDA expressed how the option of providing disclosures electronically is in tension with the FDA's statute and regulations requiring disclosures on food labels.[515] Most importantly, the FDA stated that the definition of "bioengineering" would result in a "somewhat narrow cope of coverage" and explained that the phrase "that contains genetic material" will exclude many foods from GE sources from labeling requirements, such as oil made from GE soy, starches, and purified proteins.[516] The scope of coverage to foods where the genetic modification "could not otherwise be obtained through conventional breeding or found in nature" would be difficult to show.[517]

As just demonstrated, there are several contrasting views of S. 764 and the federal preemption of state GMO labeling laws.[518] While there is a wide range of opinions on these issues, one idea remains undeniable: the United States has seen a dramatic shift in GMO regulatory policy as a result of the state movement towards GMO labeling.[519] This causal relationship greatly mirrors the implementation of mandatory GMO labeling requirements in the European Union as result of Member State action that brought about the 1997 EU crisis, which is discussed below in Part Section II.B.[520]

B. EU Opposition to GMOs

This Section will describe how the European Union faced public opposition similar to what the United States has experienced

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514. *See FDA Comments On S. 764*, *supra* note 512 (explaining and reiterating the FDA's policy on GMOs under the 1992 FDA Statement of Policy).

515. *See FDA Comments On S. 764*, *supra* note 512 (setting forth some of the agency's objections to the disclosure methods under S. 764).

516. *See FDA Comments on S. 764*, *supra* note 512 (highlighting one of the biggest concerns about S. 764 with regards to this definition).

517. *See FDA Comments on S. 764*, supra note 512 (discussing the complications with the application of S. 764).

518. *See supra* notes 490-517 and accompanying text (providing an overview of some of these views).

519. *See supra* Sections I.A, II.A (explaining the history of GMO labeling in the United States).

520. *See infra* Section II.B (providing an overview of the 1997 EU crisis).

concerning GMO labeling. Section I.B.1 will describe the labeling requirements before the crisis in the European Union and what led to public unrest about GMO labeling while Section I.B.2 will detail the actual crisis. Section I.B.3 will explain the reform of the labeling regime through the *2001 Deliberate Release Directive* and the *Traceability and Labeling Regulation*.

While the European Union has a much stricter GMO labeling regime than the United States, it has faced and still faces public opposition to its policies that call for even greater restrictions on the cultivation of GMOs and the use of these genetically engineered products on the market.[521] As discussed in Part I of this Note, the precautionary principle is the foundation of the EU GMO regulatory system and thus the regulation of GMOs is based on a detailed risk assessment system that relies on current scientific evidence and independent assessments.[522] While this detailed system has a main objective of protecting human health and the environment, the EU public still distrusts GMOs in general, including those that have been approved under the current regulatory system.[523] And while the European Union has moved to a more streamlined approach to GMO approval since the 1998 de facto moratorium on GMOs, public opinion has not followed this shift and continues to oppose GMOs vehemently across the board.[524]

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521. *See generally supra* Sections I.A-B (explaining the stark differences between the two regulatory systems); *see also infra* note 524 (highlighting the request of Member States to ban cultivation of GMOs in their territories).

522. *See generally supra* Section I.B. (explaining the precautionary principle and the risk assessment procedures in the EU regulatory system).

523. *See* Wilinska, *supra* note 19, at 155-56 (explaining how European consumers are extremely skeptical of GM foods and exhibit a lack of trust in their governments' food safety regulations); Sella-Villa, *supra* note 294, at 973 (stating that as opposed to US citizens, Europeans are deeply skeptical about GMO's environmental impact and do not trust government food regulations since the 1990s Mad Cow scare).

524. *See* Federici, *supra* note 39, at 542 (describing how a majority of Europeans do not support GM foods, as they are not considered useful but risky to society, even after much stricter regulations have been imposed on GMOs in the European Union); Wilinska, *supra* note 20, at 155 (stating that genetic research and development of GM foods have been at the center of hot debate and vehement resistance in Europe).

1. Labeling Requirements in the European Union Before the 1998 De Facto Moratorium on GMOs and the 1997 EU Crisis

Public opinion has been a strong factor in EU GMO regulation and has greatly influenced the European Union's mandatory labeling regime.[525] As discussed in Part I of this Note, there was a de facto moratorium on GMOs being cultivated or approved in the European Union, which led to an international dispute at the WTO.[526] Before this de facto moratorium occurred, the European Union did not require labeling of GMOs and did not require manufacturers to include a plan for labeling in their approval applications.[527] Due to the lack of a labeling regime, a crisis erupted in the European Union when Bt-maize was approved without any labeling requirements and was set to enter the EU market without any indication that it contained the approved GMO.[528] As previously discussed, GMO regulation went through a series of reforms and changes as a result of this crisis, including the introduction of a more streamlined approach that focuses heavily on independent risk assessment conducted by the EFSA and input from the Member States.[529]

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525. *See generally* Wilinska, *supra* note 19, at 541-46 (giving an overview of the way in which public opinion in the European Union concerning GMOs has greatly influenced the regulation of such products); Sella-Villa, *supra* note 294, at 973-74 (detailing how the differences between the legal regimes of the United States and European Union with respect to GMOs reflect different social and cultural approaches to GMOs).

526. *See generally supra* Section I.B. (discussing the de facto moratorium).

527. *See 1990 Deliberate Release Directive*, *supra* note 150, art. 11, at 1 (detailing how a notifier "may propose not to comply" with one or more of the requirements of Annex III B, which set out the requirements for a proposal of labeling and packaging, if the notifier considered either on the basis of the results of any release notified under Part B of the Directive or on substantive reasoned scientific ground that the placing on the market and use of the product did not pose a risk to the environment or human health); *see also* Stewart & Johanson, *supra* note 243, at 258 (describing how there was no labeling requirement under *1990 Deliberate Release Directive*, since notifying parties could propose not to comply to the requirements of Annex III.B, which set forth rules for labeling).

528. *See* Stewart & Johanson, *supra* note 243, at 260-78 (giving a detailed explanation of the crisis that took place in the European Union and its roots in the controversial approval of Bt-maize in 1997); *see also* Mereu, *supra* note 182, at 206 (describing the problems resulting from the approval of Bt-maize over the objection of most Member States and the de facto moratorium stemming from the Member States' reliance on the Safeguard Clause of the 1990 Deliberate Release Directive and desire for transparency and traceability).

529. *See generally supra* Section I.B. (explaining these reforms).

Part of this reform included an expansion of subject matter covered by the regulation.[530] Under the *1990 Deliberate Release Directive*, the development of GM crops and placing of live GMOs including fruit, seeds, and other products "containing viable GMOs" were included in the Directive because it specifically applied to raw materials.[531] However, this did not include processed products that contained GMOs.[532] This narrow application ceased under the *Novel Foods Regulation*, which regulated novel foods and novel food ingredients.[533] According to the *Novel Foods Regulation*, novel foods included foods containing GMOs that were further processed and were the finished products that consumers bought in stores.[534] Specifically, novel foods were foods that "had not been used for human consumption to a significant degree within the Community before May 1997" and fell into one of six categories.[535] This sometimes made it difficult for manufacturers to determine if their products were included in the Regulation and were thus required to obtain premarket authorization.[536]

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530. *See generally* Federici, *supra* note 39, at 543-46 (highlighting the scope of the reform, specifically regarding GMO labeling); Sella-Villa, *supra* note 294, at 982-91 (explaining the changes in the EU regulatory system from the 1990s through 2003).

531. *See* Stewart & Johanson, *supra* note 243, at 256 (discussing the 1990 Deliberate Release Directive as "[concerning] the placing in the market of GMO products that may be described as raw materials"); Hilary Ross, *Genetically Modified Food: The EU Regulatory "Maize"*, 18 NAT. RESOURCES & ENV'T. 9, 9 (2003-2004) (discussing the types of GMOs that were covered under the 1990 Deliberate Release Directive).

532. *See* Ross, *supra* note 531, at 9 (explaining the 1990 Deliberate Release Directive's failure to regulate processed products containing GMOs as the Directive's "major failing"); *see also* Stewart & Johanson, *supra* note 243, at 256 (distinguishing raw foods, which were covered by the 1990 Deliberate Release Directive, from novel foods, which would be covered under a separate Regulation).

533. *See Novel Foods Regulation*, *supra* note 197; *see also* DEBRA HOLLAND & HELEN POPE, EU FOOD LAW AND POLICY 112 (2004) (explaining the Novel Foods Regulation).

534. *See* Stewart & Johanson, *supra* note 243, at 256 (explaining novel foods and how they compare to raw foods). *See generally* Ross, supra note 531, at 9 (introducing the Novel Foods Regulation).

535. Ross, *supra* note 531, at 9 (defining novel foods and describing the category system under the Novel Foods Regulation); *Novel Foods Regulation*, *supra* note 197, art. 1, at 2 (stating what the Regulation applies to and the six categories).

536. *See* Ross, *supra* note 531, at 10 (highlighting a difficulty faced by manufacturers under the Novel Foods Regulation). *See generally* GERALD C. NELSON, GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE: ECONOMICS AND POLITICS 112 (2001) (discussing market uncertainty that resulted from the Novel Foods Regulation).

As part of the *Novel Foods Regulation*, manufacturers of novel foods were required to have their goods authorized before bringing them to market and the Regulation mandated labeling for novel foods or food ingredients if they fit certain requirements.[537] Under the *Novel Foods Regulation*, novel foods or food ingredients had to be labeled if (1) they were no longer equivalent to a conventional food or ingredient, (2) raised health implications for certain sections of the population, (3) contained material which gave rise to ethical concerns, or (4) contained live GMOs.[538] If a manufacturer determined that his product had not been used for human consumption to a significant degree before May 15, 1997 and that it fell into one of the six categories found in Article 1, he then had to apply for premarket approval and fulfill labeling requirements as part of the application.[539] For any characteristics of a food that made it no longer equivalent to a conventional food or ingredient, the label had to give details to inform consumers of such characteristics.[540] One of the main deficiencies of this labeling requirement was that since it did not include specific guidelines, but rather gave general principles, there was not a set framework to use in order to determine if a product required labeling under the Regulation.[541] A second problem was that it was not retroactive and thus only applied to "novel foods" that were seeking market approval after May 1997.[542]

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537. *See generally Novel Foods Regulation, supra* note 197 (applying rules and requirements to manufacturers of novel foods).

538. *See id.* art. 8, at 1 (setting forth the requirements for labeling).

539. *See id.* art. 1, at 2 (providing the six categories to which this regulation applied); Ross, *supra* note 531, at 10 (discussing the requirements under the Novel Foods Regulation*)*.

540. *See Novel Foods Regulation*, *supra* note 197, art. 8, at 1 (detailing how a product had to be labeled in this situation); Ross, *supra* note 531, at 10 (giving the requirements regarding these characteristics).

541. *See* HOLLAND & POPE, *supra* note 533, at 113 (stating that since the provisions were only general principles, it was extremely difficult to predict whether they would apply in practice); Ross, *supra* note 531, at 9-10 (explaining some of the complications with the Novel Foods Regulation, such as manufacturer confusion).

542. *See* HOLLAND & POPE, *supra* note 533, at 112-13 (stating that this regulation only applied to foods that were not used to a significant degree before May 1997); Ross, *supra* note 531, at 10 (discussing the May 15, 1997 date).

2. A Temporary Solution to the 1997 European Union Crisis

While the implementation of the *Novel Foods Regulation* attempted to allay the fears of the public, consumers were still concerned with GMO products that had been authorized under the *1990 Deliberate Release Directive* that were not under this labeling requirement since the *Novel Foods Regulation* was not retroactive.[543] Thus, Regulation 259/97, which took effect as of January 27, 1997, did little to avoid the crisis that occurred as a result of the Commission's approval of Bt-maize, which granted France the authority to place Ciba-Geigy's GMO maize on the market without a labeling requirement since the product did not "present safety concerns."[544] As discussed in Part I of this Note, Austria and Luxembourg banned Bt-maize from their territories based on Article 16 of the *1990 Deliberate Release Directive*, which allowed Member States to ban an approved GMO if they had justifiable reasons to believe that the product might adversely affect human health or the environment.[545] In addition to the *Novel Foods Regulation*, other regulatory changes were attempted in order to rectify the situation and to quench the public's desire for GMO labeling.[546] On April 2, 1997, the Commission proposed to amend the *1990 Deliberate Release Directive* so that products that contained or may have contained GMOs would be labeled.[547] While this was not the permanent solution

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543. *See* Ross, *supra* note 531, at 10 (stating that the Novel Foods Regulation was not retrospective in its application); Sella-Villa, *supra* note 294, at 983 (explaining how this regulation defined "novel foods" as foods and ingredients that had not been used for human consumption to a significant degree within the Community before May 15, 1997).

544. *See* Stewart & Johanson, *supra* note 243, at 263 (discussing the authorization of Bt-maize and the rationale behind the lack of mandatory labeling of the product); Ross, *supra* note 531, at 9-11 (explaining how the crisis still occurred despite efforts to calm public unrest through these measures).

545. *See generally supra* Section I.B (explaining the Member State response to the approval of Bt-maize); Stewart & Johanson, *supra* note 243, at 267 (discussing the Member State reaction to the authorization of Bt-maize).

546. *See* Stewart & Johanson, *supra* note 243, at 269 (explaining these attempted measures and their purposes). *See generally* Ross, *supra* note 531, at 10 (giving an overview of the attempts to settle the public dissent).

547. *See* European Commission Press Release, IP/97/259, The European Commission Has Decided to Propose Further Labelling of Genetically Modified Organisms (Apr. 2, 1997) (proposing to amend the 1990 Deliberate Release Directive); Stewart & Johanson, *supra* note 243, at 269 (discussing this proposal).

to the labeling issue in the European Union, it was a transitional repair that was made in anticipation of the Commission's review of the *1990 Deliberate Release Directive*.[548] The main reason behind this change was the Member State demand for labeling, as most Member States objected to placing Bt-maize on the market without labeling.[549] Another reason was the clear stance that Austria and Luxembourg took in banning the approved product, as they too demanded labeling, in addition to further regulation of GMO products.[550]

The Regulatory Committee approved the Commission's proposal to amend the *1990 Deliberate Release Directive* on May 29, 1997 and the Commission adopted the labeling amendment, the *1997 Adapting Directive*, on June 18, 1997.[551] Under this new Directive, Member States had to conform to the decision by July 31, 1997.[552] Products that contained GMOs now required labeling and when GMO products were mixed with non-GMO products, the label had to indicate that genetically modified organisms "may be present."[553]

A crucial part of this Directive is the way in which it was adopted.[554] Because of the crisis in the European Union, the Commission decided to act quickly in order to calm public outrage over the authorization of GMOs such as Bt-maize and to bring

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548. *See* Stewart & Johanson, *supra* note 243, at 268 (discussing this temporary solution). *See generally* Ross, *supra* note 531, at 10 (explaining one of the temporary solutions to the unrest of the EU public).

549. *See* Stewart & Johanson, *supra* note 243, at 268-69 ("[A]ccording to Ritt Bjerregaard, the European Union's Environmental Commissioner, the strong support of the Member States for labeling was a major impetus behind the Commission's decision."); Nelson, *supra* note 536, at 112 (stating that shortly after Bt-maize was approved by the Commission, the 1990 Deliberate Release Directive was amended by the 1997 Adapting Directive to require labeling products that contained or may have contained GMOs).

550. *See* Stewart & Johanson, *supra* note 243, at 268-69 (discussing these demands). *See generally* Nelson, *supra* note 536, at 112 (stating that the Commission amended the 1990 Deliberate Release Directive to mandate GMO labeling).

551. *See* Stewart & Johanson, *supra* note 243, at 270 (explaining the directive); GERALD C. NELSON, GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE: ECONOMICS AND POLITICS 112 (2001); Nelson, *supra* note 536, at 112 (explaining 1997 Adapting Directive).

552. *See 1997 Adapting Directive, supra* note 290, art. 2 (giving this deadline).

553. *See id.* Annex III (C) (setting these requirements); Stewart & Johanson, *supra* note 243, at 270-71 (discussing the changes under the 1997 Adapting Directive).

554. *See* Patrick Chalmers, *EU Gene-Produce Label Rules Possible Within Weeks Plans Mandatory GMO Labeling*, REUTERS (Mar. 21, 1997) (covering the sudden movement towards reform); Stewart & Johanson, *supra* note 243, at 270 (explaining the special way in which the directive was adopted).

consistency back to GMO regulation.[555] Specifically, the Commission was concerned that the Member States' refusal to adopt its decision concerning Bt-maize frustrated the purpose of the *1990 Deliberate Release Directive* and would lead to a total halt to authorization of GMOs (which it did during the de facto moratorium on GMOs from 1998-2004).[556] To amend the *1990 Deliberate Release Directive*, the Commission proposed a "fast track" to make it a technical process that would eliminate the involvement of the Council and the Parliament.[557] This process would only require the Commission's and Regulatory Committee's approval, which would allow the amendment to be adopted within weeks, as opposed to between a year or two under the traditional process.[558] It was through this fast track approach that the Commission adopted the *1997 Adapting Directive* and mandated GMO labeling.[559] While the Directive could not be retroactive, as this is not within the Commission's authority, most companies that had submitted notifications voluntarily agreed to label their products to indicate that they contained GMOs.[560]

3. GMO Labeling Reform Through The 2001 Deliberate Release Directive and the Traceability and Labeling Regulation

As previously discussed, the *1997 Adapting Directive* was only a temporary solution to settle the 1997 crisis in the European Union that led to the de facto moratorium, which lasted until 2004.[561] As early as

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555. *See* Stewart & Johanson, *supra* note 243, at 270 (discussing this method); Chalmers, *supra* note 554 (covering the sudden movement towards reform).

556. *See* Stewart & Johanson, *supra* note 243, at 269 (discussing the motivation behind the Commission's actions); Ross, *supra* note 531, at 10-11 (describing that no efforts worked to prevent the de facto moratorium in 1998).

557. *See* Stewart & Johanson, *supra* note 243, at 269-70 (detailing this method).

558. *See* Stewart & Johanson, *supra* note 243, at 270 (explaining how the Commission expedited the process). *See generally* Chalmers, *supra* note 554 (discussing the process).

559. *See* European Commission Press Release, IP 97/528, EU Commission Press Release on GMO Labeling (June 18, 1997) [hereinafter Commission Press Release, IP 97/528]; Stewart & Johanson, *supra* note 243, at 270-71 (stating that the Commission used this fast-track process to adopt the Novel Foods Regulation).

560. *See* Commission Press Release, IP 97/528, *supra* note 559; Stewart & Johanson, *supra* note 243, at 271 (stating that most companies agreed to comply with the directive).

561. *See* Ross, *supra* note 531, at 10-11 (stating that nothing prevented the de facto moratorium that took place in 1998); Stewart & Johanson, *supra* note 243, at 268 (explaining how this was a temporary solution); Mereu, *supra* note 182, at 206 (describing the de facto moratorium).

1996, the Commission was anticipating a review of the *1990 Deliberate Release Directive*, which ultimately resulted in the formation of the current GMO regime in the European Union under the *Genetically Modified Food and Feed Regulation* and the *Traceability and Labeling Regulation*.[562] First came the *2001 Deliberate Release Directive*, which sought to resolve consumer concerns about GMOs and was an attempt to solve the problems of the *1990 Deliberate Release Directive*, placing greater emphasis on the precautionary principle and a case-by-case analysis of each proposed product.[563] Furthermore, the *2001 Deliberate Release Directive* clearly required that any application must give the proposed packaging of the product, including a section of the label or an accompanying document that clearly states that the product contains genetically modified organisms.[564]

Though the *2001 Deliberate Release Directive* was a much more detailed and clear set of requirements concerning the approval and labeling of GMO products, it was not until the *Traceability and Labeling Regulation* amended the *2001 Deliberate Release Directive* that a threshold requirement was set for labeling GMO food products.[565] Even though the labeling requirements were largely brought about due to public dissent, these further requirements under the *Traceability and Labeling Regulation* were also meant to ensure

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562. *See* Stewart & Johanson, *supra* note 243, at 268 (explaining how the Commission anticipated adding a GMO labeling provision to the 1990 Deliberate Release Directive*)*; MACMAOLAIN, *supra* note 334, at 246 (discussing the 1990 Deliberate Release Directive).

563. *See* MACMAOLAIN, *supra* note 334, at 246 (analyzing the shift from the 1990 Deliberate Release Directive to the 2001 Deliberate Release Directive and how the 2001 Deliberate Release Directive was "largely moulded by a vastly increased consideration for consumer concern"); *see also* Carrau, *supra* note 21, at 1181 (explaining that a moratorium occurred because the 1990 Deliberate Release Directive was not sufficient to assure confidence among citizens in the European Union).

564. *See 2001 Deliberate Release Directive, supra* note 151, art. 13, at 2(f) (stating the application requirements for labeling); MACMAOLAIN, *supra* note 334, at 247 (summarizing the labeling requirements under the directive's premarket approval process).

565. *See* MACMAOLAIN, *supra* note 334, at 250-51 (giving an overview of the traceability requirements under the *Traceability and Labeling Regulation*, including the threshold level); Sella-Villa, *supra* note 294, at 990 (explaining how the *Traceability and Labeling Regulation* set a threshold standard in order to enhance traceability).

further traceability and to promote the precautionary principle.[566] Specifically, the justifications for these new traceability requirements were to facilitate the removal of products whose unforeseen negative effects on human health, animal health, and the environment are established, and to also allow for the implementation of other precautionary risk management measures when necessary.[567] This traceability is twofold, as it mainly allows for unsafe GMO products to be efficiently removed from the market by allowing food operators to identify who supplied the product and which other businesses have been supplied with the product by the same source.[568] Also, the traceability requirements permit consumers to receive accurate information about the foods they are eating, as the food is able to be tracked in all stages of production, processing, and distribution.[569] Specifically, the Regulation states that this accurate information should be made available to operators and consumers to allow them to use their freedom of choice in an effective manner.[570]

In order to ensure traceability, Article 4 of the *Traceability and Labeling Regulation* requires traceability at the first stage of placing a product consisting of or containing GMOs on the market.[571] The operator that is sending the product to another operator must state in

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566. *See* MACMAOLAIN, *supra* note 334, at 250 (explaining the purposes of the *Traceability and Labeling Regulation*); *Traceability and Labeling Regulation, supra* note 151, recital 3 (stating the goals of traceability requirements under the regulation).

567. *See* MACMAOLAIN, *supra* note 334, at 250 (discussing the motivation behind the *Traceability and Labeling Regulation)*; *see also Traceability and Labeling Regulation, supra* note 151, recital 3 (setting forth the objectives of the regulation).

568. *See* Alemanno, *supra* note 157, at 153 (discussing the dichotomy of traceability requirements); MACMAOLAIN, *supra* note 334, at 250 (stating that one of the reasons behind the traceability requirements is to make the removal of harmful products from the market more efficient).

569. *See Traceability and Labeling Regulation*, *supra* note 151, recital 4 (articulating that the traceability requirements should be put into place in order to allow consumers to freely choose with accurate information); Alemanno, *supra* note 157, at 154 (discussing the general principle of traceability in the European Union).

570. *See Traceability and Labeling Regulation*, *supra* note 151, recital 4 (describing the relationship between accurate information and consumer choice); *see also* Alemanno, *supra* note 157, at 153 (stating that traceability enables consumers to be provided with targeted and accurate information regarding a certain product).

571. *See Traceability and Labeling Regulation*, *supra* note 151, art. 4, at 1 (stating the requirements of operators at the first stage of placing on the market). *See generally* MACMAOLAIN, *supra* note 334, at 250 (explaining how the regulation is meant to ensure traceability at all stages of the food production process).

writing that the product contains or consists of GMOs and must also include a "unique identifier" assigned to those GMOs in accordance with Article 8.[572] Under the *Traceability and Labeling Regulation*, this information must continue down the chain to operators at all subsequent stages of the production and marketing process.[573] This traceability requirement extends longer than the supply chain, as all operators that are a part of the marketing chain and food production chain must have systems and standardized procedures in place to keep that information for five years after each transaction.[574]

Under Article 4, operators of products containing or consisting of GMOs must include labels stating "this product contains genetically modified organisms" or "this product contains genetically modified [name of organism(s)]" on the label.[575] If the product is not pre-packaged, the phrases "this product contains genetically modified organisms" or "this product contains genetically modified [name of organism(s)]" must appear on or in connection with the display of the product.[576] As discussed in Part I of this Note, these requirements do not apply to traces of GMOs in products in levels under a threshold

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572. *See Traceability and Labeling Regulation*, *supra* note 151, art. 4, at 1 (providing different requirements for products consisting of or containing mixtures of GMOs to be used only and directly as food, feed, or for processing); MACMAOLAIN, *supra* note 334, at 250 (explaining the unique identifier).

573. *See Traceability and Labeling Regulation*, *supra* note 151, art. 4, at 2 (requiring operators to ensure that the information received is transmitted in writing to the operators receiving the products "at all subsequent stages of placing on the market of product"); *see also* MACMAOLAIN, *supra* note 334, at 250 (describing Article 4(2) of the *Traceability and Labeling Regulation*).

574. *See Traceability and Labeling Regulation*, *supra* note 151, art. 4, at 4 (stating that operators must have systems and standardized procedures in place to hold the information for five years from each transaction); MACMAOLAIN, *supra* note 334, at 250 (detailing this requirement for all operators in the chain).

575. *Traceability and Labeling Regulation*, *supra* note 151, art. 4, at 4(B)(6) (detailing how products consisting of or containing GMOs must be labeled); MACMAOLAIN, *supra* note 334, at 250 (explaining how operators at the initial stage of production must clearly state in writing that the product consists of or contains a GMO).

576. *See Traceability and Labeling Regulation*, *supra* note 151, art. 4, at 4(B)(6) (mandating how products consisting of or containing GMOs that are not pre-packaged are to be labeled); MACMAOLAIN, *supra* note 334, at 251 (describing the requirements for products that are not pre-packaged).

amount prescribed by the *2001 Deliberate Release Directive* and *Genetically Modified Food and Feed Regulation*.[577]

The European Union's current GMO labeling requirements went through many important changes and served as a significant part of the solution in calming public unrest about the safety of GMOs.[578] While many other changes were made to the European Union's regulatory system, the labeling reforms were a temporary fix that addressed the 1997 crisis by meeting the desires of the majority of the Member States and the public.[579] This greatly parallels the public unrest that has existed across the United States concerning the FDA's refusal to require GMO labeling and the state movement to enact GMO labeling laws in the face of the US House of Representatives and the FDA.[580] Due to the 1992 FDA Statement of Policy on GMOs that does not mandate GMO labeling, the states took it upon themselves to defy the agency and create their own laws.[581] Likewise, in 1997, EU Member States took it upon themselves to ban an approved GMO in their territories despite the Commission's approval.[582] While the European Union's structure is different from that of the United States, the complications of the push for GMO labeling laws are quite similar and bring about another issue with respect to GMO labeling, which is uniformity.[583]

As discussed previously in this Note, the Commission was greatly concerned with the lack of uniformity in the European Union as a result of the Member States' refusal to adopt the Commission's

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577. *See generally Traceability and Labeling Regulation*, *supra* note 151, art. 4 (exempting products that contain a trace amount of GMOs); MACMAOLAIN, *supra* note 334, at 251 (discussing the trace exemption and the threshold levels found in the 2001 Deliberate Release Directive and the Genetically Modified Food and Feed Regulation).

578. *See supra* notes 505-60 and accompanying text (detailing these changes).

579. *See generally supra* Section II.B (explaining this temporary solution).

580. *See generally supra* Part II (detailing the increasing public demand for GMO labeling and the reaction of the FDA and the US House of Representatives).

581. *See generally supra* Section I.A (discussing the 1992 FDA Statement of Policy); *supra* Section II.A (explaining the state movement towards mandatory GMO labeling).

582. *See* Stewart & Johanson, *supra* note 243, at 266-67 (giving an overview of the Member State reaction to the authorization of Bt-maize and their reliance on Article 16 of the 1990 Deliberate Release Directive); THE YEAR IN TRADE, *supra* note 282, at 104 n.180 (explaining the actions of several Member States in reaction to the approval of Bt-maize).

583. *See supra* notes 362-63 and accompanying text (highlighting concerns over a "patchwork" system that might arise as a result of different state GMO labeling laws).

decision to allow Bt-maize to be marketed in the European Union without labeling.[584] Because of these concerns, GMO labeling in the European Union would be regulated under one system, instead of allowing the Member States to craft their own rules and legislation to require labeling.[585] Specifically, the *Traceability and Labeling Regulation* states that differences between national laws, administrative provisions, and regulations that concern traceability and labeling of GMOs as products or in products may hamper their free movement and therefore create unequal and unfair competition.[586] Furthermore, the Regulation says that in order to contribute to the effective functioning of the internal market, there should be a "harmonized" Community framework for labeling and traceability of GMOs.[587] Thus, according to the *Traceability and Labeling Regulation*, the labeling requirements for GMOs within the Community framework have to be uniform in order to allow GMOs to be unhindered in the market and to allow the EU market to function in an effective and harmonized way.[588] It is clear from this determination that a uniform labeling system under the *Traceability and Labeling Regulation* was a key component of GMO labeling reform in the European Union and a preferred solution to differing national laws and regulations.[589]

4. Member States Cultivation Directive

The European Union's stance on labeling and traceability has not changed since 2003, as the labeling of GMOs is still governed by the *Traceability and Labeling Regulation* and no major changes have been made to the requirements, including the 0.9% threshold limit.[590]

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584. *See supra* note 480 and accompanying text (explaining the Commission's position).

585. *See Traceability and Labeling Regulation, supra* note 151, recital 2 (explaining the need to have uniform rules concerning this area of GMO regulation).

586. *Id.* (explaining the possible complications of non-uniform traceability and labeling requirements).

587. *Id.* (stating the need for uniform labeling and traceability standards).

588. *Id.* (discussing how the harmonized Community framework in this area contributes to the effective functioning of the internal market).

589. *Id*. (highlighting the need for uniform traceability and labeling requirements for the benefit of the internal market).

590. *See* Sella-Villa, *supra* note 294, at 983 (stating that the *Traceability and Labeling Regulation* is a part of the reform and highlighting the need for uniform traceability and

The same cannot be said concerning the cultivation of GMOs in Member State territories.[591] After thirteen Member States requested the Commission to give them the ability to make decisions on GMO cultivation in their territories, the request was granted under the *Member States Cultivation Directive***,** which gives Member States two different options to restrict GMO cultivation in their territories.[592] Before a GMO is authorized, a Member State can demand that part or all of its territory be exempt from the geographical scope of the application with the agreement of the applicant.[593] There are nuances to this option that this Note does not cover, but one important point is that it does not require the Member State to include a justification for its exclusion.[594]

The second option allows a Member State to opt out.[595] Here, a Member State can adopt measures to restrict or ban GMO cultivation on part or all of its territory at any time after the GMO has been authorized.[596] However, unlike the first option, the Member State must justify its decision based on reasoned grounds that do not conflict with the EU assessment of risks on health or the environment.[597] These include land use, socio-economic impacts, public policy, environmental/agricultural policy objectives, and town and country planning.[598] As part of the Directive, special attention must also be paid to the prevention of cross-border contamination

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labeling requirements for the benefit of the internal market); Federici, *supra* note 39, at 543 (discussing the transition from the old guidelines to the current instructions under the *Traceability and Labeling Regulation*).

591. *See infra* notes 592-99 and accompanying text (discussing the new directive that allows Member States to restrict GMO cultivation in their territories).

592. *See generally* Directive (EU)2015/412 of the European Parliament and of the Council of 11 March 2015 Amending Directive 2001/18/EC as regards The Possibility For The Member States To Restrict Or Prohibit The Cultivation Of Genetically Modified Organisms (GMOs) In Their Territory, 2015 O.J. L 68/1 [hereinafter *Member States Cultivation Directive*].

593. *See Member States Cultivation Directive, supra* note 592, art. 1, at 2 (giving Member States this option before a GMO is authorized).

594. *See id.* (failing to list a requirement for a justification).

595. *See id.* (allowing Member States to opt out).

596. *See id.* (stating what Member States that did not demand exemption before authorization may do with respect to the cultivation of authorized GMOs).

597. *See id*. (explaining the different requirement for the Member State under this option).

598. *See id*. (listing the justifications upon which the measures must be based).

from a Member State that permits cultivation of a GMO to a Member State that prohibits it.[599] In accordance with EU general public opinion, many Member States have taken advantage of the *Member States Cultivation Directive*.[600] As of October 2015, two-thirds of Member States have chosen the opt-out option under the Directive and have requested opt-outs from the cultivation of genetically modified crops for all or part of their territory.[601]

As shown by the *Member States Cultivation Directive*, the European Union continues to address issues with respect to GMOs by changing existing procedures to better deal with specialized issues within GMO regulation.[602] According to the Directive, experience shows that cultivation is addressed more thoroughly at the Member State level, while issues related to the placing on the market and the import of GMOs should remain regulated at the Union level in order to preserve the internal market.[603] Therefore, measures governing the labeling and traceability of GMOs remains at the Union level because, unlike cultivation, the uniform regulation of GMO labeling is still considered to be paramount to the internal market and therefore is not left to Member State discretion.[604]

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599. *See id*. recital 10 (explaining how particular attention must be paid to preventing cross-border contamination among Member States who have made different cultivation decisions).

600. *See infra* note 601 and accompanying text.

601. *See Two Thirds of EU States Reject GMO Crops, File Cultivation Opt-Out Requests*, RT (Oct. 5, 2015, 3:11 AM), https://www.rt.com/news/317638-eu-gmo-cultivation-opt-out/ (stating that two thirds of EU Member States have requested to be allowed to ban growing GMO crops in their territories by using the "opt-out" clause of the directive); Jonathan Stearns, *Most EU Countries to Ban Cultivation of 8 GMOs Using New Rules*, BLOOMBERG BUS. (Oct. 5, 2015, 2:42 AM), http://www.bloomberg.com/news/articles/2015-10-05/most-eu-countries-to-ban-cultivation-of-8-gmos-using-new-rules (announcing that more than half of the EU Member States demanded that all or part of their territory be shielded from eight pending applications to grow GMO crops in their countries); Lorraine Chow, *It's Official: 19 European Countries Say 'No' To GMOs*, ECOWATCH (Oct. 5, 2015, 10:32 AM), http://ecowatch.com/2015/10/05/european-union-ban-gmos/ (explaining how the Member States "specifically targeted" the cultivation of Monsanto's MON 810 Maize and how this crop, which was under review, was the only GMO crop grown in Europe at the time).

602. *See supra* notes 590-604 and accompanying text (explaining the innovative policies under the Member States Cultivation Directive).

603. *See Traceability and Labeling Regulation*, *supra* note 151, recital 2 (stating the need for uniform labeling and traceability standards).

604. *Id*. (justifying the uniform approach taken for labeling and traceability).

III: ADVANCING GMO TRANSPARENCY UNDER THE CONSUMER RIGHT TO KNOW POLICY

This Note was originally written with the intention of proposing a federal solution to the debate that would prevent the United States from experiencing a situation similar to the 1997 EU crisis. However, during the course of writing this Note, President Obama signed S. 764 into law, making federal GMO labeling a reality and shutting down the state movement that paralleled the Member State actions in 1997 during the EU crisis. As a result, the focus of this Note shifted from a stance of warning to a position of observation and suggestions for improvement. Thus, this Part will argue that while the United States successfully avoided a crisis similar to that of the European Union, it did not respond to public outcry as effectively as the European Union did in mandating GMO labeling through the *Traceability and Labeling Regulation*. This Part proposes a solution to the critical debate occurring in the United States over mandatory GMO labeling based on the Consumer Right to Know Policy that corrects the deficiencies under the new federal national standard established by S. 764.

A. How the United States Avoided a Crisis Similar to the 1997 EU Crisis

Just as the European Union reached a pinnacle in its GMO labeling debate in 1997, the United States was at its apex, as individual states defied the FDA and passed laws requiring GMO labeling at the state level.[605] Similar to the 1992 FDA Statement of Policy, the *1990 Deliberate Release Directive* did not require GMO labeling in direct conflict with public opinion.[606] When Bt-maize was under consideration for approval in 1997 in the European Union, the Commission approved the GMO product for the market despite Member State objections.[607] This parallels the response of the US federal government in 2015 with the passing of H.R. 1599 by the US House of Representatives, which would have implemented a

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605. *See generally supra* Part II (discussing the state movement).

606. *See generally supra* Part I (explaining the 1990 Deliberate Release Directive).

607. *See generally supra* Section I.B (describing the conditions surrounding the approval of Bt-maize in 1997).

voluntary GMO labeling system that defiantly rejected the state laws of Vermont, Connecticut, and Maine requiring GMO labeling by manufacturers.[608] More broadly, the two responses are strikingly similar in their defiance to public opinion concerning GMO transparency and greater regulation of such products.[609] Just as the Commission ignored public opinion concerning GMO transparency for several years, the US federal government has repeatedly refused to mandate GMO labeling based on the Consumer Right to Know Policy.[610] It is this open defiance and refusal to consider public opinion that brought about the 1997 EU Crisis and the recent US national debate over GMO labeling, and which prompted severe action in both situations.[611]

The responses to these actions are also eerily similar, as both the Member States in the European Union and individual states in the United States took GMO regulation into their own hands and imposed severe restrictions on GMOs in their borders.[612] While the Member States of the European Union did not implement their own regulation of such products as the United States did, they did refuse to adhere to the decisions of the Commission and thereby demanded intense change.[613] Furthermore, many of the concerns surrounding such action were the same, as those in both the European Union and United States feared a resulting patchwork system that would affect the marketing of GMO products based on the borders they entered.[614]

However, the most important similarity between these two situations is the remedy used to calm public outrage and action from the Member States in the European Union and the individual states in

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608. *See generally supra* Section II.A.8 (providing details about the voluntary system under H.R. 1599 and how it would affect the GMO labeling laws of these states).

609. *See generally supra* Part II (highlighting the strong public disapproval of such responses).

610. *See generally* Parts I-II (detailing how the EU Commission and US federal government reacted to public demand for more GMO transparency).

611. *See generally* Parts I-II (analyzing how intense public opinion concerning GMOs influenced GMO regulation in both the United States and European Union).

612. *See generally supra* Parts I-II (demonstrating how the Member States of the European Union and individual states of the United States took significant action in an effort to meet public concern over GMOs).

613. *See generally supra* Section II.B.1 (highlighting how the Member States pushed for significant reform in GMO regulation).

614. *See generally supra* Sections II.A-B (discussing such concerns).

the United States.[615] In both the European Union and United States, mandatory GMO labeling was implemented and individual state action ceased.[616] In the European Union, voluntary compliance with GMO labeling standards under the *1990 Deliberate Release Directive* was replaced with mandatory rules governing the strict labeling of GMOs based on a threshold amount of genetic material found in the end food product under the *Traceability and Labeling Regulation*.[617] Almost identically in the United States, the proposed voluntary GMO labeling system under H.R. 1599 was superseded by the mandatory national standard under S. 764, which requires GMO labeling based on an amount of bioengineered substance found in a food.[618]

Thus, the United States avoided a debacle like the 1997 EU Crisis by implementing a system that greatly mirrors that of the European Union under the *Traceability and Labeling Regulation* and requires GMO labeling based on an amount found in the end product, as opposed to mandating labeling based on genetic engineering alone.[619] The urgency with which S. 764 was implemented also greatly parallels the actions of the European Union during the 1997 Crisis, in which the Commission implemented a temporary fix and used a fast track procedure to implement the necessary changes.[620] S. 764 was crafted and passed within less than a year of H.R. 1599's exclusion from the Federal Spending Bill and within a month of July 1, 2016, which was the date that Vermont's Act 120 went into effect.[621] Therefore, it is clear that the United States avoided a crisis

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615. *See generally supra* Parts I-II (providing an extensive discussion about how the European Union and United States developed solutions to the significant public unrest about the lack of GMO transparency).

616. *See generally supra* Parts I-II (demonstrating how the implementation of GMO labeling requirements stopped individual action).

617. *See generally supra* Sections II.B.2-3 (detailing how mandatory GMO labeling requirements were introduced to the European Union through the *Traceability and Labeling Regulation*).

618. *See generally supra* Sections II.A.8-9 (showing how the proposed voluntary system under H.R. 1599 was replaced with the mandatory system under S. 764).

619. *See generally supra* Section II.A.9 (explaining the requirements under S. 764).

620. *See generally supra* Sections II.B.2-3 (explaining the actions of the Commission during this time).

621. *See generally supra* Section II.A.9 (discussing the circumstances surrounding the passage of S. 764).

much like that of the European Union by using a very similar solution with the same sense of haste and necessity.[622]

1. The United States Avoided a Crisis, But Missed the Goal

As just demonstrated, the United States has taken crucial steps that eliminated a patchwork system of state GMO labeling laws and that will likely prevent a crisis similar to what the European Union experienced in 1997 with regard to GMO labeling.[623] However, the avoidance of such a crisis is not the sole indicator of success here, as the new GMO labeling requirements under S. 764 do not adequately address the concerns of many consumers who desire GMO transparency and have significant deficiencies that result in inaccessibility to GMO information for certain parts of the population.[624] It is because of these issues that S. 764 is not as successful of a solution to the GMO conflict in the United States as the *Traceability and Labeling Regulation* was in the European Union.[625] The rest of this Note highlights these shortcomings and argues that S. 764 should be repealed and replaced with a mandatory federal GMO labeling system that is based on the process used in the production of the food, instead of how much bioengineered matter is present in a final food product.[626] Through this mandatory system, the United States can simultaneously avoid a crisis like that of the European Union and also meet the call of the US population for GMO transparency under the Consumer Right to Know Policy.[627]

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622. *See generally supra* Section II.B.2 (demonstrating the fast track approach used to enact GMO reform in the wake of the 1997 crisis).

623. *See supra* notes 605-22 and accompanying text (providing an overview of these steps).

624. *See generally supra* Section II.A.10 (describing some of the criticisms of S. 764).

625. *See generally supra* Section II.B.3 (explaining how public concerns in the European Union were adequately addressed by the *Traceability and Labeling Regulation*).

626. *See infra* notes 628-726 (highlighting the deficiencies of S. 7764 and suggesting improvements to correct them).

627. *See generally supra* Section II.A.1 (detailing the Consumer Right to Know Policy); *supra* Section II.B (discussing the 1997 EU Crisis).

B. The Deficiencies of S. 764

1. S. 764 Does Not Provide the GMO Transparency Desired Under the Consumer Right to Know Policy

One of the most significant issues with S. 764 is the way in which GMO information is presented to consumers on the food packaging.[628] Even though S. 764 is only applicable to foods that have been deemed "bioengineered" under the standards set forth by the Secretary of Agriculture, the words "bioengineered," "genetically engineered," or "genetically modified" will not appear on the packaging.[629] In fact, such language is not permitted to accompany the three methods of disclosure, as manufacturers must only put language indicating that such disclosures will provide "food information."[630] There is an argument to be made that if disclosures were required to be accompanied by terms such as "bioengineered" or "genetically modified," certain manufacturers would be at a disadvantage and consumers might be unnecessarily deterred from purchasing foods with such labels.[631] However, the demands of the Consumer Right to Know Policy clearly outweigh such possibilities, as a failure to require such terms severely threatens the goals of GMO transparency and might result in consumers remaining largely uninformed about the GE nature of their foods.[632]

Forbidding language such as "genetically engineered" or "genetically modified" to accompany disclosures on packages may also result in serious consumer confusion and misinformation.[633] While consumers may become aware that the statement "call for more food information" indicates that a food has been genetically modified, this is only a possibility that could take years to become a reality.[634]

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628. *See generally supra* Section II.A.9 (discussing how such information is displayed).

629. *See generally supra* Section II.A.9 (explaining the packaging requirements under S. 764).

630. *See generally supra* Section II.A.9 (setting forth this prohibition).

631. *See generally supra* Section II.A.7 (generally explaining some of these arguments with respect to GMO labeling laws that require such language on packaging).

632. *See generally supra* Section II.A.1 (presenting the goals of the Consumer Right to Know Policy).

633. *See generally supra* Section II.A.10 (highlighting this argument).

634. *See generally supra* Section II.A.9 (explaining that the only language to appear on food packaging is "call for more food information").

Until that time, consumers will be responsible for discovering that such a statement correlates to information about bioengineering and that any food containing this statement is subject to federal GMO labeling requirements.[635] Additionally, consumers might mistakenly believe that the words "food information" concern nutritional information, allergen content, or some other aspect of food information that does not involve genetic engineering.[636] This possible consumer misinformation and confusion greatly defeats the stated purpose of S. 764 and GMO labeling requirements in general, while also falling short of the goals of the Consumer Right to Know Policy.[637]

2. S. 764's Burden on Consumers

In addition to consumer confusion and misinformation, the absence of GE information directly on the package places a burden on consumers that will likely decrease GMO transparency.[638] By placing the burden on the consumer to find out GMO information by either calling a telephone number or using their mobile device to access a website, consumers will lose their own valuable time and must overcome an extra hurdle to access the GMO information they wish to procure.[639] If consumers are required to spend their time and resources to find out this information for each food product they wish to purchase, consumers might either not attempt to find out such information or not purchase the food at all.[640] Either of these results produce negative consequences, as consumers will still remain uninformed about the GMO status of their food and manufacturers might be disadvantaged if consumers unnecessarily avoid certain

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635. *See generally supra* Section II.A.10 (discussing the burden on consumers under S. 764 to find out this information).

636. *See generally supra* Section II.A.10 (discussing the obscurity of the phrase "call for more food information").

637. *See generally supra* Section II.A.1 (explaining the goals of the Consumer Right to Know Policy with respect to GMO transparency).

638. *See generally supra* Section II.A.10 (highlighting this critical view of S. 764).

639. *See generally supra* Section II.A.10 (detailing this burden on consumers).

640. *See generally supra* Section II.A.10 (analyzing how the disclosure requirements of S. 764 results in the use of consumer time and effort).

foods that they might otherwise purchase if they knew more specific GMO information.[641]

These burdens also might result in inaccessibility to GMO information for many consumers and therefore make GMO transparency only available to those who have easy access to telephones or the internet.[642] As discussed in Part II, individuals who are elderly or financially disadvantaged might not have the devices necessary to make such phone calls or log onto the companies' websites.[643] By allowing disclosure only through these measures, S. 764 essentially eliminates these consumers from any possible increased GMO transparency and disadvantages significant portions of the US population based on factors that cannot easily be changed.[644]

As just demonstrated, S. 764 puts a severe burden on consumers that can result in consumer confusion, misinformation, and exclusion from GMO transparency.[645] This clearly conflicts with the idea of GMO transparency in general, which is based on increasing consumer access to GMO information and removing any obstacles to such access.[646] By hindering consumer access and thereby discouraging GMO transparency, S. 764 fails to achieve the goals of GMO labeling and the Consumer Right to Know Policy.[647]

3. Problems with Basing GMO Labeling Requirements on the Final Product and a Threshold

Perhaps the most severe deficiency of S. 764 is the way in which foods become subject to the law's federal GMO labeling

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641. *See generally supra* Section II.A.10 (highlighting some of the negative consequences of S. 764 and the burden that it places on consumers).

642. *See generally supra* Section II.A.10 (describing the critical challenges facing these individuals as a result of the disclosure requirements under S. 764).

643. *See generally supra* Section II.A.10 (explaining the special challenges facing these groups).

644. *See generally supra* Section II.A.9 (setting forth the disclosure methods of S. 764, which do not include using direct language on the packaging that indicates the GE status of a food).

645. *See generally supra* Section II.A.10 (describing this burden).

646. *See generally supra* Section II.A.1 (showing the purposes of the Consumer Right to Know Policy with respect to GMO labeling).

647. *See generally supra* Section.A.1 (highlighting these goals).

requirements.[648] Instead of requiring foods to be labeled based on the genetic engineering process alone, S. 764 will only require a food to be labeled if it meets the threshold amount of bioengineered substance required to deem it a bioengineered food under the law.[649] While the statute does not use the word "threshold," the language of the statute implies this term.[650] According to S. 764, the Secretary of Agriculture must determine the amounts of a bioengineered substance that may be present in a food product in order for it to be a bioengineered food.[651] Thus, any food that contains that specified amount will be deemed a bioengineered food and subject to the labeling requirements.[652] This implements a threshold requirement, as a food will only be labeled under the law if it contains the determined amount of bioengineered substance in the final product.[653] Therefore, any reference in this Note to a threshold level under S. 764 will refer to this statutory language.[654]

As previously discussed, this assignment of responsibility places the regulation of GMOs, which were historically regulated solely by the FDA with regards to food, under another part of the regulatory system.[655] The FDA expressed concerns about this assignment before S. 764 became law, warning that the new GMO standards may conflict with existing FDA regulations and places GMO regulation outside the sole jurisdiction of the FDA.[656] According to the FDA, these conflicts could have serious implications for consumers and convolute the effort to provide more transparency on food labeling because different labeling requirements can create confusion or

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648. *See generally supra* Section II.A.9 (demonstrating how foods become subject to the requirements).

649. *See generally supra* Section II.A.9 (explaining how a food product will only have to be labeled if it meets the threshold level for bioengineered foods under S. 764).

650. *See generally supra* Section II.A.9 (providing the language of the statute).

651. *See generally supra* Section II.A.9 (describing this requirement).

652. *See* generally *supra* Section II.A.9 (detailing how foods become subject to the requirements).

653. *See generally supra* Section II.A.9 (discussing the threshold level).

654. *See generally supra* Section II.A.9 (discussing the threshold level).

655. *See generally supra* Section I.A.2 (detailing the responsibilities of the FDA with respect to GMOs under the Coordinated Framework).

656. *See generally supra* Section II.A.9-10 (setting forth these concerns).

inconsistencies in packaging, thereby restricting GMO transparency.[657]

In addition to possible conflicts with FDA requirements, labeling GMOs based on the contents of the final product presents other serious problems that further restrict GMO transparency and stand contrary to the goals of the Consumer Right to Know Policy.[658] As indicated by the FDA, the definition of bioengineered foods in S. 764 is narrow and may eliminate several foods that come from GE sources, including oil made from GE soy, starches, and purified proteins.[659] Furthermore, S. 764 applies labeling rules to foods only where the genetic modification cannot otherwise occur through conventional breeding or be found in nature.[660] According to the FDA, proving that such modification "could not" be obtained through conventional breeding or occur in nature might be difficult.[661] This could potentially further narrow GMO labeling requirements and allow manufacturers to argue that their foods need not be labeled since it cannot be proven that their genetic modification cannot be obtained through conventional breeding.[662] By excluding many foods from GMO labeling requirements through this potential loophole, S. 764 results in inadequate GMO transparency and fails to achieve the goals of other measures, such as Act 120, that do not require such proof.[663]

Mandating GMO labeling based on a threshold also fails to provide information to many consumers who desire GMO transparency for various reasons under the Consumer Right to Know

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657. *See generally supra* Section II.A.1 (explaining the transparency goals of GMO transparency labeling with pursuant respect to the Consumer Right to Know Policy).

658. *See generally supra* Section II.A.10 (setting forth some of these serious problems).

659. *See generally supra* Section II.A.10 (presenting the arguments of the FDA regarding the scope of the definition and the possible exclusion of such foods from GE sources from the labeling requirements).

660. *See generally supra* Section II.A.9 (explaining this specific requirement under S. 764).

661. *See generally supra* Section II.A.10 (discussing this difficulty).

662. *See generally supra* Section II.A.10 (giving an overview of the argument that S. 764 will allow manufacturers to hide GMO information from consumers through potential loopholes and conditions).

663. *See generally supra* Section II.A.10 (describing how S. 764 contains possible loopholes that would restrict GMO transparency).

Policy.[664] As previously discussed, there are a myriad of reasons why individuals want to know if their food has been genetically engineered or modified, including religious and ethical beliefs.[665] For example, a person might want to avoid food that has been genetically engineered due to a personal objection to the genetic modification of food.[666] Under S. 764, such an individual would still not be able to avoid all genetically modified food, since genetic engineering alone does not subject a food to federal labeling requirements.[667] If a food has been genetically engineered but does not meet the threshold level of a bioengineered substance in the final product to be classified as a bioengineered food, that food will not be required to meet the GMO disclosure requirements under S. 764.[668] Thus, the individual who wishes to avoid any genetically modified food will not be aware that a food has been genetically modified and will unknowingly violate his or her beliefs by consuming it.[669]

As also previously discussed in Part II, there are many individuals who want to avoid certain GMOs due to religious beliefs, including those who keep Kosher diets.[670] An individual who is keeping a Kosher diet and wants to avoid a certain substance entirely would encounter the same dilemma as an individual who is ethically opposed to genetic modification of food.[671] The person keeping a Kosher diet would not be aware that a final food product contains a certain amount of that substance if it does not meet the threshold

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664. *See generally supra* Section II.A.9 (explaining how GMOs will come under labeling requirements based on a threshold level for bioengineered food).

665. *See generally supra* Section II.A.1 (highlighting some of these reasons under the Consumer Right to Know Policy).

666. *See generally supra* Section II.A.1 (listing this type of objection as one of the many justifications for GMO labeling under the Consumer Right to Know Policy).

667. *See generally supra* Section II.A.9 (explaining how foods become subject to the GMO labeling disclosure requirements under S. 764, which is based on whether a food meets the definition of "bioengineered food" under the law and not whether the food was genetically engineered).

668. *See generally supra* Section II.A.9 (stating that a food will only be required to contain a GMO disclosure if it meets the threshold level of bioengineered substances).

669. *See generally supra* Section II.A.1 (discussing the concerns of this type of individual under the Consumer Right to Know Policy).

670. *See generally supra* Section II.A.1 (highlighting the concerns of such individuals).

671. *See supra* notes 367-68 and accompanying text (explaining the problem faced by such an individual).

level.[672] This would cause such an individual to consume a substance that violates his or her beliefs and therefore increase consumer misinformation.[673] This is yet another way in which S. 764 fails to result in optimal GMO transparency and does not meet the high standards of the Consumer Right to Know Policy, which should serve as the basis for GMO labeling in the United States.[674]

4. S. 764 Fails to Achieve the Goals of the Consumer Right to Know Policy

While S. 764 has brought GMO labeling under a federal regime that avoids the patchwork system consisting of the state GMO labeling laws of Vermont, Connecticut, and Maine, it clearly fails to achieve the goals of the Consumer Right to Know Policy and contains many severe deficiencies that limit GMO transparency.[675] Instead of increasing consumer access to GMO information, S. 764 increases consumer confusion and misinformation by regulating GMO labeling based on a threshold system and barring descriptive GMO information on food labels.[676] Such a system presents an even more dangerous reality than the lack of labeling under the 1992 FDA Statement of Policy: misperception of GMO transparency.[677] This misperception could occur because consumers may believe they have more GMO information than they actually do.[678] As shown, S. 764 creates potential loopholes and exceptions that exclude certain foods that the public might otherwise consider genetically engineered from federal labeling requirements.[679] Thus, consumers may mistakenly believe that any food that does not bear a disclosure has not been

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672. *See generally supra* Section II.A.9 (demonstrating that even though a food has been genetically engineered, it will not be required to contain a disclosure if it does not meet the threshold level under S. 764).

673. *See generally supra* Section II.A.1 (explaining the concerns of individuals who keep a Kosher diet).

674. *See generally supra* Section II.A.1 (setting forth the goals of the Consumer Right to Know Policy regarding GMO transparency).

675. *See generally supra* Sections II.A.3-4, 6 (giving an overview of these state GMO labeling laws and their different requirements).

676. *See generally supra* Section II.A.9 (analyzing these aspects of S. 764).

677. *See generally supra* Section I.A.3 (detailing the 1992 FDA Statement of Policy).

678. *See generally supra* Section II.A.10 (discussing how S. 764 results in less GMO transparency than it projects to).

679. *See generally supra* Section II.A.10 (highlighting some of these loopholes).

genetically modified and unknowingly continue to purchase and consume it under this misperception.[680] Since GMO labeling measures should seek to avoid that very result, S. 764 is an inadequate solution to the GMO labeling debate in the United States and should be replaced with a federal law requiring GMO labeling based on the process used in food production instead of a threshold level of a bioengineered substance found in a final food product.[681] By implementing such a measure, the United States could achieve the same level of success that the European Union achieved with the *Traceability and Labeling Regulation* and meet the needs of US citizens who desire true GMO transparency under the Consumer Right to Know Policy.[682]

C. Furthering Progress in GMO Transparency

1. The Solution to the GMO Labeling Debate in the United States

As shown by the *Traceability and Labeling Regulation*, one of the main goals of EU GMO labeling regulation is to enable consumers to make an informed decision about the products they buy.[683] Thus, while the European Union does not have a statutory "Consumer Right to Know," it does acknowledge and uphold citizens' rights to make informed decisions by requiring food manufacturers to provide accurate and non-misleading information about the GMO status of their food.[684] This concern for consumer choice exists and thrives in a system that is based on independent risk assessment and traceability standards that stop risk at the source or along the supply chain.[685] This demonstrates that measures taken to protect consumers' ability to make informed choices do not oppose a

680. *See generally supra* Section II.A.9 (detailing the requirements of S. 764).

681. *See generally supra* Section II.A.1 (explaining GMO transparency through the lens of the Consumer Right to Know Policy).

682. *See generally supra* Parts I-II (explaining the desire of the American public for GMO transparency and how the European Union has achieved such transparency).

683. *See generally supra* Section II.B (highlighting this goal of the regulation).

684. *See generally supra* Section II.B.3 (describing how this right is recognized in the European Union).

685. *See generally supra* Section II.B.3 (detailing the traceability requirements and their justifications under the *Traceability and Labeling Regulation*).

system that is based on science and accurate current knowledge, and in fact can be a part of that same system.[686]

As opposed to the FDA's policy on GMOs, which is based on the belief that GMOs are GRAS and safe until proven otherwise, the European Union's regulatory system is based on the precautionary principle and presumes that GMOs are not safe until proven otherwise.[687] However, these two systems can have common ground in the Consumer Right to Know Policy because the European Union's *Traceability and Labeling Regulation* governs GMOs that have been approved through the regulatory system under the *Genetically Modified Food and Feed Regulation*.[688] Thus, any GMOs that are labeled under the *Traceability and Labeling Regulation* have already been deemed safe and not a significant risk under the *Genetically Modified Food and Feed Regulation* and the precautionary principle.[689] Through mandatory labeling, the European Union wants to ensure traceability in order to avoid future risk under the precautionary principle and to also allow consumers to make informed choices.[690] Once an approved GMO enters the EU marketplace, it is considered safe, and thus the European Union and the US FDA have a similar view of that product going forward.[691] However, the European Union still requires GMO labeling in order to ensure traceability and to allow consumers to make informed

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686. *See generally supra* Section I.B.1-3 (explaining how the EU GMO regulatory system encompasses both the precautionary principle and informed consumer choice).

687. *See generally* supra Section I.B.1-3 (explaining the precautionary principle and its function in EU GMO regulation).

688. *See generally supra* Sections I.B, II.B.8-9 (discussing the GMO scope authorization procedure and the tracing and labeling requirements that attach after such authorization is given of this regulation).

689. *See generally supra* Sections I.B, II.B.8-9 (discussing how only GMOs that have been approved under the *Genetically Modified Food and Feed Regulation* are put on the market and labeled under the *Traceability and Labeling Regulation*).

690. *See generally supra* Sections I.B, II.B.9-10 (detailing the goals of the EU regulatory system with respect to mandatory labeling).

691. *See generally supra* Sections I.B, II.B.10 (explaining the views of the United States and European Union of GMOs at each stage of approval).

decisions.[692] This is why the Consumer Right to Know Policy can be a valid basis for mandatory GMO labeling in the United States.[693]

While these two different regulatory systems do have common ground, there is an important distinction between the *Traceability and Labeling Regulation* and a US law based on the Consumer Right to Know Policy that should make a difference with respect to how GMO products are labeled in the United States.[694] While there is no indication of how the threshold level of 0.9% was determined in the *Traceability and Labeling Regulation*, it is clear from the EU system that GMO labeling is not required simply because a product was developed through genetic engineering.[695] Instead, there must be a certain amount of a GMO present in a product before it must be labeled.[696] This is to avoid requiring labels for products that have an unavoidable or undetectable amount of GMO matter.[697] Since the United States does not operate from a position resembling the precautionary principle, mandating GMO labeling based on a threshold under S. 764 does not result in the same high amount of GMO transparency as achieved by the *Traceability and Labeling Regulation*.[698]

While S. 764 and the *Traceability and Labeling Regulation* share many attributes, it is this difference in position that makes the latter a success and renders the former inadequate.[699] Because the *Traceability and Labeling Regulation* uses a threshold level in the context of the precautionary principle and an entire GMO regulatory

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692. *See generally supra* Sections I.B, II.B (discussing how GMOs that have been approved and deemed safe under the precautionary principle still must be labeled in the European Union).

693. *See generally supra* Section II.A.1 (explaining the basis for GMO labeling in the Consumer Right to Know Policy).

694. *See generally supra* Part I (describing and comparing the GMO regulatory systems of the United States and the European Union).

695. *See generally supra* Section II.B.3 (explaining this requirement under the *Traceability and Labeling Regulation*).

696. *See generally supra* Section II.B.3 (detailing this requirement within the threshold).

697. *See generally supra* Section II.B (discussing the justification for the threshold level).

698. *See generally supra* Part I (highlighting how the United States operates from the substantial equivalence doctrine, which greatly differs from the precautionary principle that serves as the basis of the EU GMO regulatory system).

699. *See generally supra* Part I (demonstrating this difference in position).

system based on independent investigation, the threshold level meets the public demand for GMO transparency and is an adequate remedy for public distrust of GMOs.[700] The use of a threshold amount in S. 764 in the United States fails to achieve the same level of success because it contrasts with the 1992 FDA Statement of Policy on GMOs and does not meet public demand, as it is not clear how this threshold level will be determined.[701] If the threshold level is established based on the effects on human health, then the GMO labeling requirements will stand in stark opposition to the FDA's presumption that GMOs are safe.[702]

Furthermore, a threshold level based on effects on human health will result in consumer misinformation.[703] Such a threshold level would significantly ignore the concerns of many individuals who wish to avoid certain GMOs or GMOs entirely because of their religious or ethical beliefs.[704] For example, an individual who ethically opposes genetic engineering will not be aware if all foods have been genetically engineered since a food will have to contain the threshold level of bioengineered substance that has an effect on human health in order to be subject to labeling requirements under S. 764.[705] As certain individuals want GMO transparency for reasons independent of the effects of GMOs on human health, this type of threshold could result in a narrow application that will deprive individuals from obtaining the information they need to live according to their beliefs.[706]

Determining the threshold using factors other than effects on human health might still lead to the same problem, since it is not clear

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700. *See generally supra* Section I.B.9 (explaining the threshold system in the shadow of the precautionary principle).

701. *See generally supra* Section I.A.3 (analyzing the 1992 FDA Statement of Policy and its emphasis on the substantial equivalence doctrine).

702. *See generally supra* Section I.A.3 (discussing the FDA's position that GMOs are substantially equivalent to their traditional counterparts).

703. *See infra* notes 704-06 (giving examples of these concerns).

704. *See generally supra* Section II.A.1 (explaining some of the concerns of such individuals and how they are protected by the Consumer Right to Know Policy).

705. *See generally supra* Section II.A.9 (describing how foods only must be labeled under S. 764 if they meet the threshold level of bioengineered substances).

706. *See generally supra* Section II.A.1 (detailing how many individuals desire GMO transparency for reasons that do not involve the effects of GMOs on human health).

what factors will be used and how they will be weighed.[707] Misinformation might still occur, as it is not guaranteed that such factors will adequately meet the concerns of US citizens who desire GMO labeling under the Consumer Right to Know Policy.[708] Factors that meet the concerns of those who desire GMO transparency for religious reasons might not be the same as those that meet the concerns of people who want it for ethical reasons.[709] Thus, choosing factors used to set a threshold might result in a disadvantage to certain groups who demand GMO transparency under the Consumer Right to Know Policy, as certain factors that meet the concerns of specific groups might be favored over others.[710]

It is because of these possible and significant complications that a threshold should not be used in mandating GMO labeling in the United States.[711] As shown by these possible consequences, a GMO labeling system based on such a threshold results in inadequate GMO transparency and frustrates the goals of the Consumer Right to Know Policy.[712] Such negative outcomes can be avoided by replacing S. 764 with a mandatory GMO labeling system based on the process used in food production, which will meet the concerns of various groups under the Consumer Right to Know Policy and result in far greater GMO transparency.[713]

2. Tailoring the Solution to US GMO Policy

While mandating GMO labeling under a universal standard like the *Traceability and Labeling Regulation* is the solution to the GMO labeling debate in the United States, it is not the complete answer to

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707. *See generally supra* Section II.A.9 (demonstrating how S. 764 directs the Secretary of Agriculture to set a threshold level for bioengineered foods).

708. *See generally supra* Section II.A.1 (analyzing many of the concerns of US citizens who demand GMO labeling under the Consumer Right to Know Policy).

709. *See generally supra* Section II.A.1 (setting forth some of the differing concerns that are at stake).

710. *See generally supra* Section II.A.1 (discussing some of these groups and their specific issues with respect to GMO consumption).

711. *See supra* notes 703-10 and accompanying text (explaining these complications).

712. *See generally supra* Section II.A.1 (setting forth some of these goals).

713. *See supra* notes 363-72 and accompanying text (discussing the concerns of different groups in society under the Consumer Right to Know Policy).

the problem.[714] As shown, mandating GMO labeling under a threshold system similar to that under the *Traceability and Labeling Regulation* limits the progress made by GMO labeling proponents and does not parallel the high success achieved under the *Traceability and Labeling Regulation* in the European Union.[715] After learning from the European Union's example and avoiding a GMO crisis by passing federal labeling requirements, the United States should now diverge from the model of the *Traceability and Labeling Regulation* and require GMO labeling for products based on the genetic engineering process used in food production, instead of basing the requirement on a threshold level of bioengineered substance in the final product.[716] This would prevent the FDA from having to change its 1992 Statement of Policy and would address the concerns of the US citizens under the Consumer Right to Know Policy.[717]

The federal law should also model the approach taken by Vermont, Connecticut, and Maine by requiring GMO information to be displayed directly on the food package or on a nearby display, depending on the type of food.[718] Specifically, any food subject to the regulation would be required to have the statement "produced with genetic engineering" printed on the label.[719] It is not clear whether the federal law should ban the use of "natural" or similar words that might mislead consumers, or if the law should define "natural," as this concerns many issues within the expertise of the FDA.[720]

Mandating GMO labeling through this type of federal law that is based on the process instead of a threshold amount would correct

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714. *See generally supra* Section II.B.9 (explaining the mandatory system under the *Traceability and Labeling Regulation*).

715. *See supra* notes 699-712 and accompanying text (explaining how a threshold system leads to these negative results).

716. *See generally supra* Section II.B (detailing the EU crisis and the European Union's response); *supra* Section III.A (describing how the United States successfully avoided such a crisis).

717. *See generally supra* Section I.A.7 (explaining the 1992 FDA Statement of Policy); *supra* Section II.A.8 (analyzing the Consumer Right to Know Policy).

718. *See generally supra* Sections II.A.3-4, 6 (detailing the packaging requirements under these state laws).

719. *See generally supra* Sections II.A.3-4, 6 (providing this language from the state laws of Connecticut, Maine, and Vermont).

720. *See generally supra* Section I.A.2 (giving an overview of the FDA's specific duties).

many of the significant deficiencies of S. 764.[721] Requiring "produced with genetic engineering" or similar language directly on a food label will eliminate much of the consumer confusion and misinformation that will result under the current disclosure requirements under S. 764, such as a telephone number or website information accompanied by the generic statement about "food information."[722] Consumers will be immediately notified that the food in their hands has been genetically engineered, thereby resulting in instantaneous GMO transparency.[723] Consumers will also be relieved of the burdens of S. 764, as they will not have to call a phone number or access a website to find out GMO information.[724] This also eradicates the disadvantage to financially disadvantaged and elderly consumers who may not be able to access GMO information under S. 764 because of limited access to phones or the internet.[725] By eliminating such burdens under S. 764, this federal law again will result in immediate GMO transparency and meet the demands of the Consumer Right to Know Policy.[726]

CONCLUSION

The parallels between the EU crisis in 1997 and the current debate in the United States are staggering.[727] As the public demand for GMO labeling was being met at the state level and essentially opposed at the federal level, a tricky battle between Congress and the individual states manifested.[728] In order to preserve order, maintain continuity, and to avoid many of the potential negative effects

721. *See supra* Sections II.A.9-10 (detailing these deficiencies).

722. *See supra* Section II.A.9 (explaining the current disclosure requirements under S. 764).

723. *See supra* notes 638-44 and accompanying text (demonstrating how a lack of language indicating GMO status directly on packages leads to consumer confusion and misinformation).

724. *See supra* Section II.A.9 (detailing these methods of accessing GMO information under S. 764).

725. *See supra* Section II.A.10 (discussing the specific challenges facing individuals in these groups in accessing GMO information under S. 764).

726. *See generally supra* Section II.A.1 (explaining the goals of the Consumer Right to Know Policy).

727. *See generally supra* Section II.A (detailing the GMO labeling dispute in the United States); *supra* Section II.B.1 (describing the 1997 EU crisis).

728. *See generally supra* Section II.A (analyzing this conflict).

discussed above, the US Congress followed the example of the European Union and enacted a federal GMO labeling law that bases GMO labeling on a threshold system with a focus on the end product.[729] While the United States successfully avoided a crisis that the European Union faced in 1997, it failed to parallel the successful example of the European Union when it enacted the *Traceability and Labeling Regulation* in response to public outcry.[730] By using a threshold system and thereby failing to mandate GMO labeling based on the genetic engineering process used in food production, the United States has provided a solution that restricts GMO transparency and does not address the concerns of its citizens under the Consumer Right to Know Policy.[731] The US Congress should correct these problems by replacing S. 764 with a federal law mandating GMO labeling based on genetic processes used in food production, as opposed to a threshold system.[732] In addition to complying with the 1992 FDA Statement of Policy, this solution will result in optimal GMO transparency and make GMO information accessible to all.[733]

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729. *See generally supra* Section III.A.1 (demonstrating how the United States avoided this crisis).

730. *See generally supra* Section II.B (discussing the success of the *Traceability and Labeling Regulation*).

731. *See generally supra* Section II.A.10 (explaining these critiques of S. 764).

732. *See generally supra* Section III.C (explaining this solution).

733. *See generally supra* Section III.C.1 (highlighting the benefits of mandating GMO labeling based on genetic processes used in food production); *supra* Section III.C.2 (discussing how the solution can be implemented in accordance with US GMO policy).