

# THE NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD: A SOLUTION TO THE GMO LABELING POLITICAL DEBATE?

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## I. INTRODUCTION

When you bite into roughly three out of four of your regular processed grocery store foods, not only are you biting in to salty, sugary, or crunchy goodness, you are also consuming genetically modified material.<sup>1</sup> Genetically modified organisms made their way into our agricultural market more than

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1. C. Eugene Emery Jr. & Mark Reynolds, *Sen. Donna Nesselbush: Three Quarters of Processed Foods Have Genetically Modified Organisms*, POLITIFACT (Mar. 22, 2015, 12:01 AM), <http://www.politifact.com/rhode-island/statements/2015/mar/22/donna-nesselbush/sen-donna-nesselbush-three-quarters-processed-food>.

thirty-five years ago.<sup>2</sup> As a result, food is produced more efficiently, sustainably, and can be sold at a lower price.<sup>3</sup> Genetically engineered, or “bioengineered,” crops allow farmers to grow more food on smaller plots of land, use fewer environmentally harmful pesticides, and allow crops to adapt to specific climates.<sup>4</sup> Yet, there are still as many pressing questions about GMOs as there are answers.<sup>5</sup>

Genetically modified organisms are made through the process of bioengineering.<sup>6</sup> “‘Bioengineering’ refers to a food—(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.”<sup>7</sup>

Concerns over the safety of GMO consumption has been a contentious issue since its inception.<sup>8</sup> Some consumers trust that GMOs are safe to consume, while others are skeptical.<sup>9</sup> The skeptics believe food that contains GMOs should be labeled so that they can make a conscious choice on whether to eat it.<sup>10</sup> So, the labeling requirements, or lack thereof, of foods produced with genetically modified organisms until recently was a political debate entrenched in state governments across the country.<sup>11</sup> The labeling issues were debated at the state level because the FDA Statement of Policy did not mandate the labeling of GMOs, so many state citizens took it upon themselves to draft ballot initiatives to attempt to label GMOs within their state.<sup>12</sup>

2. GL Woolsey, *GMO Timeline: A History of Genetically Modified Foods*, GREEN AM. (2012), <https://www.greenamerica.org/blog/gmo-timeline-history-genetically-modified-foods>.

3. Cass R. Sunstein, *On Mandatory Labeling, with Special Reference to Genetically Modified Foods*, U. PENN. L. REV. 1043, 1069 (Apr. 2017), [https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=9578&context=penn\\_law\\_review](https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=9578&context=penn_law_review).

4. *Id.*; David Rotman, *Why We Will Need Genetically Modified Foods*, MIT TECH. REV. (Dec. 17, 2013), <https://www.technologyreview.com/s/522596/why-we-will-need-genetically-modified-foods>; Mary Clare Jalonick, *Debate Over Genetically Modified Foods Continues Amid Confusion*, PBS NEWSHOUR (May 17, 2014, 11:16 AM), <http://www.pbs.org/newshour/rundown/national-debate-genetically-modified-foods-continues>.

5. See generally Editorial Board, *Some Answers and More Questions About GMOs*, CHI. TRIBUNE (May 20, 2016, 1:29 p.m.), <http://www.chicagotribune.com/news/opinion/editorials/ct-gmo-food-safety-study-edit-0523-md-20160520-story.html> (discussing the remaining questions concerning GMOs).

6. 7 U.S.C. § 1639 (2016).

7. *Id.*

8. Behrokh Mohajer Maghari & Ali M. Ardekani, *Genetically Modified Foods and Social Concerns*, AVICENNA J. MED. BIOTECHNOLOGY (July–Sept., 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3558185>.

9. Tamar Haspel, *Scientists Say GMO Foods Are Safe, Public Skepticism Remains*, NAT’L GEO. (May 17, 2016), <https://www.nationalgeographic.com/people-and-culture/food/the-plate/2016/05/17/scientists-say-gmo-foods-are-safe-public-skepticism-remains>.

10. See Sunstein, *supra* note 3, at 1076 (stating the public’s opinion that GM food is unsafe).

11. See Tennille Tracy, *GMO Labeling Faces Ballot Test in Oregon, Colorado*, WALL ST. J. (Nov. 2, 2014), <https://www.wsj.com/articles/gmo-labeling-faces-ballot-test-in-oregon-colorado-1414961328> (discussing GM food labeling debate).

12. See U.S. FOOD & DRUG ADMIN., STATEMENT OF POLICY—FOODS DERIVED FROM NEW PLANT VARIETIES (1992) [hereinafter STATEMENT OF POLICY] (available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>), (stating, “the agency does not believe that the method of development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labeling for the food.”).

Now, the federal government stepped in to institute a uniform, federally mandated labeling law, thereby preempting state GMO labeling laws.<sup>13</sup> The National Bioengineered Food Disclosure Standard, or 7 U.S.C. § 1639, “establish[es] a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered.”<sup>14</sup> The law, written and passed under the Obama Administration, creates a process for the Secretary of Agriculture to determine factors and conditions under which a food is to be considered “bioengineered,” and deliberately preempts any state law that attempts to label bioengineered foods.<sup>15</sup>

This Note analyzes the National Bioengineered Food Disclosure Standard (NBFDS) and highlights parts of the law that prevent it from being effective, useful, and clear to the consumer. Part II of this Note describes the political and social history of GMO policy and background on the NBFDS. Part II further describes the political divide between proponents and opponents of genetically modified foods, and the arguments for and against GMO labeling laws. It then provides background on previous efforts to pass GMO laws in different states, their successes and failures, and previous federal legislation that guided the topic area. Part III of this Note analyzes the provisions of the NBFDS and evaluates its effectiveness in providing a uniform GMO labeling law. In doing so, Part III argues that the exemptions and enforcement provisions of the law prevent it from being uniformly applied for all genetically modified foods. Lastly, Part IV extends final recommendations for how the USDA can best uniformly and effectively carry out a national genetically modified food labeling standard.

## II. BACKGROUND

The argument of whether to label genetically modified foods has been a social debate for decades.<sup>16</sup> This topic transformed into a political debate because the oversight and regulatory authority to produce and sell genetically modified foods is a decision left up to the federal government under the Food Drug and Cosmetic Act.<sup>17</sup> Thus, citizens who wanted labels on genetically modified foods looked to the government to act, and thus sparked a decades long political debate.<sup>18</sup>

Because GMOs are produced through genetic manipulation and are not an organic process of producing food, many consumers, scientists, and food experts are divided on its safety.<sup>19</sup> Many are skeptical of the technology and fear there are unknown future health effects of consuming GMOs,<sup>20</sup> while many scientific

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13. 7 U.S.C. § 1639i.

14. 7 U.S.C. § 1639b(a)(1).

15. 7 U.S.C. §§ 1639b(b)(2)(C); 1639(b)(e).

16. Ellen Egley, *The Great GMO Debate*, STEM JOBS (June 10, 2016), <https://stemjobs.com/great-debate-behind-gmos>.

17. 21 U.S.C. § 371(a) (2018).

18. A.S. Bawa & K.R. Anilakumar, *Genetically Modified Foods: Safety, Risks and Public Concerns—a Review*, J. FOOD SCI. TECH. (Dec. 12, 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3791249> (last visited Oct. 23, 2018).

19. 7 U.S.C. § 1639 (2018).

20. Bawa & Anilakumar, *supra* note 18.

studies find genetically modified foods as compositionally equivalent to their non-genetically modified counterparts.<sup>21</sup>

Ultimately, the federal government finds that GM foods are protected under a “presumption of safety,” and follows the substantial equivalence doctrine that states genetically modified products are safe due to the lack of differences between their physical composition and that of non-GM food.<sup>22</sup> This position differs from most other countries who follow the “precautionary principle,” which is a proposition that “precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”<sup>23</sup>

To start, this Section will address the perceived risks and benefits of genetically modified foods. It will then delve into the labeling debate that ignited due to public pleas for the “right to know” what’s inside grocery store food. This Section will further explain the regulatory history of genetically modified organisms in the United States, along with the regulatory labeling standards that were in place before the NBDfs. Last, this Section will explore the new approach taken by NBDfs and provide background on its relevant provisions.

#### A. *Genetically Modified Foods: The Perceived Benefits and Risks*

There are just as many arguments for why GMOs are beneficial to humans and the environment as there are arguments for why GMOs present risks.<sup>24</sup> One of the concerns raised by many opponents of GMOs is that GM foods are toxic to humans, such that they may induce allergic reactions.<sup>25</sup> Further, many share a concern that the genetic modification reduces the effectiveness of therapeutic antibiotics due to the antibiotic-resistant genes that are found in GM crops.<sup>26</sup>

On the other hand, there are many established benefits of GMOs, including their ability to increase crop yields.<sup>27</sup> Due to an increase in crop yields, the “agricultural footprint” needed to produce a certain amount of food is reduced,

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21. See Haspel, *supra* note 9 (considering GM food and its counterparts); Bryan Delaney, *Safety Assessment of Foods from Genetically Modified Crops in Countries with Developing Economies*, FOOD CHEMICAL TOXICOLOGY (Oct. 9, 2015), [https://ac.els-cdn.com/S0278691515300715/1-s2.0-S0278691515300715-main.pdf?\\_tid=b1893aa9-5362-474f-819b-a22ea0c0dff5&acdnat=1536429495\\_03c683bdc03f5827ece5b9bfa63b4261](https://ac.els-cdn.com/S0278691515300715/1-s2.0-S0278691515300715-main.pdf?_tid=b1893aa9-5362-474f-819b-a22ea0c0dff5&acdnat=1536429495_03c683bdc03f5827ece5b9bfa63b4261).

22. See Courtney Begley, “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?*, 40 FORDHAM INT’L L. J. 624, 633 (2017), <https://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=2474&context=ilj> (citing Rebecca M. Bratspies, *Is Anyone Regulating? The Curious State of GMO Governance in the United States*, 3 VT. L. REV. 923, 929–39 (2013)) (discussing the “presumption of safety”).

23. David Kriebel et al., *The Precautionary Principle in Environmental Science*, 109 ENV. HEALTH PERSPECTIVES 871, 871 (Sept. 2001), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1240435/pdf/ehp0109-000871.pdf>.

24. See Geoffrey Barrows et al., *Agricultural Biotechnology: The Promise and Prospective of Genetically Modified Crops*, J. ECON. PERSP. 99, 99–100 (2014) (noting some of the popular and consistent argument against GMOs).

25. *Id.* at 111.

26. *Id.*

27. *Id.* at 105.

which benefits the environment.<sup>28</sup> Further, proponents advance that GM crops are beneficial as they can adapt to certain climates and terrains.<sup>29</sup>

Along with the diverging sides of the “risks and benefits” argument, the public varies in their opinion on whether GMO’s are safe to consume.<sup>30</sup> A Pew Research study indicates that people with more knowledge about science in general are closely divided on the issue of genetically modified food safety, with 48% of the people surveyed believing eating GM foods is safe, and 47% believing it is unsafe.<sup>31</sup> As the survey reveals, Americans cannot agree on the science.<sup>32</sup>

### B. *Genetically Modified Foods: To Label or Not to Label?*

Just as the country is divided on the safety of consuming genetically engineered food, people are also divided on GMO labeling.<sup>33</sup> For example, the Pew Research survey mentioned above also surveyed respondents on the topic of how often they pay attention to GM labels (that some companies voluntarily place on food) when food shopping.<sup>34</sup> The results revealed that 25% of adults always look for such labels, 25% do it “sometimes,” 17% say “not too often,” and 31% reported that they never look for GM labeling.<sup>35</sup> This provides a snapshot of how relevant GMO labels are to the public when shopping.

However, just because a person finds that GMO’s are safe to consume, does not mean that person is automatically someone who is against a mandatory label.<sup>36</sup> Rather, the labeling debate stems from a distinct and complex argument, including but not limited to either 1) the desire to make an informed choice about what foods to purchase;<sup>37</sup> or 2) the desire to not want a GMO label due to the costs imposed on the manufacturer and the negative connotation placed on a food product that is proven to be safe by the government.<sup>38</sup>

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28. *Id.*

29. Mary Clare Jalonick, *Debate Over Genetically Modified Foods Continues Amid Confusion*, PBS NEWSHOUR (May 17, 2014, 11:16 AM), <http://www.pbs.org/newshour/rundown/national-debate-genetically-modified-foods-continues>.

30. See Barrows et al., *supra* note 24, at 111–13 (discussing human health impacts of genetically engineered crops).

31. Cary Funk & Lee Rainie, *Americans, Politics and Science Issues*, PEW RES. CTR., (2015), <http://www.pewinternet.org/2015/07/01/americans-politics-and-science-issues>.

32. See *id.* (noting the lack of consensus on the health effects of GMOs and the scientific community’s understanding of those effects, across the adult public of the United States).

33. *Id.* at 131.

34. *Id.*

35. *Id.*

36. See *Why We Support Mandatory National GMO Labeling*, CAMPBELL’S (Jan. 7, 2016), <https://www.campbellsoupcompany.com/newsroom/news/2016/01/07/labeling> (stating that even though Campbell’s supports the standardized GMO labeling law does not mean that they are disputing the science behind GMOs and their safety).

37. See Sunstein, *supra* note 3, at 1079 (arguing that without GMO labelling, the average consumer will not infer that their food has GMOs).

38. See *id.* at 1055 (suggesting that opposition to GMO labelling could be based on the fear that the label will send a signal to consumers that there is something wrong with GMOs).

C. *Genetically Modified Foods: Regulatory History in the United States*

Surprisingly, government regulation of GMOs in general is not a new concept.<sup>39</sup> The White House Office of Science and Technology started to regulate biotechnology through the issuance of the Coordinated Framework for Regulation of Biotechnology.<sup>40</sup> Instituted in 1986, the framework provides “the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products.”<sup>41</sup> The Coordinated Framework is based on the following principles:

- (1) existing law is adequate to address the regulatory needs of GM products, and
- (2) GM products inherently present no new risks beyond those of conventional analog organisms, otherwise known as the substantial equivalence doctrine. The substantial equivalence doctrine suggests that GM products are presumed safe in the absence of physical differences from the analogous components of the progenitor organisms.<sup>42</sup>

Following this framework, in 1992 the FDA announced a Statement of Policy which, up until recently, governed how GMOs were regulated by the federal government.<sup>43</sup> As established in the Statement of Policy, the FDA regulated the safety of genetically modified organisms under the Food Drug and Cosmetic Act (FDCA).<sup>44</sup> First, GMOs were regulated through the General Safety Clause, and second through the Food Additives Amendment.<sup>45</sup> The FDA in part considers a food to be “generally recognized as safe” (GRAS) if “common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food...is reasonable[] certain[] that the substance is not harmful under the conditions of its intended use.”<sup>46</sup>

The 1992 FDA Statement of Policy majorly reformed GMO regulation in the United States by lessening the burden on manufacturers to get genetically modified food products approved.<sup>47</sup> The FDA held producers responsible for

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39. See generally Begley, *supra* note 22, at 627–34 (providing an overview of regulatory approaches to GMOs).

40. OFFICE OF SCI. & TECH. POLICY, EXEC. OFFICE OF THE PRESIDENT, COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY (1986) [hereinafter FRAMEWORK FOR BIOTECH. REG.]; Begley, *supra* note 22, at 639.

41. FRAMEWORK FOR BIOTECH. REG., *supra* note 40.

42. 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) (internal quotation marks omitted).

43. STATEMENT OF POLICY, *supra* note 12; Begley, *supra* note 22, at 639.

44. Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-399h (2018).

45. Begley, *supra* note 22, at 640.

46. 21 C.F.R. § 170.30(a) (2016); 21 C.F.R. § 170.30(i) (2016).

47. See STATEMENT OF POLICY, *supra* note 12 (explaining that the FDA will focus on substances that are injurious to health, rather than GMOs as such); Begley, *supra* note 22, at 643 (noting that the 1992 FDA Statement of Policy changed the regulatory system in a manner that reduced the burden on manufacturers looking to sell GMO products).

ensuring the safety of food and that it met the FDCA safety requirements.<sup>48</sup> Thus, producers of GMO's under this 1992 statement were protected by a presumption of safety and were not subject to FDA independent research.<sup>49</sup> Producers were only regulated based on information that was voluntarily provided to the FDA.<sup>50</sup>

From 1992 until 2016, the FDA Statement of Policy governed the way GMO products were labeled.<sup>51</sup> The FDA found that developing new plant varieties, including using recombinant DNA techniques, is not usually a disclosure required for labeling food under the FDCA.<sup>52</sup> In short, the federal government did not require a GMO food label for twenty-four years.<sup>53</sup>

In lieu of a federal labeling requirement, previous efforts to put GMO labeling laws on the ballots existed in many states, and a labeling law was fully passed in Vermont.<sup>54</sup> However, fears existed that individual state labeling requirements would interfere with interstate commerce by violating the dormant commerce clause.<sup>55</sup> This is because a state labeling mandate allows the state to regulate out-of-state food manufacturers engaged in interstate commerce.<sup>56</sup> In addition, it creates a burden on interstate commerce by increasing the costs of labeling genetically modified foods that are shipped into the state of Vermont for sale.<sup>57</sup> Recognizing these challenges and others, the federal government stepped in to institute a national labeling standard.<sup>58</sup>

#### D. *Genetically Modified Foods: The New Regulatory Labeling Standard*

Due to the confusion and risks of allowing individual states to label GMOs, the House of Representatives passed a bill titled, "Safe and Accurate Food

48. See STATEMENT OF POLICY, *supra* note 12 (stating "producers remain legally responsible for satisfying section 402(a)(1) of the act, and they will continue to be held accountable by FDA through application of the agency's enforcement powers").

49. See STATEMENT OF POLICY, *supra* note 12 ("[u]ltimately, it is the food producer who is responsible for assuring safety."); Begley, *supra* note 22, at 644 (citing Rebecca M. Bratspies, *Is Anyone Regulating? The Curious State of GMO Governance in the United States*, 37 VT. L. REV. 923, 938 (2013)).

50. Begley, *supra* note 22, at 644.

51. STATEMENT OF POLICY, *supra* note 12; Begley, *supra* note 22, at 645.

52. STATEMENT OF POLICY, *supra* note 12; Begley, *supra* note 22, at 647.

53. Compare 7 U.S.C. § 1639 and STATEMENT OF POLICY, *supra* note 12 (demonstrating the disparity between the FDA's recognition of GMOs in 1992 and the passage of the National Bioengineered Food Disclosure Standard in 2016), and Begley, *supra* note 22, at 647 (stating that the 1992 FDA statement is the reason the United States did not require labeling of GMO products until 2016).

54. See Howard Weiss-Tisman, *USDA Publishes New GMO Label Rules Ahead of July 29 Deadline*, VPR NEWS (May 4, 2018), <http://digital.vpr.net/post/usda-publishes-new-gmo-label-rules-ahead-july-29-deadline#stream/0> (stating "Congress passed the National Bioengineered Food Disclosure Standard in 2016, just a few weeks after Vermont's law went into effect, and the federal law preempted the state's first-in-the-nation GMO label law."); see also Alexandra Sifferlin, *California Fails to Pass Genetically Modified Foods Labeling Initiative*, CNN (Nov. 8, 2012, 7:13 AM), <https://www.cnn.com/2012/11/08/health/california-gm-foods/index> (discussing California's effort to pass a GMO labeling law).

55. U.S. CONST. art. I, § 8; *Key Vote: "No" on Mandatory GMO Labeling Act*, HERITAGE ACTION FOR AM. (July 6, 2016), <https://heritageaction.com/key-vote/key-vote-alert-no-mandatory-gmo-labeling-act>.

56. Niraj Chokshi, *Vermont Just Passed the Nation's First GMO Food Labeling Law. Now it Prepares to Get Sued*, WASH. POST (May 9, 2014), [https://www.washingtonpost.com/blogs/govbeat/wp/2014/04/29/how-vermont-plans-to-defend-the-nations-first-gmo-law/?utm\\_term=.59e0ee8a4834](https://www.washingtonpost.com/blogs/govbeat/wp/2014/04/29/how-vermont-plans-to-defend-the-nations-first-gmo-law/?utm_term=.59e0ee8a4834).

57. *Id.*

58. 7 U.S.C. § 1639b (2018).

Labeling Act of 2015” (H.R. 1599).<sup>59</sup> The government aimed to create a law that would make GMO labeling uniform across the country.<sup>60</sup> H.R. 1599 “established a voluntary non-genetically engineered food certification program within USDA to govern the labeling of such food in a nationally uniform manner.”<sup>61</sup>

However, President Obama did not include H.R. 1599 in the spending bill at the end of 2015.<sup>62</sup> Instead, later in July of 2016, the Senate passed an amendment to H.R. 1599, designated as S. 764, and later 7 U.S.C. § 1639, or the NBFDS.<sup>63</sup> In contrast to the House-passed bill, the NBFDS establishes a mandatory labeling requirement.<sup>64</sup> This standard is to be implemented no later than two years after the date of its enactment.<sup>65</sup> It provides a process for the Secretary of Agriculture to determine what foods are considered “bioengineered,” and preempts state GMO labeling laws.<sup>66</sup>

### *E. Genetically Modified Foods: The NBFDS’s Route to Labeling*

The NBFDS proposes a new method of food labeling: an electronic disclosure.<sup>67</sup> The NBFDS “requires food manufacturers to disclose the presence of bioengineered foods using text, a symbol, or electronic or digital link (excluding Internet website links); with the disclosure option to be selected by the food manufacturer.”<sup>68</sup> Written text or a symbol on the packaging is a traditional and clear way of labeling a food product. A digital disclosure to reveal information, however, is a new concept.<sup>69</sup>

A digital link used as a label can be a QR Code.<sup>70</sup> A QR Code requires the consumer to use a smartphone, with appropriate software installed, to read a two-dimensional barcode.<sup>71</sup> “QR Codes may be used to display text to the user,

59. *Senate Amendment to S. 764—An Act to Reauthorize and Amend the National Sea Grant College Program Act, and for Other Purposes. [GMO Labeling Requirements]*, HOUSE REPUBLICANS (July 14, 2016) [hereinafter *Senate Amendment 764*], <https://www.gop.gov/bill/senate-amendment-s-764-act-reauthorize-amend-national-sea-grant-college-program-act-purposes-gmo-labeling-requirements>; Begley, *supra* note 22, at 703.

60. *Senate Amendment 764*, *supra* note 59.

61. *Id.*

62. Guest Contributor, *Congress Keeps Anti-GMO Labeling Rider Out of Spending Bill*, ECOWATCH (Dec. 16, 2015, 10:59 AM), <https://www.ecowatch.com/congress-keeps-anti-gmo-labeling-rider-out-of-spending-bill-1882130060.html>.

63. 7 U.S.C. § 1639b(a)(1).

64. *Senate Amendment 764*, *supra* note 59.

65. 7 U.S.C. § 1639b(a)(1).

66. 7 U.S.C. § 1639b(e).

67. 7 U.S.C. § 1639b(d)(2).

68. *Senate Amendment 764*, *supra* note 59.

69. See Sharon Anglin Treat, *QR Codes and GMOs: The Proposed Food Labeling Rule*, INST. FOR AGRIC. & TRADE POL’Y (July 10, 2018), <https://www.iatp.org/blog/qr-codes-gmos> (discussing the new proposal to use a digital link rather than clear on-label GMO information).

70. See Treat, *supra* note 69 (discussing the use of QR codes to provide information on products); see also Danica Lo, *New GMO Labeling Law Hides Information Behind QR Codes, Critics Charge*, FOOD & WINE (Aug. 2, 2016), <http://www.foodandwine.com/blogs/how-new-gmo-labeling-law-will-affect-your-shopping-experience> (explaining the law requires a “link disclosure” such as QR Code).

71. *What is a QR Code?*, QR CODE GENERATOR, <https://www.the-qr-code-generator.com/whats-a-qr-code> (last visited Oct. 23, 2018).

to open a URL, save a contact to the address book or to compose text messages.”<sup>72</sup>

Section 1639b(c)(1) provides that one year after the law is enacted, the USDA must conduct a study to understand potential challenges that may impact whether consumers have access to the bioengineering disclosure on a food product through electronic or digital disclosure methods.<sup>73</sup> In addition, section 1639b(c)(2) puts forth that under this study, the Secretary of Agriculture will solicit and consider comments from the public.<sup>74</sup>

Further, when promulgating regulations, the USDA has the authority to put forth other disclosure options it finds appropriate.<sup>75</sup> In section 1639b(c)(4), the NBFDS states:

If the Secretary determines in the study conducted under paragraph (1) that consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods, the Secretary, after consultation with food retailers and manufacturers, shall provide additional and comparable options to access the bioengineering disclosure.<sup>76</sup>

Thus, the Secretary of Agriculture has the discretion to require other options besides an electronic disclosure on a genetically modified product if consumers do not appear to have sufficient access to the GMO disclosures through the electronic or digital methods.<sup>77</sup>

Further, section 1639b(G) excludes from the labeling requirement, “(i) food served in a restaurant or similar retail food establishment; and (ii) very small food manufacturers.”<sup>78</sup> The NBFDS’s guide to labeling thus lays out a foundation that appears to contain many exemptions that may undermine its effectiveness and purpose.<sup>79</sup>

### III. ANALYSIS

The National Bioengineered Food Disclosure Standard attempts to put forth a uniform solution to labeling genetically modified foods.<sup>80</sup> A purpose of this law is to preempt individual state labeling of GMO’s.<sup>81</sup> It further seeks to impose a national, uniform standard for consumers.<sup>82</sup> However, as this Part will

72. *Id.*

73. 7 U.S.C. § 1639b(c)(1) (2018).

74. 7 U.S.C. § 1639b(c)(2) (2018).

75. 7 U.S.C. § 1639b(c)(4) (2018).

76. *Id.*

77. *Id.*

78. *Id.*; 7 U.S.C. § 16309b(b)(G)(i)–(ii) (2018).

79. 7 U.S.C. § 1609b; National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 19,860 (May 4, 2018) (to be codified at 7 C.F.R. pt. 66).

80. *See* National Bioengineered Food Disclosure Standard, 83 F.R. 19860, 19860–61 [hereinafter 2018 Disclosure Standard] (describing the purpose of the NBFDS to provide uniform information to consumers).

81. *Id.*; Ex Parte Meeting Notes from Discussion between Ambassador Hidenori Murakami, Executive Vice President of the Japan Food Industry Association and USDA (07/30/2018).

82. 2018 Disclosure Standard, *supra* note 80, at 19861.

argue, Congress's goal of uniformly label genetically modified foods is undermined by many provisions of the law.

The USDA was provided the authority to have a notice and comment period because this law was passed through Congress and delegated to the USDA.<sup>83</sup> The USDA Agricultural Marketing Service had two years, from the time the NBFDS was enacted on July 29, 2016, to establish a national standard and procedures for implementation.<sup>84</sup> First, the Agricultural Marketing Service prepared thirty questions to be considered by stakeholders, and the USDA used the input from these questions when it drafted the proposed rule.<sup>85</sup> The input period closed in late August, 2017.<sup>86</sup> After the rule was proposed, there was an open comment period during the rulemaking process that closed July 3, 2018.<sup>87</sup> These comments are currently under review at the time this Note was published, and thus this Note looks to the proposed rule rather than the final rule.

Under the NBFDS, Congress provides the USDA with significant discretion to modify certain provisions of the law when promulgating the accompanying regulations.<sup>88</sup> However, as it stands now, the rule does not provide other effective disclosure options and fails to beneficially expand the definitions that the agency was provided discretion to do.<sup>89</sup> When the final rule is implemented, it will be significantly undermined by the exemptions and enforcement provisions that the USDA could have mended.<sup>90</sup> Thus, the NBFDS's proposed rule causes more confusion than clarity and does little to improve GMO labeling uniformity.

#### A. *The Electronic Disclosure Method*

First, the law states that the GMO label does not need to be a traditional food label, and that industry can simply place a digital link to the product.<sup>91</sup> Since food products are not traditionally labeled this way, Congress mandated a study to identify the challenges of having consumers access GMO information through an electronic or digital disclosure.<sup>92</sup>

The study identified several challenges some consumers face when accessing electronic or digital methods of bioengineering disclosure

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83. 7 U.S.C. § 1639b(c)(2) (2018).

84. *Proposed Rule Questions Under Consideration*, U.S. DEP'T OF AGRIC., <https://www.ams.usda.gov/rules-regulations/gmo-questions> (last visited Oct. 23, 2018).

85. *Id.*

86. *Id.*

87. 2018 Disclosure Standard, *supra* note 80, at 19860.

88. *Id.*

89. *See id.* at 19860–61 (describing how the AMS will consult with the USDA to formulate definitions and procedures).

90. *See id.* (describing the two express exemptions to the disclosure requirements).

91. Chris Morran, *President Signs Law That Overturns Vermont GMO Labeling Rules, Replaces Them With Barcodes*, CONSUMERIST (July 29, 2016, 4:52 PM), <https://consumerist.com/2016/07/29/president-signs-law-that-outlaws-vermont-gmo-labeling-rules-replaces-them-with-barcodes>.

92. Deloitte, *Study of Electronic or Digital Link Disclosure: A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure*, U.S. DEPT. OF AGRIC. (July 2017) [hereinafter *Deloitte Study*], <https://www.ams.usda.gov/sites/default/files/media/USDADeloitteStudyofElectronicorDigitalDisclosure20170801.pdf>.

information, including, “difficulties recognizing the link, accessing it through use of tools, scanning the link appropriately, and loading the webpage to view information, among others.”<sup>93</sup> Further, the study found that since digital links are not typically associated with attaining food information, consumers often assume those links are for marketing and industry use.<sup>94</sup>

Additionally, this study found that many of the smartphone scanning applications contain advertisements, which goes against the way in which the NBFDS is supposed to be implemented, and further confuses the consumer.<sup>95</sup> Last, the study also found that while 97% of regional chain grocery stores and 100% of national chain stores provide a Wi-Fi network in the store, only 37% of smaller grocery stores provide Wi-Fi to customers.<sup>96</sup> So, according to this study, if QR codes were used in lieu of a traditional food label, those QR codes may not be accessible in smaller retail stores.<sup>97</sup>

The “Key Takeaways” of the study were the technological challenges in using electronic or digital links.<sup>98</sup> These challenges included the lack of association with digital links and food information, lack of access to capable equipment to scan the links, lack of guidance on which application to use when scanning, and lack of broadband connectivity to access smartphone applications.<sup>99</sup> As stated above, section 1639b(c)(4) provides that if the Secretary of Agriculture determines through the study that consumers would lack sufficient access to the bioengineering disclosure, the USDA, “after consultation with food retailers and manufacturers, shall provide additional and comparable options to access the bioengineering disclosure.”<sup>100</sup>

Although the study is still under review by the USDA and there has been no final determination yet,<sup>101</sup> it is likely the Secretary will find consumers lack sufficient access, because as of January, 2018, only 77% of Americans own a smartphone.<sup>102</sup> Further, only 42% of people 65 years and older own a smartphone, and only 64% of low-income households own a smartphone.<sup>103</sup> As a result, the digital disclosure method is inevitably going to present technological challenges because there is a large portion of the population that does not own a device that reads QR codes.<sup>104</sup>

As a proactive measure, the Agricultural Marketing Service (AMS) in the proposed rule states that if the Secretary determines that consumers would not have sufficient access to bioengineering disclosures through electronic or digital disclosure, the additional proposed option would be a text message.<sup>105</sup> The

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93. *Id.* at 35.

94. *Id.* at 40.

95. *Id.* at 41.

96. *Id.* at 11.

97. *Id.* at 26.

98. *Id.* at 11.

99. *Id.*

100. 7 U.S.C. § 1639b(c)(4) (2018).

101. 2018 Disclosure Standard, *supra* note 80, at 19875.

102. Deloitte Study, *supra* note 92, at 17.

103. *Id.*

104. *Id.*

105. 2018 Disclosure Standard, *supra* note 80, at 19876.

proposed rule states, “[t]his text message option would operate similarly to the electronic or digital disclosure under proposed § 66.106, but it would not rely on broadband access and would not require consumers to have smart phones in order to access the disclosure.”<sup>106</sup> This additional proposed option is similar to the option in § 1639b(d)(4) to include a telephone number to access further bioengineering information with the digital disclosure.<sup>107</sup> Just as the phone number is required to accompany the statement, “Call for more food information,” the proposed text message addition will also state, “text [number] for more food information.”<sup>108</sup>

Although this appears to be more straightforward than having to use a smartphone to scan a QR Code, it still presents a physical barrier between viewing a product and receiving food information. The study revealed that disclosing bioengineered information as a food label “relates directly to consumers’ desire for greater transparency.”<sup>109</sup> A phone number to send a text message is not transparent, as there is no explicit bioengineering text or “BE” label on the packaging, which is required under the two other text or symbol labeling options.<sup>110</sup> The text message would not contribute to the solution of potential confusion with electronic disclosures, as the consumer would still have to use his or her cell phone to access the information. Last, a text message is not a sufficient “additional and comparable” option.<sup>111</sup> It is in fact nearly the identical option to what section 1639b(d)(4) already mandates as an option, which is a telephone number that provides access to the GMO food disclosure.<sup>112</sup>

Forcing food manufacturers to disclose, through a label, products that are bioengineered, but then allowing the manufacturer to disclose this information through a QR Code or through contacting a phone number, does not appear to be accessible for all people.<sup>113</sup> This is in part because the United States does not traditionally label food products with QR Codes or electronic links.<sup>114</sup> It is also due to the option of otherwise labeling food that is bioengineered with a traditional “BE” label in the form of a symbol or written text.<sup>115</sup>

Allowing food manufactures to forego the traditional “BE” label and choose the third option provided in the NBFDS, the electronic disclosure option, the manufacturer can impose a QR code or telephone number on its packaging,

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106. *Id.*

107. 7 U.S.C. § 1639b(d)(4) (2018).

108. 2018 Disclosure Standards, *supra* note 80, at 19875.

109. Deloitte Study, *supra* note 92, at 12.

110. 7 U.S.C. § 1639b(c)(4) (2018).

111. *Id.*

112. 7 U.S.C. § 1639b(d)(4) (2018).

113. See Ernie Smith, *GMO Labeling Bill Becomes Law, Remains Contentious*, ASS’N NOW (Aug. 1, 2016), <https://associationsnow.com/2016/08/gmo-labeling-bill-becomes-law-remains-contentious> (presenting an argument by Patty Lovera, assistant director of Food and Water Watch stating “[t]he requirement of how to disclose GMOs gives companies an option of putting words on the package, which we know that they don’t want to do, or using things like a QR code, which we think is not acceptable, because lots of folks can’t access that technology”).

114. See U.S. FOOD & DRUG ADMIN., HOW TO UNDERSTAND AND USE THE NUTRITION FACTS LABEL (Jan. 3, 2018), (available at <https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm>) (providing information on the nutritional facts label attached to food packages).

115. 7 U.S.C. § 1639b(c)(4) (2018).

rather than a “BE” label that automatically informs consumers that the product was bioengineered.<sup>116</sup> It provides the food manufacturer the benefit of “disguising” its bioengineering label in the form of a code or number.<sup>117</sup> It “disguises” the information because consumers who are looking to avoid purchasing products that contain GMOs, and are unfamiliar with the electronic/digital disclosure provision of this law, will likely not know this product contains GMOs just by looking at the product packaging.

There needs to be an “additional and comparable” option to accompany the electronic disclosure that would prevent further lack of access to information, and not contribute to it like the phone number to receive a text message would.<sup>118</sup> The additional step to identify if the product is bioengineered would not be resolved, and is likely a contributing factor as to why the Secretary may identify that consumers would not have sufficient access to bioengineering disclosures through electronic or digital disclosure. The extra step causes confusion, inconsistencies, and is burdensome.

The purpose of this new law is to inform consumers on foods that are bioengineered.<sup>119</sup> By implementing disclosure methods where consumers must go out of their way to receive information on whether a food product contains ingredients that were produced through bioengineering undermines the intent of the law to institute a uniform labeling standard. The USDA has the legal authority to make the law more uniform and effective by including “additional and comparable” options for the electronic disclosure method, but are choosing instead to settle for a text message as an additional measure to receive the ‘BE’ information.<sup>120</sup> This text message option is not providing a solution to the underlying issues of requiring an extra step and using technology to find out food information.<sup>121</sup>

When examining a food product at the grocery store to see how many calories are in a serving, consumers are not asked to “scan here” or “call for more information” to find out, they are simply provided the caloric number in large print on the nutrition label.<sup>122</sup> Consumers value transparency in their food

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116. Sharon Anglin Treat, *QR Codes and GMOs: The Proposed Food Labeling Rule*, INST. FOR AGRIC. & TRADE POL’Y (July 10, 2018), <https://www.iatp.org/blog/qr-codes-gmos>.

117. 2018 Disclosure Standards, *supra* note 80, at 19875–76; *see* Anglin Treat, *supra* note 116 (stating “[t]he proposal fails to provide real-time information that shoppers can use to compare products, and it allows manufacturers to use discriminatory electronic disclosure methods such as QR codes”).

118. 7 U.S.C. § 1639b(c)(4).

119. *See* Greg Jaffe, *The ABCs of GMO Disclosure in the United States*, CTR. FOR SCI. IN PUB. INT. (Sept. 25, 2017), <https://cspinet.org/news/abcs-gmo-disclosure-united-states-20170925> (explaining “[t]he goal of the Disclosure Law is to provide a nationwide standard for food producers to inform customers about the foods and ingredients that come from GE crops.”).

120. 7 U.S.C. § 1639b(c)(4) (2018); National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 19875 (proposed May 4, 2018) (to be codified 7 C.F.R. pt. 66).

121. 2018 Disclosure Standards, *supra* note 80, at 19875.

122. *How to Understand and Use the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN. <https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm> (last modified Jan. 3, 2018).

products and consider a lot of information about a certain product before purchasing.<sup>123</sup>

More than a third of the respondents in a study titled “The 2016 Label Insight Food Revolution Study,” put forth they did not purchase a food product because they were not able to comprehend specific food ingredients.<sup>124</sup> Further, according to that study, 18% of the consumer participants shop specifically for a non-GMO diet, which is higher than the 14% who indicated they shop for a gluten-free diet.<sup>125</sup> Thus, since “product transparency influences purchasing decisions,” a newly implemented GMO labeling law should promote outward transparency through a clear identifiable label, and not force consumers to take extra steps to receive information.<sup>126</sup>

When implementing the electronic disclosure method, companies are provided three options to disclose if their products contained GMO’s, including an on-package text, symbol, or an electronic disclosure that is printed on the package that directs consumers to further information.<sup>127</sup> These are three very different disclosure options, which are all acceptable under this new law.<sup>128</sup> Thus, Congress contradicts itself through this piece of legislation because it provides for a uniform disclosure method, yet delegates authority to the Secretary of Agriculture to implement three different disclosure options.<sup>129</sup> Instead, perhaps Congress should have delegated the authority to the Secretary of Agriculture to institute one disclosure method option, rather than providing the Secretary with a choice among three.<sup>130</sup> One mandated disclosure method would have contributed to a more consistent interpretation of the law.<sup>131</sup>

In any event, the USDA still can build on the third option, the electronic disclosure method, if the Secretary finds that consumers are lacking access to GMO information through this method.<sup>132</sup> However, adding a text message option as the solution for a lack of access dilemma does not appear to solve the disconnect that exists when using technology to receive food information.

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123. HOW CONSUMER DEMAND FOR TRANSPARENCY IS SHAPING THE FOOD INDUSTRY 2, LABEL INSIGHT [https://www.labelinsight.com/hubfs/Label\\_Insight-Food-Revolution-Study.pdf?hsCtaTracking=fc71fa82-7e0b-4b05-b2b4-de1ade992d33%7C95a8bffc-d0cc-4b8b-8102-529d937eb427](https://www.labelinsight.com/hubfs/Label_Insight-Food-Revolution-Study.pdf?hsCtaTracking=fc71fa82-7e0b-4b05-b2b4-de1ade992d33%7C95a8bffc-d0cc-4b8b-8102-529d937eb427) (last visited Oct. 23, 2018).

124. *Id.* at 9.

125. *Id.* at 8.

126. *Id.* at 3.

127. *GMO Labeling Law Update: USDA Releases Study Exploring Potential Challenges of Using Electronic and Digital Disclosures on Food Labels*, DAILY INTAKE (Sept. 11, 2017), <https://www.dailyintakeblog.com/2017/09/gmo-labeling-law-update-usda-releases-study-exploring-potential-challenges-of-using-electronic-and-digital-disclosures-on-food-labels>.

128. 7 U.S.C. § 1639b(d) (2018).

129. 7 U.S.C. § 1639b(b)(1) (2018).

130. 7 U.S.C. § 1639b(b)(2)(D) (2018).

131. See Deloitte Study, *supra* note 92, at 37 (discussing some challenges consumers face when accessing information).

132. 7 U.S.C. § 1639b(c)(4) (2018).

*B. The Exemptions that Prevent Transparency:*

The NBFDS contains several exemptions and, as a result, only requires disclosure of GMOs in *certain* foods.<sup>133</sup> To start, the NBFDS provides the Secretary the authority to “determine the amounts of bioengineered substance that may be present in food . . . in order for the food to be a bioengineered food.”<sup>134</sup> In the proposed rule, the USDA puts forth that GM foods below an established threshold level are exempt from disclosure, and proposes three separate threshold standards.<sup>135</sup> AMS proposed and sought comment on three separate threshold standards for an entity to apply to a product to show it is not subject to the bioengineering disclosure.<sup>136</sup> The alternative threshold options that AMS proposes in the rule include:

Alternative 1-A: “ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than five percent (5%) of the specific ingredient by weight, would not be subject to disclosure as a result of that one ingredient.”

Alternative 1-B: food that has an ingredient that contains a BE substance “that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (.9%) of the specific ingredient by weight, would not be subject to disclosure as a result of that one ingredient.”

Alternative 1-C: “allow regulated entities to use a small amount of BE ingredients up to a certain threshold, such as 5% of the total weight of the product, before being required to label a product with a BE disclosure.”<sup>137</sup>

Since the NBFDS charged the USDA with establishing the threshold levels, the USDA has the opportunity to promulgate fair and transparent threshold levels.<sup>138</sup> The proposed rule itself even states that AMS “seeks to minimize costs and impacts on the domestic and international value chain while providing practicality and consistency for regulated entities and consumers regarding implementation.”<sup>139</sup> However, the only proposed threshold option that succeeds in this mission is Alternative 1-B.<sup>140</sup> The other two threshold proposals seem to focus more on the concerns of the regulated entities rather than balancing the concerns and compromising between what would be best for regulated entities *and* consumers.<sup>141</sup>

Second, the law states that “food served in . . . restaurant[s] or similar retail food establishment[s]” are exempted from the NBFDS.<sup>142</sup> The USDA proposes to define “similar retail food establishment” as:

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133. 7 U.S.C. § 1639b(b)(2)(G) (2018).

134. 7 U.S.C. § 1639b(b)(2)(B) (2018).

135. 2018 Disclosure Standard, *supra* note 80, at 19868–69.

136. *Id.*

137. *Id.*

138. 7 U.S.C. § 1639b(b)(2)(B) (2018); 2018 Disclosure Standard, *supra* note 80, at 19868.

139. 2018 Disclosure Standard, *supra* note 80, at 19861.

140. *Id.* at 19868–69.

141. *Id.*

142. 7 U.S.C. § 1639b(b)(2)(G)(i) (2018).

a cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within the retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.<sup>143</sup>

Thus, the law itself excludes restaurants and "similar retail establishments" to restaurants from a "BE" labeling requirement.<sup>144</sup> The fact that "similar retail establishments" also encompass food stands, saloons, taverns, bars, or lounges is logical, because those places function as restaurants to the average person.<sup>145</sup> However, the USDA stated that "the NBFDS is not a food safety rule, but a marketing rule, and costs on the supply-chain must be balanced with consumers right-to-know."<sup>146</sup> Since these costs must be balanced with a "consumers right-to-know," the USDA should not include "a cafeteria or lunch room" as a "similar retail establishment" to a restaurant. This is because cafeterias and lunch rooms may sell commercial products in their original packaging, and do not typically function as traditional restaurants.<sup>147</sup> Thus, this creates not only more confusion for the consumer, but also for the product manufacturer.

The USDA has the discretion to define what "similar retail establishments" are.<sup>148</sup> Excluding cafeterias and lunch rooms undermines the purpose of the law, which is to provide consumers with uniform access to bioengineering information on foods they purchase.<sup>149</sup> If a consumer purchases the same product in a cafeteria that he or she does in a grocery store, that product essentially is subject to different labeling requirements depending on the location the consumer purchased it.<sup>150</sup>

Third, the NBFDS exempts "very small food manufacturers" from displaying a bioengineered disclosure.<sup>151</sup> The USDA is charged with defining "very small food manufacturer," and proposes the definition of "any food manufacturer with annual receipts of less than \$2,500,000."<sup>152</sup> The USDA further sought comment on both alternative revenue cutoffs of \$500,000 and \$5,000,000, but a final version of the rule has not been released yet as of the date

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143. 2018 Disclosure Standard, *supra* note 80, at 19885.

144. *Id.*

145. These function as "restaurants" because the food is typically prepared in a kitchen and then served to customers outside of packaging, where a cafeteria or lunch room does not necessarily cook all the food that it sells. On the contrary, many cafeterias and lunch rooms in the school or work setting sell pre-packaged food that one could also find in a grocery store.

146. Ex Parte Meeting Notes from Discussion between Ambassador Hidenori Murakami, Executive Vice President of the Japan Food Industry Association and USDA (07/30/2018).

147. See *Self-Checkout Corporate Cafeterias: Micro Markets that Offer Employees Fresh Food 24x7*, CAFÉ SERV., <https://www.corporatediningservices.com/cafeteria-management/micro-market-self-checkout-cafeteria.htm> (last visited Oct. 23, 2018) (noting that the store prints out its own labels for its grocery packages).

148. 7 U.S.C. § 1639b(b)(2)(G)(i).

149. See 2018 Disclosure Standard, *supra* note 80, at 19860 (stating that "AMS was mindful that the purpose of the NBFDS is to provide a mandatory uniform disclosure standard for BE food to provide uniform information to consumers.").

150. See *id.* at 19885 (including cafeterias and lunch rooms as "similar retail establishments.").

151. 7 U.S.C. § 1639b(b)(2)(G)(ii).

152. 2018 Disclosure Standard, *supra* note 80, at 19885.

of this Note.<sup>153</sup> The USDA evaluated the impact of this definition for manufacturers and consumers:

The number of products gives us a sense of how much the costs of the rule would likely be reduced by an exemption at a given level (as well as the number of products that will not provide consumers with the additional bioengineering information). The proportion of sales gives us insight into how likely it is for a consumer to encounter an unlabeled product (that may otherwise require disclosure) in the marketplace.<sup>154</sup>

Under the proposed definition, where food manufacturers with annual receipts of less than \$2.5 million, 74% of food manufacturers would be provided regulatory relief.<sup>155</sup> Additionally, the products covered would be reduced by 4% and the number of purchases by 1% for food and dietary supplement manufacturers.<sup>156</sup>

However, if the USDA instead chose to apply a different definition, which it has the discretion to do and discusses in the proposed rule, those projections could be significantly smaller and thus would effectively provide consumers with more information.<sup>157</sup> For example, the USDA states that the “FDA exempts certain food from certain labeling requirements or subjects it to special labeling requirements if the food is offered for sale by certain persons who have annual gross sales made or business done in sales to consumers that are not more than \$500,000 under certain conditions.”<sup>158</sup> So, if the USDA applied the same exemptions the FDA uses, it would only exempt 45% of manufacturers, 1% of products, less than 0.5% of sales for food manufacturers, and roughly .01% of products and sales for supplement manufacturers.<sup>159</sup>

In short, the labeling requirements for “small food manufacturers” contribute to the law’s confusion and lack of uniformity. This is because a food product that contains the same ingredients and genetically modified material as another food product produced by a larger manufacturer would not require the same label.<sup>160</sup> Since the USDA is provided discretion under the NBFDS to define “very small food manufacturer,” it can effectively reduce the number of products that will not require a label by instituting the narrower definition.<sup>161</sup>

Last, Congress did not provide very stringent enforcement requirements in the NBFDS.<sup>162</sup> It states, “[e]ach person subject to the mandatory disclosure requirement under this section shall maintain, and make available to the Secretary, on request, such records as the Secretary determines to be customary or reasonable in the food industry, by regulation, to establish compliance with

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153. *Id.*

154. *Id.* at 19867.

155. *Id.* at 19868.

156. *Id.*

157. *Id.*

158. *Id.* at 19868.

159. *Id.*

160. *Id.*

161. 7 U.S.C. § 1639b(b)(2)(G)(ii).

162. *See* 7 U.S.C. § 1639b(g) (allowing the Secretary of Agriculture the discretion in determining compliance).

this section.”<sup>163</sup> Since the NBFDS simply states, “to establish compliance with this section,” it leaves room open for the USDA to possibly make the enforcement methods stricter.<sup>164</sup> As such, the USDA has the authority to, upon request, inquire about the compliance with this law.<sup>165</sup> The USDA has the opportunity to add a more consistent approach to improve upon this enforcement provision, such as establishing consistent “request” periods to review the entity’s BE records to establish compliance.

*C. Examples of the NBFDS Applied:*

The NBFDS directs the Secretary of Agriculture to come up with a GMO labeling standard by 2018, providing the USDA two years from the law’s passage to implement a standard.<sup>166</sup> As of the date of this Note, the proposed standard was announced, but the final standard is still pending due to the USDA’s responsibility to review the comments submitted.<sup>167</sup>

Recently, the United States District Court for the Southern District of New York heard a case where the National Bioengineered Food Disclosure Standard was discussed.<sup>168</sup> In the case of *In re KIND LLC “Healthy & All Natural” Litigation*, the plaintiffs alleged that the KIND company’s “Non-GMO” representations were false because the food product contained ingredients derived from GMO’s.<sup>169</sup> The plaintiffs identified the presence of GMO’s in some of KIND’s food products after conducting test samples.<sup>170</sup>

In that case, KIND contended that if the court allowed a fraudulent “Non-GMO” claim to proceed under the theory that the ingredients in its products were derived from genetically modified crops, the court would define what is considered “Non-GMO,” rather than the USDA.<sup>171</sup> The court weighed in favor of a stay until the USDA offered guidance on what is considered “Non-GMO.”<sup>172</sup> Thus, prosecution of the plaintiff’s “Non-GMO” claim is stayed until the Secretary of Agriculture establishes a product threshold for bioengineered ingredients.<sup>173</sup>

Alternatively, in a similar case, the United States District Court for the Northern District of California partially decided a case based on the substantive language of the NBFDS itself.<sup>174</sup> In *Kao v. Abbott Labs., Inc.*, Abbott labeled a baby formula “Non-GMO,” but consumers conducted independent testing and

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163. 7 U.S.C. § 1639b(g)(2).

164. *Id.*

165. *Id.*

166. 7 U.S.C. § 1639b(a).

167. 2018 Disclosure Standard, *supra* note 80.

168. *In re KIND LLC “Healthy & All Nat.” Litig.*, No. 15-MD-2645, 2018 U.S. Dist. LEXIS 34595 (S.D.N.Y. Mar. 2, 2018).

169. *Id.* at \*8.

170. *Id.* at \*9.

171. *Id.* at \*18.

172. *Id.*

173. 7 U.S.C. § 1639b(a); *In re KIND LLC “Healthy & All Nat.” Litig.*, 2018 U.S. Dist. LEXIS 34595, at \*33, 34.

174. *Kao v. Abbott Labs., Inc.*, No. 17-cv-02790-JST, 2017 U.S. Dist. LEXIS 187379 (N.D. Cal. Nov. 13, 2017).

found traces of a genetically engineered version of soy.<sup>175</sup> The court analyzed the provision of the NBFDS which states, “[f]ood manufacturers may voluntarily label their foods with information about whether the foods were not produced using bioengineering, as long as such information is truthful and not misleading.”<sup>176</sup> Abbott argued the plaintiff’s state-law claims, including misrepresentation, were preempted by the NBFDS.<sup>177</sup> The court found that the plaintiffs were not trying “to impose a new regulatory system or require a manufacturer to provide specific additional information to consumers,” but rather ensure that products do not contain misrepresentations and that labels are truthful.<sup>178</sup>

Based on this, the Northern District of California did not find the plaintiff’s state-law claims were preempted by the NBFDS.<sup>179</sup> This is because the plaintiffs were arguing from the angle of consumer protection and misrepresentation, and not attempting to define what falls under the umbrella of a genetically modified food product.<sup>180</sup> The court denied Abbott’s motion to dismiss on that claim, but elected to stay the case in its entirety “pending the USDA’s issuance of rules regarding GMO labeling.”<sup>181</sup>

In both cases, the outcomes are potentially determinative on the USDA’s final rule, i.e., how strict or lenient the agency chooses to carry out the provisions it has authority to expand on.<sup>182</sup> However, even if the USDA chooses to, for example, institute an extremely low and strict threshold level of traces of bioengineered substances allowable in foods to not require a label, the court would still uphold the threshold if it is considered reasonable.<sup>183</sup>

For example, in the *In re KIND LLC* case mentioned above, the court put a stay on the decision until the USDA established a product threshold for bioengineered ingredients.<sup>184</sup> Thus, the court is implying that it would follow the USDA’s threshold for bioengineered ingredients contained in a product to require a label.<sup>185</sup> This is clear because the court even noted it was reluctant to define what is considered “non-GMO” instead of the USDA.<sup>186</sup> Thus, even if the USDA established an extremely low threshold level to require a

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175. *Id.* at \*4.

176. *Id.* at \*25.

177. *Id.* at \*17.

178. *Id.* at \*27.

179. *Id.*

180. *Id.* at \*9.

181. *Id.*

182. *Id.*; *In re KIND LLC “Healthy & All Nat.” Litig.*, 2018 U.S. Dist. LEXIS 34595.

183. *See Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–44 (1984) (stating “[i]f Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.”).

184. *In re KIND LLC “Healthy & All Nat.” Litig.*, at \*18.

185. *Id.*

186. *Id.*

bioengineered label, the agency has discretion to do so under the statute and the court would likely provide the agency deference in making that determination.<sup>187</sup>

#### IV. RECOMMENDATION

Under the National Bioengineered Disclosure Standard, the USDA has the authority to define and establish certain provisions of the implementing regulation.<sup>188</sup> In the current rule proposal, the USDA fails to equally consider the consumer and the regulated entity, and thus implements the statute in a way that undermines its purposes and does not fill the gaps in many of the inconsistent provisions and exemptions.<sup>189</sup> However, Congress provided the USDA, specifically the Agricultural Marketing Service, with ample discretion to carry out several key provisions of this law.<sup>190</sup> Thus, the USDA can take lawful measures to improve many of the shortcomings this law puts forth.<sup>191</sup>

First, if the Secretary of Agriculture finds that consumers lack sufficient access to bioengineered information under the law as it stands, the agency should provide consumers with more than just a text message as an “additional and comparable option.”<sup>192</sup> This is because forcing the consumer to send a phone number a text message to receive food information still erects two barriers: 1) the need for the consumer to have a cell phone handy while shopping; and 2) the extra step of sending a text to receive food information.

While providing a text message option is different than a digital link, as it does not require broadband internet connection, many of the technological barriers are still present, such as the need to own a cell phone, have that cell phone out with you while you are shopping, and have enough service in the store to send a text message.<sup>193</sup> Further, this is not how food is typically labeled in the United States, so there is no association between accessing information and sending a text.<sup>194</sup> Thus, a text message does not appear to be the most effective “additional and comparable” option that the USDA has the discretion to declare.

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187. See *Chevron*, 467 U.S. at 843–44 (“If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.”).

188. 7 U.S.C. § 1639b(a).

189. See Treat, *supra* note 69 (describing the proposed rule and its deficiencies).

190. See 7 U.S.C. § 1639b(a)(1)(2) (“Not later than 2 years after the date of enactment of this subtitle, the Secretary shall—(1) establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered; and (2) establish such requirements and procedures as the Secretary determines necessary to carry out the standard.”).

191. See *id.* (showing that the agency has the discretion to implement provisions that it finds “necessary to carry out the standard”).

192. 2018 Disclosure Standard, *supra* note 80, at 19875–76.

193. See *generally id.* (explaining the “additional and comparable” option requires consumers to have cell phones handy).

194. See *How to Understand and Use the Nutrition Facts Label*, U.S. FOOD & DRUG ADMIN. [hereinafter U.S. FOOD & DRUG ADMIN.], <https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm274593.htm> (explaining the nutrition facts label).

Instead, an “additional and comparable” option to the digital links should be the placement of the same text or symbol provided as the two other options in the statute next to the phone number or digital disclosure.<sup>195</sup> This way, the USDA would still be carrying out the law mandated by Congress, i.e., providing an electronic disclosure method option for manufacturers. However, upon finding consumers are still lacking access to bioengineering information, the USDA should use its authority to add an “additional and comparable” option to that digital disclosure by simply mandating a BE text or symbol next to it.

Although it may sound redundant, it is in fact within the USDA’s authority to choose an “additional and comparable” option, and, if by deciding that option is simply the BE symbol or text provided as the other option for manufacturers to use, the USDA would simply be using its discretion to ensure the law is carried out clearly and uniformly.<sup>196</sup>

While a text or symbol is extremely clear, straightforward, and traditionally what consumers expect on their labels, an electronic disclosure is not.<sup>197</sup> When Congress provided that a text, symbol *or* an electronic disclosure was allowable as a third option for the BE label, it weakened the law by providing manufacturers with a non-uniform and unclear method to inform consumers about the bioengineered ingredients (emphasis added).<sup>198</sup> However, the USDA has the opportunity to make the law more clear by using its discretion to include an “additional and comparable” option in the form of the predetermined text or symbol that is already included as the other options in the proposed rule.<sup>199</sup> The text or symbol would be considered “additional and comparable” because it would be placed on the product *in addition to* the electronic or digital disclosure method if a manufacturer so chooses to utilize that method, and it is *comparable* because it serves the same purpose as the electronic or digital disclosure, i.e., it informs consumers about bioengineering information.<sup>200</sup>

Second, the USDA should adopt Alternative Threshold Option 1-B, but for enforcement purposes, the agency should not restrict it to only “inadvertent and technically unavoidable” BE substances.<sup>201</sup> Option 1-B mandates that any food that has an ingredient that contains a bioengineered substance “that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (.9%) of the specific ingredient by weight, would not be subject to disclosure as a result of that one ingredient.”<sup>202</sup> This is the most stringent threshold proposed in the rule.<sup>203</sup>

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195. See 2018 Disclosure Standard, *supra* note 80, at 19876 (indicating the statute provides two additional options for disclosure: by telephone number and by internet website).

196. See *id.* at 19860 (explaining that the proposed rule intends to provide a mandatory uniform national standard for disclosure of information about the BE status of foods to consumers).

197. See generally U.S. FOOD & DRUG ADMIN., *supra* note 194 (explaining what people should expect to see on their food labels).

198. 7 U.S.C. § 1639b(b)(2)(D).

199. 7 U.S.C. § 1639b(c)(4).

200. *Id.*

201. 2018 Disclosure Standard, *supra* note 80, at 19869.

202. *Id.*

203. *Id.*

The USDA should adopt Option 1-B and establish nine-tenths percent of any BE ingredients may be present before it needs to be labeled, not just technically unavoidable amounts of BE. This will serve three purposes: 1) it will relax the burden on the USDA to inspect records of cross pollination and make conclusions about tracing non BE products with BE products; 2) it will ease the burden on manufacturers to not have to monitor how nine-tenths of their crop attained bioengineered substances; and 3) it will contribute to the uniformity desired under this law by ensuring that anything more than nine-tenths of a bioengineered ingredient, no matter how it got there, would be deemed a BE product and labeled as such.

One of the other proposed threshold options “would likely decrease the number of foods subject to disclosure, and may require regulated entities to create and maintain records they do not currently keep.”<sup>204</sup> By implementing Alternative Option 1-B, while adding the recommendations stated in this Section, the regulation will provide consumers with more transparent food products due to the low threshold of BE ingredients requiring a label, ease the burden on the manufacturer, and make it easier for the USDA to regulate.<sup>205</sup>

Third, in defining what “similar retail establishments” are when referring to the law’s labeling exemptions for restaurants and “similar retail establishments,” the USDA should not include cafeterias or lunch rooms.<sup>206</sup> This is because cafeterias and lunch rooms may sell commercial products that are also found in grocery stores in their original packaging.<sup>207</sup>

Cafeterias and lunch rooms are becoming increasingly more common in the form of a mini marketplace or convenient store,<sup>208</sup> and mandating that manufacturers are exempt from providing a GMO label on foods sold in those settings is confusing and inconvenient to both the manufacturer and the consumer. This is because the manufacturer can now potentially sell a certain product that would otherwise require a label in the grocery store without such label in a lunch room or cafeteria. If an entity opted to utilize this exemption, a consumer would be purchasing a product that contains GMO’s in the cafeteria or lunch room and not even know it. This goes against the purpose of this law, which is to create a uniform labeling standard.<sup>209</sup> Further, the USDA has the discretion to define “similar retail establishment,”<sup>210</sup> and thus, it would be within

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204. *Id.* at 19869.

205. *See id.* (explaining how Alternative Option 1-B would work).

206. *Id.* at 19885.

207. *See Self-Checkout Corporate Cafeterias: Micro Markets that Offer Employees Fresh Food 24x7, CAFÉ SERVS.*, <https://www.corporatediningservices.com/cafeteria-management/micro-market-self-checkout-cafeteria.htm> (last visited Nov. 7, 2018) (discussing what is sold in corporate cafeterias).

208. *See Susanna Kim, The 9 Coolest Company Cafeterias and Food Perks in the Country, ABC NEWS* (Jan. 2, 2013), <https://abcnews.go.com/Business/top-coolest-company-cafeterias-food-perks-us/story?id=17813651> (“[t]he Venice office also stocks eight ‘Micro Kitchens’ with snacks, organic dairy and fruits, with all products sourced from growers no more than 200 miles away.” The company Return Path “has a fully stocked fridge with food and beverages, and cabinets with healthy snacks.” McMurry “provides ‘minibars’ around its offices with . . . fresh fruit, Cliff bars, and 20 different types of beverages”).

209. *See* 2018 Disclosure Standard, *supra* note 80, at 19860 (explaining that the proposed rule intends to provide a mandatory uniform national standard for disclosure of information about the BE status of foods to consumers).

210. 7 U.S.C. § 1639b(b)(2)(G)(i).

the USDA’s discretion to enforce a regulation where cafeteria and lunch rooms are not under the umbrella of “similar retail establishments.”

Last, the USDA, under its authority “to establish compliance with [the enforcement] section,”<sup>211</sup> and to “conduct an examination, audit, or similar activity with respect to any records required” should institute a consistent “request” period to review an entity’s BE records to establish compliance. This “request” period will ensure that manufacturers are always complying with this regulation, as they will be put on notice through the regulation that every six months, the Secretary of Agriculture will request records that are customary or reasonable in the food industry.

This will contribute to transparency in the law, as regulated entities will regularly, upon the Secretary’s request, provide the USDA with bioengineered food records and provide the USDA with a regular mechanism to carry out this law. If the USDA does not establish a regular request period to review these documents, the regulated entities will not be consistently and equally enforced. This is because although the USDA can, upon request, review these records, it does not necessarily mean that the USDA ever *has* to request an entity subject to the disclosure requirement’s records (emphasis added).<sup>212</sup> Thus, “on request,” the USDA should establish that every six months, or at least more than once per year, the USDA maintain records from the regulated entities. This will act as a “check” on these entities to keep them honest in their disclosure requirements and to not assume that the Secretary will let this provision fly under the radar. This would be allowable under the law because the regulated entity would still be receiving “notice” before the audit and can still be provided an opportunity for a hearing on the results of the audit. Regulated entities should be provided a more consistent audit.

## V. CONCLUSION

It is surprising to think that it has been more than thirty-five years since the Food and Drug Administration approved the first genetically modified organism patent, yet there are still contentious debates surrounding the topic.<sup>213</sup> These debates include, among others, how safe bioengineered substances are to consume, and if those substances within food ingredients should be labeled.

The NBFDS seeks to resolve the labeling tensions by instituting a uniform labeling requirement. However, it does so in a way that may in fact undermine its effectiveness, due to the exemptions and enforcement the law includes.

The USDA should, in promulgating the labeling requirements, take into consideration the confusion that the NBFDS creates. To ensure the USDA can effectively provide information to consumers, the AMS should require a symbol or text as the “additional and comparable” option in addition to the electronic

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211. 7 U.S.C. § 1639b (g)(2).

212. *Id.*

213. GL Woolsey, *GMO Timeline: A History of Genetically Modified Foods*, ROSEBUD MAG. (2012), <http://www.rosebudmag.com/truth-squad/gmo-timeline-a-history-of-genetically-modified-foods> (last modified Dec. 3, 2013).

and digital disclosure. In addition, the AMS should adopt Alternative Threshold Option 1-B, but for enforcement purposes the agency should not restrict it to only “inadvertent and technically unavoidable” BE substances. Also, cafeterias and lunch rooms should not fall under the definition of “similar retail establishment” when defining what service providers are exempted from selling food with a BE label. Last, the USDA, in promulgating its final regulation, should ensure a method of regular enforcement for manufacturers. This can be accomplished by using the agency’s authority to request bioengineering records of regulated entities every six months, rather than just state in the regulation these records must be made available “on request.” Instituting a specific timeline to review these records throughout a given year will ensure the labeling requirements are more consistently enforced.

If a GMO label does not make it on the shelf due to one of the confusing exemptions or lax enforcement methods, a consumer will not have the same experience purchasing that product compared to an identical one that required a label under the law. This defeats the goal of instituting a uniform labeling standard. The USDA should use its limited discretion under the NBFDS and implement a rule that significantly improves the uniformity, clarity, and effectiveness of the statute.