

# ARTICLES

## SCIENCE-BASED FOOD LABELS: IMPROVING REGULATIONS & PREVENTING CONSUMER DECEPTION THROUGH LIMITED INFORMATION DISCLOSURE REQUIREMENTS

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## I. INTRODUCTION

*“Our guiding principle here is very simple: that you as . . . a consumer should be able to walk into your local grocery store, pick up an item off the shelf, and be able to tell whether it’s good for your family.”*

*-Michelle Obama<sup>1</sup>*

Over the last century, federal regulation of food branding and labeling has adapted to address evolving scientific understanding about nutrition, consumer demand, and impacts of food production.<sup>2</sup> Such regulations, at least early on, primarily ensured that food is safe to eat—that it is of a “wholesome” quality.<sup>3</sup> In many respects, consumers can be confident that their food is safe to eat.<sup>4</sup> However, regulations grew broader to address not just safety, but other values as well.<sup>5</sup> Some regulation has

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<sup>1</sup> *FDA Proposes Updates to Nutrition Facts Label on Food Packages*, FDA.GOV (Feb. 27, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm387418.htm>.

<sup>2</sup> See *infra* Part II (discussing the history of food regulation).

<sup>3</sup> See *infra* Part II.A (describing the Pure Food and Drug Act).

<sup>4</sup> Tacy Katherine Hass, *New Governance: Can User-Promulgated Certification Schemes Provide Safer, Higher Quality Food?*, 68 FOOD DRUG L. J. 77 (2013) (“[T]he food-safety legislation which the United States had in place prior to 2011 resulted in one of the safest food supplies in the world.”).

<sup>5</sup> See *infra* Part II.C–D (discussing nutritional and organic labeling).

progressed to create flexibility for manufacturers to allow for a broad range of products to be produced and available to consumers while ensuring that consumers can still make informed decisions about what food to buy.<sup>6</sup> Our modern nutrition label is meant to allow consumers to make informed decisions about what they are eating.<sup>7</sup> However, consumers increasingly make choices not necessarily based on the nutrition label, but on other messages and labels on food, such as “organic,” “GMO free,” and even claims as simple as “healthy.”<sup>8</sup> In some cases these labels combine with false consumer expectations leading to consumer deception.<sup>9</sup> The deception may be caused by a shift in regulation of food products to regulating the food process—the way in which food is made—or the result of the goals of the regulatory agency.<sup>10</sup> The problems are exacerbated by recent progress in regulation focusing on areas that do not address pertinent problems, but instead respond to consumer demand without recognizing the underlying goals of regulation.<sup>11</sup> Consumer demand, on its own is not enough to steer the direction of regulation.<sup>12</sup> Unlike past regulation, recent regulations have taken an approach that undermines consumer protection, is not adequately responding to emerging information, and inappropriately allocates limited regulatory resources.<sup>13</sup> By returning to scientifically sound regulation meant to protect and accurately inform consumers and not just respond to consumer demand, food regulation can be improved.<sup>14</sup>

## I. THE HISTORY OF FOOD REGULATION

*“I aimed at the public’s heart, and by accident I hit it in the stomach.”*

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<sup>6</sup> See *infra* Part II.B (for example, the Fair Packaging and Labeling Act).

<sup>7</sup> See *infra* Part II.C (discussing nutritional labeling reform).

<sup>8</sup> See *infra* Part II.D (discussing organic labeling and consumer responses to certain phrases).

<sup>9</sup> See *infra* Part III (discussing external and internal factors that lead to consumer deception).

<sup>10</sup> See *infra* Part III.A–B (describing the process versus nutritional quality distinction).

<sup>11</sup> See *infra* notes 173–79 and accompanying text (explaining how organics is used as a marketing tool).

<sup>12</sup> See *infra* Part IV.A (describing considerations behind FDA policy choices).

<sup>13</sup> See *infra* Parts III and IV (emphasizing the need for better labeling requirements).

<sup>14</sup> See *infra* Part IV (setting forth considerations and suggestions for improved labeling).

-Upton Sinclair<sup>15</sup>

Often, regulation is the result of society sensing a problem that requires a response.<sup>16</sup> Part II examines various food regulations as they arose in response to problems (or at least perceived problems). Beginning with the Pure Food and Drug Act of 1906 in Part II.A and going forward to present-day regulation, food regulation has evolved over time to address not only consumer concerns, but also an increasing understanding of particular food attributes.<sup>17</sup> While regulation can take many forms, the regulations explored below mainly take the form of information disclosure requirements—that is the labels that appear on foods.<sup>18</sup> Information approaches, such as labeling, can be understood as a consumer-oriented approach to regulation when it allows and enables consumers to make choices based on the relevant and available data presented.<sup>19</sup> Information and labeling requirements work well when many choices are available to consumers and a consumer can decline to purchase a product in lieu of other options.<sup>20</sup> Because many options for food exist, labeling requirements have had a positive impact on consumer choices.<sup>21</sup> However, Part II.B provides an example of how strict

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<sup>15</sup> Upton Sinclair, *What Life Means to Me*, COSMOPOLITAN MAGAZINE, Oct. 1906, at 594.

<sup>16</sup> See ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 127 fig. 2.5 (5th ed. 2006) [hereinafter Percival et al.] (describing risks to health and damage to the environment as catalysts for regulation).

<sup>17</sup> See *infra* Part III (discussing labeling and scientific understanding of organics).

<sup>18</sup> Percival et al., *supra*, note 16 at 135 (defining “[i]nformation [d]isclosure [r]equirements”).

<sup>19</sup> Christopher Chen, *Food and Drug Administration Food Standards of Identity: Consumer Protection Through the Regulation of Product Information*, 47 FOOD & DRUG L.J. 185, 196 (1992) (noting that “every product has a potential substitute, an alternative product that a consumer might buy if he or she cannot buy his or her first choice.”).

<sup>20</sup> Percival et al., *supra*, note 16, at 135 (explaining, for example in the pollution context, “information disclosure and labeling requirements are more likely to be effective when the regulatory target is a product that informed consumers can decline to purchase”).

<sup>21</sup> See, e.g., Tobias J. Gillett, *Lessons from Nutritional Labeling on the 20th Anniversary of the NLEA: Applying the History of Food Labeling to the Future of Household Chemical Labeling*, 37 WASH. U. J.L. & POL’Y 267, 334 (2011) (“Researchers have generally considered the current nutritional labeling scheme administered by the FDA a success”); Brenda M. Derby & Alan S. Levy, *Do Food Labels Work?: Gauging the Effectiveness of Food Labels Pre- and Post*

food regulation can limit options through labeling requirements operating like “[p]roduct [b]ans or [u]ses [l]imitations” rather than “[i]nformation [d]isclosure [ ] [r]equirements.”<sup>22</sup> When successful, labeling regulations respond to problems on the basis of the relevant scientific evidence available. For example, Part II.C looks at the Nutritional Labeling and Education Act of 1990

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*NLEA*, HANDBOOK OF MARKETING AND SOCIETY 372, 374–78, 394–95 (Paul N. Bloom & Gregory T. Gundlach eds., 2001) (examining the use of labels by consumers and concluding that labels have a positive influence on purchasing decisions: “[t]he food label can play [an important role] as a source of accurate, reliable, and relevant information characteristics of foods.”); Alan D. Mathios, *The Impact of Mandatory Disclosure Laws on Product Choices: An Analysis of the Salad Dressing Market*, 43 J. L. & ECON. 651, 671 (2000) (concluding that the move to mandatory labeling under the NLEA should result in lower sales for higher-fat salad dressings and noting that the introduction of the new nutrition labels helped consumers gather and understand nutrition information); Jayachandran N. Variyam & John Cawley, *Nutrition Labels and Obesity* 20 (Nat’l Bureau of Econ. Res., Working Paper No. 11956, 2006), <http://www.nber.org/papers/w11956> (concluding that following the passage of the NLEA obesity rates declined among non-Hispanic white female consumers who used nutrition labels and indicating that the probability of obesity in that demographic was lower than would have been in the absence of the labels.); Marian L. Neuhouser et al., *Use of Food Nutrition Labels is Associated with Lower Fat Intake*, 99 J. AM. DIETETIC ASS’N 45, 49–50 (1999) (concluding that use of post-NLEA nutrition labeling by consumers reduced their fat consumption); Alan R. Kristal et al., *Trends in Food Labeling Use Associated with New Nutrition Labeling Regulations*, 88 AM. J. PUB. HEALTH 1212, 1215 (1998) (concluding that the NLEA and related FDA labeling rules increased use of nutrition labels by consumers); Jessie A. Satia et al., *Food Nutrition Label Use Is Associated with Demographic, Behavioral, and Psychosocial Factors and Dietary Intake Among African Americans in North Carolina*, 105 J. AM. DIETETIC ASS’N 392, 400 (2005) (concluding that nutrition label use increased fruit and vegetable consumption and reduced fat intake among African Americans in North Carolina); Sung-Yong Kim et al., *The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis*, 25 J. AGRIC. & RESOURCE ECON. 215, 215 (2000) (finding that label use improved appropriate consumption of fiber and decreased the intake of calories from total fat, saturated fat, cholesterol, and sodium); Robert E. Post et al., *Use of the Nutrition Facts Label in Chronic Disease Management: Results from the National Health and Nutrition Examination Survey*, 110 J. AM. DIETETIC ASS’N 628, 631 (2010) (finding that patients with chronic disease who read food labels consumed less calories, saturated fat, carbohydrates, and sugar, and more fiber); D. Weaver & M. Finke, *The Relationship Between the Use of Sugar Content Information on Nutrition Labels and the Consumption of Added Sugars*, 28 FOOD POL’Y 213, 218–19 (2003) (finding that frequent use of labels for information regarding sugar content was associated with lower added sugar consumption).

<sup>22</sup> See also PERCIVAL ET AL., *supra*, note 16 at 133–35 (describing the types of regulation including “[p]roduct [b]ans or [u]se [l]imitations as well as “[i]nformation [d]isclosure ([l]abeling) [r]equirements”).

(NLEA).<sup>23</sup> The goal of the regulation was to help consumers make healthier choices, and the regulations and results reflect that goal through policies that take scientific evidence into account.<sup>24</sup> When information disclosure is voluntary or at least less restrictive, the underlying goal of the regulation may determine what data can and should be available to consumers.<sup>25</sup> Additionally, not all information requirements are the same and food labeling can be further subdivided into product regulation and process regulation. Part II.E examines how organic labeling, unlike earlier regulation, focused on the process—that is how food is made—while earlier regulation focused on the content of food, such as its nutritional qualities.<sup>26</sup>

### A. Pure Food & Drug Act

Federal regulation of food adulteration and misbranding began as early as the 1900s.<sup>27</sup> A rise in corporate food producers, urbanization, powerful lobbying, and limited regulation resulted

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<sup>23</sup> See Virginia Wilkening, *The Nutrition Labeling and Education Act of 1990*, NAT'L NUTRIENT DATABANK CONF., 227, [http://www.nutrientdataconf.org/pastconf/ndbc17/8-2\\_wilkening.pdf](http://www.nutrientdataconf.org/pastconf/ndbc17/8-2_wilkening.pdf) (last visited Sept. 12, 2015) (discussing the passage of the Nutrition Labeling and Education Act of 1990 signed into law by President Bush).

<sup>24</sup> *Id.*

<sup>25</sup> See Julie A. Caswell, *How Labeling of Safety and Process Attributes Affects Markets for Food*, 27 AGRIC. AND RESOURCE. ECON. REV. 151, 151 (1998) (“Labeling policies may be used as a substitute for more restrictive forms of government regulation or as a complement to other policies. In either case, governments can use labeling policies to reach food quality targets, to encourage competition in product markets, and to provide consumers with information and protection from deception.”).

<sup>26</sup> See *infra* Part III.A (discussing past regulatory focus on the nutritional qualities of food).

<sup>27</sup> See, e.g., Chris Burns, *Bogus Butter: An Analysis of the 1886 Congressional Debates on Oleomargarine Legislation*, 32–34 (May 2009) (Unpublished MA thesis, University of Vermont) (located at <http://scholarworks.uvm.edu/cgi/viewcontent.cgi?article=1035&context=graddis>) (requiring prominent labeling of colored oleomargarine in order to distinguish it from butter); See Eric F. Greenberg, *The Changing Food Label: The Nutrition Labeling and Education Act of 1990*, 3 LOY. CONSUMER L. REP. 10, 10 (1990) (explaining federal food regulation beginning in 1906); see also Gillett, *supra* note 21, at 272 & n.30 (explaining how regulation “began in earnest at the dawn of the twentieth century.” Also of note, prior regulations of products such as tea, oleomargarine, and meat products began even earlier); Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 45–46 (1984) (laws prior to the 1900s primarily addressed economic concerns regarding foreign trade and competition among domestic industries).

in food posing serious health and public safety concerns.<sup>28</sup> Advocates for food safety and publications such as Upton Sinclair's *The Jungle* brought the increasing risks to the public's attention.<sup>29</sup> The result was the Pure Food Act of 1906 (PFA).<sup>30</sup> The PFA forbade the production of "any article of food or drug which is adulterated or misbranded,"<sup>31</sup> banned its sale in interstate commerce and to foreign purchasers (unless permission of the foreign country is given),<sup>32</sup> and provided for "examinations of specimens of foods" by the Bureau of Chemistry of the United States Department of Agriculture (USDA).<sup>33</sup> While no affirmative labeling requirement existed, the PFA did require labels to be an accurate reflection of the product within the package.<sup>34</sup>

While a significant step forward, the PFA left many unscrupulous practices unregulated.<sup>35</sup> For example, while prohibiting false labeling, the burden of proof to demonstrate falsehood was on the government rather than the manufacturer.<sup>36</sup> Additionally, the Supreme Court limited the scope of the PFA to only apply to "false statements . . . [which]

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<sup>28</sup> Gillett, *supra* note 21, at 272–73.

<sup>29</sup> UPTON SINCLAIR, *THE JUNGLE* (Grosset & Dunlap Publishers 1906); Gillett, *supra* note 21, at 272–73, 273 n.34 (describing how the Federal Meat Inspection Act of 1906, ch. 3913, 34 Stat. 669, 674–79 (codified as amended at 21 U.S.C. §§ 601–625 (2006)) was also passed around this time)).

<sup>30</sup> Pure Food Act, ch. 3915, § 1, 34 Stat. 768, 768 (1906), *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059.

<sup>31</sup> *Id.*; Pure Food Act, ch. 3915, § 7, 34 Stat. 768, 769–70 (1906) *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059 (the PFA defined food as "adulterated" if any substance had been removed or substituted, if ingredients were added intentionally to "injuriously affect its quality or strength," if the food "contain[ed] any added poisonous or . . . deleterious ingredient," or if it contained "a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food"); Pure Food Act, ch. 3915, § 7, 34 Stat. 768, 770 (1906) (the PFA also defined a "misbranded" food product as one that bore "any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular").

<sup>32</sup> Pure Food Act, ch. 3915, § 4, 34 Stat. 768, 769 (1906) *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059.

<sup>33</sup> *Id.* § 4 at 769, *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059.

<sup>34</sup> *Id.* § 8 at 770 *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059 (prohibiting "false or misleading" statements).

<sup>35</sup> Gillett, *supra* note 21, at 274.

<sup>36</sup> Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA.GOV (January-February 2006) <http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/CentennialEditionofFDAConsumer/ucm093787.htm>.

determine the identity of the article,”<sup>37</sup> leaving health claims on foods virtually unchecked.<sup>38</sup> Congress thought the PFA was adequate because, although prohibiting blatant fraud, it was passed on the maxim of caveat emptor (“let the buyer beware”).<sup>39</sup> Thus, while protecting against watered-down milk and jam containing negligible amounts of fruit, it could not be used to combat new products with distinctive names.<sup>40</sup> For example, a product called “Bred Spred” was found not to be an adulterated version of jam despite the close resemblance and lack of fruit, because it was not called jam and therefore not misbranded.<sup>41</sup> However, the PFA still found its roots in the limited scientific evidence available at the time, and relied on the expertise of the Bureau of Chemistry to inspect food.<sup>42</sup> The scientific approach to labeling would continue with the passage of the Food Drug and Cosmetic Act.

### B. Food Drug & Cosmetic Act

In response to the gaps in the PFA, the Food, Drug, and Cosmetic Act<sup>43</sup> (FDCA) was passed in 1938.<sup>44</sup> The FDCA gave more detailed requirements for misbranding of food,<sup>45</sup> created extensive packaging and labeling regulation,<sup>46</sup> and banned all “false or misleading” labeling.<sup>47</sup> The requirements included food to bear labels of the “name and place of business of the manufacturer, packer, or distributor,” as well as “the quantity of the contents in terms of weight, measure, or numerical count.”<sup>48</sup> The FDCA also mandated labeling to include the common or

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<sup>37</sup> United States v. Johnson, 221 U.S. 488, 497 (1911).

<sup>38</sup> Gillett, *supra* note 21, at 274.

<sup>39</sup> Chen, *supra* note 19, at 192.

<sup>40</sup> *Id.* at 192–93.

<sup>41</sup> United States v. Ten Cases, More or Less, Bred Spred, 49 F.2d 87, 89 (8th Cir. 1931) (according to the record, Bred Spred strawberry flavor, contained 17 parts of strawberries, 55 parts of sugar, 11 1/2 parts of water, 1/4 part of pectin, and .04 of a part of tartaric acid).

<sup>42</sup> Pure Food Act, ch. 3915, § 4, 34 Stat. 768, 769 (1906), *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059.

<sup>43</sup> 21 U.S.C. § 301 (2015) (discussing the cited chapter as the Federal Food, Drug, and Cosmetic Act).

<sup>44</sup> See Gillett, *supra* note 21 at 275–77 (for a detailed summary of the events surrounding the passage of the FDCA).

<sup>45</sup> 21 U.S.C. § 343 (2010) (defining circumstances in which food shall be deemed misbranded).

<sup>46</sup> *Id.* § 343(e).

<sup>47</sup> *Id.* § 343(a).

<sup>48</sup> *Id.* § 343(e).

usual name of the food, if any there be and the common or usual name of each ingredient except for “spices, flavorings, and color[s].”<sup>49</sup> In the decades following its passage, the FDCA was further amended with additional requirements.<sup>50</sup> While appearing to act as information disclosure regulation, the FDCA was initially implemented harshly, leading to product bans and use limitations.\*

### 1. Recipe Standards

Under the FDCA, the FDA was given leeway in determining how to approach and enforce food standard regulation.<sup>51</sup> Initially, the FDA used detailed “recipe” standards of identity.<sup>52</sup> At the time, many people, including members of Congress, believed that traditional foods such as “time-honored” recipes of housewives and “reputable manufacturers” were superior to fabricated foods.<sup>53</sup> “A typical recipe standard prescribes mandatory and optional ingredients, and fixes the amounts and proportions of each.”<sup>54</sup> For example, going back to “Bred Spred,” the United States in arguing that Bred Spred violated the PFDA stated that, “manufacturers [considered jam] as not less than 45 parts of fruit to 55 parts sugar [and] [h]ousekeepers usually make jam of 50 per cent. [sic] fruit and 50 per cent. [sic] sugar.”<sup>55</sup> Unlike the PFDA, the FDCA would allow the FDA is to use such evidence to curtail manufacturers from making imitations if the labeling would mislead consumers.<sup>56</sup>

In the decade following the passage of the FDCA, more than thirty standards were put in place, mostly for canned goods, as well as, the packaged versions of traditional foods like fruit preserves.<sup>57</sup> The process accelerated and by 1980, there were 275

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<sup>49</sup> *Id.* § 343(g).

<sup>50</sup> *See e.g.*, Gillett, *supra* note 21, at 277–78 (describing amendments such as the 1954 Miller Pesticide Amendment, the Food Additives Amendment of 1958, the Color Additives Amendment of 1960, and the Fair Packaging and Labeling Act of 1966).

\* *See* Gillett, *supra* note 21, at 276–78 (discussing the FDCA’s “far more robust and detailed requirements”).

<sup>51</sup> Chen, *supra* note 19, at 193–94.

<sup>52</sup> *Id.* at 194.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *United States v. Ten Cases, More or Less, Bred Spred*, 49 F.2d 87, 89 (8th Cir. 1931).

<sup>56</sup> Chen, *supra* note 19, at 194–95.

<sup>57</sup> *Id.*

standardized foods.<sup>58</sup> While not all standards followed the “recipe” format, the vast majority did and thus restricted the choice of ingredients manufacturers could use.<sup>59</sup> While the policy was mostly rooted in “tradition,” it had a scientific component as well by favoring the prohibition of potentially dangerous chemical additives whose safety had not been demonstrated.<sup>60</sup>

While standardization helped protect health and safety, “recipe” standards in particular created a new set of problems.<sup>61</sup> For example, during this period, section 403(g)’s “purports to be or is represented as” language was read broadly to prohibit food that resembled standard food in appearance, packaging, or taste.<sup>62</sup> Thus, many foods were challenged even when they were truthfully labeled as nonstandard and there was no conclusive proof of consumer deception.<sup>63</sup> In *36 Drums of Pop’n Oil*, mineral oil used for theatre popcorn was seized despite being labeled truthfully and there was no standard promulgated for mineral oil when it was found it was “represented as” melted butter.<sup>64</sup> The court found that, from a scientific standpoint, mineral oil had no food value, it resembled butter, and consumers may never see the labels because the cartons sold in theatres did not contain labels.<sup>65</sup> However, the court found most persuasive that “melted butter is superior to mineral oil” and thus condemnation of the mineral oil was proper.<sup>66</sup> Thus, because consumers might believe they were getting superior butter when they were actually getting mineral oil, theatres could not put the product on their

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<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> See, e.g., *Atlas Powder Co. v. Ewing*, 201 F.2d 347, 351–54 (3d Cir. 1952), *cert. denied*, 345 U.S. 923 (1953) (upholding—primarily on safety grounds—the FDA standard of identity for flour, which did not permit use of polyoxyethylene monostearate as a softening agent); See also, Richard A. Merrill & Earl M. Collier, Jr., “*Like Mother Used to Make*”: *An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 568–69 (1974) (The detachment from science came where the FDA, instead of studying the effects of the new substances, simply used section 401 to prohibit them.).

<sup>61</sup> Chen, *supra* note 19, at 195–98 (discussing for example: administrative costs, restriction of food substitutes, and barriers to entry).

<sup>62</sup> Richard A. Merrill & Earl M. Collier, Jr., “*Like Mother Used to Make*”: *An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 571–74 (1974).

<sup>63</sup> See, e.g., *United States v. 36 Drums of Pop’n Oil*, 164 F.2d 250, 252 (5th Cir. 1947) (holding that mineral oil colored and flavored to appear as butter was ‘adulterated’ despite being truthfully labeled).

<sup>64</sup> *Id.* at 251–52.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at 253–54.

popcorn.<sup>67</sup> The court's reasoning, as well as the FDA's was that, from a scientific standpoint, mineral oil was nutritionally inferior, however, the strict recipe standards sometimes led to more questionable policy choices.<sup>68</sup>

Under the recipe standards, even foods that contained ingredients making them arguably superior to the standard were challenged.<sup>69</sup> For example, in *Federal Security Adm'r v. Quaker Oats*,<sup>70</sup> Quaker Oats produced farina, a highly refined wheat product resembling flour, and had then added vitamin D.<sup>71</sup> The product was labeled as "Quaker Farina Wheat Cereal Enriched with Vitamin D," or "Quaker Farina Enriched by the Sunshine Vitamin."<sup>72</sup> At the time, there was a recipe standard for farina as well as a recipe standard for "enriched farina."<sup>73</sup> The definition of farina gave no leeway for the addition of ingredients, such as vitamin D.<sup>74</sup> Thus, farina with vitamin D added could not be labeled as farina.<sup>75</sup> Furthermore, "enriched farina" required the addition of many more vitamins such as vitamin B1, riboflavin, and iron.<sup>76</sup> The court agreed with the agency that varying composition of enriched wheat products would confuse consumers and a standard for "enriched" was needed.<sup>77</sup> Even though the label was accurate, the court stated that the PFDA had previously prohibited only "false and misleading labeling" but the FDCA goes further "to protect the consumer from 'economic adulteration' . . . [a product] inferior to that which the consumer expected."<sup>78</sup> The court characterized the FDCA as "promulgat[ing] definitions and standards of identity" and the regulations were "not confined to a requirement of truthful and

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<sup>67</sup> *Id.* at 252 (While, potentially, labeling the cartons of popcorn could remedy the problem, the court did not suggest that such a remedy would be appropriate and such labeling would be beyond the control of the producers since the mineral oil was shipped to theatres in drums containing appropriate labels.).

<sup>68</sup> *Id.* at 251–52.

<sup>69</sup> *See, e.g.*, *Federal Sec. Adm'r v. Quaker Oats*, 318 U.S. 218, 232 (1943) (label challenge to vitamin D added to milled wheat product; *United States v. 20 Cases, More or Less, etc.*, Federal 130 F.Supp. 715, 717–18 (D. Del. 1954), *aff'd*, 228 F.2d 912 (3d Cir. 1956) (label challenge involving added gum gluten).

<sup>70</sup> *Quaker Oats*, 318 U.S. 218.

<sup>71</sup> *Id.* at 224.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 223.

<sup>74</sup> *Id.* at 220.

<sup>75</sup> *Quaker Oats*, 318 U.S. at 224.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.* at 226, 235.

<sup>78</sup> *Id.* at 230.

informative labeling.”<sup>79</sup> Thus, even when truthfully labeled and superior to farina, the product violated the standards of the FDCA.<sup>80</sup>

To an extent, the FDA’s early implementation of the FDCA made the regulation a “product ban or use limitation” regulation and not an “informational disclosure” regulation.<sup>81</sup> As a result of the strict standards, manufacturers were forced to label many foods as “imitations” under section 403(c) to avoid penalties under section 403(g) for misrepresentations.<sup>82</sup> The regulation showed not that consumers could not be trusted to be able to make choices, rather, the regulations reflected a belief that consumers were “[unable] . . . in some cases to determine, solely

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<sup>79</sup> *Id.*

<sup>80</sup> *See id.* at 235 (upholding the standards of the FDCA).

<sup>81</sup> *See generally* PERCIVAL ET AL., *supra* note 16 at 132–33, 135 (describing different types of regulations including “[p]roduct [b]ans or [u]se [l]imitations” and “[i]nformation [d]isclosure ([l]abeling) [r]equirements” and defining the former as “prohibit[ing] a product [such as food additives] or activity or limit its use”).

<sup>82</sup> Chen, *supra* note 19, at 194–95 (citing 62 Cases of Jam v. United States, 340 U.S. 593 (1951) (product resembled standardized jam)); *See, e.g.*, United States v. 651 Cases, More or Less, of Chocolate Chil-Zert, 114 F.Supp. 430, 431 (N.D.N.Y.1953) (product resembled nonstandardized ice cream). Even when labeled as imitations, the FDA attempted the seizure of some products such as “Delicious Brand Imitation Jam.” 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. at 594. While labeled as an “imitation” the FDA attempted to seize the fruit spread because it contained only twenty-five percent fruit, despite the requirement that fruit jam contain “not less than 45 parts by weight of the fruit ingredient.” 340 U.S. at 594–95 [quotations omitted]. The agency attempted to preempt the entire market for fruit spreads with its jam standard; however, the Court would not let the FDA go so far and would allow “imitations” because the label clearly conveyed to consumers that it was an inferior product. 340 U.S. at 600–01. Still, the problem remained that many *superior* products were forced to bear the label and the badge of inferiority was an unwelcome addition for many manufacturers. *See* Merrill & Collier, *supra* note 63, at 579 (discussing FDA food standards and the application of §403(c)). Thus, in the challenge to “Chil-Zert,” a dessert similar to ice-cream but using soy fat and protein rather than milk, even when prominently labeled as “Not an Ice Cream” and “Contains No Milk or Milk Fat[!]” “Chil-Zert” was found to be an imitation and seized. 651 Cases, 114 F.Supp. at 432. Ultimately, during a period of increased focus on nutrition, which is discussed in Part III.C, the required imitation labeling of Chil-Zert and others was criticized as uninformative and inaccurate. *See* Tom Bellis, et al., *Behind the Label: Federal Food Standards*, Rural Development Publications Collection, Yearbook of Agriculture 61–62 USDA NATIONAL AGRICULTURAL LIBRARY (1974), <http://naldc.nal.usda.gov/naldc/download.xhtml?id=CAIN759008155&content=PDF> (noting a White House Conference on Food, Nutrition, and Health wherein the recommendation was made that “oversimplified and inaccurate terms such as ‘imitation’ should be abandoned as uninformative to the public.”).

on the basis of informative labeling, the relative merits of a variety of products.”<sup>83</sup>

The costs associated with recipe standards caused the FDA to shift towards a different approach.<sup>84</sup> An often-cited infamous case leading to the change involves a 1940 inquiry from peanut butter manufacturers about the addition of glycerin to peanut butter to prevent oil separation.<sup>85</sup> The inquiry resulted in eleven years of arguments, formal hearings, over 7,000 pages of printed record, and a Supreme Court case.<sup>86</sup> As a result of strict regulation, the standardization of peanut butter also prohibited the sale of any peanut spread containing less than ninety percent peanuts.<sup>87</sup> The FDA’s strict regulation shifted labeling requirements away from an information disclosure requirement and effectively resulted in regulation through product bans and use limitations.<sup>88</sup> If consumers wanted a cheaper product with fewer peanuts, that choice was unavailable and the higher priced spreads were the only option. The problems with strict recipe standards led to change in 1965.

## 2. More Flexible “Safe and Suitable” Regulations

The FDA began to utilize more flexible standards in 1965 when promulgating a standard for “frozen raw breaded shrimp.”<sup>89</sup>

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<sup>83</sup> Federal Sec. Adm’r v. Quaker Oats, 318 U. S. at 230.

<sup>84</sup> See Chen, *supra* note 19, at 195–97 (discussing the burdensome costs associated with recipe standards and the different approaches taken).

<sup>85</sup> Suzanne White Junod, *Food Standards in the United States: The Case of the Peanut Butter and Jelly Sandwich*, in FOOD, SCIENCE, POLICY AND REGULATION IN THE TWENTIETH CENTURY 167, 183–84 (David F. Smith & Jim Phillips eds., 2000); see *Corn Products Co. v. Dep’t of Health Educ. & Welfare*, 427 F.2d 511 (3d Cir. 1970) (the Third Circuit affirmed the FDA’s standards of fat and additives in peanut butter).

<sup>86</sup> Chen, *supra* note 19, at 195 (citing 21 C.F.R. § 130.17 (2015); 37 Fed. Reg. 26,340 (Dec. 9, 1972); 40 Fed. Reg. 21,721 (May 19, 1975)) (Chen, in advocating for the continued use of recipe standards, has pointed out that the FDA has since addressed some of the administrative burdens through additional regulations such as temporary permits); see also, *Derby Foods, Inc. v. Food and Drug Admin.*, 400 U.S. 957, 957 (1970) (referring to the Supreme Court’s denial of certiorari and affirmation of the Third Circuit’s ruling in *Corn Products Co. v. Dep’t of Health Educ. & Welfare* 427 F.2d 511 (3d Cir. 1970)).

<sup>87</sup> 21 C.F.R. § 164.150(a) (2005). For those who want a cheap and less nutty spread, regulations in 1977 opened up the market to “peanut spread.” See 21 C.F.R. § 102.23(a) (2015) (requiring the term “peanut spread” and “a statement of percentage by weight of peanuts”).

<sup>88</sup> See Chen, *supra* note 19, at 196 (discussing restrictions of substitute foods).

<sup>89</sup> 21 C.F.R. § 161.175 (2015); See also Chen, *supra* note 19, at 202

While requiring the main ingredient to be “shrimp material” the requirements for the remainder of the food only needed to be “safe and suitable” ingredients.<sup>90</sup> By creating a more flexible standard without affixing particular ingredients necessary for breading and batter, manufacturers were free to create a variety of products without fear of being subject to section 403(g) as a misrepresentation.<sup>91</sup> Consumers were still protected because the ingredients must be “safe and suitable” which the FDA defined as ingredients that perform an appropriate function in food, in no higher than necessary quantity, and that are not colors or food additives within the meaning of the Act.<sup>92</sup> After the initial success of the more flexible standards, the FDA began widespread reform of all of its standards in 1972.<sup>93</sup>

The shift to more flexible standards allowed for more food variety and enabled consumers to make choices for themselves.<sup>94</sup> Recognizing the importance of allowing consumers to choose, Congress enacted the Fair Packaging and Labeling Act (FPLA) in 1966, reaffirming the policy that “[i]nformed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons.”<sup>95</sup> The FPLA required labeling the quantity of contents, identity of product, name of manufacturer, and serving size for a wide range of products.<sup>96</sup> Labels needed to be placed prominently on packaging and be of a conspicuous type size.<sup>97</sup> Thus, consumers were free to pick between jam or Bred Spread,<sup>98</sup> melted butter, or mineral oil,<sup>99</sup> and

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(discussing how the FDA’s flexible standards first began with ingredients for “frozen raw breaded shrimp”).

<sup>90</sup> 21 C.F.R. § 161.175 (2015); *See also* Chen, *supra* note 19, at 202 (discussing the FDA’s standard for the remaining ingredients).

<sup>91</sup> Chen, *supra* note 19, at 191.

<sup>92</sup> 21 C.F.R. § 130.3(d) (2015).

<sup>93</sup> Chen, *supra* note 19, at 202.

<sup>94</sup> *See id.* at 200–01 (discussing how FDA recipe standards allowed for less confusion, thus empowering consumers to make their own choices as well as facilitating manufacturer’s innovation of new food products).

<sup>95</sup> 15 U.S.C. § 1451 (1966).

<sup>96</sup> Fair Packaging and Labeling Act, Pub. L. No. 89-755, § 4, 80 Stat. 1296, 1297–98 (1966) (codified as amended at 15 U.S.C. § 1453 (2015)).

<sup>97</sup> *Id.* at 1297.

<sup>98</sup> *See supra* note 41 and accompanying text (discussing labeling of Bred Spread).

<sup>99</sup> *See supra* note 64–68 and accompanying text (discussing labeling of Pop’n Oil).

decide just how many vitamins they wanted in their farina.<sup>100</sup>

### C. Nutritional Labeling

The FDA also experienced reform due to a new problem in 1969 when “the Nixon Administration convened the White House Conference on Food, Nutrition, and Health to address” public interest in the nutritional content of food in the face of rising “food production, processing, and packaging.”<sup>101</sup> The event led the FDA to “require[] nutritional labeling on any food product making a claim regarding its nutritional value or to which the manufacturer had added nutrients.”<sup>102</sup> Additionally, manufacturers were subject to certain labeling formats and required to identify certain nutrients on the labels.<sup>103</sup> Furthermore, “labeling of fat and cholesterol content . . . [was required] . . . in a per-serving form, but only if the manufacturer . . . [had] label[ed] the product with fat and cholesterol content.”<sup>104</sup> As a result, “approximately 60 percent of processed and packaged foods . . . [contained] nutrition labeling” as early as 1989.<sup>105</sup>

Much like preceding regulation, while the new labeling requirements were marked improvements for consumer knowledge, there remained significant gaps in the information disclosure requirements.<sup>106</sup> Through scientific research and reports, the importance of diet to overall health became increasingly apparent.<sup>107</sup> With evidence clearly establishing the negative effects of fat consumption, the voluntary labeling requirements were revealed as inadequate measures.<sup>108</sup>

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<sup>100</sup> See *supra* note 71–81 and accompanying text (discussing labeling of Quaker Oats with added vitamin D).

<sup>101</sup> Gillett, *supra* note 21, at 278.

<sup>102</sup> *Id.* (citing Nutrition Labeling, 38 Fed. Reg. 6,951, 6,959 (Mar. 14, 1973)).

<sup>103</sup> Gillett, *supra* note 21, at 278.

<sup>104</sup> *Id.* at 278–79 (citing Labeling of Foods With Information on Cholesterol and Fat and Fatty Acid Composition, 38 Fed. Reg. 6,961 (Mar. 14, 1973)).

<sup>105</sup> *Id.* at 279 (quoting Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29,487, 29,490 (Jul. 19, 1990)).

<sup>106</sup> Gillett, *supra* note 21, at 279.

<sup>107</sup> *Id.* (citing Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg. 29,487, 29,490 (Jul. 19, 1990) “detailing comments received by the FDA in preparation for potential new labeling regulation”).

<sup>108</sup> See Greenberg, *supra* note 27, at 11 (explaining the negative reaction as a result of the lack of requirements making it mandatory to list cholesterol or fiber contents despite medical advice to consume in moderation).

Additionally, with updated scientific evidence finding nutrients such as fiber to be beneficial, there was a need to expand labels to include such information as well.<sup>109</sup> Furthermore, labeling remained inconsistent due to conflicting state requirements,<sup>110</sup> FDA's inconsistency in overseeing health claims,<sup>111</sup> and confusing units of measurement.<sup>112</sup> Proponents of reform stated that better and more uniform labeling requirements would create incentives for manufacturers to produce healthier food and discourage the use of misleading health claims.<sup>113</sup> As a result, both Congress and the FDA began looking for solutions.<sup>114</sup>

To address labeling deficiencies, Congress passed the Nutrition Labeling and Education Act of 1990 (NLEA).<sup>115</sup> The NLEA helped create uniformity and reduce confusion by creating national labeling requirements, giving the Secretary of the Department of Health and Human Services authority to define certain terms, and giving enforcement power to the FDA under the FDCA.<sup>116</sup> Rather than voluntary labeling, the NLEA required most foods to be labeled with serving sizes in "common household measure[s]," number of servings, and calories, including identification of calories from all sources and calories from fat.<sup>117</sup> Additionally, certain specified nutrients needed to be listed, and allowed the Secretary to require listing for other nutrients deemed

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<sup>109</sup> Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, 55 Fed. Reg., 29,487, 29,490 (Jul. 19, 1990).

<sup>110</sup> See INST. OF MED., FOOD LABELING, TOWARD NATIONAL UNIFORMITY 85–140 (Donna V. Porter & Robert O. Earl eds., 1992) (discussing labeling requirements across states); Gillett, *supra* note 21, at 280.

<sup>111</sup> Gillett, *supra* note 21, at 280.

<sup>112</sup> The recommended dietary allowances (RDAs) at this time used standard measurement (grams and milligrams) while the typical American consumer did not understand the significance of these figures. See David A. Kessler et al., *Developing the "Nutrition Facts" Food Label*, 4 HARV. HEALTH POL'Y REV. 13, 15 (2003) (explaining for example that some relatively large numbers confusingly represented small intakes).

<sup>113</sup> See Fred R. Shank, *The Nutrition Labeling and Education Act of 1990*, 47 FOOD & DRUG L.J. 247, 249 (1992) (explaining that the labeling requirements provided a disincentive to introduce healthier food products).

<sup>114</sup> See Greenberg, *supra* note 27, at 11 (describing a "two-track" response to labeling problems).

<sup>115</sup> 21 U.S.C. § 343 (2015) (statute codified and amended from the Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, §2, 104 Stat. 2353, 2353–57).

<sup>116</sup> See Christine Lewis Taylor & Virginia L. Wilkening, *How the Nutrition Food Label Was Developed, Part 1: The Nutrition Facts Panel*, 108 J. AM. DIETETIC ASS'N 437, 438–39 (2008) (discussing some "guiding principles" of the design of the new food label).

<sup>117</sup> 21 U.S.C. § 343(q).

relevant.<sup>118</sup> To address consumer confusion over the use of grams and milligrams, the FDA required that labeling include the percentage of U.S. Recommended Daily Allowance (RDA) of each nutrient, expressed on the label as “% Daily Value.”<sup>119</sup> To prevent consumer deception, certain information was required to be in “larger type, bold type, or contrasting color.”<sup>120</sup> To create uniformity, State labeling laws were preempted and no State could create regulations inconsistent with the Act.<sup>121</sup> Finally, the NLEA limited the use of health claims on food packages while leaving further claim regulation to be determined by the FDA.<sup>122</sup> The NLEA in many ways addressed problems while remaining flexible and providing uniform regulation.

#### *D. Organic Labeling*

At the same time as enactment of the NLEA, Congress also passed the Organic Foods Production Act of 1990 (OFPA), to regulate organic labeling regulations.<sup>123</sup> The original rationale for organics was that compost, rather than pesticides or chemical

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<sup>118</sup> *Id.* (labeling required inclusion of “[t]otal fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein,” and any other nutrients that that Secretary determined would “assist consumers in maintaining healthy dietary practices”).

<sup>119</sup> Kessler et al., *supra* note 113, at 15–16 (The FDA found this approach was most helpful to consumers because it allowed them to quickly tell if a product contained a large or small portion of the recommended amount. Thus, a food containing 140 mg of sodium and 5 g of saturated fat may initially confuse a consumer into thinking there is little fat and a lot of sodium, but with the percentages the consumer is able to see that there is actually very little sodium and relatively high levels of saturated fats.).

<sup>120</sup> 21 U.S.C. § 343(q)(1)(E) (2015).

<sup>121</sup> See Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6, 104 Stat. 2353, 2362 (1990) (discussing preemption of the “National Uniform Nutrition Labeling”).

<sup>122</sup> *Id.* § 3. (The NLEA specifically ordered the Secretary of the Department of Health and Human Services to develop standards for claiming a relationship between “calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease.” The NLEA permitted claims only when “significant scientific agreement” supported them. The NLEA also required the Secretary to develop definitions for certain common terms, including “free,” “low,” “light or lite,” “reduced,” “less,” and “high.”).

<sup>123</sup> Organic Foods Production Act of 1990, Pub. L. No. 101-624, 104 Stat. 3935 (codified as amended at 7 U.S.C. § 6501); Michelle T. Friedland, *You Call That Organic? - The USDA’s Misleading Food Regulations*, 13 N.Y.U. ENVTL. L.J. 379, 381 (2005) (the organic movement can be traced back to 1942, with the founding of a magazine called “Organic Farming and Gardening”).

fertilizers, would lead to more fertile soil and healthier crops.<sup>124</sup> While initially ridiculed by the scientific community, much like Upton Sinclair's The Jungle did for food safety, Rachel Carson's, Silent Spring,<sup>125</sup> helped gain traction for a movement against the use of pesticides.<sup>126</sup> With consumer demand came fraudulent claims and organic labeling grew until twenty-two states had organic labeling requirements by 1990.<sup>127</sup> OFPA helped to unify the varying standards under a single certifying authority.

Under the OFPA, USDA was given authority to create a program for certifying products as "organic," including the creation of a "USDA Organic" seal to be used on labels to demonstrate compliance with the USDA's National Organic Program (NOP).<sup>128</sup> The OFPA created uniformity but still allowed states to create organic certification programs at least as restrictive as the USDA's standards.<sup>129</sup> The OFPA established the National Organic Standard Board which "assist[s] in the development of standards for substances to be used in organic production" and works with the government to implement the organic certification program.<sup>130</sup>

The OFPA took a process-oriented approach and specified what practices a farmer could or must use in order to qualify as organic.<sup>131</sup> Specifically, the OFPA regulations' focus is on processes such as how food is grown, harvested, and prepared.<sup>132</sup> This leads to requirements such as crop pest management protocols, soil fertility management, and livestock care.<sup>133</sup> In

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<sup>124</sup> Friedland, *supra* note 123, at 381.

<sup>125</sup> See RACHEL CARSON, SILENT SPRING (Houghton Mifflin 1962) (an environmental science book documenting the harmful effects on the environment resulting from the use of pesticides).

<sup>126</sup> *See id.*

<sup>127</sup> Jessica Ellsworth, The History of Organic Food Regulation (2001) (unpublished Third Year Paper) (on file with the Harvard University DASH repository).

<sup>128</sup> See Organic Foods Production Act of 1990, *supra* note 124, at §§ 6503–6505; See generally The Organic Integrity Quarterly, USDA (May 2014) <http://www.ams.usda.gov/sites/default/files/media/2014-Organic-May-Newsletter.pdf> (outlining organic seal requirements under OFPA and the functions of the National Organic Program).

<sup>129</sup> See Organic Foods Production Act of 1990, *supra* note 124, at § 6507 (describing federal requirements for state-based organic certification programs).

<sup>130</sup> *Id.* § 6518.

<sup>131</sup> See generally *id.* § 6508–6512 (describing acceptable and prohibited methods of crop and animal care that farmers may use).

<sup>132</sup> Friedland, *supra* note 124, at 384.

<sup>133</sup> *Id.*

contrast, previous regulations were product-based and focused on the observable characteristics of the product such as fat content, fiber, and ingredient composition.<sup>134</sup> The focus on the process rather than the end product separated the OFPA from other labeling regulations.

## II. INFORMATION DISCLOSURE REGULATION & CONSUMER DECEPTION

*“Let me be clear about one thing. The organic label is a marketing tool. It is not a statement about food safety. Nor is ‘organic’ a value judgment about nutrition or quality.”*

– Secretary of Agriculture Dan Glickman<sup>135</sup>

Food labeling, like all informational disclosure requirement regulation can help combat consumer deception. Consumer deception occurs when (1) sellers have more knowledge of their product than consumers, (2) sellers disclose some information to consumers, (3) based on the disclosed information, consumers form expectations and beliefs (4) based on the formed expectations and beliefs, consumers make product choices, and (5) some of the consumers’ beliefs and expectations are false.<sup>136</sup> Consumer deception causes harm by creating distorted individual purchasing decisions, preventing people from satisfying their actual product preferences, and creating an inefficient allocation of resources.<sup>137</sup> Thus, to avoid consumer deception, labeling should help ensure the accuracy of consumers beliefs and expectations about the attributes of certain products.

When beliefs and expectations are false, there is a problem. As stated in the introduction, regulation is often the result of a problem, or at least a perceived problem, often related to a disparity between expectations and reality.<sup>138</sup> For food labeling, regulation often addressed concerns that consumer expectations and beliefs were not being met. For the passage of the NLEA and its predecessors, that problem was growing concerns over the nutritional quality of food and allowing consumers to make

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<sup>134</sup> See generally *supra* Part II.A–C (describing the history of food regulation and substantial changes in focus of regulation policy over time).

<sup>135</sup> *New USDA Label Will Clearly Identify ‘Organic’ Foods*, WEBMD (Dec. 20, 2000), [www.webmd.com/food-recipes/20001220/new-usda-label-will-clearly-identify-organic-foods?page=1](http://www.webmd.com/food-recipes/20001220/new-usda-label-will-clearly-identify-organic-foods?page=1).

<sup>136</sup> Chen, *supra* note 19, at 186.

<sup>137</sup> *Id.*

<sup>138</sup> See *supra* Part I.A; see also Sinclair, *supra* note 29 (exposing the realities of food hygiene much to the shock of readers).

informed choices about foods based on expectations and the relative nutritional quality of foods.<sup>139</sup> Scientific evidence demonstrated that the nutritional value of food mattered and the regulation was a reflection of that science.<sup>140</sup> Qualities of food, such as fat content, were important to consumers because such qualities had an effect on health and by requiring that information to be available to consumers, the NLEA allowed for healthier choices to be made.<sup>141</sup> Additionally, up until the passage of the NLEA all labeling had similarly been focused on the nutritional quality of the food and ensuring consumer beliefs and expectations were met.<sup>142</sup> Even recipe standards were based on the belief at the time, however misguided it was, that traditional foods were “superior” and allowing for alternatives could confuse and defraud consumers.<sup>143</sup> Thus, up until 1990, regulation had conveyed to consumers that what appeared on food labels was there to provide information about the nutritional value of food and protect consumer expectations as to the quality of food.<sup>144</sup>

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<sup>139</sup> See *supra* Part II.C (discussing nutritional labeling).

<sup>140</sup> See *supra* notes 104–114 and accompanying text (discussing scientific findings and their facilitation of changes to label requirements).

<sup>141</sup> See, e.g., Gillett, *supra* note 21, at 334–35 (examining the use of labels by consumers and concluding that labels have a positive influence on purchasing decisions); Mathios, *supra* note 21, at 671 (concluding that the move to mandatory labeling under the NLEA should result in lower sales for higher-fat salad dressings and noting that the introduction of the new nutrition labels helped consumers gather and understand nutrition information); Variyam & Cawley, *supra* note 21, at 20–21 (concluding that following the passage of the NLEA obesity rates declined among non-Hispanic white female consumers who used nutrition labels); Neuhouser et al., *supra* note 21, at 49–50 (concluding that use of post-NLEA nutrition labeling by consumers reduced their fat consumption); Kristal et al., *supra* note 21, at 1214–1215 (concluding that the NLEA and related FDA labeling rules increased use of nutrition labels by consumers); Satia et al., *supra* note 21, at 400 (concluding that nutrition label use increased fruit and vegetable consumption and reduced fat intake among African Americans in North Carolina); Kim et al., *supra* note 21, at 215 (finding that label use improved appropriate consumption of fiber and decreased the intake of calories from total fat, saturated fat, cholesterol, and sodium); Post et al., *supra* note 21, at 628 (finding that patients with chronic disease who read food labels consumed less calories, saturated fat, carbohydrates, and sugar, and more fiber); Weaver & Finke, *supra* note 21, at 217–18 (finding that frequent use of labels for information regarding sugar content was associated with lower added sugar consumption).

<sup>142</sup> See Caswell, *supra* note 25, at 151 (stating that the market effects of labeling depend on its impact on consumer perceptions of the product attributes, “the benefits and costs of labeling for companies, and the goals of government policy”).

<sup>143</sup> Chen, *supra* note 19, at 194.

<sup>144</sup> See Caswell, *supra* note 25, at 151 (discussing consumer perceptions). The

Naturally, consumers would then believe that the new label for organics was also meant to convey information relating to the nutritional value of food. Indeed, according to the Organic Trade Association (OTA), the primary driving force behind the consumer choice to buy organic is “for health reasons.”<sup>145</sup> However, there is currently no scientific consensus identifying organics as either healthier or safer than alternatives.<sup>146</sup>

Unlike the NLEA, where the regulation was passed in response to scientific consensus on the value of certain food characteristics, organic labeling was passed without scientific consensus and studies are still underway to determine what, if any, value organic food has for consumers.<sup>147</sup> Meanwhile, consumers are operating under the unsupported belief that purchasing organic products has a significant affect on their health.<sup>148</sup> Two details about federal regulation of organics

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consumer perceptions of organic product attributes are discussed in Part III.A while the goals of the OFPA are discussed in Part III.B. The benefits and costs of labeling are discussed in Part IV.C, but only to examine how the preemption of other potential organic labels may affect the market.)

<sup>145</sup> See *id.* (discussing consumer perceptions); See e.g., Elizabeth Weise, *Here’s Proof That Organic Foods Aren’t Much More Nutritious Than Regular Foods*, BUSINESS INSIDER (Sep. 4, 2012), <http://www.businessinsider.com/youre-wasting-money-if-you-think-organic-foods-have-more-nutrients-2012-9> (discussing various studies of consumer motivation for purchasing organic foods: for example, a 2010 study wherein 76% of consumers reported buying organics “believing they are healthier,” and a study by the Organic Trade Association showing that 48% of parents reported believing organic foods “are healthier for me and my children.”)

<sup>146</sup> Crystal Smith-Spangler et al., *Are Organic Foods Safer or Healthier than Conventional Alternatives?: A Systematic Review*, ANNALS OF INTERNAL MED., 2012 348, 348 (concluding that “published literature lacks strong scientific evidence that organic foods are significantly more nutritious than conventional foods,” but also noting that “[c]onsumption of organic foods may reduce exposure to pesticide residues and antibiotic-resistant bacteria”).

<sup>147</sup> See *id.* (discussing lack of scientific evidence that organic foods are more nutritious than “conventional” alternatives).

<sup>148</sup> Weise, *supra* note 146. Recent analysis has gone even further to suggest that “widespread, collaborative and pervasive [organic] industry marketing activities are a primary cause for false and misleading consumer . . . perceptions” and that there is “a widespread organic and natural products industry pattern of research-informed and intentionally-deceptive marketing and advocacy related practices with implied use and approval of the U.S. government endorsed USDA Organic Seal.” *Organic Marketing Report* ACADEMICS REVIEW, [http://academicsreview.org/wp-content/uploads/2014/04/AR\\_Organic-Marketing-Report\\_Print.pdf](http://academicsreview.org/wp-content/uploads/2014/04/AR_Organic-Marketing-Report_Print.pdf). (last visited Jan. 9, 2016). While this paper examines the goals and policies of the OFPA in relation to consumer deception, it does not comment on whether or not the consumer deception has been intentional.

illuminates this problem: (1) the OFPA focuses on the process of production rather than the end product in regulating organics<sup>149</sup> and (2) the USDA, rather than the FDA, is tasked with regulating organic labeling.<sup>150</sup>

A. *The National Organic Program: Organics as a Process*

The Senate Report accompanying the OFPA states, “Organic food is food produced using sustainable production methods that rely primarily on natural materials.”<sup>151</sup> The “organically produced” label authorized under this bill therefore pertains to the production methods used to produce the food rather than to the content of the food.”<sup>152</sup> While market reports suggest many consumers of organic products have not read the Senate Report accompanying the OFPA, the Act remains focused on the process of organic food and does not purport to convey information about the nutritional quality of the end product.<sup>153</sup> While regulation of the food-making process may help to convey information to consumers, often, the information is more accurately and precisely conveyed through direct information about the product.<sup>154</sup> Even for expectations that rely on the process, such as environmental impacts of food production, better labeling requirements than organic certification can convey the necessary information.<sup>155</sup>

1. Product vs. Process: OMEGA-3 and -6 FATTY ACIDS

In order to convey information to meet health expectations, regulating the product rather than the process is ideal. For example, omega-3 fatty acids are considered an essential fatty

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<sup>149</sup> See *infra* Part III.A (discussing organics as a process).

<sup>150</sup> See *infra* Part III.B (discussing OFPA).

<sup>151</sup> Charles Campbell, *What's Organic? Puzzles Farmers, Consumers*, LA TIMES (Oct. 07, 1990), [http://articles.latimes.com/1990-10-07/news/mn-2835\\_1\\_organic-food](http://articles.latimes.com/1990-10-07/news/mn-2835_1_organic-food).

<sup>152</sup> S. Rep. No. 101–357, at 4672 (1990), *reprinted in* 1990 U.S.C.C.A.N. 4656.

<sup>153</sup> *Id.*; see e.g., Kenneth C. Amaditz, *The Organic Foods Production Act of 1990 and its Impending Regulations: A Big Zero for Organic Food?*, 52 FOOD DRUG L.J. 537, 550 (1997) (noting that “most consumers do not read the Federal Register . . . [and therefore OFPA] is unlikely to make consumers more knowledgeable about organic foods than they were before Congress passed the OFPA.”).

<sup>154</sup> See *infra* Part III.A.1 (discussing conveyance of information to consumers).

<sup>155</sup> See *infra* Part III.A.2 (discussing consumer expectations about environmental impacts of food production).

acid, necessary for health, and the body does not make them.<sup>156</sup> There has been widespread research showing that consumption of omega-3 fatty acids is beneficial to human health.<sup>157</sup> However, much like the optional labeling of fats before passage of the NLEA, the amount of omega-3 fatty acids in foods is required only when the label states the product contains omega 3-fatty acids.<sup>158</sup> Additionally, evidence indicates that the traditional Western diet promotes a ratio of omega-3 fatty acids to omega-6 fatty acids that is unhealthy and could lead to adverse health impacts.<sup>159</sup> This evidence, like the scientific evidence that led to regulation in the past, shows a problem that could be addressed

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<sup>156</sup> *Omega-3 Fatty Acids*, UNIV. OF MD. MED. CTR., <http://umm.edu/health/medical/altmed/supplement/omega3-fatty-acids> (last visited Oct. 12, 2015).

<sup>157</sup> See e.g., A. Aben & M. Danckaerts, *Omega-3 and Omega-6 Fatty Acids in the Treatment of Children and Adolescents with ADHD*, 52 *TJDSCHRIFT VOOR PSYCHIATRIE* 89, 97 (2010) (“There is a growing trend towards the use of alternative forms of treatment for attention deficit hyperactivity disorder (adhd), such as the food supplements omega-3 and omega-6 fatty.”); Peter Angerer & Clemens von Schacky, *n-3 Polyunsaturated Fatty Acids and the Cardiovascular System*, 3 *CURRENT OPINION IN CLINICAL NUTRITION AND METABOLIC CARE* 439, 439 (2000) (“n-3 Polyunsaturated fatty acids, mainly those contained in fish oils, are candidates for inclusion in secondary prevention programmes for coronary heart disease, based on the results of recent randomized trials in humans”); Esther Boelsma, Henk FJ Hendriks & Len Roza, *Nutritional Skin Care: Health Effects of Micronutrients and Fatty Acids*, 73 *AM. J. CLINICAL NUTRITION* 853, 855 (2001) (“In the search for means to improve human health, n-3 polyunsaturated fatty acids (PUFAs) have been promoted as valuable dietary compounds.”); see generally, BM Yashodhara, S. Umakanth, J.M. Pappachan et. al, *Omega-3 Fatty Acids: A Comprehensive Review of Their Role in Health and Disease*, 85 *POSTGRAD MED. J.* 84 (2009) (“Omega-3 fatty acids (n-3 FAs) are essential fatty acids with diverse biological effects in human health and disease.”).

<sup>158</sup> See *Guidance Document: Labeling and Nutrition, Nutrient Content Claims*, U.S FOOD AND DRUG ADMIN. (Jan. 2013), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064908.htm> (“To use the words ‘contains’ or ‘provides’ for nutrients without DVs, the specific amount of the nutrient must be stated. The statements ‘contains x grams of omega-3 fatty acids per serving’ or ‘provides x g of omega-3 fatty acids’ are permitted. However, ‘contains omega-3 fatty acids’ or ‘[p]rovides omega-3 fatty acids’ (without the specific amount statement) would not be permitted. Such claims would be synonyms for a “good source” claim which is not permitted for nutrients that do not have established DVs.”); see also 21 C.F.R. § 101.54 (2015) (setting forth requirements for “good source” claims).

<sup>159</sup> A.P. Simopoulos, *The Importance of the Ratio of Omega-6/Omega-3 Essential Fatty Acids*, 56 *BIOMEDICINE & PHARMACOTHERAPY* 365, 365 (2002) (citing adverse health impacts such as the “promot[ion of] the pathogenesis of many diseases, including cardiovascular disease, cancer, and inflammatory and autoimmune diseases.”).

through information disclosure requirements.<sup>160</sup> Arguably, organic regulation conveys this information since organic processes may improve the fatty acid ratios of foods.<sup>161</sup> Additionally, different processes of livestock care, in general, yield different ratios.<sup>162</sup> However, the FDA could directly require omega-3 and -6 fatty acids to be put on nutrition labels with the RDA and recommended ratio as well. Regulating the end product, not the process, allows for specific labeling showing the exact ratio and content of the food, which is the best way to ensure consumer expectations are met. Since consumers are largely motivated by health expectations when making purchases and direct nutritional labeling is the best way to convey that information, labeling should focus on the product not the process to meet consumer expectations about nutrition.<sup>163</sup>

## 2. Expectations About the Environmental Impact of Food

Secondary to health benefits, consumers buy organic because of beliefs about the environmentally friendly nature of organic production.<sup>164</sup> While research on organics is still ongoing, evidence does indicate that organic products may be worse for the environment in at least some instances.<sup>165</sup> Much like health

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<sup>160</sup> See *supra* notes 107–122 and accompanying text (discussing Congress’s past treatment of labeling deficiencies).

<sup>161</sup> Charles M. Benbrook et al., *Organic Production Enhances Milk Nutritional Quality by Shifting Fatty Acid Composition: A United States–Wide, 18-Month Study*, 8 PLOS ONE 1, 2 (2013) (explaining how a cow’s consumption of grass can affect omega-3 concentrations in cow milk).

<sup>162</sup> See, e.g., Maryline Kouba & Jacques Mourot, *A Review of Nutritional Effects on Fat Composition of Animal Products with Special Emphasis on n-3 Polyunsaturated Fatty Acids*, 93 BIOCHIMIE 13, 13 (2011) (“The fatty acid composition of animal products (eggs, milk and meat) is the reflect of both the tissue fatty acid biosynthesis and the fatty acid composition of ingested lipids.”).

<sup>163</sup> See *supra* notes 146–149 and accompanying text (discussing consumer health expectations regarding organics).

<sup>164</sup> See, e.g., ALYSSA-MARIE G. TISON, A STUDY OF ORGANIC FOOD CONSUMERS’ KNOWLEDGE, ATTITUDES AND BEHAVIOR REGARDING LABOR IN ORGANIC FARMS 9 (2012), [http://nature.berkeley.edu/classes/es196/projects/2012final/TisonA\\_2012.pdf](http://nature.berkeley.edu/classes/es196/projects/2012final/TisonA_2012.pdf) (when asked to define “organic,” respondents to study of consumer perception of organics wrote “environmentally friendly” among other descriptions inconsistent with the United States National Organic Certification Standards definition.); DEL I HAWKINS ET AL. CONSUMER BEHAVIOR: BUILDING MARKETING STRATEGY 87 (Tata McGraw-Hill ed. 11th ed. 2010) (noting a Whole Foods study showing that 58% of Americans “believe that organic is better for the environment.”).

<sup>165</sup> H.L. Tuomisto et al., *Does Organic Farming Reduce Environmental Impacts? – A Meta-Analysis of European Research*, 112 J. OF ENVTL. MGMT. 309,

expectations, while labeling something as “organic” may sometimes signify that the product is better for the environment, it is an imprecise definition that does not adequately consider the environmental impacts associated with the process.<sup>166</sup> In order to help consumers make food choices based on environmental impacts, labels could include precise measurements such as greenhouse gas emissions per unit and energy consumption per unit.<sup>167</sup> At the very least, the labels should reflect a scientific evaluation of the relative environmental impact of the methods of production. Thus, a label conveying information about the environmental impact of certain foods would not be based on the process being organic or not, but on the quantifiable impacts that the process has.<sup>168</sup> For example, similar to the FDA’s abandoned

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309, 314 (2012) (Among the findings, the research analysis demonstrated that organic milk, cereals, and pork generated higher greenhouse gas emissions per product than conventional ones but organic beef and olives had lower emissions in most studies. Additionally, because organic farming tends to have a lower yield per acre, some environmental benefits are deceiving. For example, organic farms have lower nitrous oxide emissions per unit of field area, but higher when measured per unit of product).

<sup>166</sup> See Nick Feinstein, *Learning From Past Mistakes: Future Regulation to Prevent Greenwashing*, 40 B.C. ENVTL. AFF. L. REV. 229, 238 (2013) (While recognizing that organic processes may have some environmental benefits, and that quantifying environmental benefits or harms is often difficult, the OFPA does not attempt to use scientific data to compare production methods to find the most environmentally beneficial one, but instead seeks to choose a method based on an imprecise definition of what is “organic,” and such a definition is not rooted in science. Indeed, many commentators have accused the OFPA of “greenwashing,” a term used when a product is described as environmentally friendly when it is not. (citing Elizabeth Allen, *Food Regulations: Natural Selection?; Federal Rules Limit the ‘Organic’ Label, But Set Off Loophole Hunts*, SAN ANTONIO EXPRESS-NEWS, May 21, 2003, at 1E; Blake M. Mensing, *USDA Organic: Ecopornography or a Label Worth Searching For?*, 2008 SUSTAINABLE DEV. L. & POLY 24 (criticizing the USDA for allowing certain synthetic substances, including nitrites and nitrates, in organic-labeled meat); Chenlin Liu, *Is “USDA ORGANIC” a Seal of Deceit?: The Pitfalls of USDA Certified Organics Produce in the United States, China and Beyond*, 47 STAN. J. INT’L L. 333, 378 (2011)).

<sup>167</sup> As meta-analysis of available data demonstrates, there is a vast amount of information measuring the environmental impacts of food production with specific values rather than imprecise guidelines, and these values could be incorporated into labels. See e.g., Tuomisto et al., *supra* note 166, at 318 (finding specific data on environmental impacts per unit of area of land used for organic farming).

<sup>168</sup> Michael Pollan, *Behind the Organic-Industrial Complex*, NY TIMES (May 13, 2001), <http://www.nytimes.com/2001/05/13/magazine/13ORGANIC.html?pagewanted=all> (stating that “it has always been easier to make the environmental case for organic food than the health case” but that organics face a marketing challenge since “[t]he chief reason [consumers] buy organic is for

notion that “time honored” recipes were superior;<sup>169</sup> the OFPA allows the use of pesticides that naturally occur based on the (largely unsupported) notion that what is natural is better.<sup>170</sup> However, evidence suggests that natural pesticides may pose similar risks as synthetic counterparts.<sup>171</sup> Thus, the underlying problem remains that the OFPA does not use scientific data to determine what processes should be allowed.<sup>172</sup> In any case, if labels are meant to inform consumers, the agency in charge of overseeing informational requirements should have expertise pertaining to the information—health, environmental, or otherwise.<sup>173</sup> Thus, the second problem with organic labeling is the USDA’s goal of marketing.

### B. *The USDA: Organics as a Marketing Tool*

Prior to the passage of the OFPA, organic food was growing in

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the perceived health benefits”).

<sup>169</sup> See *supra* Part II.B.2 (discussing the FDA’s use of more flexible standards in the 1960’s).

<sup>170</sup> USDA, *Organic Production/Organic Food: Information Access Tools*, USDA NAT’L AGRIC. LIBRARY (June 2007), <http://www.nal.usda.gov/afsic/pubs/ofp/ofp.shtml> (noting that organic food may still have some residue); *But see* ACADEMICS REVIEW, *supra* note 149, at 2 (“While oft touted as the ‘traditional’ way we used to farm, today’s organic industry and practices are relatively young . . . . [E]arly ideas and writings promoted a shift to chemical-free farms.”).

<sup>171</sup> Lois Swirsky Gold et al., *Rodent Carcinogens: Setting Priorities*, 258 SCIENCE 261 (1992) (noting that while the public “tends to view chemicals as only synthetic and [thinks] synthetic chemicals [are] toxic despite the fact that every natural chemical is also toxic at some dose.”).

<sup>172</sup> See Jason J. Czarnezki, *The Future of Food Eco-Labeling: Organic, Carbon Footprint, and Environmental Life-Cycle Analysis*, 30 STAN. ENVTL. L.J. 3, 15 (2011) (“OFPA creates process-based standards but does not implement standards or require tests for actual chemical content in food, nor assessment of overall land use practices.”).

<sup>173</sup> 16 C.F.R. § 260.1 (2015) (the Federal Trade Commission (FTC) currently provides guides for the use of environmental marketing claims); Keith Schneider, *Guides on Environmental Ad Claims*, NY TIMES (July 29, 1992), <http://www.nytimes.com/1992/07/29/business/guides-on-environmental-ad-claims.html> (some unsuccessfully called for the Environmental Protection Agency (EPA) to use its authority to create more robust regulations that may have helped create environmental labels); K. Alexandra McClure, *Environmental Marketing: A Call for Legislative Action*, 35 SANTA CLARA L. REV. 1351, 1361–62 (1995) (describing the Senate’s failure to pass proposed legislation that would have given the EPA authority to regulate environmental marketing terminology); Feinstein, *supra* note 167, at 229, 236–238 (discussing inadequacies in regulation of environmental marketing). Thus, the fact remains that current regulations have the potential to, and very well do cause consumer deception based on false environmental beliefs.

popularity thus giving producers an incentive to label their products as “organic.”<sup>174</sup> Between private and state regulation, there was a lack of uniformity and consumer confusion as a result.<sup>175</sup> The confusion had the potential to hurt the growth of the emerging organic market.<sup>176</sup> Thus, the National Association of State Departments of Agriculture, American Farm Bureau Federation, several major organic industry trade associations, as well as consumer interests pressed Congress to act.<sup>177</sup>

While the OFPA can be seen as similar to other regulation because it was a response to a problem, the problem leading to the passage of the OFPA was quite different. For the PFDA, PDCA, and the NLEA, the problem was ensuring consumers had access to safe, healthy, and nutritious food.<sup>178</sup> Thus the FDA, an agency of the US Department of Health and Human Services, was given authority because the agency “is responsible for protecting the public health by assuring the safety, efficacy, and security of . . . our nation’s food supply.”<sup>179</sup> However the NLEA was a response to ensuring the survival and growth of the organic market.<sup>180</sup> Thus, the USDA’s goals are “to provide economic opportunity through innovation, helping rural America to thrive,” which fit with the goals of organic regulation—goals that are not closely tied to the health and safety of Americans.<sup>181</sup> Rather than consumer-oriented, the approach is producer-oriented meant to address the needs and demands of the producers of organic products. The approach is reflected in the three main goals of the OFPA: “(1) to establish national standards governing the marketing of certain agricultural products as organically produced products; (2) to assure consumers that organically produced products meet a consistent

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<sup>174</sup> See Lauren Zeichner, *Product vs. Process: Two Labeling Regimes for Genetically Engineered Foods and How They Relate to Consumer Preference*, 27 ENVIRONS ENVTL. L. & POL’Y J., 467, 471 (2004) (noting that food could be labeled “organic” “regardless of whether it contain[ed] 100 or 20 percent organically grown ingredients”).

<sup>175</sup> *Id.* at 471–72.

<sup>176</sup> *Id.* at 472.

<sup>177</sup> *Id.*

<sup>178</sup> See *supra* Part II and accompanying text (discussing various food regulations as they arose in response to a problem).

<sup>179</sup> *About FDA*, FDA.GOV (last updated Aug. 5, 2014), <http://www.fda.gov/aboutfda/whatwedo/>.

<sup>180</sup> See *supra* Part III.B and accompanying text (discussing the purpose of the NLEA).

<sup>181</sup> *What We Do*, USDA (last modified Aug. 27, 2015), [http://www.usda.gov/wps/portal/usda/usdahome?navtype=MA&navid=ABOUT\\_USDA](http://www.usda.gov/wps/portal/usda/usdahome?navtype=MA&navid=ABOUT_USDA).

standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.”<sup>182</sup> The NLEA’s labeling requirements were meant to “assist consumers in maintaining healthy dietary practices.”<sup>183</sup> Thus, the NLEA ensured that consumer expectations about the nutritional content of food products were accurate.<sup>184</sup> Contrastingly, organic labeling does not ensure the accuracy of consumer expectations and beliefs about the attributes of organic products.

The OFPA as a response to industry demands is reflected in the provisions of the OFPA, which cater to industry interests perhaps to the detriment of consumers.<sup>185</sup> For example, following a lawsuit, the USDA was required to strengthen its organic standards.<sup>186</sup> However, Congress amended the OFPA to allow the standards to remain unchanged.<sup>187</sup> A major reason for the lack of change was the potential financial impact the changes would have on the organic industry.<sup>188</sup>

However, consumers can also have an impact on organic standards because, as a marketing tool, it is meant to address consumer demand.<sup>189</sup> For example, despite many organic advocates being against the use of genetic engineering, the practice was initially included in the permissible organic practices promulgated by the USDA.<sup>190</sup> As a result, 275,603 comments were submitted to the USDA, with almost universal

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<sup>182</sup> 7 U.S.C. § 6501 (2015). Even the second goal, which mentions consumers, can be understood as facilitating consumer trust in order to better promote the sale of organics.

<sup>183</sup> 21 U.S.C. § 343(q)(1)(E) (2015).

<sup>184</sup> See *supra* Part III.A.1 and accompanying text (discussing NLEA requirements).

<sup>185</sup> Claire S. Carroll, *What Does “Organic” Mean Now? Chickens and Wild Fish are Undermining the Organic Foods Production Act of 1990 (Evolution of the Legal Definition of “Organic”—Business Interests Must be Stopped from Redefining “Organic” Contrary to the Purposes of the Organic Foods Production Act of 1990)*, 14 SAN JOAQUIN AGRIC. L. REV. 117, 126 (2004).

<sup>186</sup> Fatema Merchant, *Got Organic Milk? “Pasture”-Ize It!: An Analysis of the USDA’s Pasture Regulations for Organic Dairy Animals*, 14 ANIMAL L. 237, 248 (2008).

<sup>187</sup> *Id.*

<sup>188</sup> *Id.* (reporting the consequences of the Harvey lawsuit and possible detrimental effects on organic businesses that would have had to comply with the court’s rulings).

<sup>189</sup> Zeichner, *supra* note 175, at 476 (“Consumer expectation is key to the National Organic Program because one of the goals of the Organic Foods Production Act is the creation of a marketing regime that is uniform, for the sake of both producers and consumers of organics.”).

<sup>190</sup> *Id.* at 474.

public opposition to the use of genetic engineering in organic production systems.<sup>191</sup> Responding to consumer demand, the USDA subsequently prohibited the use of genetic engineering.<sup>192</sup>

While seemingly a victory for consumers, the prohibition on genetic engineering emphasizes the point that the OFPA is about marketing, not health and safety. As will be seen below, the FDA, in accordance with the Office of Science and Technology Policy, takes a very different approach to genetic engineering.<sup>193</sup> From a scientific standpoint, there is nothing inherently dangerous about genetic engineering, but to ensure that consumers will buy organic it became apparent that the definition of organic must prohibit genetic engineering even if the need is based on false consumer expectations and beliefs.<sup>194</sup> The status quo remains the same: the OFPA is focused on marketing organics. As a result, there is very little incentive for the USDA to help resolve confusion over the perceived benefits of organics. A consumer belief, even if false, that leads consumers to buy organic products meets the marketing goals of the organic industry and thus the goals of the OFPA. However, it undermines the policy of food labeling to ensure that consumer expectations are met.<sup>195</sup> Consumers are further defrauded because organic food is often more expensive than alternatives, and consumers are willing to purchase the more expensive option because they are willing to pay more for what is perceived as a healthier option.<sup>196</sup>

Organic labeling may cause other problems for consumers as well. First, recent analysis suggests that because consumers think organic food is more nutritious, there is a tendency to eat too many calories when eating organics.<sup>197</sup> Referred to as the “health halo effect,”<sup>198</sup> the impact is less pronounced when

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<sup>191</sup> *Id.* at 475.

<sup>192</sup> 7 C.F.R. § 205.105 (2015).

<sup>193</sup> *See infra* Part IV.A.1 and accompanying text (discussing biotechnology regulation).

<sup>194</sup> *Id.*

<sup>195</sup> *See supra* notes 129–136 and accompanying text (discussing the approach of the OFPA).

<sup>196</sup> *See supra* Part III.A and accompanying text (discussing consumer motivation for purchasing organics).

<sup>197</sup> *See* Jenny Lee Wan-chen, et al., *You Taste What You See: Do Organic Labels Bias Taste Perceptions?* 29 *FOOD QUALITY AND PREFERENCE* 33, 33 (2013) (participants estimated lower calories in foods labeled organic and found that foods labeled organic tasted lower in fat and higher in fiber than foods not labeled organic).

<sup>198</sup> *Id.*

consumers read nutrition labels.<sup>199</sup> However, by setting up a robust regulatory body around organic labeling, the federal government has reinforced that “organic” has some value, consumers have attached false health values to the label, and as a result the labeling may be causing harm to the health of consumers.<sup>200</sup> Thus, the USDA’s regulation of organics may be undermining the FDA’s informational regulation and leading to consumer deception. While further studies are needed, without evidence of the health benefits of organics and evidence that organic labeling is counterproductive to ensuring consumer expectations are met, federal organic labeling should be withheld to prevent consumers from falsely believing that organic products are superior.<sup>201</sup>

### III. LIMITING GOVERNMENT INFORMATION DISCLOSURE REQUIREMENT REGULATIONS

*“[It’s] utter nonsense . . . the first thing any consumer must do with any product is to assume the claims on the front of the label are a pack of lies and scrutinize the fine print on the back to learn what’s actually in the product.”*

*-Stephen Gardner, Chief Litigator, Center for Science in the Public Interest<sup>202</sup>*

Labels need to be limited to information that clearly conveys relevant data to consumers and allows for informed purchasing decisions to be made with accurate beliefs and expectations. The law surrounding warning labels is instructive and states that a label’s location is important.<sup>203</sup> Often, less important labels such as “organic” will be presented on the front of a food product, immediately visible to the consumer, while the nutritional label is on the back.<sup>204</sup> Furthermore, where a product poses multiple

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<sup>199</sup> *Id.*

<sup>200</sup> See Maria K. Magnusson et al., *Choice of Organic Foods is Related to Perceived Consequences for Human Health and to Environmentally Friendly Behaviour*, 40 *APPETITE* 109, 115 (2003) (“Consumers believing that organic foods are healthier than conventional foods may perceive short-term health consequences when consuming organic foods.”).

<sup>201</sup> See *infra* Part IV.A.1 (the FDA has taken this approach to labels conveying information about genetic engineering).

<sup>202</sup> Eric Spitznagel, *Drink Deception and the Legal War on Vitaminwater*, *BLOOMBERG BUSINESS* (July 26, 2013), <http://www.bloomberg.com/bw/articles/2013-07-26/drink-deception-and-the-legal-war-on-vitaminwater>.

<sup>203</sup> Kenneth Ross & Matthew W. Adams, *Legally Adequate Warning Labels: A Conundrum for Every Manufacturer*, 2008 *FOR THE DEFENSE* 7, 7, 8.

<sup>204</sup> See e.g., *O Organics—Organic from the Source*, *SAFEWAY*, <http://www>.

risks, to prevent dilution, only the most important information should be on the label, with others being put in reference manuals.<sup>205</sup> Similarly, food products should have simple labels that convey the most relevant and necessary information as quickly and clearly as possible.<sup>206</sup>

Together, the guidance on labeling generally and the lessons learned from the history of food labeling reveal that policymakers should be cautious before implementing additional information disclosure requirements. When additional regulation is required, it should look to the relevant scientific data as well as the potential for consumer deception. The FDA's approach to labeling provides context to how these principles function in practice.<sup>207</sup>

From a broader perspective, while an increase in the number of health- and nutrition-related claims on foods may seem to call for more regulation, the current FDA regulation's focus on what is scientifically relevant can adequately curtail these claims if they are misleading.<sup>208</sup> Finally, in lieu of government regulation, for information that consumers may want but lacks scientific validity and/or may cause consumer deception, private certification may provide a solution.<sup>209</sup>

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safeway.com/ShopStores/O-Organics/OOCereal.page (last visited Oct. 12, 2015) (demonstrating examples of where organic labels can be found in certain types of organic breakfast foods).

<sup>205</sup> See, e.g., *Broussard v. Continental Oil Co.*, 433 So. 2d 354, 358 (La. Ct. App. 1983), *writ denied*, 440 So. 2d 726 (La. 1983) ("As a practical matter, the effect of putting at least ten warnings on the drill would decrease the effectiveness of all of the warnings."); see generally J. Scott Dutcher, Comment, *Caution: This Superman Suit Will Not Enable You to Fly - Are Consumer Product Warning Labels Out of Control?*, 38 ARIZ. ST. L. J. 633, 633–34 (2006) (arguing that manufacturers need to limit warnings to the most applicable and useful ones).

<sup>206</sup> Caswell, *supra* note 25, at 157 ("The use of labeling to influence the operation of markets for food safety and process attributes is limited [by] . . . space on the label . . . . Mandatory labeling programs use some of this precious space, which marketers resist. Because only a limited amount of label space may be used by labeling regulations, governments must make decisions about what are the highest and best uses of the scarce labeling resource. [Further,] labeling is [also] a scarce resource in that consumers devote only a limited amount of time to using label information, especially at the point of purchase.").

<sup>207</sup> See *infra* Part IV.A and accompanying text (discussing the FDA's approach to additional labeling).

<sup>208</sup> See *infra* Part IV.B and accompanying text (discussing health and nutrition-related claims).

<sup>209</sup> See *infra* Part IV.C and accompanying text (discussing private certification as an option).

### A. *The FDA's Approach to Additional Labeling*

Three FDA policy choices demonstrate the benefit of limiting labels based on relevant scientific data and the potential for consumer deception. First, taking genetic engineering information disclosures for example, when there is no scientific data compelling regulation, mandatory labeling should not be put in place and even voluntary labeling should be limited to prevent consumer deception.<sup>210</sup> Second, even where information disclosure requirements are a reflection of scientific data, such as the nutrition label, agencies should ensure that consumers are not attaching false expectations to the information and ensure that the information is presented in a consumer-friendly manner.<sup>211</sup> Third, even where consumers may attach false expectations to some information disclosures, regulation is sometimes required for compelling public health and safety concerns.<sup>212</sup>

#### 1. Limiting GMO Labeling

For biotechnology regulation agencies look to the Office of Science and Technology Policy (OSTP), which has created guidance on biotechnology regulations since 1986.<sup>213</sup> The guidelines were crafted by an interagency group, which “sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.”<sup>214</sup> The Framework invokes the principle that “techniques of biotechnology are not inherently risky and that biotechnology should not be regulated as a process, but rather

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<sup>210</sup> See *infra* Part IV.A.1 and accompanying text (discussing GMO labeling).

<sup>211</sup> See *infra* Part IV.A.2 and accompanying text (discussing FDA's consideration of nutrition label updates reflecting newly emerged scientific information).

<sup>212</sup> See *infra* Part IV.A.3 and accompanying text (discussing how gluten-free labeling has potential to cause consumer deception).

<sup>213</sup> Zeichner, *supra* note 175, at 478–79; National Science and Technology Policy, Organization, and Priorities Act of 1976, Pub. L. No. 94–282, Title II, §205, 90 Stat. 464 (1976) (codified as amended 42 U.S.C. §§ 6614 (1976)) (Congress established the OSTP in 1976 with the passage of the National Science and Technology Policy, Organization, and Priorities Act of 1976. The OSTP's policy is to advise agency efforts and provide guidance related to “scientific and technological analysis and judgment.”).

<sup>214</sup> Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

that the products of biotechnology should be regulated in the same way as products of other technologies.”<sup>215</sup> The OSTP determined that ensuring the safety of biotechnology required a focus on the characteristics of the product rather than on the process of the product’s creation.<sup>216</sup> Based on scientific observation, the OSTP justified the risk-based approach because “genetically modified organisms are not per se of inherently greater risk than unmodified organisms.”<sup>217</sup>

Relying, on the guidance provided by OSTP, the FDA issued a “Statement of Policy” in 1992 discussing how the FDA would regulate genetically engineered foods.<sup>218</sup> The FDA applied the “substantial equivalence” doctrine to genetically engineered foods, meaning that if a genetically engineered food has similar health and nutritional characteristics to conventional counterparts, then it will not be subject to special scrutiny.<sup>219</sup> The FDA states in its Policy that

the agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.<sup>220</sup>

Subsequent litigation demonstrated that consumer demand for labeling is a secondary consideration and the FDA’s primary concern was the relevance of the information to health.<sup>221</sup> In

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<sup>215</sup> COMMITTEE ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS (NATIONAL RESEARCH COUNCIL), *GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION* 25 (National Academy Press 2000), *quoted in* Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. L. J. REFORM 403, 431 (2002).

<sup>216</sup> Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992).

<sup>217</sup> See Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992). (as detailed in Part III, the USDA drastically departed from these guidelines) Zeichner, *supra* note 175, at 478 (explaining the OSTP’s risk based approach).

<sup>218</sup> Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed Reg. 22,1984 (May 29, 1992).

<sup>219</sup> Council for Biotechnology Information, *Substantial Equivalence in Food Safety Assessment* (Mar. 2001), [http://foodsafety.ksu.edu/articles/497/Substantial\\_Equivalence.pdf](http://foodsafety.ksu.edu/articles/497/Substantial_Equivalence.pdf).

<sup>220</sup> Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed Reg. 22,984 (May 29, 1992).

<sup>221</sup> Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 172 (D. D.C. 2000) (although this was not the first time the FDA had been challenged for

*Alliance for Bio-Integrity*, plaintiffs challenged the FDA's failure to require labeling for genitally engineered foods.<sup>222</sup> Under the FDCA, foods shall be deemed misbranded if their labeling "fails to reveal facts . . . material with respect to consequences which may result from the use of the articles to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual."<sup>223</sup> While the plaintiffs argued that "consumer interest" was material, the court deferred to the FDA's interpretation of the statute that "material" information was limited to facts that could impact health and safety.<sup>224</sup> Thus, the FDA's decision was upheld.<sup>225</sup>

In follow-up guidance, the FDA stated "[a] statement that a food was not bioengineered . . . may be misleading if it implies that the labeled food is superior to foods that are not so labeled."<sup>226</sup> Since, in accordance with the OSTP, there is nothing inherently better or worse about the characteristics of food produced through a genetically engineered process, labeling should not suggest to the contrary. Thus, despite not giving consumers what they wanted, the FDA's policy is still in the best interest of consumers. Much like organic labeling, requiring labeling for genetically engineered foods would affect consumer decisions, but would do so based on false expectations about the characteristics of the product.<sup>227</sup> Likely, consumers would avoid genetically engineered products, purchase more expensive

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genetically engineered labeling); *See* *Stauber v. Shalala*, 895 F. Supp. 1178, 1182, 1194 (W.D. Wis. 1995) (The FDA was challenged for not labeling milk produced from cows treated with certain drugs. The court held that "[i]n the absence of evidence of a material difference between rBST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate [the FDCA].").

<sup>222</sup> *Alliance*, 116 F. Supp. 2d. at 178.

<sup>223</sup> 21 U.S.C. § 321(n).

<sup>224</sup> *Alliance*, 116 F. Supp. 2d at 178, 181.

<sup>225</sup> *Id.* at 181.

<sup>226</sup> *DRAFT Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance*, FDA.GOV (Jan. 2001), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm> (last visited Oct. 10, 2015).

<sup>227</sup> *See Alliance*, 116 F. Supp. 2d at 181 (demonstrating the wide-spread consumer interest in avoiding genetically engineered foods for health and other reasons despite a lack of evidence that genetically engineered foods are substantially different than conventional counterparts); *See also supra* Part III.A–B and accompanying text for additional information (discussing organics and consumer perception thereof).

options, and be paying more for a “substantially equivalent” product.<sup>228</sup> Thus, by adhering to the underlying goals of regulation, relying on sound scientific evidence, and resisting uneducated consumer demand, the FDA’s policies limiting labeling requirements prevent consumer deception.<sup>229</sup>

## 2. The FDA’s New Food Label

The FDA is currently considering changes to the Nutrition Facts label, originally introduced twenty years ago.<sup>230</sup> Principally, the updates reflect newly emerged scientific information such as known links between nutrients and chronic diseases.<sup>231</sup> Additionally, in order to ensure that consumers both receive and understand the label,<sup>232</sup> updates in how the information is displayed is needed.<sup>233</sup> For example, calories and serving sizes would be more prominent to reflect their importance in addressing current public health concerns.<sup>234</sup> In contrast to ignoring how consumers receive and interpret the USDA’s organic label,<sup>235</sup> the FDA’s policies reflect attempts to allow consumers to effectively and beneficially utilize nutrition labels.<sup>236</sup> Additionally, the FDA’s approach seeks to limit the information to what is scientifically relevant and allow

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<sup>228</sup> See *supra* Part III.A–B and accompanying text (discussing consumer expectations).

<sup>229</sup> *The Dark Act*, JUST LABEL IT, <http://justlabelit.org/dark-act/> (last visited Oct. 12, 2015) (The organic industry, and the USDA by proxy, have taken action to undermine the FDA’s attempts to prevent consumer deception about genetic engineering through the use of the industry-funded “Just Label It” campaign which is designed to raise questions about the safety of genetically engineered products.); ACADEMICS REVIEW, *supra* note 149, at 4 (Noting the lack of scientific evidence compelling such labeling, it has been suggested that the organic industry’s goal is to create fear about conventional foods in order to convince consumers to buy organic, even if the decision is based on false beliefs.).

<sup>230</sup> Food Labeling: Revision of the Nutrition and Supplement Facts Label, 79 Fed. Reg. 11,880 (Mar. 3, 2014).

<sup>231</sup> *Id.*

<sup>232</sup> See 21 U.S.C. § 343 (defining misbranded food).

<sup>233</sup> Food Labeling: Revision of the Nutrition and Supplement Facts Label, 79 Fed. Reg. 11,880 (Mar. 3, 2014).

<sup>234</sup> *The Proposed New Nutrition Facts Label at a Glance*, FOOD POLITICS, <http://www.foodpolitics.com/wp-content/uploads/Fact-Sheet.pdf> (last visited Jan. 12, 2016).

<sup>235</sup> See *supra* Part III and accompanying text (discussing consumer deception).

<sup>236</sup> See *The Proposed New Nutrition Facts Label at a Glance*, *supra* note 235 (showing the FDA’s proposed updates to labeling and serving size requirements in order to help consumers make healthier choices).

consumers easy access to the most relevant information.<sup>237</sup>

### 3. Gluten-Free Labeling

Unlike mandatory genetic engineered labeling, or the ever-present Nutrition Facts label, the FDA has also taken a consumer-oriented approach to voluntary labeling, such as “Gluten Free.”<sup>238</sup> Much like organics, gluten free sales experienced a large market increase between 2009 and 2012.<sup>239</sup> While people with celiac disease need to avoid gluten, other consumers seem to prefer it based on scientifically unsupported (and thus possibly false) beliefs about its effect on health.<sup>240</sup> However, the FDA’s focus in creating a standard for gluten-free focused exclusively on the need to protect those with celiac disease.<sup>241</sup> Setting the standard at a maximum gluten content of < 20 ppm, the FDA considered what affect such exposure of gluten would have on those with celiac disease as well as the potential inability of those with celiac disease to find adequate nutrition with a more restrictive standard.<sup>242</sup> Thus, the FDA did not focus on what manufacturers were willing to set the standard at, but what would be the best standard for consumers affected by gluten.<sup>243</sup>

While beneficial, gluten-free labeling, like organic labeling, has the potential to cause consumer deception where consumers attach false expectations to gluten-free products resulting in a “health halo” effect.<sup>244</sup> The FDA, in compliance with the Food

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<sup>237</sup> *Id.*

<sup>238</sup> See generally, *Guidance Documents: Gluten-Free Labeling of Foods*, FDA.GOV, <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm362510.htm> (last updated June 15, 2015) (discussing the prevalence of celiac disease, which is triggered by a gluten intolerance, as well as alternative sites to learn more about gluten-free labeling).

<sup>239</sup> Jeanine Ibrahim, *Cashing in on the Booming Wheat-Free Market*, CNBC (Aug. 26, 2013, 12:03 PM), <http://www.cnbc.com/id/100987975>.

<sup>240</sup> *Id.*

<sup>241</sup> Food Labeling; Gluten-Free Labeling of Foods, 78 Fed. Reg. 47,154, 47,154–55 (Aug. 5, 2013) (to be codified at 21 C.F.R. pt. 101).

<sup>241</sup> *Id.* at 47,159–60.

<sup>242</sup> *Id.* at 47,160.

<sup>243</sup> *Id.*

<sup>244</sup> See Steve W. Martinez, *Introduction of New Food Products with Voluntary Health- and Nutrition-Related Claims, 1989-2010*, ECON. INFO. BULL. NO. 108, 21, 28, (2013) (finding that, beyond sufferers of celiac disease, surveys suggest that consumers attribute other health benefits to a gluten-free diet and that health- and nutrition-claims are troubling when consumers create false beliefs

Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) also has a duty to protect those who suffer from celiac disease.<sup>245</sup> While labeling will never perfectly address all concerns, at least with gluten-free labeling the need to protect those with celiac disease counterbalances the potential harm caused by any “halo” effect the label may have. Gluten-free is just one of many health- and nutrition-related claims that has come up in recent years. While those with celiac disease provide a reason for the FDA to set standards for gluten-free labeling, other claims offer a different perspective.

### *B. Health- and Nutrition-Related Claims*

Due in large part to the passage of the NLEA, health and nutrition-related claim use dropped during the 1990’s.<sup>246</sup> However, the following decade saw an increase in health- and nutrition-related claims.<sup>247</sup> These claims reflect “increases in low/no calorie, whole grain, high fiber, and low/no sugar claims, along with relatively new claims related to no gluten, no trans fats, antioxidants, and omega-3.”<sup>248</sup> The claims are a natural market response to consumer demand for healthy foods.<sup>249</sup> With new claims, such as those related to omega-3’s and gluten-free, regulation should respond to them based on available scientific data and the potential for consumer deception.<sup>250</sup> However, hidden trade-off claims about sugar, fat, or other information that is already on the label presents a different problem. While not usually false, hidden trade-off claims are misleading because they focus consumers on a single attribute while drawing

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leading to a health “halo” effect).

<sup>245</sup> Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, Title II, § 202, 118 Stat 891, 906 (codified as amended at 21 U.S.C. § 43 (2004)).

<sup>246</sup> Martinez, *supra* note 245, at iii. The NLEA’s efforts to reduce misleading claims and thus reduce consumer deception also offers another contrast to the OFPA. While the OFPA regulates what may be defined as “organic” it leaves other similar terms such as “natural” unregulated, despite consumer confusion over the relevance and distinctions between these terms; *see e.g.*, Organic Foods Production Act of 1990, *supra* note 124, at § 2103, 104 Stat. 3935 (the list of definitions does not include a definition of “natural”).

<sup>247</sup> Martinez, *supra* note 245, at iii.

<sup>248</sup> *Id.* at i.

<sup>249</sup> *See supra* Part III.B.1 and IV.A.3 and accompanying text (discussing consumer perceptions and labeling regulations).

<sup>250</sup> *See supra* Part IV.A and accompanying text (discussing limiting information disclosure requirement regulations).

attention away from other detracting product features.<sup>251</sup> A recent example is seen in Cytosport Inc.'s use of a claim that a protein drink was "healthy," despite the high fat content of the drink.<sup>252</sup> The FDA's response and subsequent litigation reveals that when such claims mislead consumers, current information disclosure requirements can adequately address the problem.

On June 29, 2011 the FDA sent a warning letter to Cytosport Inc.,<sup>253</sup> producers of Muscle-Milk, a protein nutrition shake designed and marketed to fitness enthusiasts.<sup>254</sup> The first problem with Muscle-Milk is that it does not contain any milk.<sup>255</sup> However, the product's additional labeling stated that it "Contains No Milk" which may harm the lactose-intolerant since the product contains milk-derived products such as calcium and sodium caseinate.<sup>256</sup> Additionally, the product claimed to be "healthy" despite exceeding fat limits for such a claim.<sup>257</sup> Additionally, because the product made the claim "0g Trans Fat" and also had more than 13g of total fat, it needed to include a disclosure stating "'See nutrition information for \_\_\_\_\_ content' with the blank filled in with the identity of the nutrient exceeding the specified level."<sup>258</sup> Despite the high-fat content, misleading trade off claims, and a lack of over-all information, many consumers purchased Muscle-Milk to aid in living a healthy lifestyle.<sup>259</sup>

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<sup>251</sup> See generally, TERRACHOICE, *The Sins of Greenwashing: Home and Family Edition*, SINS OF GREENWASHING 10 (2010), <http://sinsofgreenwashing.org/index35c6.pdf> (While used here in connection with misleading nutrition claims, the "sin of the hidden trade off" is included in "The Seven Sins of Greenwashing" and more often refers to a suggestions that a product is "green" based on an "unreasonably narrow set of attributes without attention to other important environmental issues.").

<sup>252</sup> *Warning Letter to Cytosport Inc.*, FDA.GOV (June 29, 2011), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm261684.htm>.

<sup>253</sup> *Id.*

<sup>254</sup> See generally, MUSCLE MILK, <http://www.muscle milk.com/> (last visited Jan 12, 2016) (featuring various athletes presumably using Muscle Milk as a means to improve their athletic performance).

<sup>255</sup> *Warning Letter to Cytosport Inc.*, *supra* note 253.

<sup>256</sup> *Id.*

<sup>257</sup> *Id.* (citing 21 C.F.R. § 101.65(d)(2)).

<sup>258</sup> *Id.* (citing 21 C.F.R. § 101.13(h) & (i)).

<sup>259</sup> See *Cytosport 100% Whey Protein Powder 6LBS*, COSTCO WHOLESALE (2015), <http://www.costco.com/Cytosport-100%25-Whey-Protein-Powder-6LBS.product.100225865.html> (For the sake of full disclosure, the author of this piece has consumed several Muscle-Milk products, both before and after the label was changed.).

Following a class-action lawsuit,<sup>260</sup> Muscle-Milk's label now informs consumers that it contains no milk but does contain milk proteins, includes the total calories on the front label, and does not use the word "healthy."<sup>261</sup> In less than five years since the warning letter was issued, Cytosport is now paying consumers and its label is, arguably, an accurate reflection of its nutritional content.<sup>262</sup> By eliminating misleading hidden tradeoff claims, consumers are able to make informed decisions based on the nutrition labels that give all the relevant information. Thus, despite increased health and nutrition-related claims, when it comes to nutritional labeling, consumer deception is adequately combated by existing information disclosure requirements—in other words less labeling, not more, helps avoid consumer deception because additional labeling detracts from relevant scientifically-rooted information disclosure requirements. While Muscle-Milk claimed to be "healthy,"<sup>263</sup> that statement did not help consumers despite its relative truth. By limiting the label and requiring disclosure where needed, food labeling helps consumers make healthy choices, meet expectation, and avoid deception.<sup>264</sup>

### C. Other Options: Private Certification

From the history of food labeling two fundamental lessons have emerged: (1) overly strict information disclosure requirements, such as recipe standards, can cause harm by limiting choices,<sup>265</sup> and (2) information disclosure requirements based on scientifically relevant data, such as the NLEA, improve consumer

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<sup>260</sup> See *Delacruz v. Cytosport, Inc.*, No. C 11-3532 CW, 2012 WL 1215243, at \*1 (N.D. Cal. 2012) (action against Cytosport alleging Cytosport's misleading of consumers through misrepresentations in advertising).

<sup>261</sup> See generally *Muscle Milk Products*, MUSCLEMILK.COM <http://www.muscle milk.com/products/ready-drink/genuine/> (featuring one type of Muscle Milk product with the required FDA labeling) (last visited Oct. 13, 2015).

<sup>262</sup> *Id.*

<sup>263</sup> See *Warning Letter to Cytosport Inc.*, *supra* note 253 (describing Muscle Milk's labeling of certain protein enriched products with the phrase "Healthy Sustained Energy").

<sup>264</sup> See Caswell, *supra* note 25, at 152 ("Mandatory disclosure requirements may force disclosure of negative attributes or the balanced disclosure of positive and negative attributes. For example, nutrition labeling may require a complete accounting of the nutrient content of a product or require that if a voluntary claim is made (e.g., high fiber), then information on all nutrients must be provided (e.g., fat and cholesterol content).").

<sup>265</sup> See *supra* Part II.B.1 (describing the changes that resulted from altering recipe standards).

choices.<sup>266</sup> The OFPA fails in both regards.<sup>267</sup> First, it creates a strict standard preempting labels that could include other “organic” values, and second, it is not rooted in science and may harm consumer choices as a result. On the other hand, without federal regulation, there was widespread organic certification that lacked uniformity.<sup>268</sup> Kosher labeling demonstrates that the solution to such labeling confusion does not have to be federal intervention.<sup>269</sup>

The organic labeling scheme can be paralleled to the failed recipe standards employed by the FDA. Similar to a fixed recipe standard, defining what is organic is difficult due to several definitions and a basis in tradition rather than science.<sup>270</sup> Thus, like recipe standards, as the organic market broadens it becomes increasingly difficult to identify the particular characteristics that consumers would expect.<sup>271</sup> The FDA was able to move away from recipe standards because flexible standards could still ensure food was safe and suitable.<sup>272</sup> However, if the USDA’s goal is to create a consistent definition of “organic” and consumers have varying definitions of “organic” then continued use of the USDA label is contrary to consumer interests.

Some see “organic” as encompassing an entire way of life.<sup>273</sup> Some have even gone so far as to refer to “organics as religion.”<sup>274</sup>

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<sup>266</sup> See *supra* Part II.C (discussing the passage of the NELA and positive impact the law brought).

<sup>267</sup> See *supra* Part III (discussing the relationship between consumer satisfaction and labeling requirements).

<sup>268</sup> See *supra* Part III.B (describing the lack of uniformity that resulted from conflicting state and private requirements).

<sup>269</sup> See generally TIMOTHY D. LYTTON, *KOSHER: PRIVATE REGULATION IN THE AGE OF INDUSTRIAL FOOD* (2013) (describing the role of private regulation in success of kosher labeling).

<sup>270</sup> Richard A. Merrill & Earl M. Collier, Jr., “*Like Mother Used to Make*”: *An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 567 (1974).

<sup>271</sup> *Id.*

<sup>272</sup> See *supra* Part II.B.2 (describing the balance created between flexible food standards and safe and suitable food options).

<sup>273</sup> Mark Bittman, *Eating Food That’s Better for You, Organic or Not*, NEW YORK TIMES (Mar. 21, 2009), <http://www.nytimes.com/2009/03/22/weekinreview/22bittman.html>.

<sup>274</sup> SUSAN A. SCHNEIDER, *FOOD, FARMING, AND SUSTAINABILITY* 659 (2011) (discussing organic production practices) (citing Bryan Endres, *An Awkward Adolescence in the Organics Industry: Coming to Terms with Big Organics and Other Legal Challenges for the Industry’s Next Ten Years*, 12 DRAKE J. OF AGRIC. L. 17, 19 (2007) (discussing “organics as a religion”); see also Sigman, *supra* note 275, at 595 (stating that “[t]here is no scientific definition of *organic*; thus, an organic diet is a form of secular religion.”).

Thus, kosher labeling regulations rooted in *kashrut* (Jewish dietary law) may help provide solutions to some of the problems with organic labeling.<sup>275</sup> Organic can mean different things to different people, thus reflecting a need for a variety of labels.<sup>276</sup> For example, Joel Salatin; a farmer, lecturer, and author, has rejected federal regulation because “‘organic’ identifie[s] an idea and a paradigm rather than a visceral list of dos and don’ts. And . . . people realize that no system can regulate integrity.”<sup>277</sup> If expectations about organics such as health and environmental benefits are better communicated through other means,<sup>278</sup> then the remaining concerns about the “integrity” of organic farming processes is best left to private industries responding to varying consumer demands and incentivized by brand competition based on loyalty.<sup>279</sup> As Salatin’s efforts demonstrate, organic labeling has the potential, like kosher labeling, to feature a “unique group of sophisticated consumers, who vigilantly attempt to identify mistake and fraud within the food industry.”<sup>280</sup> Thus, zealous consumers can stage boycotts against fraudulent vendors and use their inter-connected community to spread information to promote honesty by producers.<sup>281</sup> As kosher labeling demonstrates, multiple private certifiers are less of a problem when the label is based on somewhat divergent theories and

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<sup>275</sup> See generally William H. Shea, *Clean and Unclean Meats*, BIBLICAL RESEARCH INSTITUTE (Dec. 1988), [https://adventistbiblicalresearch.org/sites/default/files/pdf/CleanandUnclean%20Meats\\_0.pdf](https://adventistbiblicalresearch.org/sites/default/files/pdf/CleanandUnclean%20Meats_0.pdf) (describing the law in Judaism regarding clean and unclean animals).

<sup>276</sup> Benjamin N. Gutman, *Ethical Eating: Applying the Kosher Food Regulatory Regime to Organic Food*, 108 YALE L. J. 2351, 2352 (1999) (“‘Organic’ refers to a set of philosophical beliefs about our relationship with the environment, not merely to the physical characteristics of a product.”); see also Sigman, *supra* note 275, at 595 (noting the similarities between diet and religion).

<sup>277</sup> Megan Phelps, *Everything He wants to Do is Illegal*, MOTHER EARTH NEWS (Oct. 1, 2008), <http://www.motherearthnews.com/homesteading-and-livestock/joel-salatin-interview.aspx#axzz2zYqSbYTy>.

<sup>278</sup> See *supra* Part III.A.2 (discussing reasons consumers buy organic products).

<sup>279</sup> See Gutman, *supra* note 276, at 2352 (“Defining the precise ‘meaning’ of organic through uniform regulations deprives these people of the right to make choices in harmony with their own beliefs.”); see also Timothy Lytton, *Kosher Certification: A Model of Reliable Food Label Regulation*, FOODUCATE (Mar. 25, 2013), <http://blog.fooducate.com/2013/03/25/kosher-certification-a-model-of-reliable-food-label-regulation> (discussing the kosher food business and brand competition among kosher certifiers).

<sup>280</sup> Sigman, *supra* note 274, at 565.

<sup>281</sup> *Id.*

groups zealously seek to ensure that the certification meets their expectations.<sup>282</sup>

However, if organic buyers are a diverse group, then only the portion very involved will be able to utilize private labeling. Organic buyers can be classified into three categories: core, mid-level, and periphery.<sup>283</sup> The core consumers are highly engaged, passionate about organics, and make up the majority of organic consumers.<sup>284</sup> Thus, for the majority of organic consumers, private labeling is a viable option. However, mid-level consumers may second-guess how “deep” they want to go into organics and periphery consumers are minimally involved.<sup>285</sup> The disparate labeling of organics would also help those who are less zealous in their pursuit of eating organic and simply want healthier food. Much like previous regulation, organic regulation arose from consumer mistrust of existing food safety regulations.<sup>286</sup> The current problems that many consumers believe organic labeling addresses—health and environmental problems—are not adequately included in the goals of the OFPA.<sup>287</sup> However, for these consumers, the government labeling has increased trust of organic products.<sup>288</sup> Thus, consumers more readily attach false beliefs to organics when there is a uniform government label, and removing that label helps avoid consumer deception and make clear what “organic” truly encompasses—a value system that is

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<sup>282</sup> *Id.* at 579.

<sup>283</sup> *Beyond Organic & Natural 2010 Resolving Confusion in Marketing Food and Beverages Report Review*, THE HARTMAN GROUP, INC., (Feb. 2010), <http://store.hartman-group.com/content/organic-and-natural-2010-overview.pdf>.

<sup>284</sup> *Id.* (“[core] organic consumers continue to be the largest organic purchasers, and have the largest number of motivations to purchase organic.”).

<sup>285</sup> *Id.* (explaining that mid-level consumers can be split into “outer mid-level” and “inner mid-level” and that Outer mid-level consumers “remain occasional organics consumers” while inner mid level consumers “use organic products on a regular basis, and periphery consumers are “least intensely involved in the [w]orld of [o]rganics.”).

<sup>286</sup> See Gutman, *supra* note 276, at 2354, n.14 (citing Gordon G. Bones, *State and Federal Organic Food Certification Laws: Coming of Age*, 68 N.D. L. REV. 405, 405 & n.2 (1992) (discussing the effects of the Alar scare on the demand for organic food) and citing OLUF CHR. BOCKMAN ET AL., AGRICULTURE AND FERTILIZERS: FERTILIZERS IN PERSPECTIVE 212 (1990) (“The present problems [concerning food and health] derive from composition of the diet and amounts consumed, not from the way food is produced on farms.”).

<sup>287</sup> See *supra* Part III.A. (describing the purpose and focus of the OFPA).

<sup>288</sup> Organic Belief Study, *supra* note 146; Schroeder, *supra* note 149, at 1 (“Since its formal launch in 2001, the trade association arm of the organic industry has stated that the USDA Organic Seal endorsement has been a critical element in establishing consumer trust in their product offerings.”).

more about spirituality than scientific reality.<sup>289</sup> Additionally, because consumers believe that the OFPA helps address health and environmental problems, there is less pressure to create regulation that actually does address these problems.<sup>290</sup> As a result, removing the government standard would create the opportunity to explore better labeling options, based on scientific evidence that actually addresses the underlying problems.<sup>291</sup>

#### IV. CONCLUSION

When it comes to food regulation, information disclosure requirements can often offer a relatively simple solution to large problems.<sup>292</sup> However, if such regulations lack a scientific basis and fail to consider the potential for consumer deception, then they may create problems of their own.<sup>293</sup> Thus, government agencies should give careful consideration to the implications of

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<sup>289</sup> Ron Strohlic, *Regulating Organic: Impacts of the National Organic Standards on Consumer Awareness and Organic Consumption Patterns*, CALIF. INST. FOR RURAL STUDIES 12 (Dec. 2005) <http://www.cirsinc.org/publications/category/9-food-systems#> (The Agricultural Marketing Service concluded that the USDA seal and marketing program was responsible for increased consumer trust in and willingness to pay more for organic products.).

<sup>290</sup> See WILLIAM T. BIANCO, RICHARD FENNO'S CONVENTIONAL WISDOM *in* CONGRESS ON DISPLAY, CONGRESS AT WORK 1, 8 (William T. Bianco, ed.) (2000) (stating that "by being accessible to constituents and presenting themselves in a way that suggests agreement with constituent interests, legislators gain voting leeway—the ability to vote as their personal policy preferences dictate rather than as their constituents demand.").

<sup>291</sup> Even if the OFPA is abolished and replaced by private certification a potential health halo effect may still exist, after all, 55 percent of all American Kosher consumers buy Kosher for health and safety reasons. *Go Kosher Now - Become Kosher Certified*, KOSHER MICH. KOSHER CERTIFICATION AGENCY, <http://koshermichigan.com/go-kosher-now/> (last visited Oct. 7, 2015). While the solution is not perfect, it would likely lead to a reduction in consumer deception. See *supra* note 273–73. Furthermore, perceptions of Kosher may also be attributed to the fact that Kosher foods are more carefully inspected. See Deborah Kotz, *U.S. News & World Report: Is Kosher Food Safer?*, ORTHODOX UNION (Jan. 11, 2008), [https://www.ou.org/news/us\\_news\\_and\\_world\\_report\\_is\\_kosher\\_food\\_safer/](https://www.ou.org/news/us_news_and_world_report_is_kosher_food_safer/) (describing how kosher food is closely monitored). As an example, a Kosher slaughterhouse will process less animals per hour than a conventional one due to slower line speed. See Temple Grandin & Joe M. Regenstein, *Religious Slaughter and Animal Welfare: A Discussion for Meat Scientists*, MEAT FOCUS INT'L. 115, 115–123 (1994), [www.grandin.com/ritual/kosher.slaugh.html](http://www.grandin.com/ritual/kosher.slaugh.html) (discussing how stunning, a pre-slaughter procedure that maintains high line speeds, is not common in Muslim and Jewish practices).

<sup>292</sup> See *supra* Part II and accompanying text.

<sup>293</sup> See *supra* Part III and accompanying text.

additional labels.<sup>294</sup> Finally, when labeling is done voluntarily by the manufacturer or through private certification, limited government oversight focusing on the scientific value of the information and the potential for consumer deception can help curtail consumer deception, permit a wide-variety of choices, and avoid inadequate solutions to problems potentially requiring additional regulation.<sup>295</sup>

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<sup>294</sup> See *supra* Part IV.A and accompanying text.

<sup>295</sup> See *supra* Part IV.B–C and accompanying text.