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# The Paradox of Clean Food and the Food Safety Modernization Act: Understanding the FDA's Preventive Controls for Human Food Rule

*Melissa M. Card\**

The marathon is coming to an end as manufacturers cross the finish line with their new food products. Manufacturers such as Panera Bread,<sup>1</sup> Subway,<sup>2</sup> Kraft,<sup>3</sup> and General Mills<sup>4</sup> raced to create “clean” versions of their old products. Why did manufacturers bother to join the race? Consumers forced them to.<sup>5</sup> The newest diet craze obsesses over clean foods.<sup>6</sup> Fad diets have made clean foods the focus of meal plans, celebrities swear that clean foods are the reason for their slim waistlines, and “health experts” claim that health adversities will be eliminated with a clean diet.

The diet craze towards clean food negatively impacts food safety. Lack of food safety poses a public health concern in the United States.<sup>7</sup> If there is a lack of food safety, more Americans will experience adverse effects from foodborne illnesses. The Center for Disease Control estimates that each year 48 million Americans become sick due to foodborne illnesses, 128,000

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1. *What Does “Eating Clean” Mean?*, PANERA BREAD, <https://www.panerabread.com/en-us/articles/what-does-eating-clean-mean.html> (last visited Mar. 2, 2017) (stating that Panera Bread has made a commitment to remove artificial additives from its menu before the end of 2016).
2. Caroline Praderio, *15 Big Food Companies That Are Going “Clean,”* PREVENTION (May 27, 2015), <http://www.prevention.com/eatclean/big-food-companies-going-clean/slide/4> (asserting that Subway will ban azodicarbonimide—the “yoga mat chemical”—from its breads).
3. *Id.* (announcing that Kraft will phase out artificial food dyes (which may cause hyperactivity in children)).
4. *Id.* (affirming that the cereal giant pledged to ban all artificial colors and flavors).
5. *Id.* (stating that “Big Food” Companies have lost money because their products are not health conscious, which has forced companies to create products that are healthier).
6. Kathleen Zelman, *The Eat-Clean Diet: Diet Review*, WEBMD, <http://www.webmd.com/diet/features/eat-clean-diet-review#1> (last updated Mar. 4, 2016).
7. *Estimates of Foodborne Illness in the United States*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/foodborneburden/estimates-overview.html> (last updated July 15, 2016).

Americans are hospitalized, and 3,000 Americans die from such illnesses.<sup>8</sup> In addition, foodborne illness outbreaks are becoming more severe. For instance, a 2006 E. coli outbreak associated with spinach affected over 200 people, including three deaths.<sup>9</sup> Lack of food safety and clean foods coincide. Many of the processing practices that are used to keep foods safe are eliminated from clean foods. Now the the Food and Drug Administration (FDA) must find a way to maintain its commitment to food safety despite the clean food trend.

This article assesses whether the FDA can align the food safety culture, created by the Food Safety Modernization Act (FSMA), with consumers' demand for clean food. Part I introduces the FSMA, specifically discussing the tension created between the FSMA and the clean food trend. Part II details the Preventive Controls for Human Food Rule.<sup>10</sup> Part III poses a hypothetical and offers a solution that allows the FDA to align a food safety culture with the clean food trend. Finally, this article concludes that the FDA should encourage manufacturers to educate consumers that certain processing techniques do not affect food "cleanliness."

## I. OVERVIEW: THE FOOD SAFETY MODERNIZATION ACT

The FDA is a public health agency responsible for the regulation of processed food.<sup>11</sup> Part I begins with the history of food safety, then provides an overview of the FSMA, and ends with the identification of issues concerning consumer trends and food safety.

### A. Food Safety: Emerging from the Jungle into a Battle for Public Health

The FDA's mission includes protecting public health by assuring the safety of the nation's food supply.<sup>12</sup> Historically, the FDA has carried out its

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8. *Id.*

9. *FDA Finalizes Report on 2006 Spinach Outbreak*, U.S. FOOD & DRUG ADMIN. (Mar. 23, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108873.htm>.

10. FDA Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 21 C.F.R. § 117 (2015) (referred to in this article as the Preventive Controls for Human Food Rule or the PC Rule).

11. Claudia L. Andre, *What's in that Guacamole? How Bates and the Power of Preemption Will Affect Litigation Against the Food Industry*, 15 GEO. MASON L. REV. 227, 229 (2007) (providing a history of the FDA's regulation for food labels).

12. *About FDA: What We Do*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/default.htm> (last updated Oct. 24, 2016) ("The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of . . . our nation's food supply. . .").

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mission through regulating adulterated foods.<sup>13</sup> The FDA began regulating adulterated foods in 1906 with the Federal Food and Drugs Act of 1906.<sup>14</sup> Upton Sinclair's book *The Jungle* provoked the FDA into action by exposing the meat packaging industry's practice of selling a combination of cows' guts and garbage as "potted ham."<sup>15</sup> In response to the "potted ham," the 1906 Act prohibited the addition of any ingredients to food products that would conceal damage, pose a health hazard, or constitute a filthy or decomposed substance.<sup>16</sup>

Gradually, the FDA published other regulations relating to adulterated food. One of these regulations, the Food, Drug, and Cosmetic Act of 1938,<sup>17</sup> prohibited the movement of adulterated and misbranded foods in interstate commerce.<sup>18</sup> Despite the Act's purpose, the adulterated-foods prohibition did not prevent foodborne illnesses from occurring. The Act only allowed the FDA to react to food safety and adulteration issues, rather than granting it the power to prevent contamination.<sup>19</sup>

Merely reacting to foodborne illnesses was not sufficient to prevent additional outbreaks. As previously mentioned, the 2006 spinach *E. coli* outbreak sickened over 200 people and led to three deaths.<sup>20</sup> Then in 2008, the largest meat recall in U.S. history occurred; 143 million pounds of beef were recalled because of "downer" cattle meat processing.<sup>21</sup> Between 2008 and

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13. *See generally About FDA: FDA History - Part I*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm> (last updated June 18, 2009).

14. *Id.* (stating that the Food and Drugs Act of 1906 prohibited the interstate transport of unlawful food and drugs).

15. *See id.*; *see also* UPTON SINCLAIR JR., *THE JUNGLE* 115 (1906).

16. *See About FDA: FDA History - Part I*, *supra* note 13.

17. *E.g.*, Gail H. Javitt, *Supersizing the Pint-Sized: the Need for FDA-Mandating Child-Oriented Food Labeling*, 39 *LOY. L.A. L. REV.* 311, 317 (2006) (noting that the Food, Drug, and Cosmetic Act established tolerance levels for poisonous or otherwise harmful substances added to food during the manufacturing process, and granted the FDA authority to issue standards for food).

18. *See generally About FDA: FDA History - Part II*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm> (last updated Sept. 24, 2012) (stating that the Act corrected abuses in food packaging and quality, and it mandated legally enforceable food standards).

19. *See* 21 U.S.C. § 342 (2005) (stating that food shall be deemed adulterated if it bears or contains poisonous, insanitary, etc., ingredients).

20. *E.g.*, *FDA Finalizes Report on 2006 Spinach Outbreak*, *supra* note 9.

21. *Recall Release*, USDA: FOOD SAFETY AND INSPECTION SERVICES, [https://www.fsis.usda.gov/wps/wcm/connect/8c3e741f-4d49-4530-812c-72a65ea50e43/Recall\\_005-2008\\_Release.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/8c3e741f-4d49-4530-812c-72a65ea50e43/Recall_005-2008_Release.pdf?MOD=AJPERES) (last visited Feb. 17, 2016).

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2009, there was an outbreak of Salmonella in peanut products.<sup>22</sup> This outbreak resulted in a recall of over 3,900 peanut products produced by more than 360 companies.<sup>23</sup> Salmonella struck again in 2010, and 500 million eggs produced in Iowa were recalled.<sup>24</sup> The Centers for Disease Control Prevention (CDC) estimated that this batch of adulterated eggs caused 1,939 illnesses.<sup>25</sup> These four events combined with the general risks of foodborne illnesses, fueled Congress to pass the FSMA, which granted the FDA more regulatory power.<sup>26</sup>

### i. Overview of the Food Safety Modernization Act

The FSMA increased the FDA's regulatory power.<sup>27</sup> Before the FSMA, the FDA was restricted to reacting to food safety and adulteration issues.<sup>28</sup> But the FSMA shifted the FDA's focus from responding to contamination to acting in a more proactive manner. This proactivity helps prevent contamination that leads to the adulteration of food and food safety issues.<sup>29</sup> For example, the FSMA expands the FDA's powers to: (1) inspect and recall; (2) establish risk-based priorities; and (3) address major weaknesses in import safety assurances.<sup>30</sup>

The FSMA not only expands the FDA's powers but also requires the FDA to create rules and guidances to assist the industry.<sup>31</sup> One such rule is

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22. See James Andrew, *2009 Peanut Butter Outbreak: Three Years On, Still No Resolution for Some*, FOOD SAFETY NEWS (Apr. 16, 2012), <http://www.foodsafetynews.com/2012/04/2009-peanut-butter-outbreak-three-years-on-still-no-resolution-for-some/#.WD32nDuwccg>.

23. See *id.* (asserting that even years after the outbreak occurred, many of those affected by the outbreak had not found a resolution).

24. Sam Robinson, *Eggs in Nationwide 2010 Recall Had USDA Mark of Quality*, FOOD SAFETY NEWS (Aug. 13, 2013), <http://www.foodsafetynews.com/2013/08/eggs-in-nationwide-2010-recall-had-usda-mark-of-quality/#.WD33Qjuwccg>.

25. *Salmonella*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Dec. 2, 2010), <http://www.cdc.gov/salmonella/2010/shell-eggs-12-2-10.html>.

26. *FDA Food Safety Modernization Act (FSMA)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/> (last updated Jan. 31, 2017) (noting that the Food Safety Modernization Act aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it).

27. *Id.* (stating that the FDA Food Safety Modernization Act is the most sweeping reform of the food safety laws in the United States in more than 70 years).

28. See 21 U.S.C. § 342 (2005).

29. See generally 21 U.S.C. § 2201 (2011).

30. See *id.*

31. See 21 U.S.C. § 2201(b) (2011).

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the Preventive Controls for Human Food Rule (PC Rule).<sup>32</sup> The PC Rule requires manufacturers to implement food safety plans, which must identify hazards and articulate hazard-minimization procedures.<sup>33</sup> As discussed later in this article, the PC Rule and the Clean Food trend create tension that complicates the FDA's job to promote food safety.

## ii. Clean Food

The "clean label" trend is currently sweeping the food industry.<sup>34</sup> Clean label may refer to a product containing natural, organic, or minimally processed ingredients; or eliminating additives or chemically modified ingredients, which consumers perceive negatively.<sup>35</sup> The term clean, however, does not have a statutory or administrative definition.<sup>36</sup> There is also no industrywide definition for clean.<sup>37</sup> Caselaw does not give any guidance either because the term clean has not been litigated. Since the term clean is largely undefined, the usage of the term varies from one company to the next. Nevertheless, consumers have an expectation that clean food is natural, organic, minimally processed, has few additives, or does not contain chemically modified ingredients.<sup>38</sup>

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32. *Key Requirements: Final Rule on Preventive Controls for Human Food*, U.S. FOOD & DRUG ADMIN. 1, (Sept. 10, 2015), <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461834.pdf>.

33. *Id.*

34. REINHOLD CARLE & RALF SCHWEIGGERT, *HANDBOOK ON NATURAL PIGMENTS IN FOOD AND BEVERAGES: INDUSTRIAL APPLICATIONS* 24 (1st ed. 2016) (stating that the clean label trend has the purpose of "cleaning up" product labels by replacing artificial additives wherever possible); *see also* Lauren Torrisi, *What the Heck is Clean Eating?*, ABC NEWS (Apr. 5, 2013), <http://abcnews.go.com/blogs/lifestyle/2013/04/what-the-heck-is-clean-eating> (stating "clean eating" advocates that the shorter the ingredient list the better, therefore, the focus is eating whole foods that lack artificial preservatives, sugars, and other additives).

35. *See generally* YADUNANDAN LAL DAR & JOSEPH LIGHT, *FOOD TEXTURE DESIGN AND OPTIMIZATION* (2014).

36. *See* 21 U.S.C. § 321 (defining specific terms for the Food, Drug, and Cosmetic Act). There is no legal definition of clean labeling; however, generally, clean labeling means the removal of chemical-sounding ingredients such as artificial food additives and ingredients with E-numbers or the reduction of salt or fat in order to create a simpler ingredients' list that also includes natural-origin-sounding ingredients or a healthier nutrient profile. *See* Ignacio Carreno & Paolo Vergano, *Clean Labels and "Self-Evident" and "Flagrantly Misleading" "Palm Oil-Free" Claims*, 6 EUR. J. RISK REG. 284 (2015) (internal citation omitted).

37. PAUL BERRYMAN, *ADVANCES IN FOOD AND BEVERAGE LABELLING: INFORMATION AND REGULATIONS* (1st ed. 2014).

38. DAR & LIGHT, *supra* note 35.

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## B. Tension Between Clean Food and Food Safety Modernization Act

The movement toward clean food stems from consumers' negative perception concerning processed foods, food additives, and chemically modified ingredients.<sup>39</sup> Whether this perception is warranted is not within this article's scope. If manufacturers continue to create products that consumers consider clean, their products will have shorter shelf-lives.<sup>40</sup> In addition, to create a truly clean product, manufacturers would have to eliminate processing intended to make the product safer to consume. This presents the issue as to whether the clean food trend can even align with the FSMA's food safety culture.

The FDA effectuates its mission to protect public health by regulating adulterated foods.<sup>41</sup> Adulterated foods include foods that are unsafe for human consumption.<sup>42</sup> Manufacturers process food products to ensure safe consumption.<sup>43</sup> Such processing, even though minimal, could prevent a food from being labeled as clean. There is a trend of consumers wanting clean foods.<sup>44</sup> Under the FSMA, the FDA has promulgated the PC Rule requiring manufacturers to act in a proactive manner to prevent contamination in food.<sup>45</sup> The PC Rule has created tensions between the FDA's desire to create a food safety culture and consumers' desire for clean food. The way to resolve this tension is through educating consumers that certain processing techniques do not affect the cleanliness of a food product.

## II. THE LAW CONCERNING FOOD SAFETY

This part begins with an overview of the PC Rule, followed by a discussion of PC Rule exemptions. Lastly, this part will exemplify that the PC Rule creates a culture of food safety.

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39. *Id.*

40. MARK SCHMIDL & THEODORE LABUZA, *ESSENTIALS OF FUNCTIONAL FOODS* (2000). Problems with natural flavoring include: (1) cost; (2) limited shelf life potential; and (3) possible incompatibility with the functional food. *Id.* Artificial flavoring offers strength and stability, but consumers deem artificial flavors to unhealthy. *Id.*

41. *About FDA: What We Do*, *supra* note 12.

42. See 21 U.S.C. § 342 ("A food shall be deemed to be adulterated, [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health . . .").

43. SCHMIDL & LABUZA, *supra* note 40.

44. Monica Watrous, *Trend of the Year: Clean Food*, FOOD BUS. NEWS, <http://features.foodbusinessnews.net/corporateprofiles/2015/trend-index.html> (last visited Mar. 2, 2017).

45. See Food Safety Modernization Act, 21 U.S.C. § 350g (2012); see also *Key Requirements: Final Rule on Preventive Controls for Human Food*, *supra* note 32.

### A. Facilities Required to Comply with the Preventive Controls for Human Food Rule

Under the FSMA, the FDA had authority to promulgate the PC Rule.<sup>46</sup> The PC Rule requires food facilities have food safety plans that articulate how each facility will identify and minimize hazards.<sup>47</sup> The PC Rule requires food facilities to think proactively in reducing contamination.<sup>48</sup>

Not all food facilities are required to have a food safety plan. In general, the PC Rule's food safety plan requirement only applies to facilities that manufacture, process, pack, or hold food.<sup>49</sup> Specifically, the facilities covered by the PC Rule, or "covered facilities," include facilities that are required to register with the FDA under Section 415 of the Food, Drug, and Cosmetic Act (FD&C Act).<sup>50</sup> The PC Rule applies to both domestic and imported food.<sup>51</sup>

The PC Rule excludes farms; thus they need not have a food safety plan.<sup>52</sup> To understand why farms are excluded from the PC Rule, one needs to assess various provisions of the FD&C Act. Section 415 of the FD&C Act is applicable because the PC Rule applies to facilities that are subject to reg-

46. See generally 21 C.F.R. § 117. The rule was originally proposed in January 2013. *Key Requirements: Final Rule on Preventive Controls for Human Food*, *supra* note 32. There were more than 8,000 public comments for the original proposal. *Id.* Due to much controversy surrounding the original rule, a supplemental rule, adding specific language to compromise on important provisions, was proposed September 2014. See *id.* The supplemental proposal received more than 1,300 public comments. After the FDA took all of the public comments into consideration, the final rule was issued on September 10, 2015. *Id.* While the final rule was issued almost a year ago, the food industry was given at least a year to come into compliance. Compliance dates for some businesses began in September 2016. *Id.*

47. See 21 C.F.R. § 117.126 (mandating that food facilities prepare, or have prepared, and implement a written food safety plan, and that the food safety plan is prepared, or its preparation overseen, by one or more preventive controls qualified individuals).

48. See *id.* (asserting that the food safety plans must include written preventive controls as required by 21 C.F.R. § 117.135(b)).

49. *Key Requirements: Final Rule on Preventive Controls for Human Food*, *supra* note 32.

50. See generally Registration of Food Facilities, 21 C.F.R. § 1.225 (2011) (noting that these new provisions would apply to domestic and foreign facilities that are required to register under section 415 of the FD&C Act and the regulation for Registration of Food Facilities).

51. See *id.*

52. See *Key Requirements: Final Rule on Preventive Controls for Human Food*, *supra* note 32.



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ister under Section 415 of the FD&C Act.<sup>53</sup> Section 415 of the FD&C Act states in part that “the Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary.”<sup>54</sup> The FD&C Act defines facility as:

Any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels.<sup>55</sup>

By definition, facility excludes farms.<sup>56</sup> Therefore, farms do not need to register under Section 415 of the FD&C Act. Since farms do not have to register under Section 415 of the FD&C Act, they are not subject to registered facilities’ requirements, such as complying with the PC Rule.

## B. The Definition of Farm

Farms do not have to register under Section 415 of the FD&C Act. Therefore farms are not required to comply with the PC Rule. Since farms are exempted from complying with the PC Rule, the definition of farm was a point of contention.<sup>57</sup> The original farm definition was created as a part of the implementation of the Bioterrorism Act of 2002.<sup>58</sup> The concern of the FDA under the Bioterrorism Act was traceability.<sup>59</sup> Under the Bioterrorism Act’s definition of farm, farms would need to have records if they packed or held agriculture commodities from another farm of different ownership. If the Bioterrorism Act’s definition of farm was to be applied under the PC Rule, then someone would be subject to different requirements if he or she packed or held his or her own agriculture commodities rather than packing or holding

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53. 21 C.F.R. § 1.225; *see supra* text accompanying note 50.

54. *See* 21 U.S.C. § 350d(a).

55. *See* 21 U.S.C. § 350d(c).

56. *See id.* (“Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels”).

57. *See Key Requirements: Final Rule on Preventive Controls for Human Food*, *supra* note 32 (modified the definition of farm from the original proposed rule to reflect modern farming practices).

58. *See Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, Pub. L. No. 107-188, 116 Stat. 594.

59. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 56170-01 (Sept. 17, 2015) (to be codified at 21 C.F.R. pt. 11, 16, 117, 500, 507, and 579).

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another's.<sup>60</sup> Because the Bioterrorism Act's definition of farm created different compliance requirements that depended on whose agricultural commodities were held or packed, stakeholders had concern.

Due to stakeholders' concerns, the definition of farm was modified. The final PC Rule clarified the definition of farm and expanded it to include two kinds of operations: (1) Primary Production Farms; and (2) Secondary Activities Farms.<sup>61</sup> A Primary Production Farm "is an operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities."<sup>62</sup> This kind of farm can pack or hold raw agricultural commodities, such as fresh produce, and may conduct certain manufacturing and processing activities, such as dehydrating grapes to produce raisins and packaging and labeling raisins.<sup>63</sup>

A Secondary Activities Farm "is an operation not located on the Primary Production Farm [and] is devoted to harvesting, packing and/or holding raw agricultural commodities."<sup>64</sup> The Secondary Activities Farm "must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm."<sup>65</sup> The Secondary Activities Farm definition allows for certain limited additional manufacturing, processing, and holding, the same as those for a Primary Production Farm.<sup>66</sup>

### C. Exemptions to the Preventive Controls for Human Food Rule

While the definitions for Primary Product Farm and Secondary Activities Farm are broad, many operations would be subject to the PC Rule if other exemptions did not apply. Other exemptions include: (1) activities subject to HACCP regulations (i.e. seafood and juice); (2) manufacturing, processing, and packing and holding of dietary supplements; (3) alcoholic beverages at certain facilities; and (4) activities subject to low-acid canned food regulations (microbiological hazards only).<sup>67</sup> For these exemptions to

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60. *Id.*

61. *See Key Requirements: Final Rule on Preventive Controls for Human Food, supra* note 32.

62. *Id.*

63. *Id.*

64. *See id.* (clarifying that that "not located on the Primary Production Farm" could mean not located on the place where the crops are grown).

65. *Id.*

66. *See id.* (an example of the secondary activity farms include off farm packing houses).

67. 21 C.F.R. § 117.5 (2015).

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apply, the operation must be in compliance with applicable FDA regulations.<sup>68</sup>

#### **D. Complying with the Preventive Controls for Human Food Rule**

If a food facility is not a farm and no other exemptions or modifications apply, then a food facility must comply with the PC Rule. Under the PC Rule, each food facility must have a food safety plan in place that sets forth how it will identify and minimize hazards.<sup>69</sup> The food safety plan contains a collection of written documents describing activities that ensure food safety during manufacturing, processing, packing, and holding.<sup>70</sup>

The first step of creating a food safety plan is identifying where hazards pertaining to food safety exist in the facility.<sup>71</sup> These hazards could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain.<sup>72</sup> Controls to prevent the hazards must be put into place, including an established recall procedure.<sup>73</sup> The written plan must show how the preventive controls are monitored and managed to ensure effectiveness.<sup>74</sup> In addition, there are verification and validation requirements.<sup>75</sup> All of these steps require documentation. While keeping detailed records might seem tenuous, this documentation benefits food facilities in the long run. If the FDA investigates a food facility due to possible foodborne illness issues, the more documentation the food facility has the better the food facility will be able to defend itself.

Compliance dates for businesses are staggered over several years after publication of the final rule.<sup>76</sup> Very small businesses averaging less than a

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68. *See id.*

69. 21 C.F.R. § 117.126 (2015).

70. *See id.*

71. Ingredient Identity, 21 C.F.R. § 117.130 (2015).

72. *See id.*

73. *Key Requirements: Final Rule on Preventive Controls for Human Food*, *supra* note 32.

74. *Id.* (Facilities conduct monitoring as appropriate to the preventive control. “For example, monitoring of a heat process to kill pathogens would include actual temperature values and be more frequent than monitoring preventive maintenance activities used to minimize metal hazards, which could be a simple record of the date on which the activity took place.”).

75. *Id.* (explaining that validation means the facilities’ preventive controls are working, and verification means that the controls are being implemented effectively).

76. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. at 56170-01.

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million dollars per year have three years to comply with the PC Rule.<sup>77</sup> Businesses subject to the Pasteurized Milk Ordinance also have three years to comply with the PC Rule requirements.<sup>78</sup> Small businesses have two years to comply.<sup>79</sup> All other businesses have one year to comply.<sup>80</sup>

The FSMA gave the FDA authority to promulgate the PC Rule. The PC Rule requires that food facilities have food safety plans that set forth how the food facilities will identify and minimize hazards.<sup>81</sup> Under the PC Rule, food facilities must think proactively in reducing contamination; thus the PC Rule creates a culture of food safety.

### III. EDUCATING CONSUMERS ALLOWS THE CLEAN FOOD TREND TO ALIGN WITH THE CULTURE OF FOOD SAFETY

The PC Rule has created a culture of food safety in our society, but the clean food trend conflicts with the PC Rule. The PC Rule requires food facilities to have food safety plans that set forth how the food facilities will identify and minimize hazards.<sup>82</sup> How can the clean food trend align with the culture of food safety that is created through the PC Rule? This part raises a hypothetical and proposes a solution for resolving this conflict. In particular, the FDA should encourage manufacturers to educate consumers that certain processing techniques adopted by the food industry do not affect the cleanliness of a food.

#### A. Hypothetical<sup>83</sup>

A.Bella's Apple Farm is the largest apple farm in Michigan. The farm spans 200 acres and is located just outside of Traverse City, Michigan.

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77. *Key Requirements: Final Rule on Preventive Controls for Human Food*, *supra* note 32 (noting that this amount is adjusted for inflation in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale except for records to support its status as a very small business).

78. *See id.* (asserting that the compliance dates are extended to allow time for changes to the Pasteurized Milk Ordinance safety standards that incorporate the requirements of this preventive controls rule).

79. *See id.* (stating that small business is a business with fewer than 500 full-time equivalent employees).

80. *See id.* (explaining that based on the effective date of the PC Rule, "all other businesses" had to be in compliance by September 2016, but compliance dates for supply chain programs differ).

81. 21 C.F.R. § 117.126 (2015).

82. *See id.*

83. **DISCLAIMER:** This hypothetical is a work of fiction. Names, characters, businesses, places, events, and incidents are either the products of the author's

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A.Bella's Apple Farm grows, harvests, and packs Granny Smith Apples. In addition, the Granny Smith Apples are sliced and dehydrated at A.Bella's Apple Farm to make apple chips.

A.Bella's Apple Farm reduces microbial populations to improve safety and quality of the apples by washing the apples with water containing antimicrobials. The antimicrobial water removes soil and reduces microbial contamination.<sup>84</sup> There are different antimicrobial solutions available, including sodium hypochlorite (chlorine), chlorine dioxide, hydrogen peroxide, quaternary ammonium, and other natural antimicrobials. Here, A.Bella's Apple Farm chooses apple cider vinegar and water to wash the apples. Apple cider vinegar inhibits microorganisms' growth and causes their death.<sup>85</sup>

Last month, the documentary *Clean Your Diet Up* exposed A.Bella's Apple Farm's use of antimicrobials and warned viewers that the use of the antimicrobials made food unclean. Aside from criticizing A.Bella's Apple Farm's processing methods, *Clean Your Diet Up* encouraged viewers to follow a clean diet through embracing whole foods and cutting back on refined grains, added sugars, salt, and unhealthy fats.

Due to the documentary, A.Bella's Apple Farm's consumers no longer believe that A.Bella's Apple Farm's apple chips are healthy. A.Bella's Apple Farm is conflicted. A.Bella's Apple Farm knows that it needs to have safe food, but the farm also needs to sell food to the consumers to ensure that there is a profit. What should the facility do?

## **B. Solution**

A.Bella's Apple Farm (1) should not change its food safety techniques and (2) should educate the consumers on the value of food safety provided using such techniques.

### **i. A.Bella's Apple Farm Should Not Change its Food Safety Techniques**

Food facilities like A.Bella's Apple Farm should be mindful about consumers' desires and needs. Nevertheless, A.Bella's Apple Farm should not discard merited food safety techniques merely because consumers are making misguided demands due to the documentary's unscientific and unjustified criticism. Therefore, if there is value in the means that a food facility processes its products, then the food facility should retain those processing

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imagination or used in a fictitious manner. Any resemblance to actual persons, living or dead, companies, or actual events is purely coincidental.

84. AMANDA L. SVOBODA, *ANTIMICROBIAL EFFICACY OF COMMERCIAL PRODUCE SANITIZERS AGAINST ARTIFICIALLY INOCULATED FOODBORNE PATHOGENS AND NATURAL FUNGAL CONTAMINANTS ON THE SURFACE OF WHOLE MELONS* (2015) (Ph.D. dissertation, Iowa State University) (ProQuest Dissertations Publishing).

85. *Id.*

techniques.<sup>86</sup> Here, A.Bella's Apple Farm should not change its food safety techniques due to a misguided demand when the techniques properly fulfill the safety purposes.

**ii. Food Facilities Should Educate Consumers About Food Safety Techniques**

Food facilities should educate consumers about various food safety techniques and their proper use in food processing. If a food facility does not want to disclose the food safety information to consumers, then the food facility is doing something suspect.<sup>87</sup> The FDA should issue a guidance document instructing food facilities to educate consumers that certain processing procedures do not affect food cleanliness. Through encouraging food facilities to educate consumers, the FDA can assure that a culture of food safety aligns with the clean food trend.

In the hypothetical presented above, A.Bella's Apple Farm experienced adverse economic consequences due to consumers being misinformed. Consumer education regarding food safety and clean food is critical in curbing adverse economic consequences to the food industry.<sup>88</sup> Consumers need to learn the science and shortcomings behind food safety and the clean food movement.

American consumers' ignorance of food safety is exacerbated by the clean food trend. For example, A.Bella's Apple Farm's antimicrobial wash with apple cider vinegar meets the requirements of the clean food trend. Apple cider vinegar is natural and healthy.<sup>89</sup> Consumers generally have a nega-

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86. "Value" in this context refers to providing a safe and healthy product to the consumer. Too often in the food industry manufacturers refuse to change their food processing methods because they are nervous that the changes will affect their bottom lines. If changing one's method is for the better of the consumer, rather than the benefit of the manufacturer's pocket book, then the change should be made.

87. Cf. Elaine Watson, *CSPI: There Are Legitimate Concerns About GMOs, but not Around Food Safety and Labeling Would Be Misleading*, FOOD (July 3, 2013), <http://www.foodnavigator-usa.com/People/CSPI-There-are-legitimate-concerns-about-GMOs-but-not-around-food-safety-and-labeling-would-be-misleading> (noting that consumers are suspicious of Genetically Engineered Products because manufacturers do not label genetically modified products).

88. See generally Matin Qaim, *The Economics of Genetically Modified Crops*, 1 ANN. REV. OF RESOURCE ECON. 665, 665 (2009) ("The EU, however, has established a mandatory system, which is more costly and can reinforce the notion that GM products are inherently unsafe.").

89. See, e.g., Joy Manning, *Apple Cider Vinegar and Health*, WEB MD, <http://www.webmd.com/diet/obesity/features/apple-cider-vinegar-and-health#1> (last visited Nov. 30, 2016) (explaining that natural and healthful are undefined terms, but the FDA is in the processes of requiring comments for defining natural).

tive perception of antimicrobials because some antimicrobials are harmful to either the consumers or the environment.<sup>90</sup>

The use of antimicrobials is becoming standard operating procedure with the passage of the FSMA.<sup>91</sup> Processors use antimicrobials to eliminate pathogens, to elongate shelf life, and to improve the quality of food.<sup>92</sup> While washing produce with water containing antimicrobials reduces microbial contamination,<sup>93</sup> the available sanitizers vary in effectiveness against microbial contaminants.<sup>94</sup> Differing antimicrobials also have different effects on health. For example, antimicrobial washes used in the food industry increase bacterial resistance.<sup>95</sup> Concerns exist over interactions of food and antimicrobials.<sup>96</sup>

Apple cider vinegar is not an antibiotic.<sup>97</sup> A.Bella's Apple Farm could educate consumers that A.Bella's Apple Farm's use of apple cider vinegar not only ensures food safety but also serves as a healthy alternative to antimicrobial washes. By educating consumers that some processing techniques do not affect how clean a food is, A.Bella's Apple Farm, and the FDA can assure that a culture of food safety aligns with the clean food trend.

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90. *Antibacterial Soap? You Can Skip It – Use Plain Soap and Water*, U.S. FOOD & DRUG ADMIN. (Sept. 2, 2016), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm378393.htm> (“In addition, laboratory studies finding the possibility that triclosan contributes to making bacteria resistant to antibiotics. Some data shows this resistance may have a significant impact on the effectiveness of medical treatments such as antibiotics.”).

91. Debra Schug, *Chemical Cleaning in the FSMA Age*, FOOD ENG'G (Jan. 8, 2015), <http://www.foodengineeringmag.com/articles/93291-chemical-cleaning-in-the-fsma-age> (“With FSMA, antimicrobial direct intervention programs are becoming standard operating procedures in several market segments including red meat, poultry, seafood and produce”).

92. *Id.*

93. See SVOBODA, *supra* note 84.

94. *Id.* (stating that these can include the surface type of produce and presence of soil, time allowed for contact on the product, the concentration of sanitizer used, and water source, temperature, and pH) (internal citation omitted).

95. See *Antibacterial Soap? You Can Skip It – Use Plain Soap and Water*, *supra* note 90; SVOBODA, *supra* note 84 (noting that decades of antibiotic use in the medical industry has shown a large concern over bacterial resistance to antimicrobials, which has been linked to specific mechanisms utilized by antibiotics) (internal citation omitted).

96. SVOBODA, *supra* note 84.

97. Amber Keefer, *Apple Cider Vinegar & Antibiotics*, LIVESTRONG.COM, <http://www.livestrong.com/article/556171-apple-cider-vinegar-antibiotics/> (last updated Aug. 16, 2013) (asserting that apple cider vinegar contains malic acid—anti-bacterial properties; however, apple cider vinegar has not been proven as an effective treatment to fight infection).

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#### IV. CONCLUSION

The clean food trend may just be a diet craze, but it impacts food safety because, with less processing, additives, or chemically modified ingredients, foods have shorter shelf-lives and may be more susceptible to pathogens. Whether the culture of food safety can align with the clean food trend will depend on the FDA's ability to educate consumers on food safety. The FDA should issue a guidance document instructing food facilities to educate consumers that certain processing techniques do not affect the cleanliness of a food. By encouraging food facilities to educate consumers, the FDA can assure that a culture of food safety aligns with the clean food trend. Although food facilities should continue being mindful of consumers' needs and desires, they should not jump to eliminate meaningful food safety measures simply because consumers demand clean food. If there is value in a food facility's method of processing products, then it should retain those processing techniques.



