


## The Hang-Up with Hamburg: How Center for Food Safety v. Hamburg will Alter the Food Industry

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## The Hang-Up with *Hamburg*: How *Center for Food Safety v. Hamburg* will Alter the Food Industry

BETWEEN 2006 AND 2010, six highly publicized outbreaks of food borne illnesses occurred, resulting in fourteen deaths.<sup>1</sup> In 2008, a critically-acclaimed documentary portrayed the majority of the food industry as appallingly full of profit-hungry corporate giants willing to sacrifice the quality of their food and the health of the American people for lower costs.<sup>2</sup> It was in this climate that, on January 4, 2011, President Obama signed the Food Safety Modernization Act (FSMA) into law.<sup>3</sup> This act dictated that the Food and Drug Administration (FDA) implement certain food industry regulations by specific deadlines, which the FDA failed to meet.<sup>4</sup> Frustrated by the FDA's inability to adhere to these deadlines, the Center for Food Safety filed suit to compel the FDA to do so, resulting in *Center for Food Safety v. Hamburg*.<sup>5</sup> The court followed a recently-developed portion of case law, and compelled the

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1. James Andrews, *Salmonella and Peanut Butter: Victims' Stories*, FOOD SAFETY NEWS (Dec. 10, 2012), <http://www.foodsafetynews.com/2012/12/salmonella-and-peanut-butter-victims-stories/#.UjtQgRYY20t>; David Brown, *Egg Recall Spreads to Second Iowa Producer*, WASH. POST (Aug. 21, 2010), <http://www.washingtonpost.com/wp-dyn/content/article/2010/08/20/AR2010082005649.html>; *FDA Finalizes Report on 2006 Spinach Outbreak*, U.S. FOOD AND DRUG ADMIN. (Mar. 23, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108873.htm>; *Investigation of Outbreak of Infections Caused by Salmonella Saintpaul*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Aug. 25, 2008, 9:00 PM), <http://www.cdc.gov/salmonella/saintpaul/jalapeno/>; *Update on Salmonella Outbreak and Peter Pan Peanut Butter and Great Value Peanut Butter*, US FOOD AND DRUG ADMIN. (Feb. 16, 2007), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108848.htm>; Saundra Young, *Salmonella Outbreak Linked to Alfalfa Sprouts*, CNN HEALTH (Dec. 24, 2010, 5:35 AM), <http://www.cnn.com/2010/HEALTH/12/23/salmonella.outbreak.sprouts/index.html>.

2. Dan Purnell & Paul Ashigbie, *Movie Review: Food Inc. – Directed by Robert Kenner Oscar, THE MOVEMENT*, <http://www.bu.edu/themovement/past-issues/spring2011/foodinc/> (last visited Sep. 23, 2013).

3. *FDA Food Safety Modernization Act (FSMA)*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm> (last updated Sep. 17, 2013).

4. *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965, 970 (N.D. Cal. Apr. 22, 2013).

5. 954 F. Supp. 2d 965 (N.D. Cal. Apr. 22, 2013).

FDA to adhere to specific deadlines.<sup>6</sup> In so doing, the court threw the needs of an entire \$4.8 trillion industry by the wayside.<sup>7</sup>

This comment examines the specific ways the food industry<sup>8</sup> and small businesses will be negatively impacted by the decision.<sup>9</sup> Part I provides the legal background, including information about FSMA along with the *Hamburg* case facts and reasoning.<sup>10</sup> Part II gives information about the Administrative Procedure Act both as a whole and as it relates to *Hamburg*, explains why the case was correctly decided according to recent unreasonable delay case law, and the detrimental effects of the case from the erosion of the administrative principles regarding this new precedent.<sup>11</sup> Part III describes the adverse effects of the decision based on the deadlines promulgated.<sup>12</sup> Part IV delves into the specific effects this case will have on small businesses.<sup>13</sup>

## I. LEGAL BACKGROUND

### A. *The Food Safety Modernization Act*

FSMA, signed into law in January 2011, is the most complex food safety legislation since the Food, Drug, and Cosmetic Act of 1938.<sup>14</sup> Through expansion of the FDA's responsibility and authority, FSMA seeks to modernize food regulations and change the focus to preventing food borne illness – not just reacting to outbreaks.<sup>15</sup> The act tasks the FDA with creating fifty new rules, planning and conducting studies,

6. *Id.* at 972.

7. Sarah Murray, *The World's Biggest Industry*, FORBES (Nov. 15, 2007, 6:00 PM), [http://www.forbes.com/2007/11/11/growth-agriculture-business-forbeslife-food07-cx\\_sm\\_1113bigfood.html](http://www.forbes.com/2007/11/11/growth-agriculture-business-forbeslife-food07-cx_sm_1113bigfood.html).

8. The phrase the food industry includes all entities involved in the production and consumption of food and beverages, including producers and processors of food crops and animals, companies that develop and sell the tools used for farming and transporting food, and food vendors. See MARION NESTLE, *FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH* 11 (2002).

9. Although there is no universal definition for a small business, I use the phrase to refer to a business that has less than 20 employees and has less than \$500,000 in revenue. See U.S. DEPT. OF TREASURY, *METHODOLOGY TO IDENTIFY SMALL BUSINESSES AND THEIR OWNERS 2* (2011), available at <http://www.treasury.gov/resource-center/tax-policy/tax-analysis/Documents/OTA-T2011-04-Small-Business-Methodology-Aug-8-2011.pdf>; Jason Keith, *State of the Union Furthers Small Business Misperception* (Jan. 26, 2013 8:28 AM), [http://www.boston.com/business/specials/small\\_business\\_blog/2012/01/state\\_of\\_the\\_union\\_furthers\\_small\\_business.html](http://www.boston.com/business/specials/small_business_blog/2012/01/state_of_the_union_furthers_small_business.html).

10. See *infra* Part I.

11. See *infra* Part II.

12. See *infra* Part III.

13. See *infra* Part IV.

14. Susana Richardson et al., *The Food Safety Modernization Act and the FDA Facility Registration Program*, U. FLA. IFAS EXTENSION 1,1 (2013), available at <http://edis.ifas.ufl.edu/pdf/files/FS/FS23100.pdf>.

15. Conference Report, *FDLI Food Safety Conference: The FDA Food Safety Modernization Act: Putting Ideas into Action* (Jan. 27, 2011), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM254885.pdf>; *FSMA Proposed Rule for Produce Safety*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334114.htm> (last updated Dec. 5, 2013).

writing reports to Congress, and developing a series of guidance documents aimed at educating food manufacturers about its expectations.<sup>16</sup> Part 1 describes the basic areas that FSMA revolves around.<sup>17</sup> Part 2 describes the entities that are exempt from FSMA.<sup>18</sup>

### 1. *The Fundamental FSMA Focus Areas*

The fundamental FSMA focus areas are “prevention, inspections compliance and response, enhanced partnerships, and import safety.”<sup>19</sup> FSMA seeks to achieve its goal of preventing foodborne illness through requiring food-processing facilities to perform a written analysis of any current or foreseeable hazards both naturally and artificially occurring that could affect the facility.<sup>20</sup> The facility puts the result of this analysis in writing, develops scientifically sound and continually monitored hazard prevention strategies, and constructs and implements procedures for corrective action should preventive control fail.<sup>21</sup> In addition, the facility must maintain records of this entire process for at least two years.<sup>22</sup> Another provision within the prevention focus area is the provision requiring “minimum standards for the safe production and harvesting of . . . fruits and vegetables.”<sup>23</sup> This extensive compulsory provision encompasses “soil . . ., hygiene, packaging, temperature controls, animals in the growing area, and water.”<sup>24</sup> The FDA is required to make a bi-annual determination of the most significant foodborne contaminants and publish contaminant-specific guidance documents for handling them.<sup>25</sup>

In order to meet the goal of inspection compliance and response, FSMA mandates that the FDA inspect food facilities, targeting those that are high risk. Specifically, it requires the FDA to inspect domestic facilities regularly with high-risk facilities inspected more often than lower risk facilities.<sup>26</sup> The inspection of foreign facilities is not based on risk, but on a quota of total facilities that the FDA must inspect.<sup>27</sup> FSMA gives the FDA the authority to issue mandatory recalls when

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16. U.S. Food & Drug Admin., *Public Meeting on the Food Safety Modernization Act: Focus on Preventive Controls for Facilities* 27, 40 (2011), available at <http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM253612.pdf> (hereinafter “Focus on Preventive Controls”; U.S. FOOD AND DRUG ADMIN., *Implementation of FSMA*, <http://www.fda.gov/food/guidanceregulation/fsma/ucm247556.htm> (last updated July 5, 2013)).

17. See *infra* Part I.A.1.

18. See *infra* Part I.A.2.

19. Focus on Preventive Controls, *supra* note 16, at 27, 40.

20. Food Safety Modernization Act, 21 U.S.C. § 350g (2012).

21. Focus on Preventive Controls, *supra* note 16, at 27, 40.

22. 21 U.S.C. § 350g (2012).

23. 21 U.S.C. § 350h (2012).

24. *Id.*

25. 21 U.S.C. § 2201 (2012).

26. Focus on Preventive Controls, *supra* note 16, at 27, 40.

27. *Id.*

unsafe food enters the marketplace.<sup>28</sup> In addition, the FDA has augmented record-keeping requirements for tracking high-risk foods.<sup>29</sup>

FSMA addresses the focus area of import safety in several ways. First, FSMA requires importers to verify that their “foreign suppliers have adequate preventive controls in place to ensure” safe food production.<sup>30</sup> Second, the importers must have their processes in writing, and meet the requirements of the Food, Drug, and Cosmetic Act.<sup>31</sup> Third, the FDA may require food importers to provide a certification that the article of food complies with FSMA.<sup>32</sup> Food importers who agree to higher safety standards will receive expedited review and food entry.<sup>33</sup>

The theme of partnership is woven throughout the implementation of the Act. Although the FDA is the agency driving FSMA, FSMA explicitly mandates that FDA strengthen partnerships with other government agencies to improve the United States food safety system.<sup>34</sup> Specifically, the FDA is required to “leverage and enhance the food safety and defense capacities of state and local agencies” and develop a plan to expand similar capacities of foreign governments.<sup>35</sup> In addition, FSMA authorizes the FDA to work with state and other local agencies to complete the inspections required under FSMA.<sup>36</sup>

## 2. *The Exceptions to FSMA*

There are two main exceptions incorporated within FSMA. The first exception is the Tester-Hagan Amendment, which gives foreign and domestic farms that fall within the FDA definition of a small business that harvest low risk produce, and those that are engaged in direct-farm marketing (at least 50% of total farm sales are made directly to consumers or restaurants in the same state or 275 miles away)<sup>37</sup>, a variance from the minimum standards for the safe production and harvesting requirements.<sup>38</sup> Small to very small businesses get more time to comply with the standard, and farms that engage in direct-farm marketing get a complete

28. *Id.*

29. 21 U.S.C. § 2223 (2012). The FDA is required to establish a product tracing system to trace contaminated food in the United States following the establishment of a pilot project to evaluate different product tracing methods. *Id.*

30. U.S. Food & Drug Admin., *Background on the FDA Food Safety Modernization Act*, [www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM263773.pdf](http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM263773.pdf) (last updated July 12, 2011).

31. *Food Safety Modernization Act; Effect on States*, NATIONAL CONFERENCE OF STATE LEGISLATURES (2014), <http://www.ncsl.org/research/agriculture-and-rural-development/food-safety-modernization-act.aspx>.

32. 21 U.S.C. § 384a (2012).

33. *Id.* FSMA lists factors to be used in evaluating whether importers are eligible. *Id.*

34. U.S. Food & Drug Admin., *Background on the FDA Food Safety Modernization Act*, (July 12, 2011), [www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM263773.pdf](http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM263773.pdf).

35. *Id.*

36. *Id.*

37. Food Safety Modernization Act, Pub. L. No. 111-352, 124 Stat. 3903–04 (codified as 21 U.S.C. § 419).

38. 21 U.S.C. § 350h (2012).

exemption.<sup>39</sup> Small businesses get more flexibility in having to perform hazard analysis and risk-based preventative controls, and very small businesses get a complete exemption.<sup>40</sup>

Another exception built into FSMA is for food importers.<sup>41</sup> The produce requirement mandates that food importers receive a variance from FSMA's requirements when the foreign country determines that a variance is necessary based on local growing conditions.<sup>42</sup> In order to receive a variance, the procedures that would be followed need to be as "reasonably likely" to protect the public health as those under the produce requirement.<sup>43</sup> This request for a variance must be submitted in writing to the FDA, describe the type of exception requested, and provide information about the safety of the variance.<sup>44</sup>

### B. Case Facts

*Center for Food Safety v. Hamburg*<sup>45</sup> developed when Center for Food Safety, a non-profit organization that works to curtail the use of "harmful food production technologies,"<sup>46</sup> sued the FDA commissioner for the FDA's failure to follow FSMA deadlines.<sup>47</sup> The seven sets of regulations that the FDA failed to promulgate include: regulation for science-based minimum standards for hazards and safe production and harvesting of produce; activities that constitute on-farm packing, holding, manufacturing, or processing; protections against intentional adulteration of food; requirements for food transporters to use sanitary transportation practices; protections for neutrality of third party audits; and the Foreign Supplier Verification Program.<sup>48</sup>

The Center for Food Safety argued that the court had jurisdiction to compel the agency to follow these deadlines pursuant to the Administrative Procedure Act (APA).<sup>49</sup> The Center for Food Safety sought a declaratory judgment stating that the

39. *Id.*

40. 21 U.S.C. § 350g (2012); Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3998.

41. 21 U.S.C. § 350h (2012).

42. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 54, 48637 (Mar. 20, 2013) (to be codified at 21 C.F.R. pt. 16 & 21), *available at* <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM360734.pdf> [hereinafter Standards for Produce].

43. 21 U.S.C. § 350h (2012).

44. *Id.*

45. 954 F. Supp. 2d 965 (N.D. Cal. Apr. 22, 2013).

46. *About Center for Food Safety*, CENTER FOR FOOD SAFETY (2014), <http://www.centerforfoodsafety.org/about-us>.

47. *Hamburg*, 954 F. Supp. 2d at 966.

48. *Id.* at 966-67. The Foreign Supplier Verification Program will require food importers to run a risk-based analysis of their suppliers to ensure that they comply with FSMA. 21 U.S.C. § 384a (2012).

49. Complaint at 3-8, *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. Aug. 29, 2012) (No. CV 12 4529 DMR).

FDA failed to meet deadlines and an injunction compelling the agency to meet the deadlines.<sup>50</sup> The FDA argued that because the deadlines under FSMA were “self-executing,” the court did not have jurisdiction to review the agency action.<sup>51</sup> The FDA relied on precedent where the Court stated that judicial review is precluded when the statute contains “no judicially manageable standards.”<sup>52</sup> In addition, the FDA argued that the FSMA deadline was unachievable given the FDA’s limited staff and the large amount of rules in the same general subject area.<sup>53</sup>

Another APA question that was at issue was whether or not APA required the reviewing court to issue an injunction when statutory deadlines are violated or if the court has discretion about whether or not to do so.<sup>54</sup> The FDA argued that the court does have discretion, basing its conclusion on older precedent that takes into account multiple factors when deciding if courts need to issue an injunction when statutory deadlines are violated.<sup>55</sup> The Center for Food Safety argued that the court did not have discretion because the ability of the courts to take into account multiple factors only applies in the absence of statutory deadlines.<sup>56</sup>

The court ruled for the plaintiff, holding that the FDA violated FSMA and APA, and granted a declaratory judgment and injunction.<sup>57</sup> The court held the new deadlines would depend on a joint written statement from both parties setting forth new deadlines.<sup>58</sup> The court stated that if the two parties were unable to reach mutually acceptable deadlines, the court would issue its own arbitrary deadlines.<sup>59</sup>

After the case was adjudicated, the parties were unable to reach an agreement.<sup>60</sup> They submitted competing proposals, so the court was required to develop its own deadlines.<sup>61</sup> The court ordered the FDA to publish all proposed regulations by November 30, 2013, close the comment period no later than March 31, 2014, and publish the final regulations by June 30, 2015.<sup>62</sup> A month after this decision was rendered, the FDA filed a motion for reconsideration or an order staying the judgment for two out of the seven areas of regulation: intentional adulteration and

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50. *Id.* at 8–9.

51. Notice of Motion and Motion to Dismiss and for Summary Judgment at 20–22, *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. Aug. 29, 2012), (No. CV 12 4529 DMR).

52. *Id.* at 20 (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)).

53. *Id.* at 8.

54. *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965, 971 (N.D. Cal. Apr. 22, 2013).

55. *Id.* at 970.

56. *Id.* at 970–71.

57. *Id.* at 972.

58. *Id.*

59. *Id.*

60. Order Granting Injunctive Relief at 1, *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. June 21, 2013), (No. CV 12 4529 DM).

61. *Id.* at 1, 3.

62. *Id.* at 3.

sanitary transport.<sup>63</sup> The court granted the motion for the regulations regarding sanitary transport, and extended the FDA's deadline for the proposed regulations and comment period for this area of regulation to sixty days.<sup>64</sup> However, the deadline for the final regulation remains unchanged.<sup>65</sup>

After the court issued its opinion regarding FDA's motion for reconsideration, the FDA filed a motion for a stay pending an appeal for the court's granting of an injunction compelling the FDA to issue a proposed rule regarding protection against intentional food adulteration by the court's deadline.<sup>66</sup> However, the court denied this motion, leaving the results of the court's previous opinion unaffected.<sup>67</sup>

### C. The Court's Reasoning

The court based its decision to issue an injunction on APA precedent, which required courts to compel agency action when agencies act in violation of statutory deadlines. The first case the court quoted in support of this conclusion is *Forest Guardians v. Babbitt*,<sup>68</sup> which holds that when agencies fail to adhere to statutory deadlines, a reviewing court must compel the action.<sup>69</sup> The second case is *Biodiversity Legal Foundation v. Badgley*,<sup>70</sup> which holds that the balancing of multiple factors is not permitted when congressional deadlines are provided.<sup>71</sup> *Biodiversity* holds that the test for determining whether equitable relief should be granted in the case of a statutory violation is "whether an injunction is necessary to effectuate the congressional purpose behind the statute."<sup>72</sup> Using this test, the court held that an injunction is necessary in this case.<sup>73</sup> The reason for this is that since Congress intended the regulations to be implemented by certain dates, in order to effectuate the congressional purpose, deadlines must be implemented.<sup>74</sup>

In *Hamburg*, the court decided to have the FDA and Center for Food Safety try to work out their own deadlines with the looming threat of court-issued arbitrary

63. Ctr. for Food Safety v. Hamburg, No. 12-CV-04529 PJH, 2013 WL 4396563, at \*1 (N.D. Cal. Aug. 13, 2013).

64. *Id.* at \*4.

65. *Id.*

66. Ctr. for Food Safety v. Hamburg, No. 12-CV-04529 PJH, 2013 WL 5718339, at \*1 (N.D. Cal. Oct. 21, 2013).

67. *Id.*

68. 174 F.3d 1178 (10th Cir. 1999).

69. *Id.* at 1187–89.

70. 309 F.3d 1166 (9th Cir. 2002).

71. *Id.* at 1177 n.11.

72. *Id.* at 1177 (citing *TVA v. Hill*, 437 U.S. 153, 194 (1978)). The court balances its approach by bringing up *In re Barr Labs., Inc.*, which held that courts have discretion in deciding whether or not to compel the agency to adhere to statutory deadlines. 930 F.2d 72, 74 (D.C. Cir. 1991). The court does not explicitly refute the *In re Barr Labs., Inc.* holding, but simply lists the case name and holding and moves onto an analysis under the *Biodiversity* conclusion. Ctr. for Food Safety v. Hamburg, 954 F. Supp. 2d 965, 971 (N.D. Cal. Apr. 22, 2013).

73. *Hamburg*, 954 F. Supp. 2d at 971.

74. *Id.*



deadlines, should the parties not be able to work out deadlines within four weeks.<sup>75</sup> The court came to the conclusion that the parties should work out their own deadlines since both parties agreed about the purpose of FSMA.<sup>76</sup> The court stated that the issuing of deadlines would be consistent with the underlying purpose of FSMA since Congress signaled that the rulemaking be closed-ended.<sup>77</sup>

Following the inability of the parties to agree on deadlines, the court issued its own deadlines, which were universal to all of the undeveloped regulations within FSMA.<sup>78</sup> The court's deadlines were not those promulgated by either party.<sup>79</sup> In issuing their deadlines, the court rejected the FDA's proposal to issue target timeframes, rather than binding deadlines.<sup>80</sup> The court reasoned that Congress had intended for the rulemaking process to be closed-ended, which was not adequately reflected with the idea of target timeframes.<sup>81</sup> The court criticized the Center for Food Safety's deadlines as being "overly restrictive" for such complicated tasks and giving inadequate time for comment, in light of the interests at stake with FSMA.<sup>82</sup> As a result, the court issued deadlines in-between those proposed by the two parties.<sup>83</sup>

The court proceeded to, in large part, deny the FDA's motion for reconsideration and order staying the judgment based on the FDA not meeting the appropriate Federal Rules of Civil Procedure standard, as interpreted by the Ninth Circuit.<sup>84</sup> Another reason the court gave for denying the FDA's motion is its previously-stated position that Congress intended for the rulemaking process to be closed-ended.<sup>85</sup> Nonetheless the court agreed to grant an extension of the deadlines for the proposed rule and comment period for sanitary transport because the Center for Food Safety had agreed to allow the FDA this extension.<sup>86</sup> The court

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75. *Id.* at 972.

76. *Id.* at 971–72.

77. *Id.*

78. Order Granting Injunctive Relief at 1, 3, *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. June 21, 2013), (No. CV 12 4529 DM).

79. *Id.* at 2–3.

80. *Id.* at 2.

81. *Id.*

82. *Id.*

83. *Id.* at 2–3.

84. *Ctr. for Food Safety v. Hamburg*, No. C 12–4529 PJH, 2013 WL 4396563, at \*4 (N.D. Cal. Aug. 13, 2013). The Ninth Circuit interprets the applicable Federal Rules of Civil Procedure, Rules 59(e) and 60(b), to require a change in law, evidence, or fact, to prevent injustice, to appropriately navigate unusual conditions, or any other reason that justifies relief. *Id.* at \*1–2 (citing *Allstate Ins. Co. v. Herron*, 634 F.3d 1101, 1111 (2011); *Herbst v. Cook*, 260 F.3d 1039, 1044 (2001)). Without going into any detail, the court concludes that the case did not meet any of these circumstances. *Id.* at \*4. The court cites the Federal Rule of Civil Procedure requirement that stays require that an appeal be filed before a stay can be granted. *Id.* Since the FDA has not filed an appeal, the court denies the FDA's stay. *Id.*

85. *Ctr. for Food Safety v. Hamburg*, No. C 12–4529 PJH, 2013 WL 4396563, at \*4 (N.D. Cal. Aug. 13, 2013).

86. *Id.*

rejected the FDA's motion to stay pending appeal the deadline for the intentional adulteration proposed rule based on the FDA's failure to meet the relevant Supreme Court's promulgated factors for granting a stay.<sup>87</sup>

### III. THE ADMINISTRATIVE PROCEDURE ACT

#### *A. Overview of The Administrative Procedure Act*

APA is a federal statute that allows for lawsuits against federal agencies for actions "made reviewable by statute and final agency action" where there is no other judicial remedy.<sup>88</sup> It was enacted in 1946 with four primary objectives: define the scope of judicial review, allow for public participation in the rulemaking process, require agencies to keep the populace informed, and prescribe uniform standards of conduct proceedings.<sup>89</sup> Sections 701 to 706 define the scope of judicial review, which the Court has interpreted to include "a broad spectrum of administrative actions" and a presumption in favor of judicial review that can only be overcome by "clear and convincing evidence" of a conflicting legislative intent.<sup>90</sup>

Section 706(1), specifically, allows for judicial review of administrative actions when they are unreasonably delayed or unlawfully withheld.<sup>91</sup> A number of cases have found that if the court finds that the actions meet one or more of these conditions, the court is required to issue an injunction to compel the agency to follow the applicable statute.<sup>92</sup> However, other courts have found that, as advocated by the FDA, the court can exercise judicial discretion regarding whether to issue an

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87. *Ctr. for Food Safety v. Hamburg*, No. C 12-4529 PJH, 2013 WL 5718339, at \*1-3 (N.D. Cal. Oct. 21, 2013) (citing *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Wisconsin Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985)). The factors for granting of a stay are: (1) whether petitioner has made a strong showing that she is likely to succeed, (2) whether petitioner will be irreparably injured absent a stay, (3) whether issuance of stay will substantially injure the other parties' interest, and (4) where the public interest lies. *Id.* at \*1 (citing *Hilton*, 481 U.S. at 776). The court focuses its analysis on the first two factors, stating that neither factors three or four "add much to the analysis in this case" and that the first two factors are the most important. *Id.* at \*2-3. The court holds that the FDA did not make a "strong showing" that it is likely to succeed since there was no argument that the court applied the wrong standard in its previous ruling and the FDA's arguments do not eliminate the court's ability to provide an injunction. *Id.* The court holds that the factor of the petitioner being irreparably injured was not met in this case since the FDA could use the comments received in the public comment period to collect more information before promulgating a final rule and that the FDA could file another motion if it runs out of time prior to the issuance of its final rule. *Id.* at \*2.

88. Administrative Procedure Act, 5 U.S.C. § 704 (2012).

89. U.S. DEP'T OF JUSTICE, ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT § I (1947).

90. *Abbott Labs. v. Gardner*, 387 U.S. 136, 140-41 (1967).

91. 5 U.S.C. § 706 (2012).

92. *See, e.g., Brock v. Pierce Cnty.*, 476 U.S. 253, 260 n.7 (1986) (noting that the court could compel agency action if it is unreasonably delayed or unlawfully withheld). The exception to this rule is if the action is barred by a congressional moratorium on spending for that purpose. *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1187 (10th Cir. 1999); *Env'tl. Def. Ctr. v. Babbitt*, 73 F.3d 867, 869 (9th Cir. 1995).

injunction if there is unreasonable delay or unlawful withholding of an action by an agency.<sup>93</sup>

*B. The Administrative Procedure Act in Hamburg*

In *Hamburg*, the court followed the path advocated by the Center for Food Safety, which is reliant on a recently developed body of unreasonable delay case law. One case, on which the *Hamburg* court relies when determining that a court must issue an injunction compelling the agency to follow the applicable statutory deadlines, is *Forest Guardians v. Babbitt*,<sup>94</sup> which centers around a deadline imposed by the Endangered Species Act.<sup>95</sup> The statute required the then Secretary of the Department of the Interior, Bruce Babbitt, to issue a final regulation within one-year of the publishing of a proposed regulation.<sup>96</sup> However, Babbitt failed to do this in the instance of a proposed rule listing the Rio Grande silvery minnow as endangered and designating its “critical habitat.”<sup>97</sup> As a result, two non-profit organizations brought suit to compel Babbitt to make the designation within thirty days since the statutory deadline had already passed.<sup>98</sup> In response, Babbitt stated that it was impossible for him to meet the deadline due to a lack of available resources.<sup>99</sup>

The court found for the plaintiffs, holding that the relevant portion of APA does not give them discretion in deciding whether or not to compel an agency to adhere to statutory deadlines.<sup>100</sup> The relevant portion states: “the reviewing court shall—(1) compel agency action unlawfully withheld or unreasonably delayed.”<sup>101</sup> The court came to this conclusion through looking at a number of different factors. The first factor is recently-developed case law, which interprets the word “shall” to imply a mandatory decision.<sup>102</sup> The second factor is *Environmental Defense Center v. Babbitt*, which compelled Babbitt to follow a statutorily imposed deadline.<sup>103</sup> The third factor is a straightforward plain reading of the terms “unreasonably delayed” and “unlawfully withheld” to distinguish between the two of them.<sup>104</sup>

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93. *Telecomm. Research and Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984); *In re Sierra Club*, 2013 WL 1955877, at \*1 (1st Cir. 2013).

94. 174 F.3d 1178, 1187 (10th Cir. 1999).

95. *Id.* at 1181.

96. Endangered Species Act, 16 U.S.C. § 1533 (2012); *Forest Guardians*, 174 F.3d at 1181–82.

97. *Forest Guardians*, 174 F.3d at 1182.

98. *Id.* at 1181–82.

99. *Id.* at 1182.

100. *Id.* at 1187–88, 90, 93.

101. *Id.* at 1187 (quoting 5 U.S.C. § 706 (2012)).

102. *Id.* at 1187.

103. *Id.* at 1188–89.

104. *Id.* at 1190.

The court waived away Babbitt's defense that a lack of resources precludes following the statutory deadlines.<sup>105</sup> The court stated that it did not have a choice in enforcing the statutory deadlines since it believes APA precludes the traditional balancing test done by courts.<sup>106</sup> In addition, should adhering to the court-mandated deadlines be impossible, Babbitt could prove this during a contempt proceeding.<sup>107</sup> For the aforementioned reasons, the court held that APA did not afford any discretion to the court, thus requiring that it issue an injunction to compel Babbitt to follow the statutory deadlines.<sup>108</sup>

*Telecommunications Research and Action Ctr. v. FCC (TRAC)*<sup>109</sup> is the principal case that the FDA relied on when arguing that reviewing courts have discretion about whether or not to issue an injunction in the face of an agency that violates statutory deadlines.<sup>110</sup> Under *TRAC*, the court articulated several factors that courts should take into account when deciding if courts should compel agency action because of unreasonable delays.<sup>111</sup> These factors are used by other courts to make the same determination.<sup>112</sup> However, the situation in *TRAC* had a material difference from that of *Hamburg*: there were no statutory deadlines imposed.<sup>113</sup>

### C. Adverse Consequences from Hamburg's Erosion of Traditional Administrative Law

The *Hamburg* court decided to follow the more recently-promulgated body of unreasonable delay case law, resulting in the determination that the court had no discretion to decide whether or not to compel an agency to adhere to statutory deadlines,<sup>114</sup> which has resulted in an erosion of traditional administrative law. The *Hamburg* court primarily relied on the unreasonable delay case law from the more recently-decided *Forest Guardians v. Babbitt*<sup>115</sup> in coming to its decision, rather than

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105. *Id.* at 1192.

106. *Id.* at 118788, 9091.

107. *Id.* at 1192–93.

108. *Id.* at 1193.

109. 750 F.2d 70 (D.C. Cir. 1984).

110. See Reply in Support of Defendants' Motion for Summary Judgment and Response in Opposition to Plaintiffs' Cross-Motion for Summary Judgment at 4, 8, 12–14, *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. Feb. 14, 2013), (No. CV 12 4529 DM).

111. *Telecommunications Research and Action Center*, 750 F.2d at 80. The six factors are: if agencies use "rule of reason" with their timeline, whether there is a timetable in the statute, whether the delay has an impact on human welfare, whether expediting agency action would have an effect on agency's competing priorities, the nature of the interests prejudiced by the delay, and whether there is any impropriety behind the lagging timeline. *Id.*

112. See, e.g., *Tummino v. Von Eschenbach*, 427 F. Supp. 2d 212, 231 (E.D.N.Y. 2006) (using the *TRAC* factors to determine if the court should compel the Food and Drug Administration to action); *Bemba v. Holder* 930 F. Supp. 2d 1022, 1029–35 (E.D.Mo. 2013) (using the *TRAC* factors to determine if delay in adjudicating citizenship status was reasonable).

113. *TRAC*, 750 F.2d at 73.

114. See *supra* Part I.C.

115. 174 F.3d 1178 (10th Cir. 1999).

the more established *TRAC* factor test.<sup>116</sup> By choosing to follow *Forest Guardians*, rather than the more established case law by the circuit with administrative law expertise, the *Hamburg* court contributed to a material change in case law.<sup>117</sup>

The first eroded administrative law principle is that courts and Congress should give administrative agencies a fair amount of deference.<sup>118</sup> By not affording the FDA discretion, despite the rational basis for its delay, the *Hamburg* court eroded this administrative principle. Even if we ignore the fact that the deadlines set forth in the law did not take into account 2012<sup>119</sup> and 2013<sup>120</sup> FDA budget cuts and a government shutdown,<sup>121</sup> the deadlines did not afford enough time for the FDA to implement the regulations.<sup>122</sup> For example, the act gave the FDA 270 days from the passage of the bill to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food.<sup>123</sup> The goal behind this was to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death, resulting from the food being adulterated or misbranded.<sup>124</sup> By contrast, the pilot programs mandated under the Railroad Safety Improvement Act (RSIA), a consumer protection law passed around the same time as FSMA, gave the Federal Railroad Administration (FRA) two years to create a pilot program.<sup>125</sup> The discrepancy between these two timelines

116. See *supra* text accompanying notes 103–117.

117. See, e.g., WILLIAM F. FUNK ET AL., ADMINISTRATIVE PROCEDURES AND PRACTICE PROBLEMS AND CASES 67 (4th ed. 2010) (stating that the D.C. Circuit “has been recognized as having expertise in administrative law”). In addition, several statutes require those seeking judicial review of agency action to bring suit in the District of Columbia. *Id.*

118. See, e.g., *Heckler v. Chaney*, 470 U.S. 821, 838 (1985) (Brennan, J., concurring); *Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 843–44 (1984).

119. E.g., *House Cuts FDA Budget by \$285 Million!*, ALLIANCE FOR NATURAL HEALTH (June 21, 2011), <http://www.anh-usa.org/house-cuts-fda-budget-by-285-million/>.

120. E.g., Associated Press, *FDA Commissioner Margaret Hamburg: 2013 Budget Cuts Means Less Safe Food*, POLITICO (Feb. 28, 2013, 12:43 PM), <http://www.politico.com/story/2013/02/fda-commissioner-margaret-hamburg-2013-budget-cuts-mean-less-safe-food-88241.html>.

121. E.g., Jessica Hartogs, *Voices of the Shutdown: “I Had Everybody Cancel,”* CBS NEWS (Oct. 12, 2013, 6:45 AM), <http://www.cbsnews.com/news/voices-of-the-shutdown-i-had-everybody-cancel/>.

122. In addition, the FDA does not have the resources to implement FSMA. E.g., KATHLEEN SEBELIUS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, REPORT TO CONGRESS ON BUILDING DOMESTIC CAPACITY TO IMPLEMENT THE FDA FOOD SAFETY MODERNIZATION ACT 10 (2013) (demonstrating that the FDA believes it needs more money to effectively implement the law). Requiring the FDA to not only implement FSMA, but to do so on a strict time frame is unrealistic. See, e.g., *Leading Cases*, 125 HARV. L. REV. 271, 279–80 (2011) (discussing how agencies often do not meet statutory deadlines, which forces agencies to implement a wide ranging scheme when they do not have the resources to meet congressional requirements “willfully ignore[s] reality”).

123. 21 U.S.C. § 2223a(1) (2012).

124. *Id.*

125. 49 U.S.C. § 21109e(1) (2012).

shows just how short the timeline for implementing FSMA is.<sup>126</sup>

The discrepancy in the two timelines is exacerbated by the fact that the FSMA pilot programs are much more expansive than those under RSIA. RSIA establishes two pilot programs.<sup>127</sup> The goal of one program is to evaluate the efficacy of communicating to employees notice of their assigned shift time 10 hours prior to the beginning of their assigned shift, as a method for reducing employee fatigue.<sup>128</sup> The goal of the other program is to evaluate the efficacy of requiring certain railroads to assign employees to defined unscheduled call shifts followed by shifts not subject to call, as a method for reducing employee fatigue.<sup>129</sup> These narrowly focused pilot programs not only mean less agency time spent figuring out what direction the pilot program should take, but less time and resources implementing the program. In addition, RSIA allows some of the requirements to be waived.<sup>130</sup> By contrast, FSMA does not allow for the waiving of requirements, which means more time and resources are necessary to make sure the program adheres to the requirements listed in the statute.

Court decisions that modify established case law have adverse implications for industry since businesses are harmfully impacted whenever traditional administrative law is modified. The reason for this is that changes in case law foster uncertainty.<sup>131</sup> Understanding and stability are particularly important when dealing with new regulations businesses are going to be subject to in order to avoid overwhelming their resources.<sup>132</sup>

This erosion is also significant for policy reasons. Since our common law system is built on examining the results of other cases, lawyers rely on the results of the other lawsuits when deciding whether or not to file potential lawsuits. Accordingly, when potential litigants see that courts are willing to second guess the expertise of administrative agencies, as the court has done in *Hamburg*, they may become more likely to file lawsuits against administrative decisions. This not only increases the

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126. The unworkableness of the pilot program deadlines can also be seen when comparing them to the deadlines of other FDA pilot programs. *See, e.g.*, Drug Supply Chain Security Act, Pub. L. 113–54 (2013) (codified in 21 U.S.C. §§ 360eee–360eee–4) (not giving a deadline for the establishment of a pilot program); Drug Supply Chain Security Act Implementation Plan, U.S. FOOD AND DRUG ADMIN. (Mar. 11, 2014), <http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm382022.htm> (stating target time frame for pilot program will be determined in the future).

127. *Id.*

128. 49 U.S.C. § 21109e(1) (2012).

129. *Id.*

130. *Id.*

131. Changes in administrative law make it unclear how courts are going to rule next, which leads to uncertainty for businesses. *See, e.g.*, JAMES R. ATWOOD ET AL., ANTI-TRUST AND AMERICAN BUSINESS ABROAD § 19:21 (3rd ed. 2011).

132. *See, e.g.*, Lon L. Fuller, *The Morality of Law* 38–39 (2nd ed. 1969) (stating legal stability and knowledge of legal obligations are essential to avoid frustrating private and public goals).

potential for litigation, but it undermines agency authority and puts the court in a position to make decisions that it does not have the expertise to make.<sup>133</sup>

Another eroded administrative law principle is that of refraining from arbitrary behavior.<sup>134</sup> Although, there has not been one main definition of arbitrary espoused by the courts,<sup>135</sup> one definition that has been consistently used is one meaning “irrational, not based on reason.”<sup>136</sup> Not only did the *Hamburg* court concede that the deadlines it imposed were arbitrary, but the deadlines promulgated were not based on rational considerations, such as how the FDA is going to effectively implement regulation with insufficient funds and periods of agency shutdown and how the industry was going to adequately prepare for the regulation.<sup>137</sup>

#### IV. THE DISASTROUS IMPLICATIONS OF *HAMBURG* FOR INDUSTRY

The *Hamburg* decision has numerous negative implications for the food industry ranging from increased costs for businesses to inhibiting the investing and marketing success of firms. Part A describes how the *Hamburg* decisions will likely lead to increased costs,<sup>138</sup> and part B goes into the myriad of other implications and their reasons.<sup>139</sup>

##### *A. The Ways Hamburg will Likely Lead to Increased Costs for the Food Industry*

Although the court promulgated deadlines that are in between those proposed by the two parties, they are nonetheless unrealistic. A random sampling of federal agency rulemaking from 2005 and 2006 found that rulemakings only began after the agency extensively surveyed practices and consulted with industry experts.<sup>140</sup> In these cases, most rulemakings were nowhere near as extensive, novel, and complex as FSMA, and did not require that federal agencies coordinate with other federal

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133. WILLIAM F. FUNK ET AL., ADMINISTRATIVE PROCEDURES AND PRACTICE PROBLEMS AND CASES 64 (4th ed. 2010) (stating that the problem with the judiciary ordering agencies to make a decision within a prescribed period of time is that courts are not in a position to assess agency priorities).

134. 5 U.S.C. § 706 (2012).

135. See, e.g., R. George Wright, *Arbitrariness: Why the Most Important Idea in Administrative Law can't be Defined and what this Means for the Law in General*, 44 U. RICH. L. REV. 839, 839 (2010) (stating that no standard definition of arbitrariness is possible).

136. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 56–57 (1983); *Bowman Transp., Inc v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285–86 (1974).

137. *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965, 972 (N.D. Cal. Apr. 22, 2013).

138. See *infra* Part A.

139. See *infra* Part B.

140. Letter to Committee on Capital Markets Regulation (Dec. 15, 2010), available at [http://www.capmkts.reg.org/pdfs/2010.12.15\\_Rulemaking\\_Timeline\\_Letter.pdf](http://www.capmkts.reg.org/pdfs/2010.12.15_Rulemaking_Timeline_Letter.pdf).

agencies and state governments.<sup>141</sup> The court's timeline fails to take these differences into account and its unreasonable timeline prevents the FDA from doing the necessary work to promulgate its regulations. The court's June 21st injunction ordered the FDA to publish all proposed regulations five months later on November 30th.<sup>142</sup> Clearance by the Office of Management and Budget is included in this deadline,<sup>143</sup> which by itself, can take over a year.<sup>144</sup>

When unrealistic deadlines are imposed on already overburdened agencies- not only are the agencies frustrated, but resources that could be spent on tasks such as reviewing petitions and applications and issuing necessary permits and certificates for manufacturers and importers are taken away.<sup>145</sup> This is directly applicable to *Hamburg*. Since the food industry has not been regulated this extensively before or in this manner, it is impossible to prove this based on food-regulation; however, looking to other FDA-regulated industries provides a good indication about how certain types of regulations will affect industry.<sup>146</sup> One such area is the prescription drug industry. In both the prescription drug and the food industries, the FDA currently has a backlog of petitions and applications.<sup>147</sup> In the case of prescription drugs, FDA backlogs have led to extended wait times for necessary paperwork and

141. Compare 12 C.F.R. § 4.15 (2005) (detailing the straightforward process for requesting certain records), with 78 Fed. Reg. 64834 (proposed Oct. 29, 2013) (to be codified at 21 C.F.R. § 507.100) (enumerating the ambiguous recording requirements, including cross references to different parts of the code and unclear definitions).

142. Order Granting Injunctive Relief at 3, *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. June 21, 2013), (No. CV 12 4529 DM).

143. *Id.* at 2–3.

144. See, e.g., Erik D. Olson, *The Quiet Shift of Power: Office of Management and Budget Supervision of Environmental Protection Agency Rulemaking under Executive Order 12,291*, 4 VA. J. NAT. RESOURCES L. 1, 46 (1984) (noting that the Office of Management and Budget spent over a year reviewing an Environmental Protection Agency regulation on air quality standards for particulates).

145. See, e.g., M. Elizabeth Magill, *Congressional Control over Agency Rulemaking: The Nutrition Labeling and Education Act's Hammer Provisions*, 50 FOOD & DRUG L.J. 149, 161 (1995) (stating that unrealistic deadlines frustrate the agency and that resource costs associated with deadline litigation may be high); Alden F. Abbott, *Case Studies on the Costs of Federal Statutory and Judicial Deadlines*, 39 ADMIN. L. REV. 467, 475 (1987) (providing an example of how unrealistic an EPA deadline resulted in wasted costs that threatened to undermine the quality of necessary registration program).

146. *Frequently Asked Questions*, U.S. FOOD AND DRUG ADMINISTRATION (Oct. 25, 2013), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm> (detailing how FSMA changes the way and extent the food industry has been regulated).

147. H.R. REP. NO. 104-436, pt. II, IV. (1995) (stating that the FDA has a backlog of food additive petitions and applications), available at <http://www.gpo.gov/fdsys/pkg/CRPT-104hrpt436/html/CRPT-104hrpt436.htm>; June Gibbs Brown, *Review of the Food and Drug Administration's Citizen Petition Process*, DEPARTMENT OF HEALTH AND HUMAN SERVICES: OFFICE OF INSPECTOR GENERAL i, 3 (1998) (stating that FDA has a backlog of 250 petitions), available at <https://oig.hhs.gov/oas/reports/phs/c9750002.pdf>; Alaric Dearment, *GDUFA Tackles Backlog of Drug Approval Applications*, DRUG STORE NEWS (Oct. 10, 2013), <http://drugstorenews.com/article/gdufa-tackles-backlog-drug-approval-applications-fda-hires-more-staff> (stating that FDA has a backlog of generic drug approval applications).



skewing of the industry in favor of larger more established companies.<sup>148</sup> Resources that are currently being spent defending against deadline litigation and helping the FDA meet these deadlines could be spent mitigating the backlog.<sup>149</sup> This encouragement of other potential litigants could further add to the FDA's petition and application backlog. In addition, these results are exacerbated since the FDA does not believe it has enough funding or time to implement the law effectively.<sup>150</sup>

The augmentation of the backlog of applications and petitions could result in more fees for the industry, which is exactly what happened with the prescription drug industry.<sup>151</sup> The existence of the backlog, coupled with the lack of agency resources, caused the levying of a substantial fee on prescription drug companies to help the FDA mitigate the backlog.<sup>152</sup> Not only is the regulation of the prescription drug industry similar to the food industry, but there is also a lack of FDA resources dedicated to the food industry regulation.<sup>153</sup> The recent passage of a bill that would charge industry a fee to reduce the FDA's backlog shows that Congress is not opposed to passing fees for FDA-regulated industries, which makes it more likely that fees could be levied on the food industry to mitigate the application and petition backlog.<sup>154</sup>

Another adverse effect of *Hamburg* is that the decision forces businesses to come into compliance faster than they would have had to if the Food and Drug Administration's desired deadlines had prevailed. This faster compliance time means businesses have to spend more money to ensure they adhere to the

148. H. Rep. No. 104-436, at 4 (1995); Aaron Smith, *FDA Backlog = Billions for Big Pharma*, CNNMONEY (Apr. 10, 2006 9:26 AM), [http://money.cnn.com/2006/04/10/news/companies/fda\\_backlog/](http://money.cnn.com/2006/04/10/news/companies/fda_backlog/).

149. See Reply in Support of Defendants' Motion for Summary Judgment and Response in Opposition to Plaintiffs' Cross-Motion for Summary Judgment at 12, *Ctr. for Food Safety v. Hamburg*, 954 F.Supp.2d 965 (N.D. Cal. Feb. 14, 2013), (No. CV 12 4529 DM) (stating that the FDA has already begun to prioritize FSMA rulemaking); Rosemary O'Leary, *The Impact of Federal Court Decisions on the Policies and Administration of the U.S. Environmental Protection Agency*, 41 Admin. L. Rev. 549, 562 (1989) (using interviews with federal employees to prove her point that a federal agency has prioritized fulfilling court orders with its limited resources and put other programs on the backburner).

150. KATHLEEN SEBELIUS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, REPORT TO CONGRESS ON BUILDING DOMESTIC CAPACITY TO IMPLEMENT THE FDA FOOD SAFETY MODERNIZATION ACT 10 (2013) (showing the FDA believes it needs more money to effectively implement the law); Reply in Support of Defendants' Motion for Summary Judgment and Response in Opposition to Plaintiffs' Cross-Motion for Summary Judgment at 12–13, *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965 (N.D. Cal. Feb. 14, 2013) (No. CV 12 4529 DM).

151. 138 CONG. REC. S17234-03 (daily ed. Oct. 7, 1992) (joint statement of Sen. Edward Kennedy and Orrin Hatch) (stating that this bill will help reduce the backlog of applications); 138 CONG. REC. H11730-01 (daily ed. Oct. 5, 1992) (statement of Rep. William Richardson) (stating that the fee act will begin to address the backlog of prescription drug approvals); *Standard Costs for Components of the Process for the Review of Human Drug Applications*, U.S. FOOD AND DRUG ADMINISTRATION (Sep. 11, 2013), <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093484.htm> (detailing what the substantial fees are to mitigate the backlog).

152. *Id.*

153. See, e.g., National Research Council, CHALLENGES FOR THE FDA 14–15 (2007).

154. *Digest for S.622*, GOP.GOV, <http://www.gop.gov/bill/113/1/s622> (last visited Mar. 12, 2014) (describing how recently-passed S. 622 would help mitigate the FDA backlog).

regulations.<sup>155</sup> Since *Hamburg* required faster implementation of FSMA's regulations, it means that businesses will have to modify their business strategies before they would otherwise have needed to. These financial impacts are quite large impact given the substantial cost FSMA will have on the industry.<sup>156</sup> FDA estimates the produce regulations, by themselves, will cost domestic farms between \$4,967.19 and \$30,566.23 per farm, depending on the farm's size.<sup>157</sup>

In addition, since the regulation will be in effect for a longer period of time than it would be without this lawsuit, this means that there is more time for it to have its adverse effects on the industry and businesses that depend on farmers and food manufacturers and importers, such as restaurants and grocery stores. Basic economics state that when a business has a higher cost it will typically pass on this higher cost to the consumer.<sup>158</sup> In this case, other players in the supply chain use the goods, which will result in higher costs for them.<sup>159</sup> These businesses will likely pass on their higher costs to consumers who could be starting businesses of their own.<sup>160</sup> This effect is not just a basic economics principle, but has proven to be true when the cost of producing foods has risen in recent years.<sup>161</sup> Since FSMA threatens to increase the cost of food industry basics, FSMA will likely increase the cost of food to potential entrepreneurs.<sup>162</sup>

#### B. Hamburg's Other Implications for the Food Industry

The *Hamburg* decision compels the FDA to develop FSMA's regulations in a shorter time frame than it feels comfortable with, which could lead to a myriad of adverse effects stemming from the increased likelihood that the FDA's regulations will be

155. Industry fees are billed annually, so the longer the bill is in effect the more times the fees have to be paid. See 21 U.S.C. § 379j-31 (2012).

156. Helena Bottemiller, *Merrigan Expresses Worry About FSMA's Impact on Agriculture*, FOOD SAFETY NEWS (May 24, 2013), [http://www.foodsafetynews.com/2013/05/merrigan-expresses-worry-about-fsmas-impact-to-agriculture/#.Uw0sf\\_12-0s](http://www.foodsafetynews.com/2013/05/merrigan-expresses-worry-about-fsmas-impact-to-agriculture/#.Uw0sf_12-0s).

157. U.S. Food & Drug Admin., *Analysis of Economic Impacts: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption* 317-18 (2013), available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf>.

158. See Jonathan S. Masur & Eric A. Posner, *Regulation, Unemployment, and Cost-Benefit Analysis*, 98 VA. L. REV. 579, 610 (2012).

159. See, e.g., A. Bryan Endres & Nicholas R. Johnson, *United States Food Law Update: The FDA Food Safety Modernization Act, Obesity and Deceptive Labeling Enforcement*, 7 J. FOOD L. & POL'Y 135, 145 (2011) (stating how almond regulation has been passed down from handlers to producers and adds costs on domestic industry).

160. See, e.g., Kelly M. Gay, Note, *Hunger, Food Prices, and the Food Safety Modernization Act: Balancing Physical Safety and Food Security*, 65 FLA. L. REV. 1377, 1396 (2013).

161. Julie Jargon et al., *Higher Food Prices Start to Pinch Consumers*, THE WALL STREET JOURNAL (Jan. 3, 2008, 12:01 AM), <http://online.wsj.com/news/articles/SB119932361635363833> (stating how higher costs has, in part, led to increased cost of foods to consumers).

162. *FSMA: Comment on FDA's Proposed Food Safety Regulations by November 15 Deadline*, FARM-TO-CONSUMER LEGAL DEFENSE FUND (Oct. 22, 2013), [http://www.farmtoconsumer.org/news\\_wp?p=12806](http://www.farmtoconsumer.org/news_wp?p=12806) (stating that consumers will face increased food prices as a result of FSMA).

flawed.<sup>163</sup> The first such effect is increased cost of compliance and inefficiencies, which has been shown to emanate from regulation that is not clearly articulated.<sup>164</sup>

In addition, *Hamburg*'s timeline does not give the FDA adequate time to build on the lessons learned from implementation of the previous regulations since it gives the same deadline for the promulgation of all the final regulations.<sup>165</sup> By requiring this, the court denies the FDA the opportunity to learn from the implementation of different aspects of this new and complex law, and ability of the FDA to use its' expertise in promulgating the regulations.<sup>166</sup> In doing this, *Hamburg* increases the likelihood that the FDA's regulations will be poorly written, which adversely affects businesses.<sup>167</sup>

There are a number of reasons that it is important to allow time for agencies to learn from previous regulations that have been implemented. The first reason is that although regulations can seem clear when they are first written, implementation can prove to be more difficult.<sup>168</sup> Accordingly, agencies should learn from the successes and failures of past regulation<sup>169</sup> to ensure the best possible

163. See, e.g., O'Leary, *supra* note 149, at 566–67 (Relaying a story of when the Environmental Protection Agency was forced to implement regulations in a shorter time frame than requested which resulted in scientifically flawed and sham regulations); Abbott, *supra* note 145, at 467, 469, 472–74, 476, 480–81, 487 (Providing numerous examples of how court-ordered deadlines have led to poorly written rules.).

164. See, e.g., American Bar Association, *Conclusion, Project: Regulatory Reform: A Survey of the Impact of Reregulation and Deregulation on Selected Industries and Sectors*, 47 ADMIN L. REV. 665, 666 (1995) (reiterating an incident where the Internal Revenue Service's poorly-written regulation contributed to a number of businesses adopting costly compliance plans).

165. See *supra* text accompanying notes 59–62.

166. Before *Hamburg*, the FDA had decided to prioritize the development and implementation of FSMA's regulations due to the agency's limited resources. Reply in Support of Defendants' Motion for Summary Judgment and Response in Opposition to Plaintiffs Cross-Motion for Summary Judgment at 13, Ctr. for Food Safety v. Hamburg, No. 12-cv-04529 PJH, 2013 WL 781073 (N.D. Cal. Feb. 14, 2013). By forcing the FDA to implement the regulations on a strict timeline that does not allow for prioritizing regulations to be implemented, the *Hamburg* court is not adequately deferring to the agency's expertise with these complex regulations. See *Papago Tribal Utility Authority v. F.E.R.C.*, 773 F.2d 1056, 1058 (9th Cir. 1985) (stating that courts defer to an agency's substantial expertise where the subject matter is complex); *infra* note 172.

167. See, e.g., *HB 424 – Regulation Review*, 23rd Leg. 1081 (2004) (statement of David Stancliff, representing Sen. Therriault), available at [http://www.legis.state.ak.us/basis/get\\_single\\_minute.asp?session=23&beg\\_line=01376&end\\_line=01592&time=1320&date=20040227&comm=JUD&house=H](http://www.legis.state.ak.us/basis/get_single_minute.asp?session=23&beg_line=01376&end_line=01592&time=1320&date=20040227&comm=JUD&house=H) (stating how poorly-written regulation can cost millions of dollars and it is difficult for someone affected by such to obtain resolution); Patrick J. DeSouza, Note, *Regulating Fraud in Military Procurement: A Legal Process Model*, 95 YALE L.J. 390, 404–05, n.4 (1985) (stating how poorly written regulation is an element of mismanagement, which leads to adverse effects to contractors, such as forcing them to pay an insurance premium and causing their exploitation).

168. One example of this is the regulation emanating from the Clean Air Act of 1990. Despite the law being carefully scrutinized and debated for a decade and carefully thought out by a well-funded EPA, the regulation was difficult to implement. See, e.g., Howard Latin, *Regulatory Failure, Administrative Incentives, and the New Clean Air Act*, 21 ENVTL. L. 1647, 1692 (1991); Henry A. Waxman, *An Overview of the Clean Air Act Amendments of 1990*, 21 ENVTL. L. 1721, 1724 (1991).

169. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863–64 (1984) (stating that decision depended on federal agency being able to change regulatory approach to reflect past experiences).

product both for the sake of the agency and the food industry.<sup>170</sup> The second reason is that allowing the FDA to build on its lessons from previous regulations will help allay any industry anxiety and help it better prepare for newer FSMA regulations. One of the reasons the food industry is particularly anxious about FSMA is that it is an unknown comprehensive legislation.<sup>171</sup> This effect is likely to be exacerbated since the regulation is so complex and novel, and there is so much discretion left to the FDA.<sup>172</sup> Allowing the food industry to see a successful implementation of some of FSMA's regulations will not only allow the food industry to better prepare, but will let it see that the regulation could be implemented successfully.<sup>173</sup>

*Hamburg* is specifically detrimental to the investing and marketing decisions and successes of the affected businesses. As noted with environmental regulation, a stable regulatory environment is critical for investing and marketing success of businesses.<sup>174</sup> Since FSMA changes the regulation of the food industry so drastically, *Hamburg's* effects are particularly salient.<sup>175</sup>

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170. The reason for this is that poorly-written regulations can adversely affect industry and the agency itself. See Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65, 71–74 (1983) (listing the agency benefits to constructing clear rules); *supra* note 167 and accompanying text.

171. See, e.g., Cookson Beecher, *Proposed Rule for Food Processors Alarms Some*, FOOD SAFETY NEWS (July 29, 2013), <http://www.foodsafetynews.com/2013/07/proposed-rule-for-food-processors-alarms-some-confuses-many/#.UtBQlMrdvF8> (describing the proposed FSMA rule as “complicated and interwoven,” and “coming down like a ton of bricks,” and eliciting confusion); Sudhakar Kaup, *New Survey of Processing Companies Reveals Uncertainty of FSMA Implications*, FOOD SAFETY MAGAZINE (Aug. 6, 2013), <http://www.foodsafety-magazine.com/fsm-edigest/new-survey-of-processing-companies-reveals-uncertainty-of-fsma-implications/> (stating that survey of food processors reveal uncertainty as biggest concern surrounding FSMA).

172. See *Ctr. for Food Safety v. Hamburg*, No. C 12–4529 PJH 2013 WL 1741816, at \*3, \*6 (N.D. Cal. Apr. 22, 2013) (stating that the FSMA regulations are novel and complex and naming all the areas where the FDA has discretion).

173. A study of reasons industry does not comply with EPA regulations show a lack of preparation as contributing to the top reasons. EPA & CHEM. MFR. ASS'N, *EPA/CMA Root Cause Analysis Pilot Project: An Industry Survey*, EPA-305-R-99-001 (May 1999). Environmental regulations provide a good comparison to FSMA since both industries are heavily regulated by federal agencies and are closely-related to each other. See e.g., *FDA Issues Proposed Regulations for Safer Fruits and Vegetables*, CCH DRUG & COSMETICS L. REPORTER 2013 WL 6084205 (Jan. 16, 2013) (stating that environmental groups commented on proposed FSMA regulations, and environmental standards and agencies were taken into account when developing FSMA regulations); Stuart Phillips & Hal F. Morris, *The Care and Feeding of State Regulators in Chapter 11 Cases*, AM. BANKR. L.J. 8, 58 (2003) (acknowledging the environmental industry as being heavily regulated); Sudhakar Kaup, *New Survey of Processing Companies Reveals Uncertainty of FSMA Implications*, FOOD SAFETY MAGAZINE (Aug. 6, 2013), <http://www.foodsafetymagazine.com/fsm-edigest/new-survey-of-processing-companies-reveals-uncertainty-of-fsma-implications/> (implying that food industry is heavily regulated).

174. See e.g., William W. Buzbee, *Clean Air Act Dynamism and Disappointments: Lessons for Climate Legislation to Prompt Innovation and Discourage Inertia*, 32 WASH. U. J.L. & POL'Y 33, 35 (2010); *supra* note 166.

175. The FDA calls FSMA “the most sweeping reform of our food safety laws in more than 70 years” *FDA Food Safety Modernization Act*, U.S. FOOD AND DRUG ADMIN. (Jan. 1, 2014), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>; See *supra* text accompanying notes 14–42.

V. *HAMBURG'S* ADVERSE EFFECTS FOR SMALL BUSINESSES IN PARTICULAR

Although *Hamburg* will adversely affect the entire food industry, it stands to have a particularly severe effect on small businesses for two reasons. The first reason stems from the large amount of discretion given to the FDA in defining what a small business is.<sup>176</sup> The second reason stems from *Hamburg* exacerbating FSMA's effects.<sup>177</sup>

A. *The Negative Implications of Hamburg Stemming from the Amount of Discretion Given to the FDA*

The first reason for the adverse effects of *Hamburg* on small businesses is that the FDA has too much discretion to define what a small business is, and not enough time to develop a satisfactory definition. FSMA puts no limits on how the FDA defines a small business.<sup>178</sup> In addition, courts normally grant broad deference to agency action, so it is unlikely that courts will mitigate the negative effects of agency action.<sup>179</sup>

The first problem with so much deference given to the FDA in this area is that there is nothing barring the FDA from making the definition of a small business overly expansive. As it stands, federal agencies can define small businesses as having up to 500 employees and a sales volume of over \$35 million.<sup>180</sup> Due to the FSMA exemptions for small businesses, it is in the best interest of businesses to be qualified as such. Since larger businesses have easier access to regulators and lawmakers, more clout, and greater resources, it is likely they will be able to lobby for a more expansive definition of a small business.<sup>181</sup> Shorter time frames give smaller businesses less time to lobby for a more restrictive definition. If larger businesses are able to be put into the small business category, any small business protections are eradicated.<sup>182</sup> Although there is a separate category for very small businesses, because there is no definition set-aside for them either, a similar phenomenon could happen with this category.<sup>183</sup>

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176. See *infra* Part A.

177. See *infra* Part B.

178. 21 U.S.C. § 350h (2012).

179. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 865–66 (1984).

180. U.S. Small Business Administration, *Table of Small Business Size Standards Matched to North American Industry Classification System Codes*, available at [http://www.sba.gov/sites/default/files/files/size\\_table\\_01222014.pdf](http://www.sba.gov/sites/default/files/files/size_table_01222014.pdf).<sup>180</sup>

181. See, e.g., Kelly D. Brownell & Kenneth E. Warner, *The Perils of Ignoring History: Big Tobacco Played Dirty and Millions Died. How Similar is Big Food?*, THE MHLBANK QUARTERLY, Mar. 1, 2009, at 259, 262–63, 276.

182. See, e.g., *Ray Baillie Trash Haling, Inc. v. Keppe*, 477 F.2d 696, 708 (1973) (stating that the whole purpose of the enacting of a statute that protects small businesses is because they are unable to compete with large businesses in the marketplace).

183. 21 U.S.C. § 350h (2012).

A second problem with the FDA getting too much discretion in defining small and very small business is that the FDA could require small businesses to jump through hoops to get the necessary exemptions. The risk of this occurring is increased by the FDA having to promulgate their rules in haste.<sup>184</sup> This not only is detrimental since it costs all businesses that apply time and resources, but it alters the playing field in favor of those best able to navigate the agency requirements—not necessarily those who are the best performers.<sup>185</sup> In addition, when federal benefits have been intended for small business, they have lead to larger businesses being the beneficiaries.<sup>186</sup>

*B. The Negative Implications of Hamburg Stemming from its' Exacerbation of FSMA's Effects*

FSMA will work to the detriment of small businesses since government regulation in the marketplace, as a whole, more adversely affects these types of businesses.<sup>187</sup> This is particularly true with the food industry since regulations are tailored to the advantage of large businesses, which makes it more difficult for small businesses to gain entry into the marketplace.<sup>188</sup> Since *Hamburg* exacerbates the effects of a specific type of regulation, it will have a particularly egregious effect on these businesses.<sup>189</sup>

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184. See, e.g., Abbott, *supra* note 145, at 485–86 (discussing how tight deadlines forced the Coast Guard to act hastily and promulgate flawed regulations).

185. See, e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-425, 8(A) PROGRAM FOURTEEN INELIGIBLE FIRMS RECEIVED \$325 MILLION IN SOLE-SOURCE AND SET-ASIDE CONTRACTS (2010) (reporting on how larger businesses have benefitted from protections intended for small businesses).

186. Since the FDA has not extensively administered exceptions for small businesses, the effects of these exceptions are not best seen in the food industry. See 21 U.S.C. § 350g (2011) (requiring the FDA defines small and very small businesses); Nicholas R. Johnson & A. Bryan Endres, *Small Producers, Big Hurdles: Barriers Facing Producers of "Local Foods,"* 33 HAMLIN J. PUB. L. & POL'Y 49, 83 (2011) (stating how vague food regulations leave a lot of discretion to food inspectors who end up adopting a "one-size-fits-all" approach). However, when looking at a federal program where there is heavy preference for small business, it is evidence that these preferences actually benefit the large businesses. See, e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-425, 8(A) PROGRAM FOURTEEN INELIGIBLE FIRMS RECEIVED \$325 MILLION IN SOLE-SOURCE AND SET-ASIDE CONTRACTS (2010) (reporting on how larger businesses have benefitted from protections intended for small businesses).

187. See, e.g., JOEL SALATIN, FOLKS, THIS AIN'T NORMAL 338 (1st ed. 2011) (stating that whenever regulators interfere with the marketplace it hurts small farmers because they don't have the clout, manpower, or lobbying ability to curry favor with regulators); James L. Huffman, *The Impact of Regulation on Small and Emerging Businesses*, 4 J. SMALL & EMERGING BUS. L. 307, 313 (stating that regulation more adversely affects small and emerging businesses because of the minimum amount of work to adhere to the regulations).

188. See, e.g., Almonds Grown in California; Outgoing Quality Control Requirements, 72 Fed. Reg. 15031–32 (Mar. 30, 2007) (to be codified at 7 C.F.R. pt 981) (stating how several small businesses opposed the regulation on the grounds that it will put them out of businesses); JOEL SALATIN, FOLKS, THIS AIN'T NORMAL 338 (1st ed. 2011) (stating how the regulation of the food industry results in small farmers being unable to gain entry into the marketplace due to regulation that is a minor nuisance to large farms strangling small farmers, and hostile harassment and intimidation of small food producers by food inspectors).

189. See *supra* notes 60–65 and accompanying text.

The aforementioned disadvantages are exacerbated by *Hamburg* giving less time for businesses to prepare for FSMA's implementation and more time for it to be in effect. In addition, although these changes primarily affect small businesses, they will harm everyone. The reason for this is that when small businesses are harmed the whole United States economy suffers since U.S. small businesses create most new jobs and employ 50% of the workforce.<sup>190</sup> When potential consumers are out of work, all businesses suffer.<sup>191</sup>

## VI. CONCLUSION

By deciding to follow a recently-developed stream of case law regarding APA unreasonable delay,<sup>192</sup> *Hamburg* has hurt the food industry, particularly small businesses.<sup>193</sup> This is as a result of the court's deadlines,<sup>194</sup> the content of FSMA,<sup>195</sup> and the erosion of basic administrative law principles.<sup>196</sup>

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190. U.S. SMALL BUSINESS ADMINISTRATION, THE SMALL BUSINESS ECONOMY: A REPORT TO THE PRESIDENT, 1 (2009).

191. See, e.g., Philip Harvey, *Human Rights and Economic Policy Discourse: Taking Economic and Social Rights Seriously*, 33 COLUM. HUM. RTS. L. REV. 363, 402 (2002).

192. See *supra* Part II–III.

193. See *supra* Part IV–V.

194. See *supra* Part IV.

195. See *supra* Part IV.

196. See *supra* Part III.C.