FOOD SAFETY MODERNIZATION ACT'S PRODUCE RULES: IS THE INCREASED FLEXIBILITY ACTUALLY A BURDEN ON THE FARMER?

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I. INTRODUCTION

President Barack Obama signed the Food Safety Modernization Act, commonly referred to as FSMA, into law on January 4, 2011.[1] FSMA was an amendment of the Federal Food, Drug, and Cosmetic Act specifically focused on food safety.[2] It was the start of "the first overhaul of food safety policy in [roughly] seventy years."[3] Before FSMA, the nation's food safety policy was deeply reactive.[4] The number of Americans getting sick—or even dying—from food borne illness was on the rise.[5] By creating FSMA, the United States Food

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1. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011); *Background on the FDA Food Safety Modernization Act (FSMA)*, FDA, http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM263773.pdf (last updated July 12, 2011); *The Food Safety Law and the Rulemaking Process: Putting FSMA to Work*, FDA, http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM277713.pdf (last updated Nov. 1, 2011).

2. FDA Food Safety Modernization Act §§ 1-405.

3. NICOLE FAIRES, FOOD TYRANTS: FIGHT FOR YOUR BASIC RIGHT TO HEALTHY FOOD IN A TOXIC WORLD 164 (2013).

4. *The Food Safety Law and the Rulemaking Process: Putting FSMA to Work*, *supra* note 1.

5. *See Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 1.

and Drug Administration (FDA) aimed to become more proactive in order to prevent a majority of the food safety issues through regulation of industry procedure and process.[6] More specifically, it was created to hold large processors and industrial farms accountable through increased preventative measures and detailed record keeping.[7] Additionally, it gave the FDA authority to order recalls of suspected products.[8]

The implementation of an act as large as FSMA takes several years to accomplish.[9] Congress has provided the FDA direction on implementation dates for the new rules.[10] In order to comply with the implementation dates in a timely and efficient manner the FDA created a process for the development of new rules.[11] Within this process, the timeframe for the creation of each rule can vary.[12] This timeframe is dependent on several factors including the urgency of the matter contained in the rule at hand and the funding available for implementation each year.[13]

On January 16, 2013, roughly two years after FSMA's enactment, the first proposed rules regarding produce safety were published under the title "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption."[14] The issued proposed rules, also referred to as a Notice of Proposed Rulemaking (NPRM) were published in the Federal Register and left for public comment.[15] A typical comment period lasts 30 to 90 days.[16] The first NPRM comment period for produce was scheduled to end in May of 2013 but was extended an additional 120 days to September 2013.[17] The extension was

6. *Id.*

7. FAIRES, *supra* note 3.

8. *Id.* at 164–65; *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 1.

9. *See Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 1.

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Comment Periods, 78 Fed. Reg. 24692 (proposed Apr. 26, 2013) (to be codified at 21 C.F.R. pts.16, 112); FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011); *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 1.

15. *The Food Safety Law and the Rulemaking Process: Putting FSMA to Work*, *supra* note 1.

16. *Id.*

17. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Comment Periods, 78 Fed. Reg. 48637, 48638 (proposed Aug. 9, 2013) (to be codified at 21 C.F.R. pts. 16, 112) (comment period extended).

due to requests by interested parties to allow more time to prepare and submit comments as they did not believe the original 120-day timeframe was enough to provide the FDA with an accurate response.[18]

In July of 2013 the FDA published two additional proposed rules: "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (Docket No. FDA-2011-N-0143) and "Accreditation of Third-Party Auditors/ Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (Docket No. FDA-2011-N-0146).[19] Both of these proposed rules were related to the original proposed produce rules issued January 16, 2013.[20] Due to the relation and technical difficulties, the FDA thought it would be best to again extend the deadline on the comment period.[21] This time, the FDA extended the period an additional 90 days to November 22, 2013.[22] Around this same time the FDA released an Environmental Impact Statement for the proposed rule.[23] The comment period for the Environmental Impact Statement ended on March 14, 2014.[24] Finally, the supplemental NPRM was released in September of 2014.[25] Following its release, the Supplemental Act was revised and re-submitted again for public comment.[26] On November 27, 2015 the FDA published the long awaited Final Rules, taking into consideration several years' worth of public comment.[27] These final rules are in effect as of January 26, 2016.[28]

The revised supplementary proposed produce rules, published for comment

18. *Id.*

19. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 78 Fed. Reg. 45730 (proposed July 29, 2013) (to be codified at 21 C.F.R. pt. 1); Accreditation of Third-Party Auditors/ Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45782 (proposed July 29, 2013) (to be codified at 21 C.F.R. pts. 1, 16).

20. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Comment Periods, 78 Fed. Reg. at 48638.

21. *Id.*

22. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Comment Periods, 78 Fed. Reg. 69605, 69606 (proposed Nov. 20, 2013) (to be codified at 21 C.F.R. pts. 16, 112) (extension of comment period).

23. Environmental Impact Statement for the Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Comment Periods, 78 Fed. Reg. 69006 (proposed Nov. 18, 2013).

24. *Id.*

25. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. 58434 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R. pt. 112) (referencing the timeline bar for Produce Safety Regulation).

26. *Id.*

27. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. 74547 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 112).

28. *Id.*

on September 29, 2014, were part of the FDA's efforts to make the rules more flexible, practical, and targeted.[29] There were four revised proposed rules primarily at issue: (1) produce safety; (2) preventative controls for human food; (3) preventative controls for animal food; and (4) the foreign supplier verification program.[30] The focus of this Note will specifically address the proposals and final rules pertaining to produce safety. In these rules, the FDA has attempted to make the water quality standard and testing more flexible for farmers.[31] The agency has also revised the definition of a "farm" that is within the scope of regulation and clarified the process regarding the withdrawal of exemptions.[32] Finally a decision on the manure strategy is deferred until more research is conducted to further assess the risks.[33]

This Note will address the areas of water quality and farm size within produce safety, which will change possible effects on the farmer and FSMA's ultimate food safety goals. For example these changes raise the questions: Does the increased flexibility of these rules actually decrease food safety for the consumer? Are the changes to the water quality standards reducing the burden on farmers or making regulations more complicated and costly? Are the changes to the exempted farm sizes enough? Are they too much? While this Note may not conclusively answer all these questions, it will address the concerns and advantages on both sides of the argument.

II. PROPOSED AND FINAL REGULATIONS FOR PRODUCE SAFETY

A. Water Quality Standards and Testing

The FDA proposed revised rules for water quality standards and testing for Sections 112.40–.50 under Subpart E: Standards Directed to Agricultural Water.[34] Specifically, the issues addressed in the supplement and comments for these sections are: the minimum "microbial quality standard[s] for agricultural water used during growing activities for covered produce . . . using a direct water

29. *FDA Seeks to Make FSMA Proposals More Flexible, Targeted*, FDA (Sept. 19, 2014), http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm415132.htm.

30. *Id.*

31. *Id.*; *FSMA Final Rule on Produce Safety*, FDA, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm (last updated Mar. 3, 2016).

32. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74550, 74552.

33. *FSMA Final Rule on Produce Safety*, *supra* note 31.

34. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. 58434, 58434 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R. pt. 112) (referencing the timeline bar for Produce Safety Regulation).

application[,]" the frequency of testing of the water, and the use of third parties to test agricultural water.[35]

1. Minimum Microbial Quality Standards for Agricultural Water

The FDA revised the microbial standards for water that is applied directly to the produce while it is growing.[36] By updating and revising the standards, the FDA hopes to give farmers additional ways to meet the standard and still be able to use their water even if they would have initially failed the original proposed microbial standard.[37]

In the original proposed rule, if a farm was found to have "more than 235 colony-forming units (CFU) generic *E. coli* per 100 mL, or a rolling geometric mean of more than 126 CFU per 100 mL of water" for any sample, the water source must be discontinued from use immediately.[38] If either of these are found, before the farmer is able to use the water source for produce they must re-inspect the entire agricultural water system or meet the requirements under proposed Section 112.43.[39] These standards were set by the FDA based on EPA recreational water standards.[40] While the FDA does recognize that there are major differences between water used to grow produce and water used for recreational purposes that were analyzed in the EPA standards, they are still choosing to use the study and *E. coli* as the base standards for produce water quality.[41]

Under the revised proposed and final rule, the FDA has adjusted for "a statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100mL of water."[42] However it would still maintain the geometric mean "of no more than 126 CFU per 100mL[,]" but would lose the rolling mean.[43] These numbers remain consistent with the EPA 2012 recreational water quality criteria.[44]

35. *Id.*

36. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74554–57; *FSMA Final Rule on Produce Safety*, *supra* note 31.

37. *See FSMA Final Rule on Produce Safety*, *supra* note 31.

38. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58441.

39. *Id.*

40. *Id.*

41. *Id.*

42. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74555; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58443.

43. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74555; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58444.

44. *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for

The FDA has decided to provide an allowance for microbial die-off between irrigation and harvest at a die-off rate of 0.5 log per day.[45] The time interval must be applied in days.[46] This allowance is provided for in the Final Rule as an option to farmers if their agricultural water does not meet the standards of section 112.44(b) and would be limited to a four day maximum.[47]

The FDA did not reconsider or change the use of generic *E. coli* as the indicator to test the safety of agricultural water.[48] However, this is the first time that microbiological standards of this nature will be imposed on United States farmers.[49] With these new standards, a key concern of using the 126 CFU *E. coli* per 100 ml of water as the standard is that it will not be met for a number of reasons, many outside of the farmer's control.[50] Surface irrigation water will most likely exceed the *E. coli* standard when it is impounded or reused under many current water conservation plans.[51] In order to avoid such issues, many of the current surface water users will likely switch to groundwater sources that are not as easily contaminated.[52] The problem with farmers making this change is that there are already critical groundwater shortages in some areas of the country.[53] In the agricultural valleys of the Midwest, low gradient streams that are used for both animals and plants are at risk as well.[54] Even a common weather event, like a thunderstorm, will cause higher levels of bacteria in lakes and streams, which

Human Consumption, 79 Fed. Reg. at 58443–44.

45. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74555; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58445.

46. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74555; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 79 Fed. Reg. at 58445.

47. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74555.

48. *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58443.

49. Edward R. Atwill, *Opportunities and Threats to Widespread Adoption of Bacterial Standards for Agricultural Water*, INST. ON SCI. FOR GLOBAL POL'Y (Oct. 20-23, 2013), http://scienceforglobalpolicy.org/wp-content/uploads/551f535f68f62-Atwill.pdf.

50. *See id.*

51. *Id.*

52. Kathy Holliman, *Environmental Impacts of Produce Safety Rules Open for Comment: Water Quality Standards Named as Having Potential Adverse Environmental Effect*, FOOD QUALITY & SAFETY (Jan. 27, 2015), http://www.foodquality.com/details/articles/7304401/Enviromental_Impacts_of_Produce_Safety_Rule_Open_for_Comment.html?tzcheck=1.

53. *Id.*

54. Atwill, *supra* note 49.

will result in compliance failure.[55] Further, growers that depend on a large body of water as their primary source may be prohibited by other federal and state agencies when trying to treat the water.[56] In these cases, in order for the farmer to use the source, he or she would need to install treatment technology at their specific point-of-use or somehow reduce upstream contamination.[57] Both of these options tend to be expensive and may not be feasible for the farm to implement.[58] On the other side, some small farms may only have a single well from which they irrigate, so failing to meet the standard could lead to the loss of water access entirely.[59]

One major concern voiced in the comments is that the EPA recreational water standard does not accurately translate to irrigation management.[60] The data from the EPA study was developed "to prevent gastrointestinal illness in swimmers" due to fecal contamination.[61] Those opposed also argue that the study does not accurately account for the microorganism die-off that occurs in between irrigation and harvest.[62] While commenters support the 0.5 log per day die-off, they would rather the rate be applied per hour instead of the per day period proposed to allow the maximum irrigation opportunity.[63] While the support is positive towards the die off allowance, they would like to see additional consideration for die-off with regard to covered produce.[64] This added consideration would take into account other activities that may be conducted before the actual sale of the produce.[65] They further stated that even if there is generic *E. coli* present, it does not necessarily mean that there are foodborne pathogens present as well.[66] Comparatively, if the tests do come back clear of *E. coli* then there is still a chance that foodborne pathogens, like *salmonella*, could be present.[67] Overall, opponents find that the scientific support is simply not there to impose a nation-

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. Farm & Ranch Freedom Alliance, Comment Letter on Proposed Rule to Revise Standards for the Growing, Harvest, Packing, and Holding of Produce for Human Consumption (Dec. 15, 2014)., http://farmandranchfreedom.org/produce-comments-2014/.

61. *Id.*

62. *Id.*

63. American Farm Bureau Federation, Comment Letter on Proposed Rule to Revise Standards for the Growing, Harvest, Packing, and Holding of Produce for Human Consumption (Dec. 15, 2014).

64. *Id.*

65. *Id.*

66. Farm & Ranch Freedom Alliance, *supra* note 60.

67. *Id.*

wide use of *E. coli* as the standard for water quality testing.[68] Many of those opposed voiced that if they are forced to use *E. coli* as the standard the FDA should provide an option other than treatment or completely stopping the use of that water source because the results do not conclusively show that foodborne pathogens are present.[69] The FDA has attempted to do this with Section 112.45 in the final rule by allowing a time interval to be applied between the last irrigation and harvesting of the produce.[70]

2. Frequency of Testing

Under Section 112.45(a), the original proposed rule would have required the farmer to test any agricultural water at the beginning of each growing season that was subject to Section 122.44 then continue to test every three months during the growing season.[71] Next, the proposed rule's Section 112.45(b) outlined the testing requirements for the use of untreated surface water.[72] Under the proposed rule, if the water was from any source that receives significant runoff the farmer would have been required to test the water every seven days during the growing season.[73] Further, the proposed rule stated if the untreated surface water is from any source where water is transferred from an underground aquifer and then transferred to a containment structure where it is treated in a manner to minimize runoff drainage, the water must be at the very least tested monthly during the growing season.[74]

Most comments concerning the testing frequency standards outlined above stemmed from concerns regarding the cost to the farmer.[75] The comments discussed how weekly water testing was too much of a financial burden on farmers, especially when it was unsupported by scientific data.[76] The FDA took these comments into consideration and decided to collectively address the testing requirements of Section 112.45 with a tiered approach for both untreated surface and untreated ground water in Section 112.46 of the final rule.[77]

68. *See id.*

69. *E.g.*, *id.*

70. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. 74547, 74555 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 112).

71. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. 58434, 58447 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R. pt. 112) (referencing the timeline bar for Produce Safety Regulation).

72. *Id.* at 58448.

73. *Id.*

74. *Id.*

75. *Id.* at 58449.

76. *Id.*

77. *Id.* at 58449; Standards for the Growing, Harvesting, Packing, and Holding of Pro-

a. Tiered Approach to Untreated Surface Water

The tiered approach for untreated surface water, outlined in Section 112.46(b), requires a baseline survey be conducted over a two to four year period collecting a minimum of twenty samples to develop a water quality profile for the water source.[78] The farmer will then use the baseline to determine if the water source meets the microbial standards listed in Section 112.44(b) on an annual basis.[79] The annual survey conducted and compared to the baseline would only require five samples to be collected during the growing season, as close as possible to the time the produce is harvested.[80] If the results are substantially different, the farmer would then need to create a new water quality profile which would establish a new baseline measurement.[81] In order to do this the farmer can implement one of two options based on which one bests fits the individual situation of the farm.[82] The first option is to calculate an updated water quality profile taking the current annual survey data plus the most recent initial or annual survey data from the last four years to compile a set of a minimum twenty samples.[83] The second option would let the farmer use the current annual data in combination with new samples to reach the minimum twenty samples required.[84]

b. Tiered Approach to Untreated Ground Water

The tiered approach to untreated ground water is very similar to the process outlined above for surface water.[85] The ground water would be tested initially by

duce for Consumption, 80 Fed. Reg. 74547, 74555 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 112).

78. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74555; *see* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58449–50.

79. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74555; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58450.

80. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74556; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58450.

81. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74556; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58450.

82. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74556.

83. *Id.*; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58450.

84. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74556.

85. *See id.* at 74555–56; Standards for the Growing, Harvesting, Packing, and Holding of

a minimum of four samples, each taken within one year or during a growing season.[86] If the samples meet the standards set out in Section 112.44, testing is only required once a year going forward, with only one sample needed.[87] If the yearly sample does not meet the microbial standards, then the farmer must collect the annual four minimum samples again to re-establish a baseline.[88]

The testing frequency for surface and ground water are justifiably different.[89] Ground water is rarely contaminated by pathogens, and therefore, is tested less often.[90] However this may cause farmers to abandon surface water for the less frequently tested groundwater in order to save money.[91] As previously addressed with the microbiological standard, groundwater shortage is a critical concern in certain areas where produce is grown.[92] Therefore the increased testing frequency for surface water compared to ground would further support this concern even more.[93]

Opponents of the revised testing frequency standards state that even though the FDA has reduced the amount of tests from the original proposed rule, it still creates "problems due to its complexity and ambiguity."[94] They believe that number of tests will still be too costly and too frequent for farmers, especially ones with multiple locations of varying water sources.[95] They recommended that the testing not exceed three samples per growing season, with the hope that this would eliminate at least some of the burden and reduce the testing costs.[96]

In addition to the underestimated costs and undue burden on the farmer,

Produce for Human Consumption, 79 Fed. Reg. at 58454.

86. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74556; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58455.

87. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74556; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58455.

88. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74556; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58455.

89. *See* Nathanael Johnson, *Tell the FDA What You Really Think About its New Food Safety Rules*, GRIST MAG. (Nov. 11, 2013), http://grist.org/food/tell-the-fda-what-you-really-think-about-its-new-food-safety-rules/.

90. *Id.*

91. *See id.*

92. Holliman, *supra* note 52.

93. *See id.*

94. Farm & Ranch Freedom Alliance, *supra* note 60, at 5.

95. American Farm Bureau Federation, *supra* note 63, at 8; Farm & Ranch Freedom Alliance, *supra* note 60, at 5.

96. Farm & Ranch Freedom Alliance, *supra* note 60, at 5.

there are concerns whether there is a sufficient lab capacity to handle all of the testing that will be required.[97] There are currently water-testing labs in place, but it is unknown if they will be able to meet the needs of farms on a timely basis and if prices will reflect the increased work-load of the lab.[98]

Another unknown factor of concern is how significant of an impact this will really have on America's farms.[99] The 2012 Census of Agriculture reports that there are approximately 1.2 million farms that harvest crops.[100] Among those farms there are roughly 52 million acres that are irrigated farmlands.[101] Further, 26 percent of United States surface waters are impaired due to some type of pathogens;[102] the effect could be extensive and severely detrimental to farmers.[103] In many of the Midwest states the number of farms with irrigated cropland is quite large. For example, in Nebraska alone there are 17,136 farms with over 8.2 million acres of irrigated cropland.[104] In Kansas there are 6,205 farms that have over 2.8 million acres in irrigated cropland.[105] These numbers show that there could be significant impacts to major farming states;[106] however, at this time, there has not been a rigorous cost-benefit analysis completed.[107]

3. Use of Third Parties to Test Agricultural Water

The FDA is added in the revised supplemental proposed rules and now adopted in the final rule a provision that allows farms to elect to use water sam-

97. *Id.*

98. *Id.*

99. *See id.*

100. NAT'L AGRIC. STATISTICS SERV., USDA, 2012 CENSUS OF AGRICULTURE UNITED STATES 17 tbl.9 (2014), http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf.

101. *Id.* at tbl.10.

102. *Clean Water Act Status: Entire United States*, SCORECARD.COM, http://scorecard.goodguide.com/env-releases/water/cwa-us.tcl#cause (last visited Mar. 28, 2016); *see also* Farm & Ranch Freedom Alliance, *supra* note 60, at 3.

103. Farm & Ranch Freedom Alliance, *supra* note 60, at 3.

104. NAT'L AGRIC. STATISTICS SERV., USDA, 2012 CENSUS OF AGRICULTURE NEBRASKA 17 tbl.10 (2014), http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_State_Level/Nebraska/nev1.pdf [hereinafter NEBRASKA].

105. NAT'L AGRIC. STATISTICS SERV., USDA, 2012 CENSUS OF AGRICULTURE KANSAS 17 tbl.10 (2014), http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_State_Level/Kansas/ksv1.pdf.

106. *See id*; NEBRASKA, *supra* note 105.

107. Farm & Ranch Freedom Alliance, *supra* note 60, at 4.

ples or data collected by third parties as long as they adequately represent the farm's agricultural water source.[108] This will give farms the flexibility to choose what method works best for them.[109] If the farm chooses to use a third party, the FDA further stated that for a sample collected to adequately represent a water source it must be taken from the water source itself, free of microbiological contamination.[110]

Overall, the response regarding third party testing has been positive.[111] An advantage to third party testing is the possibility for farms that share the same water source, like a reservoir, to also share in the data collection and testing.[112] This will substantially decrease costs to the farmers who are able to take advantage of sharing a water source.[113] The costs will also decrease if water resource districts and cooperatives help out with the cost of testing for their members.[114] There are still looming concerns regarding the details of third-party testing. For example, how close to third-party sampling does a farmer need to be in order to benefit from the shared testing has yet to be addressed.[115]

B. What Farms are Affected by the Regulations?

In addition to the changes to agricultural water quality standards and testing, the FDA is changing the farm size classifications to be based on the monetary value of *produce* sales.[116] The original proposed rules, under the general provisions described in Subpart A: The FDA had elected to apply the regulation to farms and mixed-type farm "facilities with an average annual monetary value

108. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. 74547, 74556 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 112); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. 58434, 58455 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R. pt. 112).

109. *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58455.

110. *Id.*

111. American Farm Bureau Federation, *supra* note 63, at 8; Farm & Ranch Freedom Alliance, *supra* note 60, at 5.

112. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58455.

113. American Farm Bureau Federation, *supra* note 63, at 8.

114. *Id.*

115. Farm & Ranch Freedom Alliance, *supra* note 60, at 5.

116. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74552; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58437; *FSMA Final Rule on Produce Safety*, *supra* note 31.

of *food* . . . more than $25,000 on a rolling basis" in the past three years.[117] This definition of *food*, taken from the Food, Drug, and Cosmetics Act, includes not only produce, bean and seed sprouts, but any article used for food or drink by man or animal.[118] The original rules proposed to use only this standard so they could identify small and very small businesses and allow them more time to comply with regulations.[119]

The majority of the comments received regarding this area were focused on the use of total *food* sales as the monetary measurement.[120] Many commenters opposed this method because not all of their food sales are generated from produce, but come from grains and cattle, making it extremely difficult and costly for them to diversify their farming efforts.[121] Due to these comments the FDA considered using "covered produce" or "produce" instead of the total food sales.[122] The FDA realized that the variability of produce grown and the changes in the amount of produce used for personal consumption would differ from year to year and change the amount considered to be "covered produce."[123] The FDA has since eliminated "covered produce" as a measurement option since it would be too difficult to monitor.[124] The revised proposed rule and now the final rule with the measure of "produce" would allow an additional 2.1 percent of farms to be exempt by the covered rules.[125]

Under the definition "produce" the FDA allows for an exemption to the rule for produce that is commonly cooked before consumption.[126] This is an exhaustive list that includes such produce as: asparagus, potatoes, eggplant, cranberries, chick-peas, sweet corn, okra, and winter squash, to name a few.[127] Pro-

117. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58436 (emphasis added).

118. *Id.*

119. *Id.*

120. *Id.* at 58437.

121. *Id.*

122. *Id.*

123. *Id.*

124. *See id.*

125. *Id.* at 58437; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. 74547, 74552 (Nov. 27, 2015) (to be codified at 21 C.F.R. pt. 112).

126. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74549; Helena Bottemiller, *Apples are Covered, Kale is Exempt: A Look at the Proposed Produce Safety Rule*, FOOD SAFETY NEWS (Jan. 17, 2013), http://www.foodsafetynews.com/2013/01/apples-are-covered-kale-is-exempt-a-look-at-the-proposed-produce-safety-rule/#.VPj_5fl4pgl.

127. *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74549; Bottemiller, *supra* note 126.

duce that would be included in the definition is a non-exhaustive list including:

> [a]lmonds, apples, apricots, avocados, bananas, blackberries, blueberries, broccoli, cabbage, cantaloupe, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines), cucumbers, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, radish, raspberries, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress and watermelon.[128]

The revised proposed qualifications under Section 112.3 had revisions to small business, very small business, and those not covered and these have not changed with the final rule.[129] A very small business is defined as "a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce . . . sold during the previous 3-year period is no more than $250,000."[130] A small business is defined as "a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $500,000" and is not a considered a very small business.[131] Further the definition for farms not covered, are those who make less than $25,000 on a rolling basis from produce sales from the previous 3-year period.[132]

There have been concerns regarding these standards from some food organizations.[133] The main argument of groups opposed to the flexibility of the stand-

128. Bottemiller, *supra* note 126; *see also* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74548.

129. *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74549; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58437 – 38.

130. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74549; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58437.

131. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74549; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58437.

132. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Consumption, 80 Fed. Reg. at 74552; Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. at 58437 (Referencing Table 1: Summary of Proposed Qualifications).

133. *See generally* Scott Horsfall, *Revised Produce Safety Rule: A Closer Look at a Daunting Task*, FOOD SAFETY NEWS (Sept. 9, 2014),

ards is that they are simply more lenient.[134] The fact that any farm would be exempt from complying with food safety rules that are put in place to protect consumers to these organizations is unacceptable.[135]

These arguments are countered by advocates for small farmers in favor of more flexible rules.[136] Many are concerned that the current rules as they are will put small, local farmers out of business as regulations increase.[137]

There was ample support for the FDA change from "food" to "produce" when calculating sales.[138] However, even those in support would have liked to see even further clarification and consistency in this area.[139] Even as the rule stands revised for "produce" it still takes into account food sales that are not covered by FSMA.[140] Under the revised produce rule, meat and grains would still be considered in the gross sales even though they are regulated by the USDA, not FSMA.[141] "[S]mall farms tend to be highly diversified, with fruit and vegetable production in addition to livestock and row crops in order to improve cash flow."[142] This will encourage small farms not to diversify for fear of being regulated by the new FSMA regulation and the USDA.[143]

However others believe that using "covered produce" opposed to just "produce" is the better option.[144] While they do support the use of "produce" over all for food sales generally, they state that "covered produce" would fully embrace growers' diversification efforts of farms.[145]

III. CONCLUSION

It is plain to see that there is not a simple and direct way to regulate such a continuously growing area. As more data is compiled the regulations regarding produce and safety will have to change in response. While the FDA has made great strides to attempt to make the water quality regulation more flexible for farmers, it may have in turn complicated the process far beyond the bounds of

http://www.lgma.ca.gov/2014/09/revised-produce-safety-rule-closer-look-daunting-task/.

134. *Id.*
135. *Id.*
136. *See* Johnson, *supra* note 89.
137. *Id.*
138. *See, e.g.*, Farm & Ranch Freedom Alliance, *supra* note 60, at 7.
139. *Id.*
140. *See id.*
141. *Id.*
142. American Farm Bureau Federation, *supra* note 63, at 5.
143. Farm & Ranch Freedom Alliance, *supra* note 60, at 7.
144. American Farm Bureau Federation, *supra* note 63, at 5.
145. *Id.*

what many small farms can handle economically and time-wise.[146] The impacts of these regulations will reach beyond the farmer. Labs may become over burdened with water quality samples and may not be able to keep up with the demand in terms of current facilities and staff.[147] Additions to facilities and staff will not be cheap and the cost will be passed on to the farmers, who will in turn increase the price of produce sold to the consumer. Overall the rules could create a chain reaction that may lead to reduced consumer purchases of produce and farmers not making enough profit to maintain their businesses.

There needs to be regulation like FSMA in place for produce safety, and the FDA is moving in the right direction by listening to consumers, farmers, and organizations that deal with these regulations on a daily basis. However with increased costs, a larger number of farms exempted from complying, and unreliable data and measuring standards, it may hard to see how FSMA is actually protecting consumers from the pathogens that could be on the produce consumed every day. Consumers and farmers must be patient and continue to give the FDA feedback in order to take food safety regulations in the right direction to ensure improved food safety for the future.

146. Farm & Ranch Freedom Alliance, *supra* note 60, at 5.

147. *Id.* (stating the testing will substantially increase the number of farmers that are required to do testing, possibly creating a burden on the labs).