EXHIBIT 1

TITLE 4. AGRICULTURE

PART 1. TEXAS DEPARTMENT OF AGRICULTURE

CHAPTER 11. TEXAS OFFICE OF PRODUCE SAFETY

The Texas Department of Agriculture (TDA or the Department) proposes new Title 1, Part 4, Chapter 11, Texas Office of Produce Safety, Subchapter A, General Provisions, §§11.1-11.4, relating to General Provisions; Subchapter B, Coverage and Exemptions, §§11.20-11.22; and Subchapter C, Compliance and Enforcement, §§11.40-11.43. The proposed new rules are for TDA's administration of the Food Safety Modernization Act (FSMA), P.L. 111-353, and the rules established by the United States Food and Drug Administration (FDA) to comply with FSMA for produce, titled "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption," 21 CFR Part 112, commonly referred to as the Produce Safety Rule. By working cooperatively with producers, the Produce Safety Rule helps shift the food safety regulations from a reactive system that focuses on responding to contamination to a proactive one that focuses on preventing them. The proposed rules establish definitions; clarify persons covered by the Produce Safety Rule; and set forth the compliance and enforcement framework.

Through a cooperative agreement with the FDA, the Department is administering the Produce Safety Rule to advance efforts for a nationally integrated food safety system. As part of the cooperative agreement, the Department established the Texas Office of Produce Safety (TOPS) within TDA to administer the Produce Safety Rule. As part of its duties, TOPS will enhance current produce programs within the Department to support the safe production of fresh fruits and vegetables. Additionally, TOPS offers additional outreach programs to educate producers and promote understanding and compliance with the requirements of the Produce Safety Rule.

The proposal is necessary for the administration of the Produce Safety Rule, and to protect Texas consumers and producers by ensuring that food grown, harvested, and packed for human consumption meets the requirements of the rule. The proposed rules are designed to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. Additionally, the proposal establishes recordkeeping requirements that, in the event of a foodborne illness outbreak, enable TOPS to review producer records and work with FDA to track the potential sources of contamination. TDA will implement the proposed rules while working in cooperation with the fresh fruit and vegetable industries in Texas, to reassure consumers in Texas and nationwide that Texas produce meets national standards designed to protect individuals and families from foodborne illness.

Prior to filing this proposal, the Department held stakeholder meetings across the state to take input on TDA's implementation of the standards contained in the FDA's Produce Safety Rule. The attendees, which included local producers, industry representatives and food retailers, provided valuable feedback regarding the administration of the national produce safety program in Texas. Stakeholder recommendations were taken under consideration in the development of the proposed rules.

Stakeholders and the public recognize that a foodborne outbreak could cause wide-spread illness in humans and have a significant negative impact on the state's economy, as well as that of local communities. Additionally, all businesses in the produce continuum such as producers, processors, transporters, and restaurants that could potentially serve contaminated produce, may suffer economic damages associated with possible recalls and litigation. Other organizations that grow, distribute, or sell the same type of produce may see decreased demand resulting in a reduction in sales volume and

market share throughout the nation. Thus, these proposed regulations protect public health, welfare and safety in addition to furthering the state and industry's economic interests.

Industry and the public are generally aware that the Produce Safety Rule includes national standards established by the FDA to comply with FSMA, and that covered farms within the State of Texas are required to follow these standards. Since the inception of the produce safety program, TDA has worked, and continues to work, to protect the public interest while minimizing the impact and cost of this program on producers.

Richard De Los Santos, Director of the Texas Office of Produce Safety, has determined that there will be no fiscal impact to state government as a result of implementing the proposed rules. The program and all associated direct and indirect costs are fully funded by the FDA. There will be no fiscal impact to local governments as a result of the implementation of this proposal.

Mr. De Los Santos has also determined that for each year of the first five years the proposed rules are in effect, the anticipated public benefit as a result of administering the proposed rules will be to safeguard consumers and provide them with reasonable assurance that produce and farms in Texas covered by the Produce Safety Rule meet national standards intended to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce. As with many federal regulations, affected producers and industry will be required to absorb compliance costs associated with the Produce Safety Rule. However, TDA lacks sufficient data to quantify the effect on small and micro-businesses at this time. The cost of compliance with the Produce Safety Rule for affected producers will depend on various factors, including the size of the operation and whether it currently utilizes documentation and other tools necessary for compliance. TDA does not anticipate that there will be an adverse fiscal impact on rural communities related to the implementation of this proposal. Any potential increases in the cost of doing business will be offset by the marketing and sales opportunities for Texas producers due to increased consumer confidence in products as a result of the implemented safety standards.

Mr. De Los Santos has provided the following information related to the government growth impact statement, as required pursuant to Texas Government Code, §2001.021. As a result of implementing the proposal, for the first five years the proposed rules are in effect:

(1) the Texas Office of Produce Safety was created;

(2) an additional 10 employee positions will be created over the course of 5 years, and no existing Department staff positions will be eliminated; and

(3) there will be an increase in future legislative appropriations to the Department.

Additionally, Mr. De Los Santos has determined that for the first five years the proposed rules are in effect:

(1) there will be no increase or decrease in fees paid to the Department, as this program is funded by the FDA, and TDA is not required to assess license or inspection fees in order to implement or finance this program;

(2) new regulations will be created by the proposal;

(3) there will be an increase to the number of individuals subject to the proposal, as this is a new program; however, many farms may claim a qualified exemption from the requirements of this proposal; and

(4) the proposal will positively affect the Texas economy by protecting the public health and Texas fruit and vegetable industry by helping prevent foodborne illness outbreaks, shifting food safety regulations from a system that focuses on responding to contaminations to one that focuses on preventing them.

Written comments on the proposal may be submitted to Richard De Los Santos, Director of the Texas Office of Produce Safety, Texas Department of Agriculture, P.O. Box 12847, Austin, Texas, 78711; or by email to *Richard.DeLosSantos@TexasAgriculture.gov.* Comments must be received no later than July 12, 2019.

SUBCHAPTER A. GENERAL PROVISIONS

4 TAC §§11.1 - 11.4

The proposal is made under §91.009 of the Texas Agriculture Code (the Code), which designates the Department as the lead agency for the administration, implementation, and enforcement of the Produce Safety Rule, and authorizes the Department to adopt rules to coordinate, implement and enforce the Produce Safety program; and, §12.020 of the Code, which authorizes the Department to assess penalties for violations of rules adopted by the Department.

Chapters 12 and 91 of the Texas Agriculture Code are affected by the proposal.

§11.1.Definitions.

In addition to the definitions set forth in 21 CFR Part 112, the following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Anniversary Date--The last day following two years from the issuance of a Qualified Exemption.

(2) CFR--Code of Federal Regulations.

(3) Department--The Texas Department of Agriculture.

(4) Egregious condition--A practice, condition, or situation on a covered farm or in a packing facility that is undertaken as part of a covered activity that is reasonably likely to lead to:

(A) serious adverse health consequences or death from the consumption of or exposure to covered produce; or

(B) an imminent public health hazard.

(5) FDA--United States Food and Drug Administration.

(6) Inspection--An initial or follow up inspection conducted by TOPS for the purpose of inspecting covered produce, a covered farm, or records related to the Produce Safety Rule.

(7) Produce Safety Rule--21 CFR Part 112: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, including any additions, amendments or revisions thereto.

(8) Raw agricultural commodity (RAC)--The term "raw agricultural commodity" is defined in Section 201(r) of the Federal Food, Drug and Cosmetic Act and means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. See 21 U.S.C. §321(4) and 21 CFR §112.3.

(9) TOPS--Texas Office of Produce Safety.

§11.2.Covered Produce.

(a) Covered produce. Covered produce includes produce listed in 21 CFR §112.1.

(b) Produce that is not covered.

(1) The following produce is "not covered" by the Produce Safety Rule under 21 CFR §112.2(a):

(A) produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management;

(B) produce that is not a RAC; and

(C) produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) A farm which solely produces produce that is "not covered" is not subject to the Produce Safety Rule or this chapter.

(3) Produce is eligible for exemption from the requirements of this part if the produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance.

§11.3.Covered Farms.

Per 21 CFR §112.4, the following farms are covered by the Produce Safety Rule and this chapter:

(1) a farm which produces covered produce sold during the previous 3-year period in an amount more than $25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment;

(2) a farm which has its primary production that is devoted to growing, harvesting (such as hulling or shelling), packing, and/or holding of RAC; or

(3) a farm which performs covered activities, including manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on RAC.

§11.4.FDA Coordinated Outbreak Response and Evaluation ("CORE") Network.

(a) Subject to its cooperation agreement with FDA, TOPS will work in coordination with the FDA's Coordinated Outbreak Response and Evaluation ("CORE") Network to respond to an outbreak which has been identified by CORE.

(b) FDA will be the lead agency conducting on-site visits and inspections related to an outbreak.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 3, 2019.

TRD-201901642

Jessica Escobar

Assistant General Counsel

Texas Department of Agriculture

Earliest possible date of adoption: July 14, 2019

For further information, please call: (512) 463-4075

SUBCHAPTER B. COVERAGE AND EXEMPTIONS

4 TAC §§11.20 - 11.22

The proposal is made under §91.009 of the Texas Agriculture Code (the Code), which designates the Department as the lead agency for the administration, implementation, and enforcement of the Produce Safety Rule, and authorizes the Department to adopt rules to coordinate, implement and enforce the Produce Safety program; and, §12.020 of the Code, which authorizes the Department to assess penalties for violations of rules adopted by the Department.

Chapters 12 and 91 of the Texas Agriculture Code are affected by the proposal.

§11.20.Qualified Exemption.

(a) TOPS may conduct a pre-assessment review to determine whether a farm is covered by the Produce Safety Rule and/or eligible for a Qualified Exemption.

(1) A covered farm is eligible for a Qualified Exemption if it meets the requirements of 21 CFR §112.5.

(2) A covered farm which is eligible for a Qualified Exemption under 21 CFR §112.5, must establish and maintain adequate records demonstrating compliance with criteria necessary for Qualified Exemption as required by 21 CFR §112.7(b).

(3) A covered farm eligible for a Qualified Exemption is subject to the modified requirements set forth in 21 CFR §112.6, and this chapter.

(b) Federal law determines whether or not a farm is subject to the Produce Safety Rule. Failure to permit TOPS to conduct a pre-assessment review does not exclude a farm from being subject to this chapter or the Produce Safety Rule.

§11.21.Verification of Exemption.

(a) A covered farm shall be required to reaffirm eligibility for a Qualified Exemption upon its Anniversary Date. Qualified Exemption determinations for covered farms shall be valid for two years from the date of verification by TOPS.

(b) TDA will provide notice of the required reaffirmation and renewal of a Qualified Exemption by sending a Qualified Exemption Verification Form to the producer's last known address, as reflected in TDA's records, at least 30 days prior to the Anniversary Date.

(c) Failure to return a Qualified Exemption Verification Form within 45 days after the Anniversary Date shall result in a required on-site visit by TOPS to reevaluate exemption, coverage, or eligibility for a qualified exemption. Failure to return a Qualified Exemption Verification Form within 60 days of the Anniversary Date shall result in the presumption by TOPS that the farm is subject to all requirements of the Produce Safety Rule and this chapter.

(d) TOPS reserves the right to schedule, at any time, an on-site visit to verify whether a farm is exempt, covered, or eligible for a Qualified Exemption.

§11.22.Change in Eligibility.

If a farm's qualification for an exemption or eligibility for a Qualified Exemption changes, or if its Qualified Exemption is withdrawn by the FDA as outlined in 21 CFR Part 112, Subpart R, the farm will be considered "Covered" and will be subject to all requirements of the Produce Safety Rule and this chapter.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 3, 2019.

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Jessica Escobar

Assistant General Counsel

Texas Department of Agriculture

Earliest possible date of adoption: July 14, 2019

For further information, please call: (512) 463-4075

SUBCHAPTER C. COMPLIANCE AND ENFORCEMENT

4 TAC §§11.40 - 11.43

The proposal is made under §91.009 of the Texas Agriculture Code (the Code), which designates the Department as the lead agency for the administration, implementation, and enforcement of the Produce Safety Rule, and authorizes the Department to adopt rules to coordinate, implement and enforce the Produce Safety program; and, §12.020 of the Code, which authorizes the Department to assess penalties for violations of rules adopted by the Department.

Chapters 12 and 91 of the Texas Agriculture Code are affected by the proposal.

§11.40.Right of Entry.

(a) Right of Entry to Determine Coverage or Verify Exceptions. TOPS may enter the premises of a farm growing produce during normal business hours to determine coverage and/or verify exceptions to the Produce Safety Rule.

(b) Right of Entry to Conduct Inspections. TOPS may enter all locations or areas of a covered farm or Qualified Exempt farm during operating hours where there are activities, conditions, produce, and equipment, or at any other location where covered activities occur, to conduct inspections.

(c) Egregious Condition. TOPS may enter the premises of a covered and exempt/or Qualified Exempt farm at any time to conduct an inspection in response to an egregious condition at all locations or areas where there are activities, conditions, produce, and equipment, or at any other location where covered activities occur.

(d) Failure to Comply. Refusal to allow a TOPS inspection, or interfering with TOPS' ability to perform its duties under this section, shall result in a violation, as stated in §11.41 of this chapter, relating to Enforcement and Penalties.

§11.41.Enforcement and Penalties.

(a) The following actions may be taken, and penalties may be assessed in response to findings of violations of the Produce Safety Rule.

Figure: 4 TAC §11.41(a) (.pdf)

(b) A corrective action plan must be developed by the producer and approved by TOPS in response to one or more findings by TOPS of a violation of the Produce Safety Rule. The producer must implement the corrective action plan and demonstrate, upon a follow up inspection by TOPS, that it has fully and permanently corrected the violations of the Produce Safety Rule made the subject of the findings by TOPS in its previous inspection.

§11.42.Stop Sale.

(a) TOPS may issue a stop sale order upon a finding of an egregious condition or for repeated failure to comply with one or more corrective action plans which may result in risk to public health.

(b) A stop sale order shall apply to all covered produce, lots, batches, or bins that are determined to be non-compliant, at-risk, or affected by an egregious condition. A stop sale order may also include covered produce that is stored or in transit.

§11.43. Complaint Investigation.

(a) Any person with reasonable cause to believe that a producer has violated the Produce Safety Rule or this chapter may file a complaint with TOPS.

(b) TOPS may, in its sole discretion, investigate the complaint and make a full written report.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 3, 2019.

TRD-201901644

Jessica Escobar

Assistant General Counsel

Texas Department of Agriculture

Earliest possible date of adoption: July 14, 2019

For further information, please call: (512) 463-4075

TITLE 4. AGRICULTURE

PART 1. TEXAS DEPARTMENT OF AGRICULTURE

CHAPTER 11. TEXAS OFFICE OF PRODUCE SAFETY

The Texas Department of Agriculture (TDA or the Department) adopts new Title 1, Part 4, Chapter 11, Texas Office of Produce Safety, Subchapter A, General Provisions, §§11.1-11.4, relating to General Provisions; Subchapter B, Coverage and Exemptions, §§11.20-11.23; and Subchapter C, Compliance and Enforcement, §§11.40-11.43. Subchapter A, General Provisions, is adopted with changes to the proposal published in the June 14, 2019, issue of the *Texas Register* (44 TexReg 2905); Subchapters B and C are adopted without changes to the proposal published in the June 14, 2019, issue of the *Texas Register* (44 TexReg 2905) and will not be republished.

The adopted rules are for TDA's administration of the Food Safety Modernization Act (FSMA), P.L. 111-353, and the rules established by the United States Food and Drug Administration (FDA) to comply with FSMA for produce, titled "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption," 21 CFR Part 112, commonly referred to as the Produce Safety Rule (Rule).

Through a cooperative agreement with the FDA, the Department is administering the Produce Safety Rule to advance efforts for a nationally integrated food safety system. As part of the cooperative agreement, the Department established the Texas Office of Produce Safety (TOPS) within TDA to administer the Produce Safety Rule.

The rules are adopted to protect Texas consumers and producers by ensuring that food grown, harvested, and packed for human consumption meets the requirements of the Produce Safety Rule. TDA will continue to work in cooperation with local farmers and the fresh fruit and vegetable industries in Texas, by offering outreach programs to educate producers and promote understanding and compliance with the requirements of the Produce Safety Rule throughout the implementation process. Through this collaborative effort, consumers in Texas and nationwide can be assured that Texas produce meets national standards designed to protect individuals and families from foodborne illness.

The Department received 12 comments on the proposal.

Susie Marshall, FSMA Program Manager for the Texas Organic Farmers and Gardeners Association (TOFGA) submitted comments expressing concerns with the effects of the rules on small farmers. TOFGA also submitted numerous questions with their comments which will not be addressed in this adoption document but will be addressed directly with the organization and producers as part of stakeholder outreach. TOFGA's comments will be addressed individually.

(1) "Mandatory registration." TOFGA opposed its perceived "mandatory registration" for farms because they believe it could create confusion and record keeping burdens on their farmers. TDA notes that there is no "mandatory registration" requirement for farms. Any farm seeking a Qualified Exemption or renewal of that exemption is only required to submit an affirmation of that status; documentation is not required to be submitted with that reaffirmation. The Produce Safety Rule provides that farmers are required to maintain records, regardless of whether they are qualified exempt under the Rule.

(2) Right of Entry. TOFGA opposed §11.40(b), stating that Qualified Exempt farms should not be subject to entry for inspections. While the Department appreciates the comment, §11.1(6), relating to definitions, defines inspections to include the review of records, and therefore no amendment to the proposed section will be made.

(3) Penalty Matrix. TOFGA expressed that the "penalties seem excessive." Administrative penalties are a deterrent for violations and help to ensure that Texas producers meet all standards required by the Produce Safety Rule to avoid any foodborne illness outbreaks. No changes will be made to the penalty matrix at this time.

Judith McGreary, Executive Director, submitted comments on behalf of the Farm and Ranch Freedom Alliance (FARFA). FARFA's comments are addressed individually.

(1) Registration. FARFA suggested that the rules create a registration requirement. This has been addressed above in response to TOFGA's first comment.

(2) Lack of Legal Authority. FARFA suggests that TDA does not have the authority to require exempt farms to "register" with the Department. The Department is authorized to administer the Produce Safety Rule as part of a cooperative agreement with FDA, and pursuant to §91.009(d) of the Texas Agriculture Code, has authority to adopt rules necessary to administer, implement and enforce the coordination of produce safety.

(3) Documentation Provisions/Burden of Proof. FARFA suggests that renewal of eligibility provisions do not provide detailed information as to what will be required as part of the submission process for renewal of qualified exemption. TDA notes that all forms are not a part of the rulemaking process and those requirements do not need to be included in this proposal. Information regarding renewal is addressed in TOFGA's first comment, above.

(4) Right of Entry. FARFA commented that the right of entry provisions are "ambiguous and overbroad" as they apply to Qualified Exempt farms. TDA has addressed this comment above, in TOFGA comment number two.

(5) Egregious Condition. FARFA states that the definition of "egregious condition" is not provided in federal or state statute or regulation and the Department is relying on a definition prepared by FDA and state departments of agriculture, which "was prepared without public input." The definition developed by FDA is being used as part of the inspection process nationally. FARFA argues that the Department lacks the statutory authority to "create a new standard." TDA appreciates the comment submitted by FARFA. As stated above, per the Texas Agriculture Code, §91.009, TDA has the authority to adopt rules and define program terminology necessary to administer the Rule. In response to FARFA's comment, the Department has changed the §11.1(4) to clarify and narrow the meaning of "egregious condition."

(6) Penalty Provisions. FARFA suggested that the penalty provisions are excessive. This comment has been addressed in TOFGA's comment three, above.

(7) Appeal Provisions. FARFA commented that there are no appeal provisions. Section 12.020 of the Texas Agriculture Code provides the process for administrative penalties, appeals and hearings. Accordingly, those provisions have not been included in the proposal as they are provided statutorily.

A comment was submitted by Susan and Dale Staub on behalf of Amador Farms opposing the registration requirement. Susan and Dale Staub submitted comments stating that a requirement to submit documentation to any agency in government is intrusion which will affect sustainability of the farm. While TDA respects their concerns, TDA reiterates the position above.

Kelly Bhatt submitted a comment regarding removal of the definition of egregious condition and excluding Qualified Exempt farms from having to submit paperwork every other year. These comments have been previously addressed and TDA will not address them at this time.

Tim Milberg submitted a comment on behalf of Millberg Farm. The comment did not address the proposed rules and TDA will not respond to it at this time.

The Department also received eight comments from various individuals. All of the submitted comments were in a form template and substantively the same. The commenters proposed the following:

(1) removing provisions which would require qualified exempt farms to submit paperwork biannually, due to the fact that they were subject to inspection at any time;

(2) removing the definition of "egregious condition," or providing XXX; and

(3) requiring farms to register with the Department because failure to "register" would result in a presumption of coverage under the Produce Safety Rule.

Because the comments submitted have been previously addressed within TOFGA and FARFA's proposals, TDA will not respond to those comments. Additionally, the comments which were not responsive to the proposed rules will not be addressed.

While TDA appreciates the time each of the above individuals took to submit their comments, after careful review and consideration the rules are adopted without changes to the proposal published on June 14, 2019 in the *Texas Register.*

SUBCHAPTER A. GENERAL PROVISIONS

4 TAC §§11.1 - 11.4

The adoption is made under §91.009 of the Texas Agriculture Code (the Code), which designates the Department as the lead agency for the administration, implementation, and enforcement of the Produce Safety Rule, and authorizes the Department to adopt rules to coordinate, implement and enforce the Produce Safety program; and, §12.020 of the Code, which authorizes the Department to assess penalties for violations of rules adopted by the Department.

Chapters 12 and 91 of the Texas Agriculture Code are affected by the adoption.

§11.1.Definitions.

In addition to the definitions set forth in 21 CFR Part 112, the following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Anniversary Date--The last day following two years from the issuance of a Qualified Exemption.

(2) CFR--Code of Federal Regulations.

(3) Department--The Texas Department of Agriculture.

(4) Egregious condition--A practice, condition, or situation on a covered farm or in a packing facility that is undertaken as part of a covered activity that directly causes, or is likely to directly cause:

(A) serious adverse health consequences or death from the consumption of or exposure to covered produce; or

(B) an imminent public health hazard.

(5) FDA--United States Food and Drug Administration.

(6) Inspection--An initial or follow up inspection conducted by TOPS for the purpose of inspecting covered produce, a covered farm, or records related to the Produce Safety Rule.

(7) Produce Safety Rule--21 CFR Part 112: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, including any additions, amendments or revisions thereto.

(8) Raw agricultural commodity (RAC)--The term "raw agricultural commodity" is defined in Section 201(r) of the Federal Food, Drug and Cosmetic Act and means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. See 21 U.S.C. §321(4) and 21 CFR §112.3.

(9) TOPS--Texas Office of Produce Safety.

§11.2.Covered Produce.

(a) Covered produce. Covered produce includes produce listed in 21 CFR §112.1.

(b) Produce that is not covered.

(1) The following produce is "not covered" by the Produce Safety Rule under 21 CFR §112.2(a):

(A) produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management;

(B) produce that is not a RAC; and

(C) produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) A farm which solely produces produce that is "not covered" is not subject to the Produce Safety Rule or this chapter.

(3) Produce is eligible for exemption from the requirements of this part if the produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance.

§11.3.Covered Farms.

Per 21 CFR §112.4, the following farms are covered by the Produce Safety Rule and this chapter:

(1) a farm which produces covered produce sold during the previous 3-year period in an amount more than $25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment;

(2) a farm which has its primary production that is devoted to growing, harvesting (such as hulling or shelling), packing, and/or holding of RAC; or

(3) a farm which performs covered activities, including manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on RAC.

§11.4.FDA Coordinated Outbreak Response and Evaluation ("CORE") Network.

(a) Subject to its cooperation agreement with FDA, TOPS will work in coordination with the FDA's Coordinated Outbreak Response and Evaluation ("CORE") Network to respond to an outbreak which has been identified by CORE.

(b) FDA will be the lead agency conducting on-site visits and inspections related to an outbreak.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on August 22, 2019.

TRD-201902861

Jessica Escobar

Assistant General Counsel

Texas Department of Agriculture

Effective date: September 11, 2019

Proposal publication date: June 14, 2019

For further information, please call: (512) 463-4075

SUBCHAPTER B. COVERAGE AND EXEMPTIONS

4 TAC §§11.20 - 11.22

The adoption is made under §91.009 of the Texas Agriculture Code (the Code), which designates the Department as the lead agency for the administration, implementation, and enforcement of the

Produce Safety Rule, and authorizes the Department to adopt rules to coordinate, implement and enforce the Produce Safety program; and, §12.020 of the Code, which authorizes the Department to assess penalties for violations of rules adopted by the Department.

Chapters 12 and 91 of the Texas Agriculture Code are affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on August 22, 2019.

TRD-201902863

Jessica Escobar

Assistant General Counsel

Texas Department of Agriculture

Effective date: September 11, 2019

Proposal publication date: June 14, 2019

For further information, please call: (512) 463-4075

SUBCHAPTER C. COMPLIANCE AND ENFORCEMENT

4 TAC §§11.40 - 11.43

The adoption is made under §91.009 of the Texas Agriculture Code (the Code), which designates the Department as the lead agency for the administration, implementation, and enforcement of the Produce Safety Rule, and authorizes the Department to adopt rules to coordinate, implement and enforce the Produce Safety program; and, §12.020 of the Code, which authorizes the Department to assess penalties for violations of rules adopted by the Department.

Chapters 12 and 91 of the Texas Agriculture Code are affected by the adoption.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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TRD-201902864

Jessica Escobar

Assistant General Counsel

Texas Department of Agriculture

Effective date: September 11, 2019

Proposal publication date: June 14, 2019

For further information, please call: (512) 463-4075

EXHIBIT 2

AFFIDAVIT OF JUDITH I. MCGEARY

1. My name is Judith McGeary. I live in Cameron, Texas, am over eighteen years of age, and am fully competent to make this declaration.

2. I currently serve as the Executive Director of the Farm and Ranch Freedom Alliance (FARFA). In that role, I manage the regular affairs of the organization. The FARFA Board of Directors has authorized me to have this lawsuit filed and take all necessary steps to pursue it on behalf of our members.

3. FARFA's members consist primarily of farmers and ranchers who use sustainable growing methods and sell through non-conventional outlets. Our members also include small food businesses, chefs, and consumers who wish to support this form of agriculture. The acreage on which our member farmers and ranchers raise food varies based on what they are growing and their region, but they are generally small in comparison to the conventional food system. Most of our members sell primarily direct to consumers (either on-farm or through farmers markets, community supported agriculture systems, and similar venues) and/or to local outlets, such as local farm-to-table restaurants, co-ops, and small grocers.

4. For example, one of our members, who is referenced anonymously in paragraph 22 of the complaint, grows vegetables on approximately one acre of her land plus a greenhouse. She distributes the food through a community-supported-agriculture (CSA) program, in which individuals sign up for a "share" of each week's production. In the past, she has also sold some of her production to local chefs for use at nearby restaurants.

5. FARFA's mission is to promote common-sense for local, sustainable agriculture. We advocate for statutes and regulations that are scale-sensitive and foster local, diversified food systems. For example, during the 2019 Texas Legislative Session, FARFA successfully advocated for several bills that support local food production: an expansion to the cottage food law, to allow more types of homemade foods to be sold directly to consumers (SB 572); reducing permit and permit fee burdens on farmers' market vendors (SB 932 and HB 1694); allowing on-farm processing of poultry and rabbits by small-scale farmers (HB 410); and requiring local health departments to respond to questions from producers about what they must do to operate legally (HB 2107).

6. The lawsuit against the Texas Department of Agriculture related to its regulations implementing the federal Produce Safety Rule seeks to protect interests that are germane to FARFA's purpose. Specifically, implementation of the Produce Safety Rule, including in particular how the exemptions and qualified exemption are implemented, will have a very significant impact on the members of FARFA who are produce farmers. The rule imposes not only monetary costs, but could require very significant changes to how farmers raise their crops, impacting both the farms' financial viability and their very existence. TDA's implementation of the Produce Safety Rule will impact many FARFA members; in addition to the direct impacts on our produce farmer members, the effects will trickle-down to many other FARFA members who are end users, such as farmers' market consumers and farm-to-table restaurant owners and chefs.

7. In 2009 and 2010, in my role as Executive Director of FARFA, I worked with other grassroots organizations around the country during the Congressional debates over the Food Safety Modernization Act (FSMA) (originally S.510, and then passed as HR. 2751). Our coalition provided input to Senator Tester's office to develop protections for small-scale and direct-marketing farmers and food businesses. These provisions were drafted in what was popularly referred to as the "Tester Amendment," attached to this declaration. The "Tester Amendment" provisions were not introduced as a formal stand-alone amendment to FSMA because they were incorporated into Senate Amendment 4715, which was adopted on November 30, 2010.

8. The "Tester Amendment" provisions established the qualified exemption to both the Produce Safety Rule and the Preventive Controls Rules. During the process, from the drafting of the amendment to the final passage of FSMA, I discussed the provisions multiple times with Senator Tester's staff, drafted letters in support of the amendment that were joined by numerous other organizations, and discussed the implications of the provisions with both supporters and opponents.

9. As FARFA's Executive Director, I was also deeply involved in the rulemaking process through which the Food & Drug Administration (FDA) adopted the Produce Safety and Preventive Controls Rules. FARFA submitted comments to the agency on both the implementation of the qualified exemption and the substantive provisions of the rules.

10. To the best of my knowledge and information, no other state has adopted regulations that require qualified exempt farmers to register with a state agency under the Produce Safety Rule, nor has any other state adopted the term "egregious conditions" as a regulatory standard.

State of Texas, County of Milam

Before me, Kellie Whitmire, notary public, on this day personally appeared Judith I. McGeary, known to me (or proved to me through DL to be the person whose name is subscribed to the foregoing affidavit and acknowledged to me that every statement contained within it is within her personal knowledge and is true and correct.

Given under my hand and seal of office this 19th day of December 2019.

Judith I. McGeary, Affiant

SUBSCRIBED AND SWORN TO BEFORE ME on December 19, 2019.

Kellie Whitmire (signature)

Kellie Whitmire (name)

KELLIE WHITMIRE
NOTARY PUBLIC
STATE OF TEXAS
ID # 13202029-4
My Comm. Expires 05-20-2023

Notary Public in and for the State of Texas. My commission expires 5-20-2023.

AMENDMENT NO._____ Calendar No._____

Purpose: To limit the written plan and produce safety requirements for direct marketing farms and certain small facilities.

IN THE SENATE OF THE UNITED STATES—111th Cong., 2d Sess.

S. 510

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. TESTER

Viz:

On page 10, between lines 21 and 22, insert the following:

(c) CLARIFICATION OF INTENT.—

(1) RETAIL FOOD ESTABLISHMENT.—The Secretary shall amend the definition of ''retail food establishment'' in section 1.227 of title 21, Code of Federal Regulations to clarify that, for purposes of applying such definition established under section 415(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(b)(1)), the term ''retail food establishment'' includes an establishment whose pri-

mary function is to sell food manufactured, processed, packed, or held by such establishment directly to consumers, including in the case that an establishment makes such sales at locations other than the location where the food was manufactured, processed, packed, or held by such establishment.

(2) CONSUMER.—For purposes of paragraph (1), the term ''consumer'' does not include a business.

On page 10, line 22, strike ''(c)'' and insert ''(d)''.

On page 17, between lines 12 and 13, insert the following:

''(l) MODIFIED REQUIREMENTS FOR QUALIFIED FACILITIES.—

''(1) QUALIFIED FACILITIES.—

''(A) IN GENERAL.—A facility is a qualified facility for purposes of this subsection if the facility meets the conditions under subparagraph (B) or (C).

''(B) VERY SMALL BUSINESS.—A facility is a qualified facility under this subparagraph—

''(i) if the facility, including any subsidiary or affiliate of the facility, is, collec-

tively, a very small business (as defined in the regulations promulgated under subsection (n)); and

"(ii) in the case where the facility is a subsidiary or affiliate of an entity, if such subsidiaries or affiliates, are, collectively, a very small business (as so defined).

"(C) LIMITED ANNUAL MONETARY VALUE OF SALES.—

"(i) IN GENERAL.—A facility is a qualified facility under this subparagraph if clause (ii) applies—

"(I) to the facility, including any subsidiary or affiliate of the facility, collectively; and

"(II) to the subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate.

"(ii) AVERAGE ANNUAL MONETARY VALUE.—This clause applies if—

"(I) during the 3-year period preceding the applicable calendar year, the average annual monetary value of

the food manufactured, processed, packed, or held at such facility (or the collective average annual monetary value of such food at any subsidiary or affiliate, as described in clause (i)) that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food manufactured, processed, packed, or held at such facility (or the collective average annual monetary value of such food at any subsidiary or affiliate, as so described) sold by such facility (or collectively by any such subsidiary or affiliate) to all other purchasers during such period; and

''(II) the average annual monetary value of all food sold by such facility (or the collective average annual monetary value of such food sold by any subsidiary or affiliate, as described in clause (i)) during such period was less than $500,000, adjusted for inflation.

''(2) EXEMPTION.—A qualified facility—

"(A) shall not be subject to the requirements under subsections (a) through (i) and subsection (n) in an applicable calendar year; and

"(B) shall submit to the Secretary—

"(i)(I) documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective; or

"(II) documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law; and

"(ii) documentation, as specified by the Secretary in a guidance document

issued not later than 1 year after the date of enactment of this section, that the facility is a qualified facility under paragraph (1)(B) or (1)(C).

"(3) DEFINITIONS.—In this subsection:

"(A) AFFILIATE.—The term 'affiliate' means any facility that controls, is controlled by, or is under common control with another facility.

"(B) QUALIFIED END-USER.—The term 'qualified end-user', with respect to a food, means—

"(i) the consumer of the food; or

"(ii) a restaurant or retail food establishment (as those terms are defined by the Secretary for purposes of section 415) that—

"(I) is located—

"(aa) in the same State as the qualified facility that sold the food to such restaurant or establishment; or

"(bb) not more than 400 miles from such facility; and

"(II) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

"(C) CONSUMER.—For purposes of subparagraph (B), the term 'consumer' does not include a business.

"(D) SUBSIDIARY.—The term 'subsidiary' means any company which is owned or controlled directly or indirectly by another company.

"(4) STUDY.—

"(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Agriculture, shall conduct a study of the food processing sector regulated by the Secretary to determine—

"(i) the distribution of food production by type and size of operation, including monetary value of food sold;

"(ii) the proportion of food produced by each type and size of operation;

"(iii) the number and types of food facilities co-located on farms, including the number and proportion by commodity and by manufacturing or processing activity;

"(iv) the incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known hazard exists; and

"(v) the effect on foodborne illness risk associated with commingling, processing, transporting, and storing food and raw agricultural commodities, including differences in risk based on the scale and duration of such activities.

"(B) SIZE.—The results of the study conducted under subparagraph (A) shall include the information necessary to enable the Secretary to define the terms 'small business' and 'very small business', for purposes of promulgating the regulation under subsection (n). In defining such terms, the Secretary shall include consideration of harvestable acres, income, the number of employees, and the volume of food harvested.

"(C) SUBMISSION OF REPORT.—Not later than 18 months after the date of enactment the FDA Food Safety Modernization Act, the Secretary shall submit to Congress a report that

describes the results of the study conducted under subparagraph (A).

''(5) NO PREEMPTION.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production of food. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.

''(6) NOTIFICATION TO CONSUMERS.—

''(A) IN GENERAL.—A qualified facility that is exempt from the requirements under subsections (a) through (i) and subsection (n) and does not prepare documentation under paragraph (2)(B)(i)(I) shall—

''(i) with respect to a food for which a food packaging label is required by the Secretary under any other provision of this Act, include prominently and conspicuously on such label the name and business address of the facility where the food was manufactured or processed; or

''(ii) with respect to a food for which a food packaging label is not required by the Secretary under any other provisions of this Act, prominently and conspicuously

display, at the point of purchase, the name and business address of facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

''(B) NO ADDITIONAL LABEL.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this Act.

On page 17, line 13, strike ''(l)'' and insert ''(m)''.

On page 17, line 22, strike''(m)'' and insert ''(n)''.

On page 18, strike line 1 through line 5 and insert the following: ''regulations—

''(A) to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation

of the preventive controls under this section; and

''(B) to define, for purposes of this section, the terms 'small business' and 'very small business', taking into consideration the study described in subsection (l)(4).

On page 18, line 7, strike ''paragraph (1)'' and insert ''paragraph (1)(A)''.

On page 18, line 13, strike ''paragraph (1)'' and insert ''paragraph (1)(A)''.

On page 19, line 17, strike ''paragraph (1)'' and insert ''paragraph (1)(A)''.

Beginning on page 24, strike line 13 and all that follows through line 6 on page 25 and insert the following:

(ii) LIMITATION.—The exemptions or modifications under clause (i) shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act, if applicable, and shall apply only to small

businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added under subsection (a)).

On page 26, line 6, strike ''subsection (m)'' and insert ''subsection (n)''.

Beginning on page 27, strike line 17 through line 9 on page 28 and insert the following:

(i) EFFECTIVE DATES.—

(1) GENERAL RULE.—The amendments made by this section shall take effect 18 months after the date of enactment of this Act.

(2) FLEXIBILITY FOR SMALL BUSINESSES.—Notwithstanding paragraph (1)—

(A) the amendments made by this section shall apply to a small business (as defined in the regulations promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added by this section)) beginning on the date that is 6 months after the effective date of such regulations; and

(B) the amendments made by this section shall apply to a very small business (as defined in such regulations) beginning on the date that is 18 months after the effective date of such regulations.

On page 30, line 23, strike ''small and very small businesses'' and insert ''small businesses and very small businesses (as such terms are defined in the regulation promulgated under subparagraph (A))''.

On page 32, line 14, strike ''; and'' and insert a semicolon.

On page 32, line 24, strike the period and insert ''; and''.

On page 32, after line 24, insert the following:

''(F) define, for purposes of this section, the terms 'small business' and 'very small business'.

On page 34, strike lines 8 through 11 and insert ''defined in the regulation promulgated under subsection (a)(1)) after the date that is 1 year after the''.

On page 34, strike lines 16 through 19 and insert ''(as defined in the regulation promulgated under subsection (a)(1)) after the date that is 2''.

On page 35, line 18, strike ''facilities'' and insert ''businesses''.

On page 35, line 25, strike ''facility'' and insert ''business''.

On page 36, line 8, strike ''facility'' and insert ''business''.

On page 40, between lines 5 and 6, insert the following:

''(f) EXEMPTION FOR DIRECT FARM MARKETING.—

''(1) IN GENERAL.—A farm shall be exempt from the requirements under this section in a calendar year if—

''(A) during the previous 3-year period, the average annual monetary value of the food sold by such farm directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such farm to all other buyers during such period; and

"(B) the average annual monetary value of all food sold during such period was less than $500,000, adjusted for inflation.

"(2) NOTIFICATION TO CONSUMERS.—

"(A) IN GENERAL.—A farm that is exempt from the requirements under this section shall—

"(i) with respect to a food for which a food packaging label is required by the Secretary under any other provision of this Act, include prominently and conspicuously on such label the name and business address of the farm where the produce was grown; or

"(ii) with respect to a food for which a food packaging label is not required by the Secretary under any other provision of this Act, prominently and conspicuously display, at the point of purchase, the name and business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

"(B) NO ADDITIONAL LABEL.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this Act.

"(3) DEFINITIONS.—

"(A) QUALIFIED END-USER.—In this subsection, the term 'qualified end-user', with respect to a food means—

"(i) the consumer of the food; or

"(ii) a restaurant or retail food establishment (as those terms are defined by the Secretary for purposes of section 415) that is located—

"(I) in the same State as the farm that produced the food; or

"(II) not more than 400 miles from such farm.

"(B) CONSUMER.—For purposes of subparagraph (A), the term 'consumer' does not include a business.

"(4) NO PREEMPTION.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production, harvesting, holding, transportation, and sale of fresh

fruits and vegetables. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.

"(5) LIMITATION OF EFFECT.—Nothing in this subsection shall prevent the Secretary from exercising any authority granted in the other sections of this Act.

On page 40, between lines 5 and 6, insert the following:

"(g) CLARIFICATION.—This section shall not apply to produce that is produced by an individual for personal consumption.

On page 40, line 6, strike "(f)" and insert "(h)".

On page 211, line 18, strike "310" and insert "309".

EXHIBIT 3

United States Department of Agriculture

Economic Research Service

Economic Information Bulletin Number 195

August 2018

Estimated Costs for Fruit and Vegetable Producers To Comply With the Food Safety Modernization Act's Produce Rule

John Bovay, Peyton Ferrier, and Chen Zhen

United States Department of Agriculture

Economic Research Service
www.ers.usda.gov

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United States Department of Agriculture

Economic Research Service

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August 2018

Estimated Costs for Fruit and Vegetable Producers To Comply With the Food Safety Modernization Act's Produce Rule

John Bovay, Peyton Ferrier, and Chen Zhen

Abstract

Under the Food Safety Modernization Act of 2011, the U.S. Food and Drug Administration started to implement its Produce Rule in phases beginning in 2018. Implementation of the rule will increase costs for farms supplying almost all fresh produce sold in the United States. This study estimates farm-level costs to comply with the rule by commodity, State, and farm size. Across commodities and States, differences in costs are driven by differences in farm size and range from 0.3 percent of annual produce sales for the largest farms to 6.8 percent for the smallest.

Keywords: food policy, food safety, Food Safety Modernization Act, FSMA, produce markets, regulation.

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About the authors

John Bovay is an assistant professor at the University of Connecticut. Peyton Ferrier is an agricultural economist at USDA's Economic Research Service. Chen Zhen is an associate professor at the University of Georgia.

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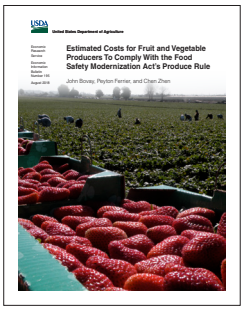


Estimated Costs for Fruit and Vegetable Producers To Comply With the Food Safety Modernization Act's Produce Rule

John Bovay, Peyton Ferrier, and Chen Zhen

What Is the Issue?

In an effort to improve food safety by reducing foodborne illnesses, the Food Safety Modernization Act of 2011 (FSMA) empowered the U.S. Food and Drug Administration (FDA) to impose new regulatory requirements on food producers and handlers, to expand requirements for and inspections of food imports, and to issue mandatory recalls of food. As a result, FDA gained expanded authority to regulate fresh-produce production practices at the farm level. The FSMA Produce Rule will be implemented in phases beginning in 2018 and will affect farms supplying almost all fresh produce sold in the United States.

As part of the rule-making process, FDA estimated the cost of compliance with the Produce Rule for a few broad categories of farms distinguished by annual produce sales value and exemption status. In its analysis, FDA estimated the total costs of compliance to be $368 million for domestic farms (annualized over 10 years, using a 7-percent discount rate) but did not estimate the costs by commodities or regions. Using those original FDA estimates, this study provides estimates of the cost of compliance with the Produce Rule by commodity, State, and farm size (based on sales). The findings of the study have implications for understanding future competitiveness of smaller farms and markets for locally grown fruits and vegetables and enable researchers to characterize effects of FSMA on retail prices, by commodity.

What Did the Study Find?

The many fixed costs associated with the administrative and personnel components and the food safety process components of complying with the Produce Rule cause compliance costs to be higher as a share of revenue for smaller farms. For this reason, fruit and vegetables produced on larger farms are estimated to have smaller compliance costs than those produced primarily on small farms. Findings on the annual costs of compliance with the Produce Rule upon full implementation of the rule in 2022 include the following:

- Farms with annual produce sales over $3,450,000 account for 58.6 percent of U.S. farm produce sales and are estimated to incur annual costs of compliance of about 0.3 percent of the value of their produce sales. Farms with annual produce sales between $500,000 and $700,000 are estimated to incur annual costs of compliance of about 4.2 percent. Small farms (annual sales between $250,000 and $500,000) and very small farms (annual sales between $25,000 and $250,000) are estimated to incur annual costs of 6.0 percent and 6.8 percent, respectively.

- Very small farms that qualify for a partial exemption from the rule are estimated to incur annual costs of around 2.4 percent of the value of their produce sales, compared with 6.8 percent for nonexempt farms of the same size.
- The annual costs of compliance with the Produce Rule are estimated to add about 0.3 percent to the farm cost of producing romaine lettuce (lowest among vegetables considered in this study) and 3.0 percent to the farm cost of producing snap beans (highest among vegetables).
- The annual costs of compliance with the Produce Rule are estimated to add about 0.7 percent to the farm cost of honeydew (lowest among fruits considered in this study). Among fruits primarily grown domestically for U.S. consumption, the highest farm cost is estimated at 3.0 percent for pears. These differences in cost of compliance across commodities reflect differences in farm sizes; fully regulated farms that grow honeydew tend to have much larger value of sales than fully regulated farms that grow pears.
- Differences in estimated cost of compliance, by State and county, depend on the average value of sales for farms subject to the FSMA Produce Rule in each locality. Fully regulated farms in Arizona tend to be quite large; on average, farms in Arizona that are subject to the FSMA Produce Rule are estimated to have the lowest annual cost of compliance among all States, at 0.6 percent of produce sales revenue. Farms in nine States with smaller produce-growing farms (Vermont, Arkansas, Minnesota, Kentucky, Mississippi, Iowa, Alabama, South Dakota, and Alaska) are estimated to have average compliance costs of 3.0 percent or higher.
- Our estimates of compliance costs assume that no farms are already in compliance prior to the enactment of the Produce Rule, thereby representing upper bounds on actual compliance costs. If large shares of farms were already in compliance prior to implementation of the rule, then actual compliance costs will be below our estimates.

How Was the Study Conducted?

This study drew on the FDA's published estimates of the 10-year cost of complying with the Produce Rule to develop a function that relates each farm's produce sales to its cost of complying with the rule. Using data from the 2012 Census of Agriculture, researchers first computed estimates of the cost of compliance for regulated farms falling within different farm size categories, with varying implementation timelines and possible exemptions over the 2016 to 2022 period. They then calculated the average estimated cost of compliance by county and State for different farm sales categories and by fresh-produce commodity.

Estimated Costs for Fruit and Vegetable Producers To Comply With the Food Safety Modernization Act's Produce Rule

Introduction

Passage of the Food Safety Modernization Act (FSMA) in 2011 marked the most comprehensive legislative change in the U.S. Food and Drug Administration's (FDA) authority to regulate food since the 1930s (Johnson, 2011; Johnson, 2014; Ribera and Knutson, 2011). The law empowers the FDA to impose new regulatory requirements on food producers and handlers, to expand requirements for and inspections of imports, and to issue mandatory recalls of food. This study examines the implications of the FSMA Produce Rule regulating fresh-produce production practices and estimates the costs of compliance at the farm level by State and across commodities.

Published in November 2015, the Final Produce Rule (FDA, 2015a) mandates certain on-farm practices related to the safe production of fresh produce. The rule's focus on raw agricultural commodities is comprehensive in terms of the number of items covered. While farms producing foods deemed to be rarely consumed raw (e.g., asparagus, beets, and sweet corn) are exempted, most farms producing fruits and vegetables marketed in a fresh state must meet the rule's specific production practice requirements beginning in January 2018.[1]

As part of the rule-making process, FDA is required to estimate and publish within a Regulatory Impact Analysis (RIA) the total expected costs (and benefits) of each of its major rules under FSMA (the Produce Rule is one of several). For the Produce Rule, FDA (2015b) used data from USDA's 2012 Census of Agriculture to estimate the number of regulated farms in each of three size categories based on annual produce sales: $25,000 to $249,999 (very small); $250,000 to $499,999 (small); and $500,000 and above (large). Farms with annual sales below the minimum threshold for very small farms are exempt from the Produce Rule. Then, FDA estimated the costs of compliance for an average farm within each of these three categories and aggregated costs across farms to estimate the total national cost of the regulation. FDA's estimates reveal that the cost of compliance with FSMA, as a share of a farm's total produce sales, is larger for smaller farms because of the many fixed costs associated with the administrative and personnel components of the regulation and with the food safety process components.

This study uses restricted-access data from the 2012 Census of Agriculture to simulate a fuller distribution of the expected costs of compliance with the FSMA Produce Rule than the FDA does in its RIA. While most produce is grown on large farms, the distribution of farm sizes differs across regions and crops. We leverage data on the distribution of farm size by crop to convert the FDA's estimate of the cost of compliance for a generic farm to a commodity-specific cost estimate, allowing for a more comprehensive analysis of the potential effects of FSMA on produce markets.

[1]As we discuss further below, large farms with annual food sales of more than $500,000 have been required to comply with the FSMA Produce Rule since January 26, 2018. Smaller farms are allowed to delay compliance for 1 or 2 years, depending on their value of sales. Note that growers of sprouts from beans and seeds had an earlier 2017 phase-in of production practices.

Background

Overview of U.S. foodborne illness outbreaks and food safety regulation

Federal involvement in food safety regulation emerged in 1906 with USDA and FDA, respectively, gaining the authority to oversee meatpacking with the Federal Meat Inspection Act and foods, drugs, medicines, and liquors with the Pure Food and Drug Act. Later legislation[2] expanded USDA's authority to encompass poultry, egg, and dairy inspections and gave the FDA authority over product adulteration and misbranding, safe tolerance levels for poisonous substances, standards related to ingredient identity and quality, and factory inspections.

Aside from the legislative process, the rule-making authority of the relevant agencies enforcing existing laws allows them to issue new regulations consistent with their legal mandate as new information becomes apparent. Two notable examples involve decisions by USDA's Food Safety and Inspection Service (FSIS) to declare the pathogen *E. coli* O157:H7 (a specific serotype of the *E. coli* bacterium that produces the Shiga toxin) an adulterant in 1994 and to declare six other serotypes of *E. coli* that also produce the toxin to be adulterants in 2011. These decisions are often associated with contemporaneous outbreaks of foodborne illness. The first stemmed from a large outbreak associated with ground beef sold by the Jack in the Box hamburger chain in the Pacific Northwest in 1993; the second arose following highly publicized deaths associated with ground beef consumption in 2009 (Moss, 2009a; Moss, 2009b; Moss, 2009c). Shortly after the first outbreak, in 1996, FSIS promulgated the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems rule, which required meat producers to systematically monitor and reevaluate microbiological contamination controls on production lines.

In addition to FSIS and FDA actions, USDA's Agricultural Marketing Service (AMS) has facilitated food safety initiatives undertaken by industry groups through marketing orders and agreements to enforce product standards (see box "Food Safety Provisions of AMS and State Marketing Orders and Agreements"). Private and collective adoption of food safety standards by both buyers and sellers has helped drive changes in norms surrounding the provision of food safety (Bovay and Sumner, 2017; Winfree and McCluskey, 2005; Pouliot and Sumner, 2012).[3]

[2]Specific legislation includes the Federal Food, Drug, and Cosmetic Act of 1938, the Poultry Products Inspection Act of 1957, the Wholesome Meat Act of 1967, the Wholesome Poultry Act of 1968, and the Egg Products Inspection Act in 1970.

[3]For perspectives on exporting food from developing countries in the presence of buyer standards, see Unnevehr (2000), Martinez and Poole (2004), and Schuster and Maertens (2013).

Food Safety Provisions of AMS and State Marketing Orders and Agreements

The Agricultural Adjustment Act of 1933 empowered the U.S. Secretary of Agriculture, through the Agricultural Marketing Agreement Act of 1937 (AMAA), to authorize the use of marketing orders and agreements at the Federal level to allow growers of a particular commodity to set rules for marketing their products. State law can allow similar authority to create marketing orders and agreements at the local level. Both marketing orders and agreements are initiated by industry to help provide stable markets for dairy products, fruits, vegetables, and specialty crops. Under a marketing agreement, only handlers who sign onto the agreement are bound by its terms with regard to production or marketing restrictions. Marketing orders can only be enacted after formal rule-making conducted by USDA and the approval of affected producers. With marketing orders, all handlers within a defined geographic area are bound by the terms of the order. These marketing orders are self-governed and self-financed by relevant industry groups. AMS provides oversight to ensure that each program operates according to the AMAA and the Federal marketing order.

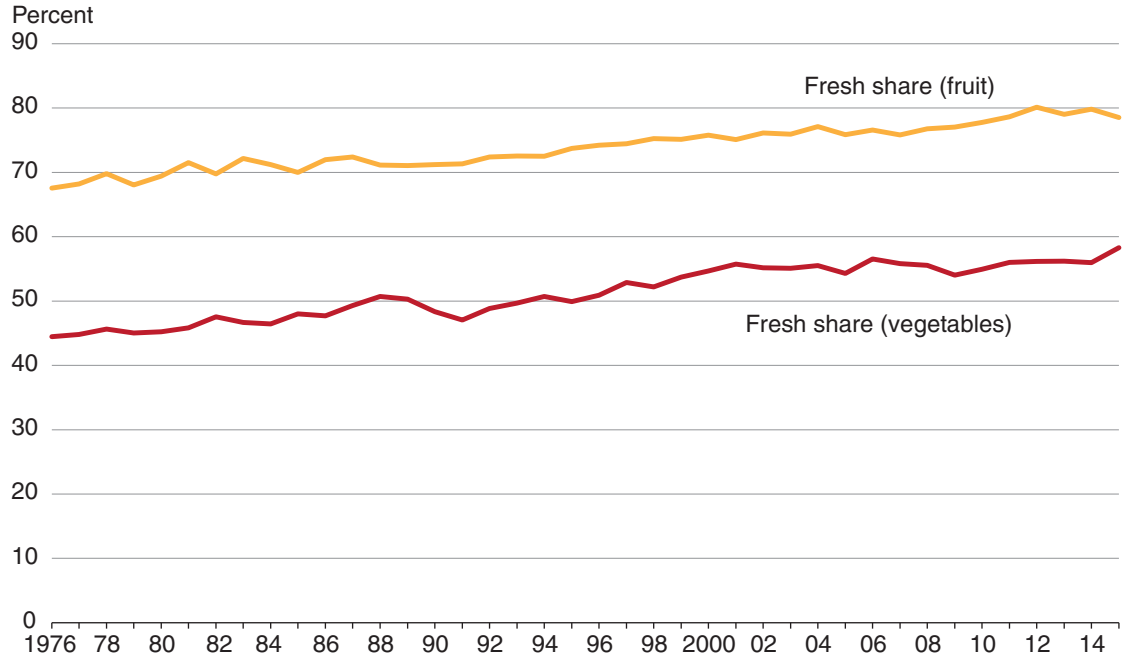
Marketing orders can have provisions that (1) require grading and inspection services to meet minimum grade levels; (2) standardize packaging and labeling of containers; (3) sponsor production research projects; (4) create market research and product promotion activities; and (5) increase or decrease the amount of product allowed into commercial channels during periods of exceedingly high or low volume. With limited authority to regulate food safety characteristics as food quality factors, AMS marketing orders are the product of industry initiatives to set and maintain standards. Recent instances of industry groups using marketing orders to address food safety concerns are increasing. The almond marketing order has funded millions of dollars in research on almond quality, food safety, and nutrition. The pistachio industry sets quality standards that require, among other things, testing for aflatoxin, a cancer-causing mold found in many nuts and grains. The hazelnut industry is working to amend the marketing order to add authority to regulate quality for the purpose of pathogen reduction. Though not a marketing order, AMS also ensures that peanuts marketed in the United States are free of aflatoxin. At the State level, the Leafy Greens Marketing Agreement (LGMA) was developed first in California and later Arizona to create a system of food safety practices and audits for 14 leafy greens products following the highly disruptive outbreak of *E. coli* in California spinach in 2006 (Arnade et al., 2009, Calvin et al., 2017).

The Food Safety Modernization Act

FSMA represents the most substantial legislative expansion of FDA regulatory authority since the 1930s (Johnson, 2011). Like previous legislation addressing food safety, FSMA was enacted in the context of changes in the industrial structure of the food industry, including trade liberalization, enhanced economies of scale in production and retailing leading to larger farm sizes, and improvements in shipping technology. These factors increased the distance that food travels before reaching consumers, substantially increasing the share of fruits and vegetables consumed fresh rather than preserved (fig. 1).

As with regulations issued by Federal agencies, the expansion of legislative authority over food safety has often been a reaction to recent food safety events or outbreaks of foodborne illness. Prior to the passage of FSMA in 2010, several high-profile incidents heightened concerns regarding food safety generally (see table 1). First, a large-scale outbreak associated with consumption of *E. coli*-contaminated spinach in 2006 reduced retail expenditures of bagged spinach by 20 percent for 68 weeks (Arnade et al., 2009). An outbreak arising from *Salmonella* in serrano peppers had just concluded when FSMA was introduced to Congress in early March 2009. In addition, media reports in 2007 and 2008 that both dairy products and pet foods in China had been intentionally adulterated increased concerns about the efficacy of food safety systems in countries exporting to the United States. Finally, an outbreak caused by *Salmonella* in peanut butter in 2008 and 2009 affected more than 700 people in 46 States and may have contributed to the deaths of 9 people (Johnson, 2011).

Figure 1
Growth in consumption shares of fresh U.S. fruits and vegetables (by volume)



Note: Shares reflect fresh per capita use as a share of total fresh, frozen, dried, and canned per capita use. Vegetables exclude melons. Fruits exclude fruit for juicing from the share calculation.

Source: USDA, Economic Research Service (2016a, 2016b).

Table 1

Confirmed foodborne illness outbreaks arising from fruit and vegetable consumption

Year	Food vehicle	Etiology	Number of illnesses	Number of deaths
1998	Tomato	*Salmonella enterica*	86	3
1998	Unspecified fruit	Norovirus	270	0
1998	Parsley	*Shigella sonnei*	486	0
1998	Lettuce	*Campylobacter jejuni*	300	0
1999	Unpasteurized orange juice	*Salmonella enterica*	398	0
2000	Watermelon	Shiga toxin-producing *Escherichia coli*	736	1
2001	Cantaloupe	*Salmonella enterica*	50	2
2001	Tomato	*Shigella flexneri*	886	0
2002	Tomato	*Salmonella enterica*	510	0
2003	Honeydew melon	*Salmonella enterica*	68	2
2003	Almonds	*Salmonella enterica*	42	1
2003	Spinach	Shiga toxin-producing *Escherichia coli*	16	1
2003	Alfalfa sprouts	*Salmonella enterica*	26	1
2003	Corn	*Clostridium perfringens*	880	0
2003	Green onion/scallion	Hepatitis A	935	0
2004	Roma tomato	*Salmonella enterica*	429	0
2005	Basil	*Cyclospora cayetanensis*	592	0
2006	Spinach	Shiga toxin-producing *Escherichia coli*	238	5
2006	Carrot juice	*Clostridium botulinum*	4	1
2006	Peanut butter	*Salmonella enterica*	715	0
2007	Tomato	*Salmonella enterica*	10	1
2008	Serrano peppers	*Salmonella enterica*	1500	2
2008	Peanut paste	*Salmonella enterica*	714	9
2008	Watermelon	*Salmonella enterica*	594	0
2009	Melon	*Salmonella enterica*	53	1
2009	Alfalfa sprouts	*Salmonella enterica*	256	0
2010	Celery	*Listeria monocytogenes*	10	5
2011	Strawberries	Shiga toxin-producing *Escherichia coli*	15	2
2011	Cantaloupe	*Listeria monocytogenes*	147	33
2012	Cantaloupe	*Salmonella enterica*	261	3
2012	Cantaloupe	*Salmonella enterica*	33	1
2013	Mixed cut fruit	Norovirus	16	1
2013	Prepackaged leafy greens	Shiga toxin-producing *Escherichia coli*	14	1
2013	Papaya	*Salmonella enterica*	13	1
2014	Nectarine	*Listeria monocytogenes*	2	1
2014	Mung bean sprouts	*Listeria monocytogenes*	5	2
2014	Cucumber	*Salmonella enterica*	275	1
2014	Caramel apple	*Listeria monocytogenes*	35	7
2015	Prepackaged lettuce	*Listeria monocytogenes*	19	1
2015	Tossed salad	*Salmonella enterica*	252	0
2015	Cucumber	*Salmonella enterica*	907	6

Note: Data reflect outbreaks associated with fruits and vegetables with at least 250 confirmed cases or with at least 1 death and do not include outbreaks also associated with products other than fruits and vegetables or outbreaks associated with home-made foods. No such outbreaks occurred during 2016, and data were not available for 2017-18 at the time of publication.

Sources: USDA, Economic Research Service using data from U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (2018, covering outbreaks from 1998 to 2016).

Requirements of the FSMA regulations

FSMA required that FDA develop and issue certain regulations or "rules" that specify required practices and standards for farms, processors, and marketers whose products fall under FDA's jurisdiction. For general context, we provide a brief list of the main subject areas for each of the rules required by the legislation:

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (111th Congress Public Law 353, Sec. 105).
  - Applies to many farms that grow certain fresh-produce commodities often consumed raw.
  - Requires testing of agricultural water, hygiene and sanitary standards, and efforts to prevent contamination of fresh produce with animal feces, with special requirements for growers of sprouts from beans and seeds.
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls (HARPC) for Human Food (Sec. 103).
  - Applies to facilities that manufacture, process, pack, or hold human food (including fresh produce).
  - Requires development and implementation of an HARPC plan, analogous to hazard analysis and critical control points (HACCP) programs currently mandatory for processors of dairy products, juice, meats, and seafood.[4]
- Foreign Supplier Verification Program for Importers of Food for Humans and Animals (Sec. 301).
  - Requires importers to verify that their suppliers are compliant with FSMA.
- Accreditation of Third-Party Auditors (Sec. 307).
  - Sets standards for the voluntary accreditation of private companies and foreign governments to conduct audits of foreign food producers.
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls (HARPC) for Food for Animals (Sec. 103).
  - Requires manufacturers of food for animals to follow similar standards as required by the rule on HARPC for human food.
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (Sec. 106).
  - Requires most facilities (foreign and domestic) that manufacture, process, pack, or hold food to design and implement plans to protect against the intentional adulteration of food as terrorism or other acts intended to cause widespread harm to human health (FDA, 2016).
  - Does not apply to farms.
- Sanitary Transportation of Human and Animal Food (Sec. 111).
  - Requires shippers, loaders, carriers, and receivers to implement and document practices to reduce the risk that food will become contaminated during shipping (FDA, 2016).

[4]Hazard analysis and critical control points (HACCP) is a system under which facility managers identify hazards that threaten food safety and implement a system for reducing or eliminating those hazards.

The FSMA Produce Rule

This study focuses on the cost effects of the FSMA Produce Rule—more formally known as "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Farms covered by the Produce Rule will have specific production practices regulated along five areas: agricultural water quality, soil amendments of animal origin, worker health and hygiene, animal intrusion, and sanitary standards.[5] Improvements to these practices are expected to reduce microbial contamination at the farm level by limiting the exposure of produce to pathogens. FDA estimated the annualized cost of compliance for U.S. agriculture for each of the major rule components (FDA, 2015), along with the basic compliance activities required as part of these rule components (see table 2).[6]

Table 2
Estimated costs of compliance with components of the FSMA Produce Rule, from FDA Regulatory Impact Analysis, domestic farms

Component	Compliance activities	Estimated cost ($ millions)
Agricultural water	No detectable *E. coli* in water for certain uses (including washing hands and washing food-contact surfaces) Nonzero *E. coli* standard for water applied for growing produce Several tests per year are required	16.11
Soil amendments of animal origin	Raw manure may not contact produce during application of the manure Stabilized compost must meet certain standards for bacteria	1.28
Domesticated and wild animals	Examine the growing area to identify and prevent animal fecal contamination	11.01
Worker training and health and hygiene	Workers must wash and dry hands at certain times, such as after using the toilet Workers, including those who handle food or food-contact surfaces, must receive training, including on the importance of health and hygiene	216.41
Equipment, tools, and buildings	Must sanitize equipment, tools, and buildings, especially food-contact surfaces	83.56
Sprouting operations	Taking measures to prevent introduction of dangerous microbes; treating seeds; testing irrigation water; testing for *Listeria*	5.55
Recordkeeping, administrative cost to learn the rule		31.98
Other		2.27
Total		368.17

Note: Unlike in other parts of the U.S. Food and Drug Administration's (FDA) Regulatory Impact Analysis, table 36 explicitly accounts for farms being allowed different deadlines for compliance with the rule components and the phasing-in of the agricultural water provisions. We view the timing of regulatory compliance as important and therefore elect to use this summary table. FSMA = Food Safety Modernization Act.

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2015), table 36.

[5]In addition, growers of sprouts from beans and seeds—which have a greater tendency toward microbial contamination than other produce commodities—have more rigorous requirements. Note that FDA uses 12 component areas in its Regulatory Impact Analysis, and we generalize them into five areas, plus requirements for sprouts, recordkeeping requirements, and other costs. See table 2.

[6]The FDA cost estimates converted one-time expenditures into (annualized) recurring costs based on a 10-year time horizon with a 7-percent discount rate, a method mandated by the Office of Management and Budget.

The FSMA Produce Rule applies the same production requirements to all types of regulated farms, but the costs of compliance with FSMA will vary based on current farm practices. OSHA regulations (79 FR 33612) require field sanitation units and handwashing stations for all agricultural establishments where 11 or more employees are engaged in hand-labor operations in the field. Farm practices vary by State, too. For example, California State law—among other States' laws—also requires that farmworkers have access to toilets and hand-washing stations in the field (California Division of Industrial Relations, 2014), but this is not a requirement under Federal law for all farms; some farms will not need to incur extra costs to comply with this component of FSMA, and other farms will. As another example, wild animals are a risk to food safety in some regions but are uncommon in others.[7] So, even among fully regulated farms of the same size, costs of compliance with the rule can vary greatly depending on region, type of crop grown, and food safety practices adopted voluntarily. Our analysis does not address these inherent differences in the cost of complying with the Produce Rule, but it does draw on the differences in cost of compliance across farm size as given in the RIA.

Coverage of the Produce Rule by commodity

The Produce Rule applies only to fresh produce commodities defined by FDA to include fruits, vegetables, mushrooms, sprouts, peanuts, tree nuts, and herbs but not grains such as barley, oats, rice, wheat, and oilseeds (80 FR 74551). The following produce commodities are excluded from the rule because FDA has determined that the products are rarely consumed raw in the United States: asparagus, dry or canned beans (e.g., black, great Northern, kidney, lima, navy, and pinto), garden beets (roots and tops), sugar beets, cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill (seeds and weed), eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, winter squash, sweet potatoes, and water chestnuts (FDA, 2016).

Qualified exemptions for small farms

FDA requires that farms with more than $25,000 in annual revenue from sales of covered commodities comply with the Produce Rule. Farms with sales of $25,000 or less are exempt from the rule.

The FSMA legislation specifies that the Produce Rule must provide an "exemption for direct farm marketing" (U.S. Congress, 2011, 124 Stat. 3903). As specified in the legislation, farms that qualify for this (partial) exemption must only label their products with the name and business address of the farm in a manner visible to consumers at the point of sale. The criteria for qualification are that farms must have less than $500,000 in annual revenue from sales of food (including produce) and must make more than half of their sales (in terms of value) directly to consumers, or directly to restaurants or retail food establishments within the same State or within a 275-mile radius. FDA may revoke the exemption for otherwise qualifying farms if it determines that an outbreak is associated with that farm or if conditions on the farm pose a threat to public health.

[7]Growers generally make efforts to keep animals out of fields, not only to address food safety concerns but also to prevent animals from eating crops.

Costs of Compliance With the FSMA Produce Rule

Under various laws and directives, regulatory agencies are required to prepare a Regulatory Impact Analysis to enumerate the costs and benefits associated with any regulation with significant costs.[8] In modeling the costs of compliance, FDA summed estimated accounting costs for farms differing by sizes within three general ranges based on total annual produce sales: very small farms ($25,001 to $250,000); small farms ($250,001 to $500,000); and large farms (more than $500,000). FDA then multiplied those estimates by the number of farms within each size category to estimate a total national cost of compliance with the Produce Rule (see table 2). The FDA analysis thus implies that all farms within a given size category have the same cost of compliance.

Compliance with FSMA entails both fixed and variable costs. Fixed costs, which do not change based on the size or output of the farm, may consist of basic bookkeeping operations to document food safety practices or water-quality tests, or labor time required to understand the regulations. Variable costs, which depend on the size of the farm, may consist of training costs for workers, supervisor compensation that depends on the number of workers on a farm, or monitoring costs that depend on the acreage or output of the farm.

If variable costs of compliance increase at a rate equal to or smaller than the rate of output as a farm expands and if fixed costs of compliance are large, then regulatory compliance requirements create economies of scale. That is, large farms have lower marginal costs of compliance with respect to output than smaller farms. Large farms have the same per-unit cost of compliance for FSMA costs that vary proportionally with farm size (e.g., certain worker hygiene requirements; animal intrusion monitoring) but a smaller per-unit cost of compliance for FSMA costs that are fixed (e.g., costs of learning the FSMA rules; accounting requirements).

Compliance with FSMA requires that farms take on both one-time costs, such as costs to management and personnel to learn the Produce Rule, and recurring costs, including water testing and sanitation of equipment. Beginning in January 2018, large farms were required to implement nearly all of the rule components. Small and very small farms can postpone implementation for 1 and 2 years, respectively. In addition, some of the rule components related to agricultural water will be implemented with a 2-year delay for each farm-size category.[9] Thus, we analyze the effects of FSMA implementation on farm costs over 2018-22 and also include in the analysis the costs of learning the Produce Rule in 2016.

[8]Executive Orders 13563 and 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612) and the Unfunded Mandates Reform Act of 1995. Currently, significant costs imply that total costs for industry must exceed $144 million (in 2013 dollars) (FDA, 2014a).

[9]In September 2017, FDA (2017) issued a new proposed rule that would delay the implementation dates for agricultural water testing requirements for several years. At the time of this report, FDA had not yet issued a final rule on this topic. Our cost estimates reflect the implementation dates of the earlier, final rule published in 2015.

FDA estimated the costs of compliance with individual rule components for three sizes of fully regulated farms. Using a standardized discount rate of 7 percent,[10] FDA converted these costs into annual expenditures. The differences in compliance costs across farm size derive mainly from labor costs associated with harvesting and are discussed in detail later in this report. In constructing the estimates in the RIA, FDA did not make any substantive effort to assess how costs of compliance would differ across commodities.[11] Farm sizes and the labor used in production are closely correlated with the commodity produced. For this reason, costs of compliance with FSMA are likely to differ systematically across commodities, where commodities produced on large farms with little labor input have a relatively small added cost (as a percentage of farm revenue), while commodities produced on large farms with large labor inputs have a relatively large average cost. In addition to these economies of scale in compliance, the FSMA Produce Rule provides some explicit exemptions from the Rule's provisions.

[10]This rate is set by the Office of Management and Budget, which oversees the procedures for cost and benefit calculations used in rule making.

[11]In two instances, FDA accounted for the collective adoption by growers of particular commodities of practices equivalent to the FSMA requirements. However, FDA's estimates of the number of farms already in compliance with components of the rule is certainly an underestimate because many farms undertake on-farm food safety practices substantially equivalent to the requirements of the components of the Produce Rule to satisfy private contractual requirements or simply to protect themselves (see, e.g., Bovay, 2017; Lichtenberg and Page, 2016), and FDA accounted for such practices in a conservative way, as we discuss in the appendix.

Contributions of This Report

As stated earlier, the FDA's Regulatory Impact Assessment does not consider how compliance costs vary across commodities or States. This study uses the FDA's estimates to compute costs of compliance by commodity as a share of revenue to facilitate more nuanced demand analysis and price forecasting (see table 3). Specifically, these data can be adapted to simulation analysis to estimate the effects of FSMA on farm and consumer prices and on producer welfare.

As discussed by Bovay and Sumner (2017), the FDA's Regulatory Impact Analysis does not consider equilibrium effects of the implementation of FSMA, instead it assumes that costs can be added to prices without affecting quantity produced, an assumption consistent with very inelastic demand. This assumption greatly simplifies the analysis since the rule's benefits (i.e., safer foods causing fewer illness) and costs (i.e., higher prices) are borne only by consumers. Bovay and Sumner (2017) simulated the equilibrium effects of FSMA implementation by calculating the specific costs of applying food safety measures to the North American fresh-tomato industry as a case study by calculating the costs of complying with the FSMA Produce Rule (as a share of revenue, based on the size distribution of farms in that industry) and then allowing the tomato market to reach a new equilibrium reflecting the shifts in supply curves for various groups of producers.

In a similar manner, we calculate the cost of compliance with the Produce Rule (as a share of revenue) for 18 fruits and 20 vegetables, nearly all the major U.S. crops affected by the rules. We calculate the average effect of FSMA implementation for covered fruits and vegetables by State, allowing for more direct insight into the distribution of compliance costs. We also summarize the expected effects of FSMA implementation crop by crop, providing insights into potential changes in the relative costs of growing various fresh-produce commodities. These cost estimates can be easily adapted to future research using a formal demand and supply framework to calculate the welfare effects for producers and consumers of regulated fresh-produce commodities.

Table 3
Side-by-side comparison of cost of compliance estimates

Breakouts by category	FDA RIA (2015b)	ERS estimates
Cost by size category	Yes	Yes
Costs by State	No	Yes
Costs by commodity	No	Yes

FDA RIA = U.S. Food and Drug Administration Regulatory Impact Analysis. ERS = USDA, Economic Research Service.

Our analysis does not independently estimate the costs of complying with individual components of the Produce Rule; rather, it draws our estimates of the costs of compliance with the Produce Rule components from the FDA's estimates contained in the RIAs (FDA, 2013, 2014a, 2015b).[12] We recognize that this approach has shortcomings. In particular, the linear interpolation method we use to estimate costs of compliance for farms across the entire distribution of farm sizes (sales values) may be inappropriate; nonlinearities may exist that are not obvious from reading the FDA RIAs. Also, reviewers have noted that FDA may overestimate or underestimate the costs of compliance with certain rule components.[13] For example, the Preliminary RIA (FDA, 2013) includes estimates of the costs of water testing and treatment for large farms that have multiple water sources; the Final RIA (FDA, 2015b) assumes that all farms have only one water source.

[12]FDA's estimates of the costs and benefits of the FSMA Produce Rule are contained in three separate documents: the Preliminary RIA (FDA, 2013), the Supplemental Preliminary RIA (FDA, 2014a), and the Final RIA (FDA, 2015b). Each of these builds on the previous documents and incorporates comments from stakeholders; the Final RIA also incorporates revisions to the requirements of the rule.

[13]It is also worth noting that our analysis assumes that farms have not already adopted food safety practices and that all regulated farms will be required to incur the full costs of implementing the FSMA Produce Rule. As discussed, there is good evidence that many farms have adopted food safety practices, so our estimates of the effects of FSMA on farm costs are likely to be inflated.

Cost Shifts

As described earlier, to estimate the cost of implementing the FSMA Produce Rule for each commodity, we combine data on the distribution of farm sizes from USDA's 2012 Census of Agriculture with data published in FDA's RIA for the Produce Rule (FDA, 2013, 2014a, 2015b). According to the RIA, factors accounting for variations in costs by farm size include differences in the number of workers who required training and in bookkeeping costs. Most strikingly, FDA estimates that the large fixed costs of the regulations will create substantial economies of scale in their implementation.

The RIA did not disaggregate the cost of implementing the Produce Rule across commodities, providing only estimates of the average cost of implementation by farm size for three sizes of fully regulated farms and for farms that qualified for exemptions and farms not covered by the rule. FDA estimates that the full costs of implementing the Produce Rule will represent 1.56 percent of total revenue from produce sales for fully regulated farms. For large farms, however, this share is only 0.92 percent (table 4). For small and very small farms, the shares are 6.04 percent and 6.77 percent, respectively.[14] Although these estimates illustrate economies of scale in complying with FSMA, they do not provide detailed information about the distributional effects on producers of different fruit and vegetable commodities covered by the FSMA Produce Rule. By using nonpublic, farm-level data from the 2012 Census of Agriculture, we are better able to show these commodity-level effects, along with estimates of how average farm compliance costs vary at the State and county levels.

The 2012 Census of Agriculture (USDA, NASS, 2014) is the primary source of data on the production of U.S. farms and includes detailed statistics on the planted acreage of each commodity, including some distinctions as to whether goods are destined for further processing. Farm sales, however, are only reported for aggregate categories such as fruit, vegetable, and berry sales, so we are unable to identify precisely the sales value of FSMA-covered production from the Census data. We cannot generate reliable estimates of FSMA-covered sales from the acreage data because yields vary greatly. Instead, we estimate the farm-level cost of compliance with the Produce Rule as a function of farm produce sales, including the following categories: vegetables, potatoes, and melons; berries; fruits and nuts; mushrooms; and pineapples. Compliance with the Produce Rule will be phased in over several years, and we present estimates of the cost of compliance as it varies by farm size across years. Our estimates of variation in costs by crop and geographic region reflect only the recurring costs of compliance under full implementation.

We develop the cost of compliance with the Produce Rule as a linear interpolation of the point estimates from the FDA RIA. In addition, we extrapolate from FDA's estimates to generate an estimate of the cost of compliance for a minimum-sized farm, and we assume that farms with produce sales in excess of $3,450,000 would incur zero marginal cost of compliance with respect to sales. See the appendix for additional discussion on the development of cost estimates for a minimum-sized regulated farm.

Note that our estimates differ from those in the FDA RIA because we use the detailed farm-level data from the 2012 Census of Agriculture and because we break out "large" farms into several subcategories (see table 4). The large-farm category accounts for 85.6 percent of total U.S. produce sales.

[14]See appendix for details on how we calculate these percentages from the FDA's estimates.

Table 4
Average cost of full compliance with the Produce Rule, by farm sales category

Category (value of annual produce sales)	Average cost of compliance (dollars)	Average cost of compliance as a share of revenue (percent)
Very small, qualified ($25,000 to $250,000)	1,738	2.45
Small, qualified ($250,000 to $500,000)	1,738	0.51
Very small, fully regulated under FSMA Produce Rule ($25,000 to $250,000)	5,560	6.77
Small, fully regulated ($250,000 to $500,000)	21,136	6.04
Large, fully regulated ($500,000 and above)	29,228	0.92
$500,000 to $700,000	24,360	4.17
$700,000 to $1,000,000	25,451	3.07
$1,000,000 to $1,600,000	27,315	2.19
$1,600,000 to $3,450,000	32,111	1.38
$3,450,000 and above	37,115	0.33

Notes: Estimates reflect the full cost of compliance upon implementation of all rule components in 2020 to 2022 (depending on farm size), relative to a farm that has not adopted any food safety practices. FSMA = Food Safety Modernization Act.

Sources: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture.

We then use our estimates of the cost of compliance by farm size to generate our estimates of the cost of compliance for affected farms by State and county. Importantly, these estimates are only based on farms growing fruits and vegetables. In many counties where the geography or climate makes large-scale fruit or vegetable production infeasible, some small farms may still operate to serve local markets. For example, Idaho's mountains and cold temperatures likely prevent large-scale fruit and vegetable farms. In these regions, estimated costs are likely to be higher with relatively few farms being be affected. Also, our estimates do not cover fruits and vegetables either grown for canning or infrequently consumed raw, such as asparagus, sweet corn, potatoes, and sweet potatoes. Consequently, our estimates of the Produce Rule compliance costs are not relevant to the cost of producing those goods.

In a similar manner, we use our estimates of the cost of compliance by farm size to generate estimates of the cost shares by commodity. First, using NASS data, we calculate each farm's share of the total planted acres for each of the considered commodities. Next, we multiply each farm's share of national acreage for each commodity by that farm's cost of implementing FSMA as a percentage of sales. For example, if the share of strawberry acres is 65 percent on large farms, 25 percent on small farms, and 10 percent on very small farms, then the cost of compliance (as a share of revenue) we report for the strawberry commodity will be the average of the large, small, and very small costs for the generic farm multiplied by those shares. Since compliance costs are higher for small farms, this method estimates higher costs for crops that are produced by smaller farms. This method also incorporates the effects of farms producing more than one type of produce. If a farm maintains only a small acreage of cucumbers, for example, then that farm's contribution to our estimate of the average implementation costs for cucumbers will be similarly small.[15]

[15]Importantly, this method only addresses farm size as source of variation in the cost of implementing FSMA and should be interpreted with the understanding that data are not available to determine a more specific cost estimate that account for differences in yields or labor use.

Results

Again, our estimates of the recurring costs of implementing the Produce Rule are likely, in many cases, to be overestimates because we have not excluded all noncovered production (specifically, fruit and vegetables grown for canning and vegetables designated as "rarely consumed raw").[16] These estimates depend on the value of produce sales and not on other factors, such as number of workers per farm or current level of adoption of food safety practices.

For vegetables, the estimated annual cost of compliance as a share of revenue ranges from 0.3 percent (romaine lettuce) to 3.0 percent (snap beans). For fruits, the estimated cost share ranges from 0.7 percent (honeydew) to 3.6 percent (mangoes). However, we note that imports account for a large share of U.S. consumption of mangoes, avocadoes, and bananas—the three fruits with the highest estimated cost of compliance. If imports of these commodities are grown on larger farms than in the United States, they will have a lower expected cost of compliance. Among fruits primarily grown domestically, the highest estimated cost of compliance is 3.0 percent (pears).

Table 5

Estimated recurring cost of compliance with the Produce Rule by regulated commodity upon full implementation of the Rule in 2022 and import shares

Vegetables	Cost as share of revenue (percent)	Import share (percent)	Fruits	Cost as share of revenue (percent)	Import share (percent)
Artichokes	0.36	80.5	Apples	2.18	7.5
Broccoli	0.44	19.5	Apricots	2.02	3.5
Cabbage	1.59	8.2	Avocadoes	3.53	81.4
Carrots	0.97	15.1	Bananas	3.47	99.9
Cauliflower	0.43	14.1	Cantaloupes	1.42	43.6
Celery	0.42	6.1	Cherries, sweet	2.70	7.9
Cucumbers	2.12	73.5	Grapefruit	1.72	2.9
Lettuce (head)	0.33	6.9	Grapes	2.06	46.1
Lettuce (leaf)	0.39	5.4	Honeydew	0.70	42.0
Lettuce (romaine)	0.31	5.4	Mangoes	3.57	99.9
Onions (dry bulb)	1.72	18.3	Nectarines	1.23	8.7
Peppers (bell)	1.29	59.3	Oranges (navel)	2.16	12.5
Peppers (chile)	2.63	NA	Peaches	2.30	8.7
Snap beans	2.99	31.4	Pears	2.97	19.8
Spinach	0.84	4.8	Plums	2.30	26.9
Squash	2.50	NA	Strawberries	1.31	12.6
Tomatoes	1.07	52.5	Tangerines	1.34	28.0
			Watermelons	2.65	32.9

Note: NA = Not available. Our cost of compliance estimates only apply to farms producing raw agricultural commodities subject to the Food Safety Modernization Act (FSMA) regulations. Fruits and vegetables processed with a "kill step" that eliminates the risk of pathogens (such as canned foods) are not subject to FSMA regulations.

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture (cost as share of revenue); and USDA, Economic Research Service (2016a, 2016b).

[16]Canned foods and processed foods that undergo a kill step are not subject to the Produce Rule. Unfortunately, shares of processed and canned production are only broken out at the national, but not at the State, level in NASS data. In essence, our analysis deals with crops grown for processing by assuming that, for example, pickling cucumbers and cucumbers to be sold fresh are grown on the same sizes of farms.

Note that while the FSMA Produce Rule does not explicitly create differential costs for producers based on location within the United States, the differential effects of FSMA implementation by farm size have implications for the long-run competitiveness of farming in States where produce tends to be grown by smaller enterprises.[17] This analysis aggregates our estimates of farm-level costs of compliance to the State level. It is important to note that these estimates only apply to farms regulated by the FSMA Produce Rule and not subject to an exemption.

Many States where produce is grown by relatively small farms will have high costs of compliance with the Produce Rule as a share of sales, including Alabama (3.7 percent of produce sales), Iowa (3.4 percent), and Kentucky (3.3 percent) (table 6, fig. 2). Conversely, States where fresh-produce production is dominated by large farms, such as Arizona (0.6 percent), Florida (1.3 percent), California (1.3 percent), and Washington (1.4 percent), have relatively low costs of compliance as a share of sales. Recall that these results are driven by total value of production in the State and by the number and size distribution of farms. There are a few exceptions: Nebraska (1.2 percent) and North Dakota (1.3 percent) are estimated to have lower costs of compliance than Florida. This difference in costs is driven by the exemptions for which many produce-growing farms in Nebraska and North Dakota will be able to qualify. County-level differences in estimated costs reflect local geography affecting crop choice and, relatedly, farm size, but also have an idiosyncratic component. For instance, in the Great Plains (e.g., Minnesota, South Dakota, and Nebraska) and west Texas, high-cost counties are often adjacent to low-cost counties or counties with no data. This patchy pattern likely reflects the relative infrequency of large-scale fruit and vegetable farms in these areas compared to counties in California, Florida, and Arizona, where farms are more uniformly large and numerous.

[17]For small farms to obtain qualified exemptions, they must make the majority of their sales directly to consumers, or to other end users within the same State or within a 275-mile radius. This criterion allows farms in large States (geographically) and population-dense regions of the country to sell their products to more buyers and creates an implicit advantage for farms in those regions. For the sake of our analysis, we assign small farms with direct sales exceeding half of revenue as qualified for an exemption.

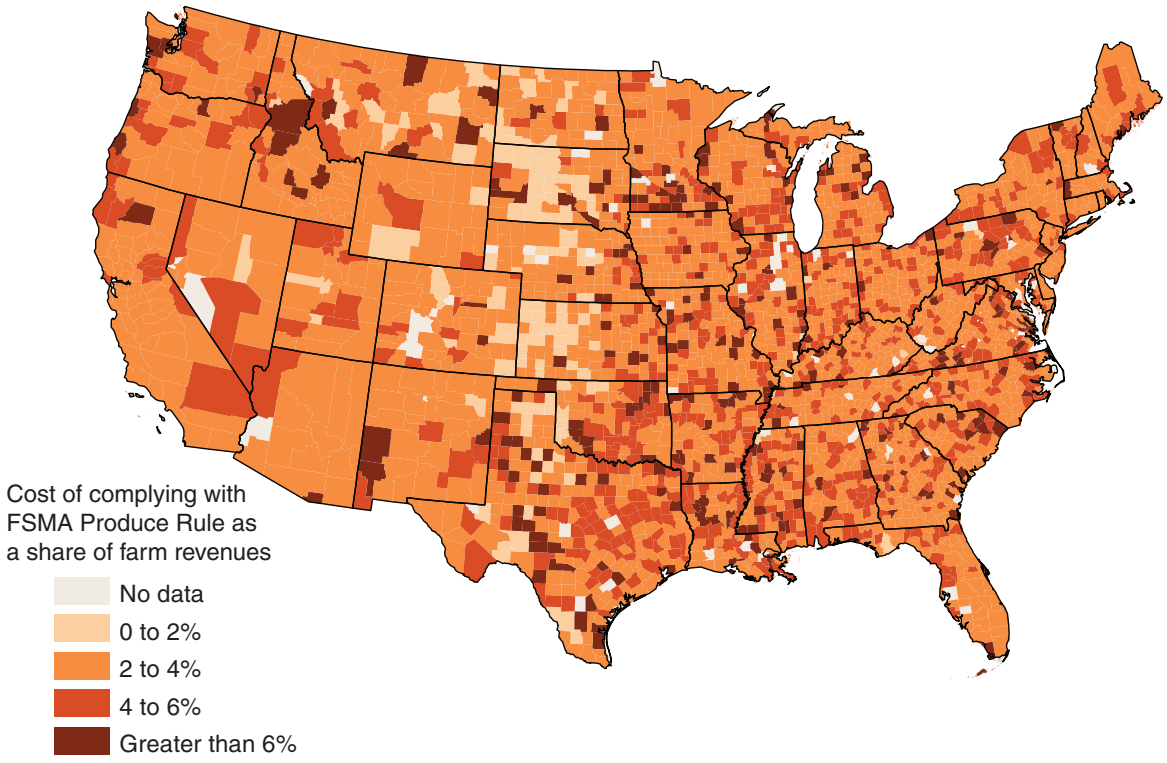
Table 6

Estimated cost of compliance, as a share of revenue, by State, upon full implementation in 2022

State	Estimated cost of compliance as share of revenue (percent)	State	Estimated cost of compliance as share of revenue (percent)
Arizona	0.61	Michigan	2.59
Nevada	1.14	Oklahoma	2.61
Nebraska	1.16	Hawaii	2.62
North Dakota	1.28	Wyoming	2.66
Florida	1.31	Oregon	2.67
California	1.32	Kansas	2.71
Washington	1.38	New Hampshire	2.72
Tennessee	1.45	Delaware	2.81
Pennsylvania	1.53	Connecticut	2.84
Idaho	1.67	Louisiana	2.87
Colorado	1.91	Maryland	2.87
South Carolina	1.92	Montana	2.88
Wisconsin	1.97	New York	2.88
Georgia	1.97	Massachusetts	2.97
Maine	2.00	Indiana	2.97
New Mexico	2.05	Rhode Island	2.99
North Carolina	2.29	Vermont	3.00
West Virginia	2.36	Arkansas	3.08
New Jersey	2.40	Minnesota	3.21
Virginia	2.42	Kentucky	3.28
Ohio	2.43	Mississippi	3.31
Utah	2.46	Iowa	3.35
Texas	2.47	Alabama	3.67
Missouri	2.48	South Dakota	3.73
Illinois	2.53	Alaska	3.82

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture (2015b).

Figure 2
County-level differences in FSMA implementation costs



Note: FSMA = Food Safety Modernization Act.

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture.

Lastly, implementation of the Produce Rule is delayed by 1 and 2 years for small and very small farms, respectively, meaning that they will not be required to comply until January 26, 2019, and January 26, 2020, respectively. Compliance with the agricultural water provisions is delayed 2 additional years for all farms.[18] Given these timelines, we find that fully regulated very small farms will incur costs between 6.5 and 6.8 percent of total produce sales between 2020 and 2022, small farms will incur costs between 5.9 and 6.0 percent of produce sales between 2019 and 2022, and large farms will incur costs of 0.9 percent of produce sales between 2018 and 2022. After the initial costs of learning the rule in 2016 and 2017, exempt farms that are very small farms will incur costs of 2.5 percent of produce sales between 2020 and 2021 and exempt farms that are small farms will incur costs of 0.5 percent of sales between 2019 and 2021.

[18]In September 2017, FDA (2017) proposed a further delay in the implementation of the water testing component of the rule. This change has not been finalized and is not incorporated in our estimates.

Table 7

Average dollar and percentage costs of implementing FSMA Produce Rule regulations, by farm size and year

	Average cost of compliance										
	Costs for exempt farms ($)			Costs for regulated farms ($)							
Year	Fully exempt	Very small qualified	Small qualified	Very small	Small	Large (all)	Large (a)	Large (b)	Large (c)	Large (d)	Large (e)
2016	171	288	288	2,885	6,725	5,550	5,550	5,550	5,550	5,550	5,550
2017	0	0	0	0	0	0	0	0	0	0	0
2018	0	0	0	0	0	28,573	23,926	24,968	26,747	31,325	36,102
2019	0	0	1,738	0	20,769	28,573	23,926	24,968	26,747	31,325	36,102
2020	0	1,738	1,738	5,375	20,769	29,228	24,360	25,451	27,315	32,111	37,115
2021	0	1,738	1,738	5,375	21,136	29,228	24,360	25,451	27,315	32,111	37,115
2022	0	1,738	1,738	5,560	21,136	29,228	24,360	25,451	27,315	32,111	37,115
	Average costs as share of sales (percent)										
2016	2.38	0.41	0.08	3.51	1.92	0.17	0.95	0.67	0.44	0.24	0.05
2017	0	0	0	0	0	0	0	0	0	0	0
2018	0	0	0	0	0	0.90	4.10	3.01	2.14	1.35	0.32
2019	0	0	0.51	0	5.93	0.90	4.10	3.01	2.14	1.35	0.32
2020	0	2.45	0.51	6.55	5.93	0.92	4.17	3.07	2.19	1.38	0.33
2021	0	2.45	0.51	6.55	6.04	0.92	4.17	3.07	2.19	1.38	0.33
2022	0	2.45	0.51	6.77	6.04	0.92	4.17	3.07	2.19	1.38	0.33

Note: FSMA = Food Safety Modernization Act. Each year begins on January 26. Farm sizes are based on annual produce sales: Very small = $25,000 - $250,000; Small = $250,000 – $500,000; Large = (a) $500,000 - $700,000; (b) $700,000 - 1,000,000; (c) $1,000,000 - $1,600,000; and (d) $1,600,000 - $3,450,000; and (e) $3,450,000 and above.

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b) and USDA, National Agricultural Statistics Service, 2012 Census of Agriculture.

Given the timing of implementation, we note that the geographical areas and commodities estimated to have higher costs of compliance, upon full implementation in 2022, will have somewhat lower costs in the intervening years. As discussed earlier, nearly 86 percent of the value of total U.S. produce sales is generated by farms with at least $500,000 in annual sales, so most of the cost increase for most commodities will be seen in 2018.

Conclusions

As the Food Safety Modernization Act and other laws are enacted, a key concern is how regulatory costs vary across producers and crops and which types of businesses gain relative advantages from regulatory implementation. In this study, we construct farm-level estimates of the cost of complying with FSMA's Produce Rule and report aggregate estimates of the cost of compliance for farms grouped by size (annual produce sales) and average costs of implementation by commodity and by State and county. Our analysis finds that differences in implementation costs can vary substantially across crops, with average compliance costs ranging from 0.3 percent of farm revenue for romaine lettuce to 3.0 percent of farm revenue for snap beans. States growing fruit and vegetables on larger farms—such as Arizona, Florida, California, and Washington—are likely to face lower implementation costs than States growing produce on smaller farms—such as Alabama, Iowa, and Kentucky.

A few caveats should be mentioned. First, our estimates of the cost of compliance with FSMA depend entirely on farm-level produce revenue, building on estimates from the FDA's Regulatory Impact Analysis. They do not account for labor or equipment costs, which vary by crop and by State. Second, we do not have Census data on farms' sales of the specific produce commodities covered by the Produce Rule, or sales of crops designated for canning (which would be exempt from coverage under the Produce Rule). Although we do have information on acreage by commodity and also acreage of vegetables to be sold for processing, the relationship between acreage and sales is nonlinear and varies across geography, time, and individual farm, so we can only use total produce sales and not focus on crops and farms that will be covered by the Produce Rule. Third, we do not account for the voluntary implementation of any food safety practices, which may have already been required by buyers or as part of marketing orders or agreements and may not necessarily align with FSMA requirements. The second and third caveats imply that we have overestimated the cost of implementing the rule. In fact, we regard the estimates presented in this report as upper bounds on the cost of implementing the FSMA Produce Rule, given FDA's estimates of the costs of compliance with individual rule components. Fourth, these estimates cover only domestic U.S. farms and not foreign farms that export to the United States. As discussed by Bovay and Sumner (2017), the Foreign Supplier Verification Program, which imposes additional costs on importers, is likely to make imports costlier and reduce the share of imports in U.S. consumption. Bovay and Sumner (2017) find that the share of imports of fresh tomatoes, for example, is likely to decrease under the program by up to 6 percentage points.[19] Finally, the estimates of commodity-level increases in farm costs must not be confused with estimates of the increases in retail prices that can be expected to result from implementation of the Produce Rule, which one might calculate using a fully specified model of supply and demand. A study of this type would incorporate additional information about demand shifts and pass-through of costs from farm to retail prices to simulate the total economic effects of implementing the Produce Rule.

[19]If, however, compliance with the FSMA Produce Rule is cheaper in foreign countries because of lower labor costs or other reasons, the import share in U.S. consumption may increase.

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Appendix—Developing the Estimates of Farm-Level Costs of Compliance

Similar to Bovay and Sumner (2017), we use estimates from the U.S. Food and Drug Administration's (FDA) Regulatory Impact Analyses (RIA) for the Food Safety Modernization Act (FSMA) Produce Rule (FDA, 2013, 2014a, 2015b) as the basis for our simulated shifts in producer costs. The RIA for the Produce Rule provides estimates of the costs of compliance for very small, small, and large farms, in addition to estimates for farms that qualify for partial exemptions and estimates of the costs of learning the rule for farms that are not covered by the rule. These costs are reported on a line-by-line basis, and for many of the rule components, costs are reported per employee or per acre. This detailed information enabled us to construct an estimate of the cost of compliance for the smallest possible fully regulated farms—those with $25,001 in produce sales, on 1 acre, with one employee, and so on. Based on this minimum cost of compliance and the three point estimates from FDA, we generated estimates of the cost of compliance with the Produce Rule for a farm with any given value of sales. We assumed that, for all farms with at least $3.45 million in sales in a given year, the marginal cost of compliance with FSMA, with respect to sales, is zero.[20] As mandatory compliance with various parts of the Produce Rule and the Foreign Supplier Verification Program (FSVP) Rule is staggered over the 5 years beginning in 2018, we were able to construct estimates of the cost of compliance across 2018-22 (see appendix figure A-1). The rules will be fully implemented by 2022, so the cost of compliance in 2022 is applied in all subsequent years. (As FDA does in the RIA, we assume that farms incurred costs to learn the rule in 2016.)

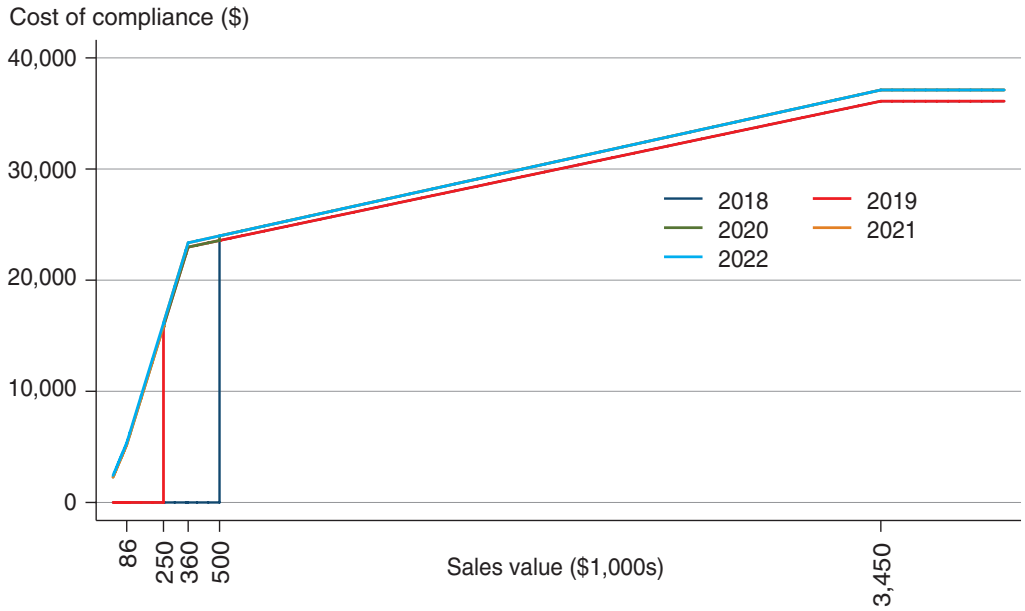
In order to estimate the commodity-level farm cost effects of implementing the FSMA Produce Rule, the next step was to calculate the share of each farm's acreage dedicated to each regulated commodity from the restricted-access Census of Agriculture data from USDA's National Agricultural Statistics Service. We used this information to calculate acreage-weighted average cost of implementation, by commodity. In other words, for a given commodity, we calculated the weighted average of costs of implementation by summing, across farms, the product of farm costs of implementation and acreage share for that commodity.

For example, suppose that there are three farms producing carrots. Both of the first two farms have compliance costs equal to 6.5 percent of revenue and produce on 20 percent of all carrot acreage (details for how these numbers might be calculated are described in the next section). The third farm has compliance costs equal to 3.5 percent of revenue and produces on the remaining 80 percent of carrot acreage. Then, the cost of compliance for carrots as a whole is 4.1 percent (=6.5 percent x .2 + 3.5 percent x .8).

[20]As discussed by Bovay and Sumner (2017), $3.45 million is the average annual sales for a large farm—all those with more than $500,000 in sales—according to the RIA. We have no basis for extrapolating the cost of compliance with FSMA for farms larger than this, but it is reasonable to assume that the costs are fixed beyond a certain size level.

Appendix figure A-1

Cost of compliance with FDA Produce Rule as a function of farm sales



Note: FDA = U.S. Food and Drug Administration. Farms with less than $25,000 in annual produce sales are not covered by the Food Safety Modernization Act's Produce Rule. FDA presents estimates for very small farms (with sales of more than $25,000 and no more than $250,000 and average sales of $86,000); small farms (with sales of more than $250,000 and no more than $500,000 and average sales of $360,000) and large farms (with sales of more than $500,000 and average sales of $3,450,000).

Source: USDA, Economic Research Service using data from U.S. Food and Drug Administration (2013, 2014a, 2015b).

As mentioned in the conclusion section of this report, this method has drawbacks. For example, consider two farms, A and B, selling produce for fresh use and fully regulated under the FSMA Produce Rule. If A grows 20 acres of tomatoes and 20 acres of apples and B grows 20 acres of tomatoes and 20 acres of strawberries, then our method overestimates the cost of compliance with the FSMA Produce Rule for tomatoes grown by farm B simply because the farm's total revenue is higher (given that per-acre revenue is higher for strawberries than apples).[21] If we had farm-level sales data by produce commodity for FSMA-regulated commodities, we would eliminate this shortcoming in our analysis. However, such data are unavailable from the Census of Agriculture, and other data sources suggest that the prices and yields of fresh-produce commodities are too highly variable to be used as an input in our model. A second shortcoming is more basic: the FDA's RIA involves the assumption that farm costs of compliance with the FSMA Produce Rule are a function of farm sales of regulated commodities. This suggests that higher priced products, such as Honeycrisp apples, would be associated with higher costs of compliance with FSMA than lower priced products, such as Red Delicious apples. (This is one of several shortcomings of the FDA's Regulatory Impact Analysis, on which all of our analysis is based.) Although these shortcomings of our approach cannot be overcome, our analysis provides the first evidence on commodity-specific effects and paints an illustrative picture of the distributional effects of FSMA implementation across commodities and geographic regions.

[21]Note, however, that our method does not ascribe the same revenues to 20 acres of tomatoes as 20 acres of strawberries.

In the Preliminary RIA (FDA, 2013), to which the Final RIA (FDA, 2015b) serves as an amendment, FDA estimated the costs of complying with approximately 100 individual rule components and aggregated these to present average and total costs across all regulated farms, within several categories. We refer to the cost estimates for the individual rule components as "line-item cost estimates." We use the line-item cost estimates as the basis for our analysis because, in its aggregation, FDA excluded a small number of farms (1,117 out of 40,211, or less than 3 percent) from incurring additional costs to comply with certain rule components on the basis of those farms undergoing USDA Agricultural Marketing Service audits for compliance with Good Agricultural Practices (GAPs), being fresh-tomato growers in Florida (where fresh tomatoes have been required to be grown under GAPs since 2008), or having status as members of the California or Arizona Leafy Greens Marketing Agreement, or the California Tomato Farmers Cooperative. Thus, the aggregate total costs of compliance presented in the FDA analysis cannot be interpreted as the sum of costs for all fully regulated growers who have zero baseline compliance; instead, the FDA's aggregation reflects partial compliance with the FSMA Produce Rule by about 3 percent of growers. Given that other evidence suggests the share of growers adopting GAPs is substantially higher than 3 percent,[22] we were left with two options: to reassess FDA's estimate of the share of growers in compliance with GAPs, in the baseline, along with the detailed information about whether their GAPs compliance brought them into compliance with each individual rule component; or to calculate costs under the simplifying assumption that zero growers were in compliance in the baseline and represent our estimates as upper bounds on compliance costs. In the absence of better information on GAPs adoption, we chose the latter option. We also calculate our costs based on their phased-in compliance, discounting the costs for rules that will not be required for all farms until 2022. For these two reasons, our table 3 estimates differ slightly with those presented in the FDA's main summary estimates.

Details of the cost functions

To construct our estimate of the cost of compliance with an individual rule component for a minimum-size regulated farm, we used one of three methods, depending on how line-item cost estimates were presented in the RIA. In the case of line-item costs presented as a function of the number of workers at very small, small, and large farms, we calculated the costs for a farm with one operator and no employees. Where line-item costs were presented as a function of farm acreage, we calculated costs for a one-acre farm. Finally, where costs were not presented as a function of farm size, we used the line-item costs for a very small farm. Combining these three approaches, these calculations yielded estimates of the cost of compliance for a minimum-size farm of $2,885 to learn the rule in 2016 or 2017; $2,278 in 2020 and 2021 before the water rule is required to be fully implemented; and $2,430 upon full implementation in 2022.

Implementation of the Produce Rule was required beginning January 26, 2018. (Sprout growers were required to begin complying earlier, but we ignore this industry throughout.) Consistent with the FDA RIA, we assume that farms incurred costs to learn the rule in 2016. As given in the RIA, these costs will be $5,550 for large farms; $6,725 for small farms; and $2,885 for very small farms.

[22]See Bovay (2017) and Bovay and Sumner (2017) for reviews of the evidence on grower adoption of food safety practices.

In 2018, large farms (those with more than $500,000 in annual sales of food) are required to implement the rule. Based on the estimates given in the RIA, we assume that the costs of compliance for these farms in 2018 and 2019 will be $23,569 plus $4.25 for every additional $1,000 in sales (beyond $500,000), with a maximum of $36,102.

Beginning on January 26, 2019, small farms (those with more than $250,000 and no more than $500,000 in annual sales of food) will be required to implement the Produce Rule. In 2019 and 2020, the cost for these farms will be $15,836 plus $64.89 for every $1,000 in sales above $250,000 and below $360,000. For sales above $360,000, the marginal cost of compliance will be $4.25 for every $1,000 in sales.

Beginning on January 26, 2020, very small farms (those with more than $25,000 and no more than $250,000 in annual sales of food) will be required to implement the rule, and large farms will begin being required to implement all components of the agricultural water rule. For very small farms, the cost of compliance in 2020 and 2021 will be $2,278 plus $47.80 for every $1,000 in additional sales beyond $25,000, up to $86,000 in sales; and for every $1,000 in sales over $86,000, the marginal cost will be $64.89. For large farms, the cost in 2020 and subsequent years will be $23,986 plus $4.45 for every $1,000 in sales over $500,000, up to a maximum of $37,115.

In 2021, small farms will be required to implement all components of the agricultural water rule. In 2021 and subsequent years, the cost of compliance for small farms will be $16,141 plus $65.65 for every $1,000 in sales above $250,000, up to $360,000 in sales. For sales above $360,000, the marginal cost will be $4.45 for every $1,000 beyond $360,000.

In 2022, very small farms will be required to implement all components of the agricultural water rule. In 2022 and subsequent years, the cost of compliance for very small farms will be $2,430 plus $48.26 for every $1,000 in sales above $25,000, up to $86,000 in sales. For sales above $86,000, the marginal cost will be $65.65 for every $1,000.

Finally, we also calculated the cost of compliance as a share of sales for farms that qualify for a partial exemption and for those that will not be covered by the rule. The FDA's estimated cost of compliance for these farms is a constant for qualified farms, $288 to learn the rule and $1,738 in recurring costs. For farms that sell less than $25,000 in produce, FDA estimates a one-time cost of learning the rule at $171, and no additional costs in subsequent years.

Appendix figure A-1 shows the cost of compliance estimates used in this analysis, as a function of farm sales, for 2018-22. Appendix table A-1 shows the distribution of farms used in the cost of compliance calculations by size by States.[23] While States with larger compliance costs typically have large shares of small and very small farms, the relationship is not exact because farms' size can vary substantially within these size categories.

[23]Because we estimate costs for farms that produce multiple regulated crops, we are unable to make a table similar to appendix table A-1 with commodity-level cost estimates by size of farm.

Appendix table A-1

Numbers of farms used in cost-of-compliance calculations, by size and State

	Farm size			
State	Number of farms	Very small	Small	Large
Alabama	355	313	20	22
Alaska	28	23	<10	<10
Arkansas	177	146	13	18
Arizona	262	156	14	92
California	17,494	10,590	2,104	4,800
Colorado	365	197	46	122
Connecticut	240	199	20	21
Delaware	130	84	11	35
Florida	2,777	1,835	291	651
Georgia	1,013	671	97	245
Hawaii	521	432	38	51
Idaho	669	247	103	319
Illinois	509	422	47	40
Indiana	337	245	41	51
Iowa	153	142	<10	<10
Kansas	95	83	<10	<10
Kentucky	272	264	<10	<10
Louisiana	207	174	14	19
Maine	519	355	45	119
Maryland	347	258	43	46
Massachusetts	638	508	57	73
Michigan	1,544	1,115	172	257
Minnesota	1,266	969	149	148
Mississippi	293	252	21	20
Missouri	320	259	25	36
Montana	199	69	110	20
Nebraska	122	65	32	25
Nevada	25	16	<10	<10
New Hampshire	119	101	<10	<10
New Jersey	612	381	<10	164
New Mexico	319	221	32	66
New York	1,560	1,136	161	263
North Carolina	777	594	11	172
North Dakota	182	25	67	90
Ohio	530	431	52	47
Oklahoma	381	353	19	<10
Oregon	1,907	1,301	224	382
Pennsylvania	1,329	1,060	101	168
Rhode Island	52	41	<10	<10
South Carolina	363	300	24	39
South Dakota	25	24	<10	<10
Tennessee	189	135	25	29
Texas	1,487	1,202	101	184

Continued—

Appendix table A-1

Numbers of farms used in cost-of-compliance calculations, by size and State—continued

	Farm size			
State	Number of farms	Very small	Small	Large
Utah	137	103	15	19
Virginia	438	351	41	46
Vermont	151	125	15	11
Washington	2,720	1,448	378	894
West Virginia	98	79	<10	15
Wisconsin	1,305	933	125	247
Wyoming	7	<10	<10	<10
All States	45,476	30,437	4,925	10,114

"<10" = Value is less than 10 and withheld from reporting.

Source: USDA, Economic Research Service using data from USDA, National Agricultural Statistics Service, Census of Agriculture (2012).

EXHIBIT 4

Farm and Ranch Freedom Alliance
P.O. Box 809, Cameron, TX 76520
254-697-2661

FARM&RANCH FREEDOM ALLIANCE

Submitted via email: Richard.DeLosSantos@TexasAgriculture.gov

July 9, 2019

RE: Comments on Texas Department of Agriculture's proposed *Food Safety Modernization Act (FSMA) Produce Safety Administrative Rule* published June 14, 2019.

The Farm and Ranch Freedom Alliance (FARFA) submits these comments on the Texas Department of Agriculture's proposed "Food Safety Modernization Act (FSMA) Produce Safety Administrative Rule," published June 14, 2019.

FARFA is a grassroots organization that advocates for common-sense policies for local, diversified agriculture. FARFA worked extensively with organizations across the country and members of Congress to incorporate provisions in the federal Food Safety Modernization Act (FSMA) that address the concerns of small-scale food producers and the consumers who wish to purchase food from them. In particular, the federal statute included exemptions for small farms and food producers who sell primarily to consumers and local restaurants and retailers. These statutory exemptions are reflected in the Food and Drug Administration's (FDA's) FSMA rules.

Without these exemptions, thousands of small farmers would, quite literally, be put out of business. FDA's and USDA's estimates vary between $21,000 and $25,000 for a small non-exempt farm to comply in the first year, with many of those costs continuing to accrue annually. *See Final Regulatory Impact Analysis, Docket No. FDA-2011-N-0921, Table 34.* Even for larger farms, many of the provisions of the Produce Safety Rule are problematic. While FARFA has concerns about the substance of the federal rule, we recognize that TDA has very limited power to differ from the federal standard.

FARFA's comments will thus focus on those provisions in the proposed rule that differ from the federal rule. In addition, since this is TDA's second proposed FSMA rule, these comments include a chart that outlines the differences between the two proposed rules as they relate to our concerns.

I. The TDA lacks statutory authority to require farm registration

In early 2018, TDA staff stated at public meetings that the agency intended to require every produce farm to register with the agency. FARFA sent a letter objecting to this plan on March 19, 2018.

While TDA's proposed rule avoids the use of the word "registration," the proposed rule, in practical terms, creates a mandatory registration requirement. Farms that have a qualified exemption under 21 CFR §112.5 would be required to file biennial paperwork, and the agency claims authority to use that submission to determine whether a farm is exempt from the substantive requirements. *See* proposed 4 TAC §11.21-11.22. This is mandatory registration, and FARFA's comments will thus refer to it as such.

In contrast to the December 2018 proposed rule, the June 2019 proposed rule does not require farms that sell les than $25,000 in produce to register. This change is an improvement. The new proposed rule also shifts from an "annual survey" to a biennial submission. But by continuing to require qualified exempt farms to register and submit paperwork, whether annually or biennially, the agency is exceeding its statutory authority.

The Food Safety Modernization Act (FSMA), codified at 21 USC 301 et seq., does not require registration of farms. HB 3227, codified at Section 91 of the Agriculture Code, which gave TDA authority to implement the Produce Safety Rule under FSMA, does not mention registration of farms. As such, TDA lacks statutory authority to require farm registration.

At no point has the agency identified any specific federal or state statutory provision that would provide the basis for the regulatory requirement. In conversations, the agency staff has provided one justification for the concept of mandatory registration: that it is "necessary" for TDA to implement the Produce Safety Rule, since it allegedly cannot fairly enforce the provisions on those farms that are subject to the rule otherwise. In other words, the agency is concerned that it may be difficult to identify which farms are subject to the rule's requirements.

But agency convenience is not a legal basis for mandatory registration. Regulatory requirements that apply only to certain activities or certain businesses, but not others, are a common feature in many laws. These laws **don't** require that every single person who would be subject to regulations *but for an exemption* also file paperwork with the agency. For example:

- Businesses must pay sales tax on most items that they sell to consumers within the state. Businesses that sell only items that are not subject to sales tax, such as most food items, *do not file anything* with the Comptroller.
- Employers with 50 or more employees must provide their employees with up to 12 weeks of unpaid leave annually under the Family Medical Leave Act. Employers who are exempt because of their size *do not file anything* with the Department of Labor.
- Retailers with annual gross sales of less than $500,000 are exempt from the nutrition labeling requirements of the Federal Food, Drug, and Cosmetic Act *without filing anything* with the Food and Drug Administration.

Presumably, the Texas Comptroller, the DoL, and the FDA would all find it easier to enforce the law if every single business filed paperwork with them each year that provided the information needed to determine whether or not that business was exempt. But that's not how any of these laws work.

Under these laws, and FSMA, the statute sets out who is subject to the requirements. Individuals and businesses read the law and determine whether they are exempt or not. They don't have to apply to an administrative agency to approve their exemption.

II. The lack of statutorily mandated registration was intentional

As an administrative agency, TDA has only that authority granted to it by statute. Thus, the simple fact that neither the federal nor the state statutes contain a provision authorizing TDA to

require exempt farms to register with the agency means that the agency lacks authority for mandatory registration and the proposed rule is *ultra vires*.

In this case, however, there is an additional basis to find that the agency has overstepped its authority. FSMA's legislative history and structure provide evidence that the lack of a registration requirement was a deliberate decision by Congress.

At issue in the proposed rule is the application of the qualified exemption, often referred to as the Tester-Hagan amendment for the two Senators who championed it. The qualified exemption is actually two-part provision, both of which exempt small-scale, direct-marketing producers from certain provisions of FSMA.

The first provision addresses the requirements for qualified exemptions from the new Preventive Controls rule, which applies to **"facilities."** Consistent with the 2002 Bioterrorism Act, farms are **not** classified as facilities. *See* 21 USC 350d(c)(1) ("The term 'facility' … does not include farms ….") The 2002 Bioterrorism Act required facilities (but **not** farms) to register with the FDA. *See* 21 USC 350d(a). FSMA added the Preventive Controls requirements to that pre-existing registration provision for facilities. In exempting small-scale facilities from the new Preventive Controls rule, the Tester-Hagan Amendment required the facility to submit a statement to FDA attesting to the fact that he/she/it meets the requirements for the qualified exemption or providing a simplified HARPC plan. *See* 21 USC 350g(l)(2)(B).

In contrast, the Tester-Hagan provision that governs **farms** under the Produce Safety Rule – the only rule that TDA has jurisdiction to implement -- does **not** require registration nor any submittal to the agency. The FSMA language simply sets out which farms are exempt from the new produce safety requirements and requires that the farms provide notification to consumers – but not the government. *See* 21 USC 350h(f). Congress' decision to **not** require exempt producers to register or submit proof of their exemption controls TDA's implementation of the Produce Safety Rule.

The fact that FSMA requires non-exempt facilities to register, but contains no such requirement for non-exempt farms, establishes that no farm (regardless of their size) should be required to register under the Produce Safety Rule.

Consistent with the statutory language and history, the FDA's implementing regulations for FSMA require registration for facilities but not for exempt or qualified exempt farms.

FSMA is not the only statute that has one exemption that requires a filing and another exemption that does not. For example, the Federal Food, Drug, and Cosmetic Act (FFDCA) exempts retailers who gross less than $500,000 annually from the nutrition labeling requirements. That exemption is found in section 343(q(5)(d) of the statute, which makes no mention of any filing requirements – and the FDA's implementing regulations similarly do not require any filing for those exempt retailers. The FFDCA has another exemption, for businesses that employ fewer than 100 full-time employees and sell fewer than 100,000 units of that food item in the U.S. annually. The statute provides that, to qualify for that exemption, the business must file an annual notice with FDA. *See* 343(q)(5(E)(i)(III). This example illustrates how the agency's

implementation of an exemption should reflect the statutory requirement – or lack of requirement – for a mandatory filing.

III. Registration is not necessary to properly enforce FSMA

As noted above, the agency's justification for requiring registration of qualified exempt farms is to make it easier to enforce the law on those farms that are not exempt. But, in practical terms, identifying non-exempt farms should not pose a major challenge for the agency.

At an informal meeting in April, FARFA and other organizations discussed how the agency could identify non-exempt farms. Since the non-exempt farms will be of a significant size (over half a million in gross sales annually) and/or selling a significant amount through wholesale channels, it will not be difficult to identify the operations that are likely to be non-exempt.

Once the size of the farm and/or the presence of a significant amount of its produce in wholesale channels raises a reasonable concern, FARFA agrees that the agency has authority to request that the farm produce its paperwork to support its claim of exemption.

Under section 11.40(a) of the proposed rule, the agency has the right to enter a farm during normal business hours to conduct an inspection to determine whether or not the farm is exempt. FARFA agrees that such inspections are allowed under FSMA. This provision of the proposed rule provides the tool needed to address the agency's concern about properly identifying non-exempt farms **without** requiring **all** qualified exempt farms to register with the agency and submit their paperwork.

IV. The documentation provisions are unclear and will waste limited government resources

Not only has TDA improperly claimed authority to conduct a "pre-assessment review" to determine whether a farm is qualified exempt or not, but the agency's rule provides no concrete information as to how this review will be done. The agency states that qualified exempt farms will have to "reaffirm eligibility" biennually – but how? What documents will farmers be required to submit?

This is not only a problem for the farmers, but also for government efficiency. TDA's division for produce safety has a total of 8 employees. Eight people are tasked with implementing all of the provisions of the Produce Safety Rule throughout Texas. That small staff cannot do a meaningful review of documents from hundreds of qualified exempt farms. The result will be that the reviews will be haphazard and subjective, creating uneven and arbitrary enforcement while wasting staff time that would be better spent on education or substantive inspections.

V. The proposed rule improperly seeks to shift the burden of proof to the farmer rather than TDA

Compounding the problem with the proposed mandatory registration is TDA's intended response. The proposed rule provides that if a farm fails to submit the required paperwork within 60 days of the deadline every other year, the agency will automatically do an inspection with the presumption that the farm is **not** exempt and is subject to the substantive requirements of the Produce Safety Rule. *See* proposed 4 TAC §11.21(c).

Neither FSMA nor HB 3227 creates such a presumption, and TDA cannot legally create one. **As with any law, the burden lies with the government to prove that an individual violated the law.** The agency cannot "bootstrap" one violation into another, claiming that the failure to comply with one requirement (filing paperwork) creates a presumption that the individual is violating another law.

Yet that would be the practical effect of this provision. The requirements of the Produce Safety Rule are vast and costly. They cover employee training, facilities and equipment, irrigation water testing, what types of soil amendments can be used and how, and much more. In practical terms, it is certain that almost no exempt farm would be in full compliance with these regulations. Thus, the effect of creating the presumption that an exempt farm is not exempt (because it failed to file the required paperwork) would be to find that the farm had violated the Produce Safety Rule's substantive provisions.

As discussed above, the proposed requirement to submit paperwork every other year is beyond the agency's authority. But even assuming for argument's sake that the agency can legally require such registration, it still cannot use that requirement to inspect farms who **are** exempt from the Produce Safety Rule and impose fines and enforcement actions as if they were not exempt.

VI. The "right of entry" provisions are ambiguous and overbroad, as applied to qualified exempt farms

The proposed rule has three different provisions for "right of entry" onto farms. The first provides that the agency can enter any farm growing produce during normal business hours to determine coverage and/or verify exemptions to the Produce Safety Rule. *See* proposed 4 TAC §11.40(a). This is consistent with the provisions of FSMA.

The proposed rule then provides that the agency may enter a covered **or qualified exempt** farm to "conduct inspections." *See* proposed 4 TAC §11.40(b). But a qualified exempt farm is only subject to inspections to confirm its exemption. These inspections are covered by 11.40(a), and should only be used to confirm that the farm is keeping the required paperwork necessary for the exemption. Qualified exempt farms are **not** subject to inspections that address the numerous substantive provisions of the Produce Safety Rule. **Thus, section §11.40(b) should be limited to covered farms only.**

The proposed rule then claims even broader right of entry powers for the agency based on "egregious conditions," which FARFA objects to for the reasons set out next.

VII. The "egregious conditions" provisions are vague, overbroad, and subjective

The TDA's proposed rule also includes novel provisions for inspections and enforcement actions based on "egregious conditions." Specifically, the agency claims that it can enter the premises of any farm (including exempt farms) "to conduct an inspection in response to an egregious condition." *See* proposed 4 TAC § 11.40(c). The agency also claims that it can issue a "stop sale order," halting the sale of perishable produce, "upon a finding of an egregious condition." *See* proposed 4 TAC § 11.42(a).

The term "egregious condition" does not appear anywhere in the relevant federal or state statutes or regulations.

Rather, this term is apparently found in the "On Farm Readiness Review" manual, a document prepared by FDA and some state departments of agriculture. The OFRR manual was prepared without public input, is not even available to the public at this time, and can be changed by the agencies at any time without any notice or process. Moreover, the on farm readiness reviews are designed as non-regulatory actions, to help farmers identify changes they need to make in order to come into compliance. The OFRR is a voluntary "conversation" between the grower and a reviewer. https://www.nasda.org/foundation/food-safety-cooperative-agreements/on-farm-readiness-review. Yet TDA is proposing to enshrine the term in regulations, and claim authority to enter any farm at any time and to stop sales from any farm based on this vague term.

Federal law already sets the standards for regulatory actions such as inspections or the recall of food. The Federal Food, Drug, and Cosmetic Act, which FSMA amended, bars the sale of adulterated food. *See* 21 USC §331. FDA's regulations implementing FSMA specifically provide that the requirements of the Produce Safety Rule apply in determining whether food is "adulterated." *See* §112.192(b). The FFDCA also sets out the grounds and procedures for seizing items of food offered for sale, including placing an administrative restraint or detention order. *See* 21 USC § 334. The federal law also set out when and under what conditions food producers can be inspected. *See* 21 USC §374.

At an informal meeting with TDA in April, FARFA and several other organizations explained our concerns about the regulatory use of the phrase "egregious conditions." We discussed, at length, how ambiguous and subjective the term was. TDA staff provided several specific examples of the agency would consider "egregious conditions," such as having a dead animal next to the water source used to irrigate or wash producer. We agreed with those specific examples, but pointed out that the proposed rule language dis not provide a clear standard and could be used to penalize farms with far less obvious or severe problems. The organizations and TDA staff discussed including a non-exhaustive list of examples of "egregious conditions" in the revised proposed rule, so as to provide some level of clarity and objectivity.

But the only change TDA made to the December 2018 proposed rule was to move the exact same words defining "egregious conditions" from the body of the proposed rule into the definitions section. This does **nothing** to make the term less ambiguous or prevent abuse.

TDA lacks the legal authority to create a new standard, nor is it a logical way for TDA to implement the Federal Produce Safety Rule; the federal standard should and does control. The fact that the proposed term is so broad and open to subjective interpretation, combined with the lack of public process in its development, means that the proposed provisions are not only unnecessary but also affirmatively harmful for producers.

VIII. The penalty provisions for failure to allow an inspection are still excessive

FARFA raised multiple concerns about the penalty provisions in the December 2018 proposed rule, and the agency has addressed most of those.

Two concerns remain:

1) The penalty provisions related to "egregious conditions." While the amount of the proposed penalties has been reduced, FARFA is concerned about the ambiguity and subjectivity of the term "egregious conditions," and thus its use to justify increased penalties.
2) The proposed rule provides for a penalty for the "failure to allow inspection," on a per day basis. As discussed above, the agency's proposed provisions for inspections of qualified exempt farms go beyond its authority under FSMA – both in terms of the scope of the inspection and the timing. As a result, a reasonable farmer who has a qualified exemption very well may object to the agency's claim that it can inspect his or her farm for compliance with the substantive portions of the Produce Safety Rule and/or that the agency could come onto his or her farm at any time. Yet, even if the farmer has reasonable grounds for the objection, he or she could face a fine of $500 the first day, $1,000 the second day, and $1,500 per day after that. In the space of just one week, while the farmer attempts to determine whether he or she really is required to comply with apparently excessive agency demands, the fines could cumulatively come to $9,000.

IX. Appeal provisions

In responses to the December 2018 proposed rule, another organization raised concerns about the lack of a provision for appeals. This concern was discussed at the April 2019 meeting, but the new proposed rule still lacks any provision for farmers to appeal. Particularly given the ambiguous and subjective provisions governing "egregious conditions," as well as the agency's claim to have authority to do pre-approval of a claim of qualified exemption, an appeal process is needed.

In particular, for any farm subject to a stop sale order, the timing of an appeal is vital. Since produce is perishable, a stop order quickly creates financial losses. Standard court appeal procedures are insufficient. The agency should create a process through which a stop sale order

is reviewed by senior agency officials within 48 hours, with an opportunity for the farmer to provide arguments and/or evidence as to why the stop order is not warranted. Normal court appeals would still be available, but an expedited process sis vital to prevent severe financial losses based on the opinion of a single inspector.

X. Comparison to December 2018 proposed rule

Below is a chart comparing the original proposed rule to the revised proposal, based on the concerns FARFA and other organizations raised in writing and at the meeting.

Issue	Topic	Dec 2018 proposal	June 2019 proposal	Notes
Exempt farms (those grossing <$25K annually)	Registration	Annual "Farm Inventory Survey" required these farms to register with the agency each year	Provision for survey removed	TDA has addressed our concern
Qualified exempt farms	Registration	Annual "Farm Inventory Survey"	Provision for survey removed.	Although the survey provision is deleted, **qualified exempt farms are still effectively required to register** given the provisions for pre-assessment review and biennial verifications.
	Pre-assessment review	"TOPS shall conduct a pre-assessment review to determine whether a farm is covered by the Produce Safety Rule and/or eligible for a Qualified Exemption"	"TOPS **may** conduct…." (remainder is identical)	The change benefits TDA, not the producers. The agency is relieved of the responsibility to conduct a review on every farm – yet it continues to require every farm to submit documentation and be subject to such review at TDA's discretion.
	Verification	"Verification of eligibility" conducted annually	"Verification of exemption" conducted every other year,	Problems: 1) Qualified exempt farms are not required to submit

			otherwise identical	documentation to the agency on a proactive basis under FSMA, and TDA should not add the requirement 2) The proposed rule contains **no** guidance as to what the farmers will have to submit. **How** will they "affirm" their eligibility? What documents will be required? We raised these specific concerns with TDA, and the agency has made no changes to address them
	Inspection authority	"At any time", TOPS reserves the right to schedule an on-site visit to verify whether a farm is exempt, covered, or eligible for Qualified Inspection	Identical	This provision is appropriate – and because of this authority, TDA does **not** need to have every farm affirmatively submit documentation. At our meeting in April, an agency staffer suggested a compromise under which the agency would only seek documentation from those farms that it had some reason to believe were not exempt. We agreed that would be reasonable – and this provision is all that is needed to implement that solution.
	Burden shifting	Failure to return a qualified exemption verification form "shall result in a	Identical	This provision is an illegal attempt to shift the burden to farmers simply for failing to submit paperwork (that

		presumption by TOPS that the farm is subject to all requirements of the Produce Safety Rule and this chapter"		they should not be required to submit in the first place). Conducting an inspection of an exempt farm under the presumption that the farm has to comply with all the provisions of the Produce Safety Rule will inevitably lead to citations and fines (because the rule's requirements are so broad and costly that no exempt farm is going to comply with all of them).
"Egregious conditions"	Definition	The provisions for stop sales defined an egregious condition as "a practice, condition or situation on a farm or in a covered location that is reasonably likely to lead to: (1) serious adverse health consequences to, or death of, a human from the consumption or exposure to covered produce; or (2) an imminent public health hazard if correction action is not taken immediately."	Definitions section defines egregious condition as "a practice, condition or situation on a covered farm or in a packing facility that is undertaken as part of a covered activity that is reasonably likely to lead to: (1) serious adverse health consequences or death from the consumption of or exposure to covered produce; or (2) an imminent public health hazard."	Our objection was to the vague, broad definition that leaves too much discretion to individual inspectors and the agency. Using effectively the same words and shifting it to the "definitions" section does not address that concern at all. As we discussed with TDA, this is not a term found in FSMA or in any FDA regulation, but only the informal documents addressing on-site consultations. Making it a regulatory term, with significant consequences, creates both new burdens and greater ambiguity.
Right of entry	General inspections	TDA can enter farms, including	This provision has been split	We agree that TDA should be able to inspect

		qualified exempt farms, during normal business hours, to examine records or to conduct inspections	into two parts, but the substance remains the same	the records and location of a qualified exempt farm **in order to confirm that it is exempt.** Broader inspections are not provided for under FSMA, and the TDA's provisions are too broad.
	Egregious conditions	TDA may enter any farm, including exempt and qualified exempt farms, "at any time" if there are egregious conditions	No substantive change (minor re-ordering of the words)	This is not included in FSMA and is beyond the agency's authority. It is also confusing and unnecessary, since FSMA has provisions for how to deal with emergency situations
Penalties	General	Very high penalties, including for actions that don't pose a public health risk	More reasonable penalties.	The agency addressed most of our concerns about the penalty structures, except for the provision mentioned next.
	Failure to allow inspections	1st offense for "failure to allow" was a warning; 1st offense for "refusal to allow" was $1,000	Only addresses "failure to allow". 1st offense is a fine of up to $500. The penalties go up on the 2nd and 3rd days and continue to accrue on a daily basis.	Abolishing the distinction between a "failure to allow" and a "refusal to allow" an inspection is a positive step that addressed one aspect of our concerns. But making it a $500 penalty for the very first failure -- especially when the agency is claiming authority to inspect even qualified exempt farms at any time – is still too high and potentially abusive. Many smaller farms may have a reasonable basis believe that the agency does not have

				authority to come onto their property at any time or to conduct inspections of the day to day operations, yet not allowing such an inspection at the very first request of the agency would not mean being subject to fines.
Appeals		No mention	No mention	At the April meeting, we requested that TDA outline procedures for farmers to appeal, particularly the vague and subjective findings of an egregious condition. The agency made no changes to address this concern.

XI. Conclusion

While FARFA generally supports the TDA in overseeing implementation of the federal Produce Safety Rule in Texas, such implementation should be limited to the terms of the federal rule. We thus object to requiring qualified exempt farms to register with the agency. Moreover, rather than claim broad new powers to inspect qualified exempt farms without probable cause or to stop sales from farms using the vague term "egregious conditions," the agency's rule should reflect the federal statutory and regulatory standards.

If you have any questions, please contact me at Judith@FarmAndRanchFreedom.org

Sincerely,

Judith McGeary
Executive Director
Farm and Ranch Freedom Alliance