Examining Two Sides of Food System Challenges: A Case Study of the Potential Impacts of the Food Safety Modernization Act on U.S. Produce Growers and a Descriptive Analysis of the International Food Certification Industry

Kathryn E. Lynch
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EXAMINING TWO SIDES OF FOOD SYSTEM CHALLENGES: A CASE STUDY OF THE POTENTIAL IMPACTS OF THE FOOD SAFETY MODERNIZATION ACT ON U.S. PRODUCE GROWERS AND A DESCRIPTIVE ANALYSIS OF THE INTERNATIONAL FOOD CERTIFICATION INDUSTRY

A Thesis Presented

by

KATHRYN E. LYNCH

Submitted to the Graduate School of the University of Massachusetts Amherst in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

September 2016

Resource Economics
EXAMINING TWO SIDES OF FOOD SYSTEM CHALLENGES: A CASE STUDY OF THE POTENTIAL IMPACTS OF THE FOOD SAFETY MODERNIZATION ACT ON U.S. PRODUCE GROWERS AND A DESCRIPTIVE ANALYSIS OF THE INTERNATIONAL FOOD CERTIFICATION INDUSTRY

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Department of Resource Economics
The Food Safety Modernization Act (FSMA) represents a major change to U.S. food policy. Because several FSMA rules require that covered businesses comply with standards by 2019 at the latest, the legislation is expected to have considerable effects on the U.S. food system in the near future. This research examines potential challenges associated with two different FSMA rules. The first essay uses farm-level data from the 2012 Census of Agriculture to estimate the number of farms and acres covered by the FSMA Final Rule on Produce Safety in the California, the Northeast, and the entire U.S. Industry information and interviews with stakeholders are assessed in conjunction with the Census data to hypothesize how farms in two distinct U.S. production regions, California and the Northeast, will fare under the rule. For the second essay, we developed unique datasets containing information on 425 food certification standards and 581 certification bodies. The certification data is used to develop a descriptive analysis of patterns in the international food certification industry. We show how offices of certification bodies that offer food safety certification services are distributed geographically, which serves as a basis for assessing international auditing capacity under the FSMA Final Rule on Accredited Third-Party Certification.
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CHAPTER 1
INTRODUCTION TO TWO ESSAYS ON FOOD SAFETY

This work examines two different aspects of the evolution of food safety efforts, with a focus on the Food Safety Modernization Act (FSMA). The essay in Chapter 2 estimates the number of U.S. farms and acres that are covered by the FSMA Final Rule on Produce Safety. Chapter 2 also discusses the potential impacts of this legislation on two distinct U.S. production regions, California and the Northeast, relative to U.S. farms outside each region. The essay in Chapter 3 describes the international food certification industry and provides a basis for assessing the capacity of food safety auditing services under the FSMA Final Rule on Accredited Third-Party Certification.

FSMA was signed into law in January of 2011. The legislation represents the most dramatic change to the Food and Drug Administration’s (FDA) food safety policies since 1938 (Hoffmann, 2011). FSMA aims to refocus FDA food safety efforts on preventative measures, rather than assessing food safety problems after outbreaks have already occurred. FSMA is composed of several rules that regulate different areas of the food system. As of August 2016 the FDA has finalized 11 FSMA rules, which mandate standards for a wide range of processes such as food imports, transportation of food, and food manufacturing (FDA, 2016 a).

While the specific compliance dates vary for each rule, FSMA requires that covered businesses comply with standards by 2019 at the latest in most cases (PMA, 2016). Therefore, the legislation will likely have considerable effects on the food system in the very near future, as food producers may have to change practices or institute new
processes in order to comply. This research assesses two different areas of food production: fruit and vegetable farms in the U.S. and the international food certification industry. Describing patterns and potential challenges in these areas contributes to an understanding of how FSMA may impact the food system.
CHAPTER 2

THE PRODUCE RULE PORTION OF THE FOOD SAFETY MODERNIZATION ACT: ANALYZING POTENTIAL IMPACTS ON FARMS IN THE NORTHEAST AND CALIFORNIA BY SIZE AND ATTRIBUTE

2.1 Introduction and Motivation

The Centers for Disease Control and Prevention (CDC) has estimated that 46% of foodborne illnesses that occurred from 1998 to 2008 were caused by contaminated produce. Contaminated produce commodities account for 38% of hospitalizations and 23% of deaths associated with foodborne illness (Painter et al., 2013). Recent widely publicized foodborne illness outbreaks and food product recalls have prompted an increased focus on food safety in both regulatory agencies and the market. In this work, we discuss recent food safety legislation and its potential impacts on fruit and vegetable producers.

In October of 2015, the FDA finalized the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption portion of FSMA. These standards regulate the fruit and vegetable industry and are commonly referred to as the Produce Rule (Calvin, 2013).

Certain farms are not covered by the Produce Rule or may qualify for exemptions. Farms with $25,000 or less in annual produce sales are not covered by the rule. Farms that only grow commodities defined by the FDA as “rarely consumed raw” are also excluded from coverage. Additionally, the Tester-Hagan Amendment determines whether produce growers can qualify for an exemption to Produce Rule coverage: Farms with less than $500,000 in annual food sales qualify for an exemption if the majority of food (by
value) is sold directly to qualified end-users. Qualified end-users include consumers, and also restaurants or retailers that are located in the same state, or within 275 miles of the farm (FDA, 2014a). Food sales differ from produce sales in that all items intended for human consumption are included.

Small farms and proponents of local food systems argue that FSMA exemptions provide an important alternative for growers who may not be able to comply with the regulations due to restrictions based on farm size, while critics argue that FSMA exemptions imply that food produced by smaller farms is inherently safer, which has not been proven by scientific research (Beyranevand, 2013). The question of who may be exempt from complying with the proposed Produce Rule is of interest to many different stakeholders. Smaller farms that will not qualify for the exemption are worried that they may be disproportionately burdened by costs associated with implementing the legislation (Adalja and Lichtenberg, 2015). Larger growers who will be required to comply with the rule are concerned that they would face economic losses if an exempt grower of the same commodity were the source of an illness outbreak. Given these concerns, it is important to develop an understanding of how many farms may be exempt from FSMA, and how current characteristics and production practices may define challenges associated with FSMA compliance for non-exempt farms.

In this analysis, we use farm-level data from the National Agricultural Statistics Service 2012 Census of Agriculture to estimate how many farms qualify for FSMA exemptions across regions. We also use Census data regarding farm practices and characteristics with potential implications for FSMA compliance to determine how grower attributes in California and the Northeast differ from those in the rest of the
nation. These practices and attributes include on-farm packing, value added production, direct marketing, manure use, and labor characteristics. We use information on the frequency of these attributes to make inferences on how FSMA will impact producers of different sizes in these regions, relative to those in the rest of the U.S.

2.2 Relevant Literature

Recent literature has explored the costs associated with implementing food safety programs and practices for produce farms of different sizes. Larger farms appear to face less burdensome food safety costs.

A study by Adalja and Lichtenberg (2015) uses survey data for fruit and vegetable growers across the U.S. to examine how costs of adopting food safety practices vary by farm size and practices. Their research concludes that many growers will have to make large organizational changes to meet the requirements of the Produce Rule, and that small and sustainability-focused growers will face disproportionately high costs, unless they take the Tester-Hagan exemption.

A 2012 study by the University of Minnesota collected data via in-person and telephone interviews with small and mid-sized vegetable growers (Driven to Discover, 2012). The information was used to estimate the costs of implementing good agricultural practices on 4 farms. This research also finds that economies of scale are a factor in food safety costs. Small Minnesota farms would incur compliance costs equal to 10% of gross revenue, while mid-sized farms would face lower costs at around 2% of gross revenue. The most notable sources of increased costs were labor associated with maintaining sanitation of rinse water, and cleaning and sanitizing packing sheds.
An analysis of the Leafy Greens Marketing Agreement (LGMA) by Hardesty and Kusunose (2009) surveyed growers in California to get a sense of program compliance costs (2009). The authors found that the amount of money growers spent on food safety practices more than doubled after adoption of the LGMA. Growers with over $10 million in revenue were best able to absorb costs associated with food safety programs due to economies of scale. Common changes that growers made as a result of the LGMA included installing new fences to mitigate wildlife intrusion, and modifying toilet and hand washing facilities for growers. Medium-sized growers faced higher seasonal food safety costs per acre than larger growers. The authors could not draw conclusions on costs for smaller growers because there were a limited number of survey respondents with farm income under $1 million. They assert that the U.S. grocery sector is highly consolidated, and as a result leafy green growers could not obtain higher prices after implementing the LGMA.

2.3 Methodology of Report

2.3.1 Farm Size Definitions

In this analysis, we divide produce farms into sales categories based on sales definitions for FSMA coverage and exemptions. Sales figures come from the 2012 Census of Agriculture. Information on the Census questions used in our analysis is available in Appendix A. The categories are defined as follows:

**Category 1:** Produce farms with $25,000 or less in produce sales. These farms are not covered by the Produce Rule.

**Category 2:** Produce farms with over $25,000 in produce sales, but less than $500,000 in *food* sales. Some of these farms may qualify for an exemption, if the majority of their sales are to qualified end users. Within this category, we further estimate the proportion
of farms that will qualify for the direct sales exemption. We make a distinction between produce and food sales to mirror the coverage guidelines of the legislation.

**Category 3:** Produce farms with $500,000 and up in food sales. These farms will have to comply with the Produce Rule.

### 2.3.2 Regional Definitions and Selections

We divide the U.S. into regions based on production patterns and traditional geographic divisions to estimate the number of farms exempt from FSMA compliance in each. In 2012, California accounted for over one third of national vegetable production and nearly two-thirds of national fruit and nut production (NASS, 2013). Since California is such a significant producer of fruits and vegetables, we analyze the state’s production separately rather than include it in a larger region. Our regions are defined as follows:

**California**

**Central Atlantic:** Virginia, North Carolina, South Carolina, Maryland, Delaware

**Midwest:** Michigan, Ohio, Indiana, Illinois, Wisconsin, Minnesota

**Northeast:** Maine, Vermont, New Hampshire, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania

**Northwest:** Idaho, Washington, Oregon

**Southeast:** Alabama, Florida, Georgia, Mississippi

**Southwest:** Arizona, New Mexico, Texas

**Other States and Territories:** Alaska, Arkansas, Colorado, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Missouri, Montana, Nebraska, Nevada, North Dakota, Oklahoma, South Dakota, Tennessee, Utah, West Virginia, Wyoming, Puerto Rico

After considering the results of our descriptive analysis for each of the regions above, we decided to focus this report on produce farms in California and the Northeast.
Both of these regions are distinct from the rest of the U.S. in terms of fruit and vegetable production, and further, they represent opposite ends of the spectrum when considering several different organizational characteristics. We discuss some initial observations on each of these regions below to emphasize why they were selected.

We compare attributes of California farms with those in the rest of the U.S. excluding California, and attributes of farms in the Northeast with those in the U.S. excluding the Northeast to highlight the unique characteristics of each region. We do not compare farms from one region with U.S. farms excluding those in both regions (for example, comparing California farms with U.S. farms excluding those in California and the Northeast) because 43% of U.S. farms with covered produce are in California or the Northeast. Thus, creating a category for U.S. farms excluding those in both California and the Northeast would exclude many farms and would not be as meaningful for our analysis.

2.3.2.1 California

On the following page, Table 1 displays a summary of the number of growers, produce acreage, produce sales, and number of workers for growers of commodities that are subject to the Produce Rule in California. We display these numbers next to the corresponding figures for the rest of the U.S. excluding California. We display these figures for each of the sales value categories, and all growers.
Table 1: Description of California farms and other U.S. farms with covered produce sales in 2012, by sales category

<table>
<thead>
<tr>
<th></th>
<th>≤ $25,000 in produce sales</th>
<th>&gt; $25,000 in produce sales, &lt; $500,000 in food sales</th>
<th>≥ $500,000 in food sales</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of growers (CA)</td>
<td>16022</td>
<td>16734</td>
<td>6199</td>
<td>38955</td>
</tr>
<tr>
<td>Number of growers (U.S. excluding CA)</td>
<td>65573</td>
<td>20675</td>
<td>6788</td>
<td>93036</td>
</tr>
<tr>
<td>% of total growers in category (CA)</td>
<td>41.1%</td>
<td>43%</td>
<td>15.9%</td>
<td>100%</td>
</tr>
<tr>
<td>% of total growers in category (US excl. CA)</td>
<td>70.5%</td>
<td>22.2%</td>
<td>7.3%</td>
<td>100%</td>
</tr>
<tr>
<td>Number of acres in produce (CA)</td>
<td>62,005</td>
<td>551,019</td>
<td>3,445,510</td>
<td>4,058,534</td>
</tr>
<tr>
<td>Number of acres in produce (US excluding CA)</td>
<td>205,862</td>
<td>662,804</td>
<td>2,595,857</td>
<td>3,464,523</td>
</tr>
<tr>
<td>% produce acres in category (CA)</td>
<td>1.5%</td>
<td>13.6%</td>
<td>84.9%</td>
<td>100.0%</td>
</tr>
<tr>
<td>% produce acres in category (US excluding CA)</td>
<td>5.9%</td>
<td>19.1%</td>
<td>74.9%</td>
<td>100.0%</td>
</tr>
<tr>
<td>Number of workers (CA)</td>
<td>18,697</td>
<td>64,848</td>
<td>272,534</td>
<td>356,079</td>
</tr>
<tr>
<td>Number of workers (U.S. excluding CA)</td>
<td>64,278</td>
<td>147,832</td>
<td>354,159</td>
<td>566,269</td>
</tr>
<tr>
<td>Produce sales as % of total value of production (CA)</td>
<td>79.5%</td>
<td>97%</td>
<td>84.5%</td>
<td>85.5%</td>
</tr>
<tr>
<td>Produce sales as % of total value of production (U.S. excluding CA)</td>
<td>38.9%</td>
<td>79.7%</td>
<td>64.1%</td>
<td>64.6%</td>
</tr>
<tr>
<td>Average produce acreage (CA)</td>
<td>3.9</td>
<td>32.9</td>
<td>555.8</td>
<td>104.2</td>
</tr>
<tr>
<td>Average produce acreage (U.S. excluding CA)</td>
<td>3.1</td>
<td>32.1</td>
<td>382.4</td>
<td>37.2</td>
</tr>
</tbody>
</table>

Source: Figures computed using 2012 Census of Agriculture data

Table 1 shows that California growers of covered produce are more highly concentrated in the 2 upper sales value categories relative to producers outside of the state. In California, only 41% of covered produce growers have $25,000 or less in produce sales, while 70% of non-California growers fall into this category. This indicates that California farms are less likely to be excluded from Produce Rule coverage based on low sales. The industry reports that very small farms are less common in California, and that these growers are more likely produce for the local market exclusively. Thus, California growers who do earn $25,000 or less in produce sales may not face the same
market pressure to enhance food safety practices as growers who sell to large distributors and national retailers.

Table 1 also shows that the total acreage of covered produce in California (4,058,533.7) is higher than the total covered produce acreage in the rest of the U.S. (3,464,522.7). Average produce acreage is slightly higher for California farms in the lower 2 sales categories, and much higher in the top sales value and total category. Further, California growers have a higher share of produce sales as a percentage of total farm sales across all sales categories. For example, considering totals for all growers, Table 1 shows that produce sales comprise 85.5% of total farm sales for California growers of covered produce. The corresponding figure for the rest of the country is lower, at 64.6%. This indicates that California growers of covered produce are more specialized in production and less likely to earn sales from other farm activities.

Given these observations, it appears that California fruit and vegetable farms are larger, more likely to have higher sales, and more specialized in growing produce than farms in the rest of the country. Next, we note how these attributes differ from those of the Northeast.

2.3.2.2 The Northeast

Table 2 displays a summary of the number of growers, produce acreage, produce sales, and number of workers for growers of covered produce in the Northeast. As with the previous table, we display these numbers next to the corresponding figures for the rest of the U.S. excluding the Northeast, to emphasize regional differences.
Table 2: Description of Northeast farms and other U.S. farms with covered produce sales in 2012, by sales category

<table>
<thead>
<tr>
<th>Sales Category</th>
<th>Number of Growers (NE)</th>
<th>Number of Growers (U.S. excluding NE)</th>
<th>% of Total Growers in Category (NE)</th>
<th>% of Total Growers in Category (US excluding NE)</th>
<th>Number of Acres in Produce (NE)</th>
<th>Number of Acres in Produce (US excluding NE)</th>
<th>% Produce Acres in Category (NE)</th>
<th>% Produce Acres in Category (US excluding NE)</th>
<th>Number of Workers (NE)</th>
<th>Number of Workers (U.S. excluding NE)</th>
<th>Average Produce Sales as % of Total Value of Production (NE)</th>
<th>Average Produce Sales as % of Total Value of Production (U.S. excluding NE)</th>
<th>Average Produce Acreage (NE)</th>
<th>Average Produce Acreage (U.S. excluding NE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ $25,000 in produce sales</td>
<td>12131</td>
<td>69464</td>
<td>67.9%</td>
<td>60.9%</td>
<td>37887</td>
<td>229981</td>
<td>8.5%</td>
<td>3.3%</td>
<td>11,605</td>
<td>71,370</td>
<td>29.2%</td>
<td>48.7%</td>
<td>3.1</td>
<td>3.3</td>
</tr>
<tr>
<td>&gt; $25,000 in produce sales, ≤ $500,000 in food sales</td>
<td>4707</td>
<td>32702</td>
<td>26.3%</td>
<td>28.7%</td>
<td>139399</td>
<td>1074424</td>
<td>31.3%</td>
<td>15.2%</td>
<td>26,146</td>
<td>18,653</td>
<td>76.8%</td>
<td>89.3%</td>
<td>29.6</td>
<td>32.9</td>
</tr>
<tr>
<td>≥ $500,000 in food sales</td>
<td>1033</td>
<td>11954</td>
<td>5.8%</td>
<td>10.5%</td>
<td>268495</td>
<td>5772871</td>
<td>60.2%</td>
<td>81.6%</td>
<td>33,639</td>
<td>59,3054</td>
<td>65.4%</td>
<td>76.6%</td>
<td>259.9</td>
<td>482.9</td>
</tr>
<tr>
<td>Total</td>
<td>17871</td>
<td>114120</td>
<td>100.0%</td>
<td>100.0%</td>
<td>445781</td>
<td>7077276</td>
<td>100.0%</td>
<td>100.0%</td>
<td>71,390</td>
<td>850958</td>
<td>63.8%</td>
<td>77.1%</td>
<td>24.9</td>
<td>62.0</td>
</tr>
</tbody>
</table>

Source: Figures computed using 2012 Census of Agriculture data

Northeast growers of covered produce are more highly concentrated in the 2 lowest sales value categories. Table 2 shows that 67.9% of Northeast growers of covered produce have $25,000 or less in produce sales, compared to 60.9% of growers in the rest of the country. This signifies that a greater proportion of Northeast produce farms will not be covered by the Produce Rule, based on produce sales. The average produce acreage for Northeast growers of covered produce is slightly lower than the corresponding figure for the rest of the country in the lowest 2 sales categories, and much lower in the highest sales and total categories. Produce sales as a percentage of the total...
value of farm production is lower for Northeast farms across all 3 sales categories and total farms. This indicates that Northeast produce farms are more likely to earn sales from other on-farm activities, and are therefore less specialized in fruit and vegetable production.

Northeast farms with covered produce appear to be smaller, less likely to have higher sales values, and more varied in production than farms in the rest of the U.S. Given the apparent contrast between the structure of Californian and Northeast growers of covered produce, we decided that analyzing these 2 regions would provide an opportunity to discuss the impacts of the Produce Rule on a wide range of growers.

2.3.3 Exclusion of Rarely Consumed Raw Commodities

The Produce Rule is not applicable to growers who only produce fruits and vegetables that the legislation defines as “rarely consumed raw.” Thus, in our analysis, we exclude growers who produce rarely consumed raw fruits and vegetables exclusively. A list of produce commodities defined as rarely consumed raw by the FDA is available in Appendix B. Producers that grow any amount of covered produce are subject to the Produce Rule and therefore included in our analysis.

The Produce Rule covers growers with more than $25,000 in annual produce sales. This sales threshold does not specify the type of produce (rarely consumed raw vs. covered produce). Therefore, a grower who has sales under $25,000 in covered produce but more than $25,000 in total produce, including rarely consumed raw produce, will still be subject to the rule. Farms are only excluded from Produce Rule coverage based on their commodities if all of the produce they grow is defined as rarely consumed raw.
2.3.4 Data

We use farm-level data from the 2012 Census of Agriculture to provide descriptions of the regional distributions of growers, produce acreage, produce sales, and food sales for farms with under $25,000 in produce sales, farms with over $25,000 in produce sales but less than $500,000 in food sales, and farms with $500,000 or more in food sales. We also compare and contrast California and Northeast producers with those in the rest of the U.S.

Our analysis includes growers of most major produce commodities. Produce crops grown in greenhouses are not included. Additionally, a small number of produce commodities such as daikon radishes and cowpeas are excluded from our analysis due to information limitations at the time the analysis was conducted. We expect that these exclusions would have only a nominal effect on our final figures. A complete list of excluded commodities is available in Appendix B.

We also collected information on the California fruit and vegetable industry and current food safety practices and challenges via in-person interviews with growers, distributors, and marketing organizations in the state during the summer of 2015. Information from these interviews helps to inform our conclusions regarding which farm attributes will be supportive of or detrimental to Produce Rule compliance.

2.4 Estimation of the Number of Covered Produce Farms

We perform an estimation of the number of farms that will be covered under the Produce Rule using 2012 NASS Census data. We refer to this process as an “estimation”
rather than a direct count due to inconsistencies between Produce Rule coverage qualifications and the information collected in the 2012 Census, as discussed at the end of this section. Appendix A contains information on the Census questions used in our analysis of the number of covered farms and farm characteristics. Table 3 displays the total number of produce growers and those who are subsequently excluded based on coverage criteria for the United States, California, and the Northeast.

We first determine the total number of produce growers by region (Row i). We then exclude farms who grow produce that the FDA has deemed “rarely consumed raw” (Row ii) and compute the remaining total (Row iii). We exclude growers who will not be covered by the rule due to having annual produce sales under $25,000 (Row iv.) and calculate the remaining total (Row v.). Of the remaining growers, we subtract those who will qualify for an exemption based on the Tester-Hagan amendment (Row vi.). Finally, we compute the total number farms and acreage covered under the Produce Rule (Row vii.).

Table 3: Total produce growers and acreage by region, by exclusion, and covered by the Produce Rule, 2012

<table>
<thead>
<tr>
<th></th>
<th>Entire United States</th>
<th>California</th>
<th>Northeast</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Total</td>
<td>158,632</td>
<td>9,303,478</td>
<td>21,968</td>
</tr>
<tr>
<td>ii. Excluded</td>
<td>(26,641)</td>
<td>(1,780,422)</td>
<td>(4,097)</td>
</tr>
<tr>
<td>iii. Remaining</td>
<td>131,991</td>
<td>7,523,056</td>
<td>17,871</td>
</tr>
<tr>
<td>iv. Excluded</td>
<td>(81,595)</td>
<td>(267,867)</td>
<td>(12,131)</td>
</tr>
<tr>
<td>v. Remaining</td>
<td>50,396</td>
<td>7,255,189</td>
<td>5,740</td>
</tr>
<tr>
<td>vi. Excluded</td>
<td>(3,480)</td>
<td>(79,835)</td>
<td>(1,110)</td>
</tr>
<tr>
<td>vii. Covered</td>
<td>46,916</td>
<td>7,175,355</td>
<td>4,630</td>
</tr>
</tbody>
</table>
2.4.1 Total Produce Farms

First, we consider the total number of produce farms in the U.S. Using the Census data, we computed the number of U.S. farms with produce sales greater than 0. This figure includes all non-greenhouse fruit and vegetable growers, even those who will not be covered and those who will qualify for exemptions. There are a total of 158,632 produce farms in the U.S. California accounts for 40,212 of these farms while the Northeast accounts for 21,968. U.S. farms comprise a total of 9,303,478 acres of produce, while California and the Northeast account for 4,117,864 and 630,510 acres, respectively.

2.4.2 Excluding Growers of Rarely Consumed Raw Produce

Next, we exclude farms that only produce fruits and vegetables that have been defined as “rarely consumed raw” by the legislation. For example, a farm that only grows potatoes would not be covered by the Produce Rule. According to our analysis, 26,641 U.S. farms grow only rarely consumed raw commodities, and thus will be excluded from Produce Rule coverage. This reduces our total number of potentially covered U.S. produce growers from 158,632 to 131,991. Similarly, this coverage qualification omits 1,257 California growers and 4,097 Northeast growers. Farms that grow rarely consumed
raw produce exclusively account for 1,780,422 acres of produce nationwide, with 59,330 and 184,729 acres of produce in California and the Northeast, respectively.

2.4.3 Excluding Growers with Less Than $25K in Total Produce Sales

Excluding growers with $25,000 or less in produce sales drastically reduces the number of growers potentially covered by the Produce Rule by 81,595 farms, from 131,991 to 50,396 farms nationwide. The number of growers for California and the Northeast decrease by 16,022 and 12,131, respectively, when we make this exclusion.

Though excluding growers with $25,000 or less in produce sales dramatically decreases the number of farms who must comply with the Produce Rule, the corresponding decrease in covered produce acreage is relatively minimal. The total produce acreage of the U.S. farms in question declines from 7,523,056 to 7,255,189 acres, which represents a decrease of only 3.5%. On average, U.S. growers with less than $25,000 in produce sales have 3.28 acres of produce. In contrast, the 50,396 remaining growers with more than $25,000 in produce sales have 143.96 acres of produce on average.

In California, excluding growers with $25,000 or less in produce sales omits 62,025 produce acres from Produce Rule coverage, which represents a 1.5% decrease. In the Northeast, excluding these growers results in a 37,887 decrease in covered produce acreage. This is a decrease of 8.5%.

2.4.4 Excluding Growers Who Qualify for Exemption

According to the Tester-Hagan Amendment, growers with less than $500,000 in total food sales who sell the majority of their products directly to consumers or to local
outlets qualify for an exemption to the Produce Rule. The amendment defines “local” sales as sales to businesses in the same state or within 275 miles of the farm. The Census asks growers to report the value of direct sales for human consumption, which includes sales from roadside stands, farmers markets, pick your own operations, door-to-door sales, or CSA’s. We use this number to estimate whether the majority of farm sales are to qualified end-users. Our figures underestimate the number of growers who qualify for the exemption, as businesses within the state or within 275 miles are also defined as qualified end users under FSMA, but are not included in the Census figure for direct sales.

According to our estimation, 3,480 farms would qualify for the exemption under the Tester-Hagan Amendment. These farms comprise 79,835 acres of produce, which is only 0.86% of all U.S. produce acreage, and 1.1% of U.S. produce acreage that is otherwise covered by the Produce Rule. Given the debates regarding the Tester-Hagan Amendment and concerns that exempt farms could potentially be responsible for illness outbreaks, it is important to note that the number of exempt farms and the produce acreage they represent are small compared to the number of covered farms and acreage of covered producers.

2.4.5 Covered Farms

The last row of Table 3 shows the number and produce acreage of farms covered by the Produce Rule. For the United States as a whole, we estimate that 46,916 farms consisting of 7,175,355 produce acres will be covered. In California, 22,413 farms and 3,985,727 produce acres will be covered by the Produce Rule. The Northeast has 4,630 covered farms, comprising 381,355 produce acres.
Figures 1-6 illustrate the distribution of produce farms and acreage by Produce Rule coverage categories for the U.S., California, and the Northeast. They show the number of covered farms, exempt farms, and farms excluded from coverage as a percentage of total farms for the relevant region (Figures 1, 2, and 3), and the distribution of covered produce acreage (Figures 4, 5, and 6). In the U.S., 30% of produce growers and 77% of produce acreage will be covered by the rule. In California, 56% of produce farms and 97% of produce acres will be subject the legislation. In the Northeast, 21% of produce farms and 61% of produce acreage will be covered.

Figure 1: Produce Rule coverage and exemptions for U.S. farms, by number of farms, 2012

![Figure 1 Diagram]

Figure 2: Produce Rule coverage and exemptions for California farms, by number of farms, 2012

![Figure 2 Diagram]
Figure 3: Produce Rule coverage and exemptions for Northeast farms by number of farms, 2012

Figure 4: Produce Rule coverage and exemptions for U.S. farms by produce acreage, 2012

Figure 5: Produce Rule coverage and exemptions for California farms by produce acreage, 2012
Figure 6: Produce Rule coverage and exemptions for Northeast farms by produce acreage, 2012

2.4.6 Coverage Estimation Limitations

Farms that grow produce for personal or on-farm consumption only will not be covered by the Produce Rule. There is nothing in the Census that indicates whether specific produce items are intended for personal consumption, so some of these farms may be mistakenly included in our analysis. However, we do not expect this to have a meaningful effect on our results: We already exclude the farms with under $25,000 in produce sales since they are not covered by the rule, and it seems implausible that there...
are many farms who grow more than $25,000 in produce designated for on-farm consumption only.

Produce that goes through certain commercial processing that “adequately reduces the presence of microorganisms of public health significance” is not covered by the Produce Rule (FDA, 2016 b). As with produce intended for on-farm consumption, we do not have a way of using the Census data to determine whether produce goes through adequate processing, so some farms may be mistakenly included as covered. Additionally, we must consider that farms with i) $25,000 or less in annual produce sales or ii) an average value of $25,000 or less in annual produce sales for the past 3 years are excluded from Produce Rule coverage (FDA, 2016 b). However, we only have information for 1 year of annual produce sales, so we are only able to estimate item i) using the 2012 Census data. Farms who had lower past produce sales values may be mistakenly included in our counts.

2.5 Structure and Practices: Comparing California and the Northeast to U.S. Averages

Tables 4 and 5 compare farm attributes for California and Northeast farms to those in the rest of the U.S. We discuss these figures and their implications for Produce Rule compliance in California and the Northeast in the subsequent sections.

Table 4: Frequency of farm activities and attributes for California and other U.S. growers of fruits and vegetables covered by the Produce Rule, by sales value category, 2012

<table>
<thead>
<tr>
<th>Growers with packing on the farm % of growers (CA)</th>
<th>≤ $25,000 in produce sales</th>
<th>&gt; $25,000 in produce sales, &lt; $500,000 in food sales</th>
<th>≥ $500,000 in food sales</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5%</td>
<td>3.4%</td>
<td>4.9%</td>
<td>4.1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of growers (U.S. excluding CA)</td>
<td>% of growers (CA)</td>
<td>% of growers (U.S. excluding CA)</td>
<td>% of growers (CA)</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>----------------------------------</td>
<td>-------------------</td>
<td>----------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Growers with value-added activities</td>
<td>7.7% 18.4% 19.5% 10.9%</td>
<td>6.2% 6.3% 4.1% 5.9%</td>
<td>13.2% 14.4% 6.9% 13%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>7.7% 18.4% 19.5% 10.9%</td>
<td>6.2% 6.3% 4.1% 5.9%</td>
<td>13.2% 14.4% 6.9% 13%</td>
<td></td>
</tr>
<tr>
<td>Growers with produce marketed directly to retail outlets</td>
<td>18.4% 10.9% 19.2% 12.3%</td>
<td>9.8% 7.5% 6.7% 8.3%</td>
<td>17.3% 26% 17.3% 19.2%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>18.4% 10.9% 19.2% 12.3%</td>
<td>9.8% 7.5% 6.7% 8.3%</td>
<td>17.3% 26% 17.3% 19.2%</td>
<td></td>
</tr>
<tr>
<td>Growers with Community Supported Agriculture (CSA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>2.8% 1.8% 1% 2.1%</td>
<td>6.5% 8.4% 2.8% 6.7%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>2.8% 1.8% 1% 2.1%</td>
<td>6.5% 8.4% 2.8% 6.7%</td>
<td></td>
</tr>
<tr>
<td>Growers with Direct Sales to Consumers</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>25.9% 9.1% 4.5% 15.3%</td>
<td>52.3% 44.8% 20.6% 48.3%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>25.9% 9.1% 4.5% 15.3%</td>
<td>52.3% 44.8% 20.6% 48.3%</td>
<td></td>
</tr>
<tr>
<td>Growers with more than 50% Direct Sales for Human Consumption</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>9.9% 3.1% 0.6% 5.5%</td>
<td>15.8% 14.3% 2.8% 14.5%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>9.9% 3.1% 0.6% 5.5%</td>
<td>15.8% 14.3% 2.8% 14.5%</td>
<td></td>
</tr>
<tr>
<td>Growers who participated in National Organic Program</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>10.5% 7.7% 8.5% 8.95%</td>
<td>9.4% 8.8% 6.0% 9.03%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>10.5% 7.7% 8.5% 8.95%</td>
<td>9.4% 8.8% 6.0% 9.03%</td>
<td></td>
</tr>
<tr>
<td>Growers with livestock on operation</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>17.7% 9.4% 9.8% 12.9%</td>
<td>44.2% 26.1% 28.1% 39%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>17.7% 9.4% 9.8% 12.9%</td>
<td>44.2% 26.1% 28.1% 39%</td>
<td></td>
</tr>
<tr>
<td>Growers who apply manure</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>10.7% 10% 12.7% 10.7%</td>
<td>21.7% 15.9% 18.6% 20.2%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>10.7% 10% 12.7% 10.7%</td>
<td>21.7% 15.9% 18.6% 20.2%</td>
<td></td>
</tr>
<tr>
<td>Growers with migrant labor present</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>2.7% 8.8% 17.9% 7.7%</td>
<td>1.4% 13.7% 35.0% 6.6%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>2.7% 8.8% 17.9% 7.7%</td>
<td>1.4% 13.7% 35.0% 6.6%</td>
<td></td>
</tr>
<tr>
<td>Growers with contract labor present</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>31.0% 59.7% 75.1% 50.3%</td>
<td>11.8% 29.9% 41.3% 17.9%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>31.0% 59.7% 75.1% 50.3%</td>
<td>11.8% 29.9% 41.3% 17.9%</td>
<td></td>
</tr>
<tr>
<td>Growers with full-time operators</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>43.1% 60.4% 82.2% 56.8%</td>
<td>49.7% 71.8% 91.4% 57.7%</td>
<td></td>
</tr>
<tr>
<td>% of growers (U.S. excluding CA)</td>
<td>17.3% 19.2% 19.2% 12.3%</td>
<td>43.1% 60.4% 82.2% 56.8%</td>
<td>49.7% 71.8% 91.4% 57.7%</td>
<td></td>
</tr>
<tr>
<td>Average # of workers per farm (CA)</td>
<td>1.2 3.9 44.0 9.1</td>
<td>1.0 7.2 52.7 6.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average # of workers per farm (US excluding CA)</td>
<td>1.2 3.9 44.0 9.1</td>
<td>1.0 7.2 52.7 6.1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Figures computed using 2012 Census of Agriculture data. **Bold, italicized** values indicate that the difference between the proportions for CA and the rest of the U.S. is statistically significant at the 5% level.

Table 5: Frequency of farm activities and attributes for Northeastern and other U.S. growers of fruits and vegetables covered by the Produce Rule, by sales value category, 2012

<table>
<thead>
<tr>
<th></th>
<th>≤ $25,000 in produce sales</th>
<th>&gt; $25,000 in produce sales, &lt; $500,000 in food sales</th>
<th>≥ $500,000 in food sales</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growers with packing on the farm</td>
<td>1.0</td>
<td>7.2</td>
<td>52.7</td>
<td>6.1</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Activity</th>
<th>% of growers (NE)</th>
<th>% of growers (U.S. excluding NE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of growers with value-added activities</td>
<td>18.0%</td>
<td>10.7%</td>
</tr>
<tr>
<td>% of growers with produce marketed directly to retail outlets</td>
<td>23.9%</td>
<td>14.4%</td>
</tr>
<tr>
<td>% of growers with Community Supported Agriculture (CSA)</td>
<td>10.2%</td>
<td>5.0%</td>
</tr>
<tr>
<td>% of growers with Direct Sales to Consumers</td>
<td>63.1%</td>
<td>44.3%</td>
</tr>
<tr>
<td>% of growers with more than 50% Direct Sales for Human Consumption</td>
<td>19.6%</td>
<td>13.8%</td>
</tr>
<tr>
<td>% of growers who participated in National Organic Program</td>
<td>15.0%</td>
<td>8.7%</td>
</tr>
<tr>
<td>% of growers with livestock on operation</td>
<td>48.5%</td>
<td>37.4%</td>
</tr>
<tr>
<td>% of growers who apply manure</td>
<td>31.8%</td>
<td>17.4%</td>
</tr>
<tr>
<td>% of growers with migrant labor present</td>
<td>0.8%</td>
<td>1.8%</td>
</tr>
<tr>
<td>% of growers with contract labor present</td>
<td>8.8%</td>
<td>16.7%</td>
</tr>
<tr>
<td>% of growers with full-time operators</td>
<td>53.4%</td>
<td>47.5%</td>
</tr>
<tr>
<td>Average # of workers per farm (NE)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Average # of workers per farm (U.S. excluding NE)</td>
<td>5.6</td>
<td>5.7</td>
</tr>
</tbody>
</table>

Source: Figures computed using 2012 Census of Agriculture data. **Bold, italicized** values indicate that the difference between the proportions for CA and the rest of the U.S. is statistically significant at the 5% level. We determined significance by conducting Pearson chi-square tests of the two proportions for each attribute compared across regions. For example, for the first set of figures in Table

The bold and italicized figures in Tables 4 and 5 indicate that the difference between the proportions for each attribute is statistically significant at the 5% level. We determined significance by conducting Pearson chi-square tests of the two proportions for each attribute compared across regions. For example, for the first set of figures in Table...
4, we test the equality between the proportion of California growers with packing on the farm and the proportion of growers with packing on the farm in the rest of the U.S. For these figures, we reject the null hypothesis of equal proportions and conclude that the difference between the proportions of California and non-California growers with on-farm packing is statistically significant. We repeated this process for each set of figures in Tables 4 and 5.

2.5.1 Packing and Value-Added Activities

The Census asks farms whether they have packing facilities or engage in value-added activities (Appendix A, items 4 and 5). Growers with on-farm packing facilities may be required to comply with additional standards under the Produce Rule. For example, they would have to extend the mandated sanitation protocol to packing areas for covered produce. Growers with value-added production may be required to comply with FSMA’s Preventive Controls for Human Food Rule in addition to the Produce Rule (FDA, 2015a). We predict that FSMA will have a more substantial impact on farms that conduct these activities, since they will have to prepare to comply with additional sections of the Produce Rule in the case of packing activities, or with the preventative controls rule in the case of value-added activities.

Overall, both the packing and value added figures indicate that produce farms in California may be more focused on growing activities only, since significantly lower proportions of California farms report conducting packing and value-added activities relative to farms in the rest of the U.S. This is consistent with industry reports of high concentration in the California produce industry: a handful of firms control activities such as packing and marketing for their own operations and other farms. California farms may
therefore have an advantage in complying with FSMA, as they are less likely to face additional regulations on packing and value-added production activities.

According to the 2012 NASS Agricultural Census, 4.46% of California growers with under $25,000 in produce sales have on-farm packing facilities, which is significantly lower than the national average of 7.7% excluding California. The figures begin to diverge more as the sales value categories become larger. In California, the proportion of growers with packing facilities remains relatively low across sales categories 2 and 3 at 3.4% and 4.9% respectively, compared to 18.4% and 19.5% in the rest of the U.S. The proportion of California farms with on-farm packing facilities is significantly less than the corresponding proportion elsewhere in the U.S., both overall and within all sales categories. This may indicate that non-California farms are less specialized in growing, as they are more likely to engage in packing. The lower frequency of packing activities may be an advantage for California growers who comply with the Produce Rule, since they will not have to make changes to packing protocols in addition to their other areas of covered fruit and vegetable production.

In California, there is also a significantly lower proportion of farms with value-added activities overall and in every income category, compared to farms elsewhere in the U.S. Only 6.3% of California farms in the second sales category conduct value-added production, compared to 14.4% of other farms in the nation with similar sale characteristics. Table 4 also shows that only 5.9% of all California farms have value-added activities, which is significantly lower than the remaining national total of 13%. As with the lower frequency of packing activities, the lower frequency of value added activities among California farms presents an advantage for those who will comply with
the Produce Rule: not having to comply with the Preventive Controls Rule may mean that these farms will have more resources to dedicate to implementing Produce Rule measures.

The Northeast figures present a different story regarding packing and value-added production. A significantly larger proportion of growers in the Northeast have on-farm packing facilities than growers outside of the region. This holds overall and within each sales category. Within the 3 sales categories, the proportions of Northeast growers with on-farm packing are 9.7%, 25.3%, and 38.4% respectively, which are significantly higher than the corresponding proportions for the rest of the nation of 6.6%, 9.7%, and 10.3% respectively. Northeast growers who comply with the Produce Rule may therefore be more likely to deal with potential costs associated with taking additional precautions and making changes in packing areas, resulting in an overall more difficult implementation of Produce Rule standards.

Similarly, a significantly larger proportion of Northeast produce growers conduct value-added activities across all sales categories. Table 5 shows that 22.2% of Northeast growers in the second sales category engage in value added production, which is significantly higher than the corresponding proportion for the rest of the nation of 9.1%. Across growers of all sales categories, 19.1% of Northeast farms conduct value-added activities, compared to only 9.6% of U.S. farms in other regions. This indicates that Northeast farms are more diversified in production activities than others. Northeast growers who do not qualify or are unable to take an exemption may therefore go through a more difficult FSMA compliance process, as they are more likely to face regulation in value added production areas under the Preventive Controls Rule.
2.5.2 CSA’s and Direct Marketing

Produce growers sell their products to a variety of sources including consumers, restaurants, retailers, shippers, processors, and other market intermediaries. In the Census of Agriculture, growers are asked to report whether they market products directly to retail outlets, including restaurants, grocery stores, schools, hospitals, or other businesses that in turn sell directly to consumers (see Appendix A, item 6). Growers are also asked if they produce agricultural products for direct human consumption, and if they market products through a Community Supported Agriculture (CSA) arrangement (see Appendix A, items 7 and 8). In addition, The Census asks growers to list the total sales value of products sold directly to consumers (see Appendix A, item 7). We divide this by their total value of production to determine whether they sell mostly to qualified end-users, and would thus meet FSMA exemption eligibility criteria. Note that this exemption criterion is based on total food sales rather than produce sales. Again, this is an underestimation of exempt growers, as restaurants and retailers within the state or 275 miles are also defined as qualified end users under FSMA.

In California, both the proportion of growers who engage in direct marketing to retail outlets and growers who market directly to consumers is significantly lower than the proportion of growers with these marketing activities elsewhere in the U.S. for all sales categories. Table 4 shows that the total proportions of California produce growers who market directly to retailers and have direct sales to consumers are 8.3% and 15.3% respectively. These figures are significantly lower than the corresponding proportions for the rest of the U.S. of 19.2% and 48.3%, respectively. There is also a significantly lower proportion of California produce farms with CSA’s than in the rest of the country on
average. For example, only 1.8% of California growers in the second sales category have CSA’s. This is significantly lower than 8.4%, the proportion for non-California farms with CSA’s in category 2.

In terms of Produce Rule compliance, the low frequency of direct marketing activities has two conflicting implications: On the one hand, California farms may be less likely to qualify for an exemption, and will have to comply with the rule. On the other hand, the low proportions for farms with direct marketing could indicate that these produce farms conduct the majority of their sales through non-direct outlets like large distributors or wholesalers. These large buyers are more likely to require strict food safety practices, according to industry statements. The presence of relationships with such intermediaries could be an advantage in Produce Rule compliance, as the farms in question would already be accustomed to complying with mandated food safety standards.

Another interesting aspect regarding direct marketing in California is that even farms who qualify for exemptions may decide to comply with the Produce Rule. According to industry interviewees, operating exclusively as a direct marketing produce farm in California is difficult; there is a lot of competition, and taking on both growing and marketing activities is time consuming. Even if a grower is able to sell the majority of their product through direct channels and therefore qualify for the exemption, they may still have valuable business with distributors or national retailers who will expect their suppliers to comply with food safety legislation. California growers who would qualify for an exemption may therefore be more likely to comply with FSMA due to market pressure than growers elsewhere, despite their legally exempt status.
State regulations specific to California may also present challenges for growers who engage in direct marketing. Recent legislation will impose some additional requirements on California growers who sell products through CSA’s and farmers’ markets. Assembly Bills 224 and 1871, which were signed into law in 2013 and 2014 respectively, include provisions that require CSA and farmer’s market growers to declare that they are producing in accordance with good agricultural practices (California Legislative Information, 2015; CCOF Certification Services, 2014). Though these laws may increase costs for growers, they may also benefit farmers who market directly to consumers by improving consumer confidence (Hardesty, 2015). However, producers report that complying with multiple different regulations and standards is difficult. We therefore expect that California farmers with direct marketing channels will face more challenges with FSMA compliance than similar growers in other states due to additional state legal requirements.

In the Northeast, the proportion of growers who market directly to retail outlets and the proportion of growers who market directly to consumers are significantly higher than the corresponding proportions in the rest of the country. Table 5 shows that 28.2% of all Northeast produce farms market directly to retail outlets, compared to 14.1% of other U.S. farms. Further, 61.9% of Northeast produce farms have direct sales to consumers, which is significantly higher than the proportion of 34.9% for non-Northeast farms. There is also a significantly higher proportion of farms with CSA’s in the Northeast (11.2%) than in the rest of the nation (4.4%), illustrating that Northeast growers are more likely to rely on direct marketing as some component of their business.
This indicates that Northeast growers with under $500,000 in food sales will be more likely to qualify for exemptions by meeting the direct sales criteria. This could present an advantage for exempt growers, who will be spared the potential costs of Produce Rule compliance. However, the relatively larger proportion of growers with more than $500,000 who engage in direct marketing could indicate that Northeast farms of this size are less likely to have existing relationships with large distributors and wholesalers that require more extensive food safety programs. This could mean that Northeast farms with over $500,000 in food sales will have to make more extensive changes to comply with FSMA than growers elsewhere, representing a disadvantage.

Tables 4 and 5 also indicate similar trends across smaller and larger sales value categories regardless of region. For example, within both California and the Northeast, there is a clear downward trend in the proportion of growers with direct sales to consumers as farm sales values increase: In California, the percentage of growers with direct to consumer sales ranges from 25.9% in the lowest sales category to 4.5% in the highest sales category. In this Northeast, this figure ranges from 63.1% in the lowest sales category to 43% in the highest sales category. This trend indicates that larger farms are less likely to participate in direct marketing. Larger producers likely rely on larger retailers or distributors, who may require that suppliers have good agricultural practices or third-party audits. Larger farms have an advantage in Produce Rule compliance relative to smaller farms, since they are more likely to be familiar with following standards. Moreover, larger farms likely have more resources to dedicate to food safety.
2.5.3 National Organic Program

The Census of Agriculture asks growers whether they participated in the National Organic Program (NOP) in 2012 (see Appendix A, item 9). To comply with NOP standards, organic growers follow specific procedures for recordkeeping, manure application, and implementing trace back systems (USDA/AMS, 2011). For example, certified organic growers must maintain documentation for activities including water and soil testing.

Compared to the rest of the U.S., California had a significantly higher proportion of farms that produced organic products according to the NOP in 2012 in the first and third sales value categories. For example, 8.5% of California growers in the highest sales value category participate in the NOP, relative to 6% in the rest of the U.S. However, the proportion of California farms who participate in the NOP across all sales categories is slightly lower in California (8.95%) than in other regions (9.03%). The difference is small but statistically significant.

The Northeast has a significantly higher proportion of growers who participate in the NOP, both overall and across each sales category. Table 5 shows that 13.8% of all Northeast growers participate in the NOP, relative to 8.25% of growers in other regions. In both California and the Northeast, the largest proportion of growers who participate in the NOP are in the smallest sales value category.

Small organic growers who produce primarily for local outlets like farmers markets, niche grocery stores, and restaurants may be less prepared for FSMA compliance than organic growers who sell to larger outlets. Small outlets may be less likely to require documentation of good agricultural practices and audit results than large
national chains. Industry reports that organic growers who sell to large grocery outlets such as Costco and Whole Foods are already accustomed to complying with food standards and undergoing third party audits. However, we hypothesize that all certified organic growers will have an advantage in complying with FSMA regulations associated with recordkeeping and documentation, since this “office work” aspect of farming will not represent a large organizational change for them. According to industry statements, implementing new recordkeeping procedures can be a challenge for growers who see little point in documenting the practices that they have been following anyway.

Additionally, certified organic growers may already have relationships with food safety authorities and certification agencies, which could make FSMA compliance and auditing less costly. For example, many organic growers in California who have third party audits prefer to achieve GlobalG.A.P. certification, which reportedly offers more cost effective audit schemes for small farmers. GlobalG.A.P. standards also includes worker welfare and sustainability components that are consistent with the missions of some organic farms. Because the scheme represents a global standard, it can be advantageous for organic growers who export their products. GlobalG.A.P. is also known as a leading food safety scheme.

Northeast farmers may be better equipped to implement processes mandated by the Produce Rule, due to high participation in the NOP relative to the rest of the country. The relationship between the proportion of California growers who participate in the NOP and the corresponding proportion for non-California growers is inconsistent across sales categories, so there is no clear likely advantage or disadvantage for growers in the state in terms of NOP participation.
2.5.4 Presence of Livestock on the Operation

Livestock presence on a farm could potentially cause difficulties with Produce Rule compliance due to the rule’s standards for domesticated and wild animals. For example, under the Domesticated and Wild Animals subpart of the Produce Rule, growers would be required to wait an appropriate amount of time before harvesting produce that was grown in fields where grazing or working animals were present (FDA, 2014b). We hypothesize that produce farms with livestock present could face more challenges in Produce Rule implementation than those without livestock. The 2012 Census has separate questions to determine whether growers have cattle and calves, hogs and pigs, equine animals, sheep and goats, poultry, and other livestock on the operation (see Appendix A, items 10-15). If a grower with produce sales responded “yes” to having any of these animals on the operation, we classify the operation as a produce farm with livestock present.

In California, there is a significantly lower proportion of produce growers with livestock present than the corresponding proportion for growers in other regions, both within and across sales categories. For all California produce farms, only 12.9% have livestock, compared to 39% of produce farms elsewhere in the U.S. This supports our hypothesis that California produce farms are more specialized in growing activities than produce farms elsewhere. In the Northeast, 42.1% of all produce growers have livestock on the operation, which is significantly higher than 29.6%, the corresponding figure in the rest of the U.S. This supports our assumption that Northeast produce farms are more varied in production, in that they are more likely to conduct other non-growing activities.
We consider this attribute to be an advantage in Produce Rule compliance for California growers, since they may be less likely to face challenges in taking additional precautions associated with livestock. Northeast growers, on the other hand, may be more likely to face implementation challenges associated with the presence of livestock, and therefore have a more difficult time complying with the Produce Rule.

2.5.5 Manure Application

Whether or not a farm uses manure is of interest in determining readiness for FSMA compliance because the Produce Rule contains regulations for biological soil amendments. In 2014, the FDA announced that it would defer its decision on establishing an appropriate interval between manure application and harvest until a risk assessment can be completed, but growers may eventually have to comply with regulations regarding biological soil amendments of animal origin (FDA, 2015b). This portion of the Produce Rule seeks to establish standards to prevent contamination caused by pathogens associated with the application of biological soil amendments of animal origin (FDA, 2014b). Growers who use manure may eventually be required to adhere to intervals between manure application and harvest, and maintain records related to treatment of soil amendments and application intervals.

The 2012 Census asks growers to list the number of acres of cropland and pastureland to which animal manure was applied (see Appendix A, item 16). If growers with produce sales responded to this question with a number greater than 0, we consider them a produce grower who uses manure. Since the Census question regarding manure use only asks farms to list the number of acres to which manure is applied, we cannot distinguish whether these growers apply manure to produce covered under FSMA, or to
other crops. Therefore, our figures may overestimate the proportion of farms who will be required to comply with the biological soil amendments of animal origin subpart of the Produce Rule.

In California, there is a significantly lower proportion of growers who report using manure, both overall and across all sales categories. Table 4 shows that 10.7% of California growers use manure, compared to 20.2% of non-California growers. We observe the opposite in the Northeast, where a significantly higher proportion of growers reports using manure. Table 5 shows that 29.3% of Northeast growers use manure, relative to 15.5% of growers in the rest of the country. FSMA compliance may therefore be less burdensome for California produce growers, since they are less likely to have to eventually change practices regarding manure. For Northeast growers, the higher frequency of manure use may pose an additional challenge to Produce Rule compliance.

2.5.6 Migrant Labor

The 2012 Census asks growers to list the number of migrant workers on the operation in 2012 (see Appendix A, item 17). If this number is greater than 0 for a farm with produce sales, we classify the operation as a produce farm with migrant labor present.

In the lowest sales category and overall, a significantly higher proportion of farms in California report employing migrant workers than farms in the rest of the U.S. Table 4 shows that 7.7% of California growers across all sales categories have migrant labor, compared to 6.6% of other U.S. growers. The difference is small but statistically significant. The presence of migrant labor on a farm can indicate a high worker turnover rate, as migrant workers may move from place to place in search of work as growing
seasons change rather than living in the same community year-round. It is more difficult to implement consistent food safety practices when managers must train different workers every year. Multiple growers and produce industry employees in California projected that providing food safety trainings to an unstable labor force would be a major challenge in complying with FSMA. Farm labor shortages in the state compound the problem: if workers find new practices and policies burdensome, they know that they can easily find a new job at another farm. Therefore, we predict that California farms will have greater difficulties associated with staff training and Produce Rule compliance relative to farms elsewhere in the U.S.

In the Northeast, the total proportion of farms that report employing migrant workers is not statistically different from the proportion of farms employing migrant workers in the rest of the U.S., at around 7%.

2.5.7 Full Time Operator Status

The Census asks growers to report whether the principal farm operator spent the majority of their work time at the farm, or at another occupation (see Appendix A, item 19). If the grower reported that the operator spent the majority of their worktime on the farm or ranch, we classified the farm as having a full time operator. The presence of a full-time operator may mean that the farm is a dedicated business operation, rather than a hobby or secondary source of income.

In California, there is a significantly lower proportion of farms with full time operators than in the rest of the U.S. within each of the three sales categories. This figure ranges from 43.1% to 82.2% in these categories in California, and from 49.7% to 91.4% for these categories in other regions. However, across all growers, the proportion of
California growers with full time operators is not significantly different from the corresponding proportion for non-California growers.

In the Northeast, there is a significantly higher proportion of farms with full time operators relative to farms elsewhere. Across all sales categories, 62.4% of Northeast produce farms have full-time operators, compared to 56.6% of farms in other regions.

Operators with other sources of income may be less likely to feel market pressure to comply with the Produce Rule. If an operator makes all of his or her income on the farm, they may be more heavily affected by the decisions of distributors and retailers, who could require increasingly stringent food safety standards as Produce Rule implementation progresses. We expect that farms with full time operators who are legally exempt from FSMA will be more likely to comply with the Produce Rule, despite their exempt status. Therefore, exempt or non-covered farms in California may be less likely to comply with the Produce Rule based on this attribute, while exempt or non-covered farms in the Northeast may be more likely to comply with the rule to attract and retain business prospects.

2.5.8 Number of Employees

The Census asks growers to report the number of hired employees who worked on the farm in 2012 (see Appendix A, item 20). Though this figure does not include contract laborers, we use it to estimate the average number of workers per farm by region.

If a farm has a large number of workers, it may indicate that production is more labor-intensive and less mechanized. There are food safety considerations associated with labor-intensive production and large numbers of workers in the field. For example, industry sources report that growers of a hand-picked crop may be more concerned with
emphasizing worker hygiene and preventing workers from disposing of trash in the fields than growers of crops with less labor-intensive harvest methods. Growers with greater numbers of employees also must dedicate more resources to food safety training for workers. We predict that growers with larger numbers of workers will be more likely to face challenges in implementing FSMA standards pertaining to worker hygiene and education.

In California, the average number of workers per farm is significantly higher overall, though not within all sales value categories. The average number of workers per farm in California for all sales categories is 9.14, which is significantly higher than the non-California average of 6.09. California could therefore face more worker-related challenges in Produce Rule compliance than growers elsewhere. In the Northeast, the average number of employees per farm is 3.99, which is significantly lower than the remaining national average of 7.46. Therefore, Northeast growers may have an advantage in instituting new food safety practices, since less workers may mean lower contamination risks.

2.5.9 Contract Labor

The Census asks growers to report their expenses for contract labor (see Appendix A, item 18). If this figure is greater than 0 for a grower with produce sales, we classify the operation as a produce farm with contract labor present.

There is a significantly higher proportion of growers who employ contract laborers in California. Across all sales categories, 50.3% of California produce farms employ contract labor, compared to only 17.9% of produce farms in the rest of the U.S. In the Northeast, there is a significantly lower proportion of growers who employ
contract labor. Table 5 shows that only 12.6% of Northeast growers employ contract labor, relative to 29.83% of growers in other regions.

The presence of contract labor has different implications for food safety. Some produce farm managers report that contracting companies are usually responsible for the training of contract workers, but the farm manager holds the contractor accountable for administering the same standard of training given to employees who are hired directly.

Some operations may use contract labor with the intention of passing on liability to the contracting company. Industry has also reported that labor contractors were once more liable for problems associated with contract workers violating food safety practices but liability has shifted more heavily onto farm management. The extent to which the presence of contract labor influences Produce Rule compliance will depend on which organization is responsible for food safety training.

2.6 Conclusions

For growers, complying with the Produce Rule portion of FSMA may present new costs and challenges. In order to illustrate how the rule is likely to effect a wide range of farmers and United States produce growers, we estimated how many farms and acres will be subject to the rule nationwide and examined the characteristics of two distinct fruit- and vegetable-growing regions, California and the Northeast.

According to our estimation of coverage nationwide, 46,916 farms and 7,175,355 acres of produce will be subject to the Produce Rule. In proportional terms, 30% of produce growers and 77% of produce acres will be covered by the rule. Of the 70% of growers that are not covered, 51% have $25,000 or less in produce sales, 17% only produce commodities that are rarely consumed raw, and 2% qualify for the exemption
according to the Tester-Hagan Amendment. Of the 23% of acres that are not covered, 19% only grow rarely consumed raw produce commodities, 3% are farms with $25,000 or less in produce sales, and 1% are exempt farms. Farms that qualify for the exemption under the Tester-Hagan Amendment account for a very small proportion of growers and acres excluded from Produce Rule coverage.

Next, we assessed the frequency of selected farm attribute information from the 2012 Census of Agriculture for California and Northeastern farms, to develop a sense of how both small produce farms with varied production and relatively low sales values and large produce farms with specialized production and relatively high sales values may fare under the Produce Rule portion of FSMA.

Overall, farms in California are more specialized: a lower proportion of farms in California engage in on-farm packing, value-added activities, and direct marketing, relative to the rest of the U.S. This could indicate that California farms will have an advantage in complying with FSMA, as they are mostly focused on growing activities and are more likely to have existing relationships with intermediaries who demand food safety practices. California growers are also more likely to participate in the National Organic Program, less likely to have livestock on the farm, and less likely to use manure. These three attributes are likely to make FSMA compliance easier for California operations. However, California has a higher proportion of farms who employ migrant workers overall, indicating that California could face FSMA implementation difficulties related to employee training.

Farmers in the Northeast are more likely to engage in non-growing activities, meaning that Northeast farmers will face difficulties in adhering to FSMA standards in
multiple areas of production, such as packing and value-added processing. Northeast farmers are more likely to distribute through direct marketing channels than growers elsewhere: while a greater proportion of Northeast farms will qualify for FSMA exemptions based on direct sales, those with relatively lower sales values who do not qualify or are unable to take an exemption may be less prepared for compliance due to a lack of engagement with intermediaries who may have more demanding food safety standards. The higher proportion of growers with livestock and growers who use manure may also present FSMA compliance challenges for Northeast growers. However, Northeast growers are more likely to participate in the National Organic Program and have a lower number of employees on average than farms elsewhere in the U.S., which may make FSMA implementation easier.

Our observations for California and the Northeast shed light on 2 different “types” of farms that may be subject to Produce Rule compliance. Smaller produce farms with direct marketing and several different production activities who just miss qualifying for the exemption or have sales values just inside the range for those of covered producers may have a more difficult time complying with the Produce Rule because they may have to take precautions in multiple areas or fruit and vegetable production. Furthermore, due to lower sales values and the likely absence of existing connections to large distributors or wholesalers, they may have less resources to dedicate to standard compliance, and less familiarity with following mandated guidelines. Larger, more specialized produce farms with little direct marketing and high sales values may not qualify for exemptions, but Produce Rule compliance will likely be easier for such growers because specializing in growing activities means that these farms will be subject to a smaller set of regulations.
Additionally, due to their high sales, these growers are more likely to have conducted business with intermediaries who impose strict food safety standards, so they are more familiar with the process documenting and adhering to strict metrics.
CHAPTER 3
A DESCRIPTIVE ANALYSIS OF THE INTERNATIONAL FOOD CERTIFICATION INDUSTRY

3.1 Introduction and Motivation

In recent years, a multitude of certification programs have emerged to verify practices and input use within the international food and agriculture industries, including food safety attributes (Albersmeier et al., 2009). Both public and private organizations are involved in setting food safety standards and verifying and enforcing compliance (Havinga, 2006). While some food safety standards are mandated by government regulations, third-party certification schemes also play a major role in the food system. In third-party certification systems, certification standards are typically established by public or private organizations, and independent certifiers are accredited to verify an organization’s compliance with the established set of standards (Hatanaka et al., 2005). The certification organizations are described as “third-party” because they are independent from businesses undergoing certification and from retailers who may require certified products (Hatanaka et al., 2005).

In many cases, certification status is communicated to consumers via labeling schemes (Caswell & Anders, 2011). Producers have taken an interest in certification because showcasing certain attributes can differentiate their products from those of competitors, ultimately leading to increased sales. Certification also serves as a means for producers to assure investors and retailers that they are taking every precaution to avoid negative publicity (Conway, 2007). Other actors in certification systems are non-governmental organizations (NGOs), who can benefit from certification systems by
creating or supporting standards that advance awareness of their causes or put pressure on industries to change practices.

Historically, government institutions are tasked with regulating negative externalities associated with economic activity, but increasingly complicated supply chains make it unfeasible for legislators to monitor certain aspects of production (Mayer and Gereffi, 2010). The proliferation of certification systems has been attributed to both the rise of global commerce and the decline in governmental regulation of social and environmental conditions (Raynolds, 2007). Increasing consumer interest in the quality and sources of products such as food in recent years has also contributed to the rising demand for certification (Higgins et al., 2008).

In this chapter, we develop a descriptive analysis of the international food certification industry by examining standards and certification bodies. We first describe how we constructed databases for international certification standards and certification bodies. We then use information from our standards database to describe attributes associated with available certification schemes. We reference our certification body database to discuss the geographical distribution and business characteristics of organizations that offer food certification services. Finally, we discuss patterns in certification standard coverage and the availability of certification services for prominent food safety standards.

Food certification systems relate to our broader discussion on the Food Safety Modernization Act (FSMA) and food system challenges in two ways. First, the FSMA Final Rule on Accredited Third-Party Certification establishes a program for the FDA to approve certification bodies to conduct food safety inspections at foreign food facilities
Foreign food producers who achieve certification may then be eligible to export their products into the U.S. through an expedited review process. Alternately, the FDA can also require that certain facilities achieve certification from an accredited body before exporting to the U.S. Understanding how certification bodies are distributed geographically and the types of food standards they work with will shed light on the international auditing capacity of these organizations under the Rule on Accredited Third-Party Certification. Second, U.S. farms and firms who have already implemented food safety programs via certification schemes may be better prepared to comply with FSMA rules that cover their production areas. Though we do not assess organizations that achieve certification, determining the extent to which food safety certification services are available in the U.S. may contribute to an understanding of current food safety practices. Thus, developing a description of the current food safety certification environment is an important step in determining how FSMA will affect the food industry.

3.2 Relevant Literature

3.2.1 The Role of Certification Schemes

Given the rise of certification schemes, literature has explored the motivation behind certification standards and certification bodies, as well as their effects on the food system. Henson and Reardon (2005) describe potential reasons behind the increasing importance of private food safety and quality standards in the global food industry. Private certification standards have been established as a result of consumer concerns and firm competition for product differentiation. The authors state that private standards are becoming “predominant drivers” of food and agricultural systems. Private standards
allow organizations to differentiate their products through the use of specific certification criteria, whereas public standards are typically geared towards homogenous commodity markets and offer little opportunity for product differentiation. Henson and Reardon conclude that the increasing influence of supermarket chains and a high degree of global concentration in the food retail sector have contributed to the international emphasis on private food safety standards and third-party certification (2005).

Havinga (2006) explores how retailers that require certification standards for suppliers affect food safety, and explains that when private companies set standards, they are protecting public interest in a safe food supply. Havinga defines self-regulation as the practice of private organizations regulating the behavior of their own organization or associates without government involvement. Private regulation is defined more broadly as any form of regulation driven by non-state actors. In the 1990’s, many European food retailers began developing their own quality assurance schemes to increase consumer confidence and mitigate risk and liability costs. In 2001, all Dutch food retailers implemented the British Retail Consortium standard, a common standard for their own-branded products. The establishment of a common standard for all retailers strongly influenced suppliers to comply. Havinga concludes that private forms of regulation can be more effective in influencing the practices of regulated firms, while public food safety regulation is less detailed and less prescriptive.

In their 2005 work, Hatanaka et al. discuss how the rise of certification systems has changed power dynamics in global agriculture. Supermarkets appear to benefit from these schemes, which allow them to minimize liability by monitoring product standards without being directly responsible for verification activities (Hatanaka, 2005). However,
smaller food producers with less resources may not be able to reap the benefits of increased consumer confidence associated with certification, since the process can be costly and involve changes to technology and employee education.

### 3.2.2 Certification Typology

Given the diversity and breadth of certification systems, literature has sought to develop definitions for different types of schemes. In their 2011 analysis, Caswell and Anders describe the different attributes of certification systems by dividing them into 6 types based on who establishes and certifies the standard in question. Types I and II comprise voluntary private standards that are certified by either product sellers (“first parties”) or product buyers such as retailers (“second parties”). For example, some organizations may advertise their internal regulation procedures that seek to advance corporate social responsibility (Mayer & Gereffi, 2010). Types III and IV include private, voluntary standards that are certified by independent third party organizations (Caswell & Anders, 2011). GLOBALG.A.P.’s Integrated Farm Assurance standards are an example of Type IV, as the standards are owned by GLOBALG.A.P. and certified by approved bodies that are independent from the producers they monitor (GLOBALG.A.P., 2016). Type V consists of voluntary standards that are set by the government and verified by either government agencies or via third party certification, while Type VI describes mandatory standards established and certified by the government (Caswell & Anders, 2011). Country of origin labeling, which is administered and enforced by the Agricultural Marketing Service within the United States Department of Agriculture for certain products as required by law, is an example of a mandatory government standard (USDA AMS, 2015). When discussing types of certification systems, it is important to
note that it is often difficult to apply definitions in practice, and that new types of certification systems continue to develop.

3.2.3 The Organization of Certification Systems

Though third-party certification has emerged as a significant regulatory mechanism, the body of work on the organization and practices of the certification industry is relatively limited. In their 2008 work, Hatanaka and Busch analyzed the use of third-party certification as a governance tool in the food and agriculture sectors by examining the websites of 45 certification and accreditation bodies, and conducting phone interviews with 10 certification bodies. They describe the functions of the different organizations involved in certification systems. Hatanaka and Busch also discuss trends in certification systems, such as how certification bodies that were first established in the global North have been expanding their services and locations to less developed countries (2008). The authors conclude that while certification and accreditation bodies are independent of food producers seeking certification, the process of third-party certification is not completely objective, since both accreditation and certification often rely on trusting relationships between organizations.

3.2.4 Third-Party Certification and FSMA Implementation

The current certification environment will affect FSMA implementation. Proposed FSMA regulations give third-party certification bodies a role in ensuring the safety of imported food. There is historical precedent for this type of relationship between government regulations and third-party certification agencies. For example, third-party
verification is used to ensure compliance with required greenhouse gas emissions reporting procedures in California, Massachusetts, and Europe (McAllister, 2012).

Fagotto (2010) describes the importance of third-party certification bodies in the new regulatory environment under FSMA: the FDA does not have an existing team of inspectors to verify the safety of the increasing amount of foreign food products entering the U.S. market, so they will rely on non-governmental certification bodies to help ensure FSMA compliance for covered entities. Thus, the distribution and organization of these certification bodies will likely affect whether the FDA can implement FSMA effectively. FSMA also contains requirements that intend to minimize conflict of interest within these agencies: certification bodies and the organizations whose products they certify cannot be a part of the same company (Fagotto, 2010). However, Fagotto warns that the interests of third-party certifiers may not always be aligned with those of the general public, and conflicts of interest could persist without adequate controls and incentives.

3.3. Data Development Protocol

3.3.1 Identifying Standards and Certification Bodies

This research entailed compiling and analyzing two databases of international certification industry information. The first database, called the Master Standards List, contains descriptive information for certification standards used in the food and agriculture sectors. We include standards for forestry and textile products as subsets of agricultural standards, because standards for these products often relate to cultivation activities. The second database, called the Certification Body Database, consists of
information on organizations that offer auditing and certification services in the aforementioned sectors.

From 2013 to 2015, researchers at the University of Massachusetts Amherst and North Carolina State University collected information on 499 standards and 300 certification bodies. We used this research as a starting point for this project. We further developed these sources using an iterative process: We identified many additional certification bodies via information on certification standard websites, and we also discovered additional standards by examining information on certification body websites. This “back and forth” process of gathering information from both certification body and standards websites was repeated throughout the development of the Master Standards List and Certification Body Database. Because we developed these two resources via internet research, some certification bodies and standards with little or no web presence may be excluded. For example, if a certification body website said that they offer certification for a certain standard but we could not find a website or further information for the standard, we did not include it on the Master Standards List. However, we do not expect this to have a significant impact on our conclusions, because standards and certification bodies with so little information available are less likely to play prominent roles in certification systems overall.

Standards and certification bodies represent different levels in certification systems. Figure 7 shows a simple certification system hierarchy. Typically, the standard setting bodies that develop certification schemes are private bodies or government agencies that operate separately from companies that sell products certified to the given standard. The standard setting body approves accreditation bodies, which in turn
determine whether certification bodies are qualified to perform certification activities related to the standard (Hatanaka & Busch, 2008). Certification bodies then verify compliance with the standard for participating organizations, which are then qualified to promote the “certified” status of their product. The Master Standards List consists of schemes developed by standard setting bodies, which comprise the topmost entry of Figure 7. The Certification Body Database consists of certification organizations, which make up the third layer in the hierarchy presented in Figure 7.
Though accreditation bodies are important components in certification systems, this work focuses on certification standards and certification bodies. We treat accreditation bodies as a black box in this research; we comment on how they interact with certification bodies but do not expand on or analyze their structures.
3.3.2 Master Standards List

The Master Standards list contains information on standards in the food and agriculture sectors. It includes the following fields:

1. Standard full name
2. Standard abbreviated or commonly used name
3. Country where standard is based
4. Type of standard
5. Sub-type of standard
6. Product of focus
7. Whether the standard represents mandatory compliance with a regulation
8. Whether the standard is part of a supplier verification program
9. Website for standard

Since the creation of the 2013-2015 list, we found additional standards listed on certification body and certification industry websites. In these cases, we confirmed the existence of the standards via internet searches and added them to the Master Standards List along with the associated information and web addresses. Additionally, we removed standards that were duplicates, standards missing significant information, and standards that were not applicable to the food or agriculture industries. The resulting Master Standards List contains 425 standards.
3.3.3 Certification Body Database

Since the creation of the 2013-2015 certification bodies list, we identified additional organizations by examining information on certification standard websites, mainly from websites for standards (such as GLOBALG.A.P., IFS, GMP+, Marine Stewardship Council, British Retail Consortium, and USDA Organic) that contain lists of certification bodies that are qualified to offer auditing and certification services for the standard. In cases where standard and certification body websites were only available in languages other than English, we used browser-based tools to translate the website information. The Certification Body database contains information on 581 organizations.

Once we identified active certification bodies, we added firm information to each entry in the Certification Body Database. We compiled this information from certification body websites and from Hoovers™, a commercial database of company information. Our recorded information includes:

1. Certification body name
2. Certification body identification number (ID for the data set beginning with 1)
3. Address (city, state/province, country)
4. Year established as reported on company website
5. Year established as reported in Hoovers™ database
6. Number of employees
7. Public or private company
8. Ticker name (if company is public)
9. Total sales revenue and year recorded
10. Net income and year recorded
11. Countries with company office locations
12. Company website

To collect this information, we first determined whether it was available on the website of the certification body in question. If some or all of the information was not available on the organization’s website, we collected it from the Hoovers™ business database. If both of these sources yielded no information, the fields were left blank and the certification body entry was excluded from the relevant analysis. In some cases, the year established listed on the certification body website differed from the year listed in the Hoovers™ database, so we listed both years and information sources. We believe these discrepancies occurred because company websites sometimes list the year that the first iteration of their business began, regardless of later name changes, mergers, or acquisitions, which Hoovers™ may take into account. Most certification body websites did not list any sales, income, or employee information, so the majority of our recorded figures for these three items are from the Hoovers™ database.

Certification bodies that appear to have multiple subsidiaries presented some identification problems. In some cases, a standard website would list a specific certification body office branch as an accredited certifier. It was unclear whether this meant that only the specified subsidiary was approved to carry out certification for the given scheme, or if the standard site was simply listing specific contact information for the certification body. Also, certification bodies with locations in multiple countries sometimes have several different country-specific websites (for example, www.dnvgl.se for DNV in Sweden, and www.dnvgl.nl for DNV in the Netherlands), but the content and
certification service information listed on each website were often similar. As a result of
the lack of clarity on standard websites and the similarity of content on websites for
certification bodies with locations in multiple countries, in these cases we list one
certification body entry and its headquarters information, and include a list of office
location countries in the entry. We obtained information on such certification bodies
through the company websites and the Hoovers™ entries associated with the
headquarters locations.

3.3.4 Associating Certification Bodies with Standards

Part of the development of the Certification Body Database entailed noting the
standards that each certification body is qualified to certify. We collected this information
from both certification body and standard websites, since some certification body
websites list standards that they cover and some standard websites list organizations that
are qualified to carry out the certification process. However, we observed many instances
of contradictory or asymmetric information between certification body and standard
websites. It was not always possible to determine which information source was correct,
especially when dealing with less prominent standards and organizations with less
informative websites.

To address this issue, we developed the following 5 categories for each
information availability situation, along with binary data fields that indicate which
category each standard-to-certification body relationship falls into. Note that categories
1-3 concern situations in which information is available on both sides but may or may not
match, while categories 4 and 5 concern situations where information is missing for
either source. Categories 4 and 5 can also include instances in which information is
obviously incomplete, such as when a certification body website says that they certify many standards but only lists examples of a couple, or when standard websites say that they work with many certification bodies but only give the names of select organizations.

We describe categories 1-5 in the following list and figure.

**Category 1:** Certification body (CB) and standard website contain matching information. For example, the CB website says that it certifies the GLOBALG.A.P. standard, and the GLOBALG.A.P. website lists the CB as a qualified certification organization.

**Category 2:** Standard is listed on CB website, but standard website does not list the CB. For example, the CB website says that it certifies the GLOBALG.A.P. standard, but the GLOBALG.A.P. website does not list the CB along with qualified certification organizations.

**Category 3:** CB is listed on the standard website, but the CB website does not list the standard. For example, the CB website does not list GLOBALG.A.P. along with its covered standards, but the GLOBALG.A.P. website lists the CB as a qualified certification organization.

**Category 4:** Standard is listed on CB website, but standard website has incomplete information on qualified CBs. For example, The CB website says that it certifies the GLOBALG.A.P. standard, but the GLOBALG.A.P. website does not provide any names of accredited CBs.

**Category 5:** CB is listed on the standard website, but the CB does not list any standards or provides an incomplete list. For example, the CB website does not list any standards that it certifies, but the GLOBALG.A.P. website lists the CB as a qualified certification organization.
As described in the previous section, there were instances in which standard websites listed specific locations for approved certification bodies. In these cases, we matched the standard to the organization headquarters entry included in our certification body database.
Additionally, some certification body websites indicated that the organization certifies certain standards “in partnership” with other certification bodies. If a certification body certifies a standard “in partnership” with another organization, we list the standard for the certification body along with the appropriate match category, and use a binary data field to indicate that it must work with another organization to conduct certification.

Some certification bodies are also standard owners. For example, the Rainforest Alliance established the Rainforest Alliance Certified™ Farms standard, and the organization also offers certification services. There is an accreditation program for this standard, which other certification bodies can go through to offer the standard (Rainforest Alliance, 2016). We include the Rainforest Alliance standard on the Master Standards list, and the Rainforest Alliance organization in the Certification Bodies database, because it appears to fit within our definition of a third-party certification system, which includes accreditation and certification bodies.

Other standards appear to be developed and certified exclusively by one certification body. For example, the certification body ASI Food Safety offers the “ASI Food Safety GMP Audit,” which appears to be unique to the organization and not available to be offered by other certification bodies (ASI, 2016). We did not include such proprietary standards in our analysis, since it is unclear as to whether the certification body goes through an accreditation process to administer certification under the standard. Such proprietary standards fall outside the scope of this work, which focuses primarily on the third-party certification system in which certification bodies are accredited to verify an organization’s compliance with a specified standard.
Occasionally, certification body websites mention that the organization offers a certain type of certification standard but do not give a specific standard name. For example, some certification bodies say that they offer halal or kosher certification, but the specific scheme they work with is unclear. In these instances, we added a generic entry for the type of standard, such as “generic kosher” or “generic halal,” and matched the generic standard to the certification body in question.

3.4 Description of Standards and Certification Bodies

3.4.1 Master Standards List Results

The Master Standards List contains information on 425 standards that are applicable to the food industry. We use the list of intrinsic quality attributes proposed by Caswell and Anders (2011) to categorize the standards based on the characteristics to which they apply. Figure 9 displays the intrinsic quality attribute categories and subcategories as applied to the entries in the Master Standards List, and the number of standards that each attribute category and sub category contains. Analyzing the distribution of standards available in the food and agriculture industry is important to understanding the types of certification services that may be available to producers.
Figure 9: Number of standards on Master Standards List by attribute category and subcategory

<table>
<thead>
<tr>
<th>Standard Attribute</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business Management Practices</td>
<td>3</td>
</tr>
<tr>
<td>Food Safety</td>
<td>146</td>
</tr>
<tr>
<td>Nutrition</td>
<td>7</td>
</tr>
<tr>
<td>Process</td>
<td>241</td>
</tr>
<tr>
<td>Sensory</td>
<td>3</td>
</tr>
<tr>
<td>Value/Compositional Integrity</td>
<td>18</td>
</tr>
<tr>
<td>Generic</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>425</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutrition Subcategory</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gluten-Free</td>
<td>5</td>
</tr>
<tr>
<td>Fat Content</td>
<td>1</td>
</tr>
<tr>
<td>Vitamin Content</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>7</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process Subcategory</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Welfare</td>
<td>12</td>
</tr>
<tr>
<td>Environmental</td>
<td>110</td>
</tr>
<tr>
<td>Fair Trade</td>
<td>5</td>
</tr>
<tr>
<td>Genetically Modified Status</td>
<td>4</td>
</tr>
<tr>
<td>Halal</td>
<td>3</td>
</tr>
<tr>
<td>Kosher</td>
<td>4</td>
</tr>
<tr>
<td>Organic</td>
<td>68</td>
</tr>
<tr>
<td>Social Justice</td>
<td>22</td>
</tr>
<tr>
<td>Traceability</td>
<td>12</td>
</tr>
<tr>
<td>Worker Safety</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>241</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sensory Subcategory</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taste</td>
<td>1</td>
</tr>
<tr>
<td>Non-specified subtype</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3</strong></td>
</tr>
</tbody>
</table>

*Source: Attributes adapted from Caswell & Anders, 2011*
The most common attribute category in our analysis of available food certification schemes is the process category, with 241 standards. This attribute category comprises standards that focus on specific characteristics of the production process. Within the process attribute category, the most common subcategories for standards are environmental (110 standards), organic (68 standards), and social justice (22 standards).

The second most common attribute category of standards in our sample is food safety. The Master Standards list contains 146 standards food safety standards.

Some standards are associated with a specific products of focus. For example, the Marine Stewardship Council label certifies the sustainability and traceability of seafood products (Marine Stewardship Council, 2016). Other standards appear to be intended for use across a broad range of products. For example, farms can achieve certification of several different types of crops and livestock under the United States Department of Agriculture’s National Organic Program (USDA, 2011).

Table 6 displays the number of standards in the Master Standards list that are associated with certain product categories, and the number of standards that are not associated with a specific product.
Table 6: Standards by product of focus

<table>
<thead>
<tr>
<th>Product of Focus</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquaculture/Seafood</td>
<td>21</td>
</tr>
<tr>
<td>Biofuel</td>
<td>4</td>
</tr>
<tr>
<td>Biomass</td>
<td>5</td>
</tr>
<tr>
<td>Coffee, Tea, and/or Cocoa</td>
<td>10</td>
</tr>
<tr>
<td>Cotton</td>
<td>2</td>
</tr>
<tr>
<td>Crops (produce and/or grains)</td>
<td>6</td>
</tr>
<tr>
<td>Dairy (eggs, milk, and/or cheese)</td>
<td>6</td>
</tr>
<tr>
<td>Feed</td>
<td>13</td>
</tr>
<tr>
<td>Fertilizer</td>
<td>1</td>
</tr>
<tr>
<td>Flowers/Ornamental Plants</td>
<td>5</td>
</tr>
<tr>
<td>Food Service</td>
<td>6</td>
</tr>
<tr>
<td>Forestry/Timber</td>
<td>19</td>
</tr>
<tr>
<td>Honey</td>
<td>2</td>
</tr>
<tr>
<td>Meat/Livestock</td>
<td>25</td>
</tr>
<tr>
<td>Olive Oil</td>
<td>1</td>
</tr>
<tr>
<td>Palm Oil</td>
<td>3</td>
</tr>
<tr>
<td>Potting Soil</td>
<td>1</td>
</tr>
<tr>
<td>Seeds</td>
<td>3</td>
</tr>
<tr>
<td>Sugar</td>
<td>1</td>
</tr>
<tr>
<td>Textiles</td>
<td>6</td>
</tr>
<tr>
<td>Water</td>
<td>1</td>
</tr>
<tr>
<td>Wine</td>
<td>6</td>
</tr>
<tr>
<td>Non-Product Specific</td>
<td>278</td>
</tr>
<tr>
<td>Total Standards on List</td>
<td>425</td>
</tr>
</tbody>
</table>

The most common products of focus associated with product-specific standard are meat and livestock (25 standards), seafood and aquaculture (21 standards), and forestry and timber (19 standards). The frequency of these standards may reflect recent consumer and media attention on potential problems in these product areas. Health issues arising from the consumption of contaminated meat have been widely covered by news outlets, and consumers are becoming more interested in farm animal welfare (McCluskey & Swinnen, 2011; Tonsor & Olynk, 2010). Recent NGO campaigns have focused on
negative environmental and labor practices associated with seafood (Bush et al., 2013). In the 1990’s, United Nations groups established definitions for sustainable forestry, increasing the interest in environmental practices associated with forest products (Bare, 2000). The relatively high proportions of standards for meat and livestock, seafood and aquaculture, and forestry and timber may indicate that certification systems are responding to consumer demands for transparency and regulation in these product areas.

3.4.2 Certification Body Database Results

The Certification Body Database contains information on 581 organizations that offer certification services in the food and agriculture industries. All of the certification bodies in our sample had websites, and there was information available for 399 of the certification bodies in the Hoovers™ database.

We recorded the year that each firm was established, when available. Of the 581 firms, 357 of them listed the year of establishment on their website. The Hoovers™ database listed the year of establishment for 373 of the organizations. As discussed in Section C., there were some discrepancies in the year established listed on the website vs. the year established listed in the Hoovers™ database, so we consider the year information available from each source separately. Figures 10 and 11 display the annual additions and cumulative total of certification bodies in the sample over time, as listed on certification body websites and the Hoovers™ database, respectively.
Figure 10: Annual additions and cumulative totals of CBs in sample, based on CB website

Figure 11: Annual additions and cumulative totals of CBs in sample, based on Hoovers™ data
The earliest year established, 1828 for the certification body Bureau Veritas, was consistent between the certification body website information and the Hoovers\textsuperscript{TM} database. Both Figure 4 and Figure 5 show similar trends, with the annual additions of certification bodies increasing throughout the 1980’s and 1990’s. According to certification body website information, the establishment of certification bodies peaked in 1997 at 22 organizations, while the Hoovers\textsuperscript{TM} database information shows that the establishment of these firms peaked in 2000, when 25 organizations were founded. For both figures, the cumulative total of certification bodies over time appears to increase rapidly in the 1990’s and start to level off in the mid-2000’s. These trends support the idea that certification has increased in prominence as a business activity in recent decades but may also indicate an approaching saturation in the market.

Information on the number of employees in the organization was available for 374 of the 581 certification bodies. The 375 certification bodies have a total of 340,945 employees between them. The mean number of employees per organization is 911.6 while the median is 18. The mean is much higher because certain certification bodies have very large numbers of employees. For example, the certification body SGS has 79,268 employees and Bureau Veritas has 66,000.

The total sales revenue for 2015 was available for 291 of the 581 certification bodies. These certification bodies have a total of $29,066,654,008 in sales revenue. The mean total sales revenue is $99,885,409 and the median is $1,590,000. As with the employee figures, the mean is much higher than the median because certain certification bodies have very large sales revenue.
The large combined figures for number of employees and total sales indicate that organizations that conduct certification activities comprise a relevant economic sector. However, it must be noted that these figures are for employees and sales revenue for entire organizations, and not for certification activities exclusively. If a certification body also conducts non-certification activities, the revenue and employees for those activities are also included because we do not have a means of separating organization information by business activity. Therefore, these figures overestimate the number of employees and sales revenue associated with certification activities.

We also documented the locations for each certification body. Several certification bodies operate in multiple countries, so we recorded headquarters locations and additional certification body locations by country. Together, the 581 certification bodies in our sample have office locations in 191 countries. Table 7 presents a description of the number of certification bodies operating in each country for the 49 countries with 20 or more certification bodies present, to highlight where the highest concentrations of these organizations are present. Figure 12 is a heat map that shows a visual description of certification bodies per country.
Table 7: Number of certification bodies present for countries with 20 or more certification bodies

<table>
<thead>
<tr>
<th>Country</th>
<th># CB present</th>
<th>Country</th>
<th># CB present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>27</td>
<td>Malaysia</td>
<td>24</td>
</tr>
<tr>
<td>Australia</td>
<td>33</td>
<td>Mexico</td>
<td>54</td>
</tr>
<tr>
<td>Austria</td>
<td>23</td>
<td>Morocco</td>
<td>21</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>26</td>
<td>Netherlands</td>
<td>31</td>
</tr>
<tr>
<td>Belgium</td>
<td>31</td>
<td>Pakistan</td>
<td>20</td>
</tr>
<tr>
<td>Brazil</td>
<td>44</td>
<td>Peru</td>
<td>21</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>32</td>
<td>Poland</td>
<td>41</td>
</tr>
<tr>
<td>Canada</td>
<td>46</td>
<td>Portugal</td>
<td>30</td>
</tr>
<tr>
<td>Chile</td>
<td>31</td>
<td>Republic of Korea</td>
<td>38</td>
</tr>
<tr>
<td>China</td>
<td>70</td>
<td>Romania</td>
<td>38</td>
</tr>
<tr>
<td>Hong Kong</td>
<td>24</td>
<td>Russian Federation</td>
<td>29</td>
</tr>
<tr>
<td>Colombia</td>
<td>22</td>
<td>Singapore</td>
<td>26</td>
</tr>
<tr>
<td>Croatia</td>
<td>20</td>
<td>South Africa</td>
<td>31</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>34</td>
<td>Spain</td>
<td>68</td>
</tr>
<tr>
<td>Denmark</td>
<td>21</td>
<td>Sweden</td>
<td>25</td>
</tr>
<tr>
<td>Egypt</td>
<td>29</td>
<td>Switzerland</td>
<td>20</td>
</tr>
<tr>
<td>France</td>
<td>49</td>
<td>Taiwan</td>
<td>24</td>
</tr>
<tr>
<td>Germany</td>
<td>81</td>
<td>Thailand</td>
<td>28</td>
</tr>
<tr>
<td>Greece</td>
<td>34</td>
<td>Turkey</td>
<td>63</td>
</tr>
<tr>
<td>Hungary</td>
<td>25</td>
<td>Ukraine</td>
<td>20</td>
</tr>
<tr>
<td>India</td>
<td>74</td>
<td>United Arab Emirates</td>
<td>25</td>
</tr>
<tr>
<td>Indonesia</td>
<td>32</td>
<td>United Kingdom</td>
<td>55</td>
</tr>
<tr>
<td>Ireland</td>
<td>22</td>
<td>United States</td>
<td>122</td>
</tr>
<tr>
<td>Italy</td>
<td>71</td>
<td>Viet Nam</td>
<td>30</td>
</tr>
<tr>
<td>Japan</td>
<td>63</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The 49 countries with 20 or more certification bodies in operation include Australia, all 3 countries in North America, 23 countries in Europe, 5 countries in South America, 14 countries in Asia, and 3 countries in Africa. Appendix C shows the countries that the continents and regional definitions presented here include. The country with the most certification bodies in operation is the United States, with 122 certification bodies. Germany, with 81 certification bodies, has the second highest number of organizations in operation. Producers seeking food product certification may have easier access to certification services and a greater choice of options where more certification bodies are in operation. The number of certification bodies within a country may also indicate the level of competition in the certification industry there.
We also tabulated the number of countries with less than 20 but more than 5 certification bodies in operation. These 63 countries included New Zealand, 16 countries in Africa, 16 in Europe, 10 in the Middle East, 9 in Central America or the Caribbean, 5 in South America, and 6 in Asia. Additionally, 64 countries have 1 to 5 certification bodies in operation. This group consists of 24 countries in Africa, 15 in Central America or the Caribbean, 8 in Asia, 6 in Europe, 2 in South America, 1 in the Middle East, and 7 Oceanic countries.

This geographical description shows that there is strong certification body presence in North America, Australia, most of Europe and South America, and some parts of Asia and the Middle East. Certain countries in South America, Central America, the Middle East, and Asia have lower numbers of certification bodies in operation. African countries and small island nations in Oceania and the Caribbean account for the largest proportion of countries with only 1 to 5 certification bodies present.

3.5 Description of Relationships between Standards and Certification Bodies

We assessed the relationship between certification bodies and certification standards by documenting the food and agricultural standards covered by each certification body. In some cases, the information offered on both certification body and standard websites was consistent, and in other cases it was inconsistent or incomplete, so we developed information “standard-certification body relationship” categories as described in section C.

We counted a total of 4483 standard to certification body relationships for the 425 standards and 581 certification bodies in our samples. This indicates that the average number of food or agriculture standards covered by a certification body in the sample is
7.72. Table 8 and Figure 13 show the distribution of categories into which the standard to certification body relationships fall.

Table 8: Distribution of standard-to-certification body (CB) relationship categories in sample, by number and percent

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>#</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Information on standard and CB sites matches.</td>
<td>2187</td>
<td>48.78%</td>
</tr>
<tr>
<td>2</td>
<td>CB site lists the standard. Standard site does not list the CB.</td>
<td>436</td>
<td>9.73%</td>
</tr>
<tr>
<td>3</td>
<td>CB site does not list the standard. Standard site lists the CB.</td>
<td>231</td>
<td>5.15%</td>
</tr>
<tr>
<td>4</td>
<td>CB site lists standard. Standard site has incomplete/missing information on CBs.</td>
<td>1517</td>
<td>33.84%</td>
</tr>
<tr>
<td>5</td>
<td>CB site has incomplete/missing information on standards. Standard site lists the CB.</td>
<td>83</td>
<td>1.85%</td>
</tr>
<tr>
<td></td>
<td>Generic Standard</td>
<td>29</td>
<td>0.65%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>4483</td>
<td>100.00%</td>
</tr>
</tbody>
</table>

Figure 13: Distribution of standard-to-certification body relationship categories in sample
In 49% of cases, we were able to confirm the relationship between standards and certification bodies on both the standard and certification body websites. The next most common case (34%) occurred when there was absent or incomplete information on the standard website. In these cases, certification bodies listed a certain standard on their website, but the website for the standard did not provide a list of certification bodies qualified to carry out certification, or presented an incomplete list. In 10% of standard-to-certification body relationships, the certification body website listed certification services for a standard on their website, but the website for the corresponding standard did not list the certification body in their list of organizations approved to certify the standard. Five percent of our cases are for the situation in which a standard site listed an organization as an approved certification body, but the certification body did not list the corresponding standard on their website. The least common case (2%) occurred when information was missing or incomplete on the certification body website. In these situations, standard websites listed an organization as an approved certification body, but the certification website did not list any specific standards they work with, or provided an incomplete list that did not include the standard in question. Since we were not able to match generic standards to specific standards, they fall outside of our 5 standard-certification body relationship categories. Generic standards accounted for a very small percent of our sample.

Our finding that information is consistent between certification body and standard websites in only 49% of standard-to-certification body relationship cases may seem surprising, because one would expect that both certification bodies and standard holders would provide detailed information on how to access their services and participate in the
schemes they offer, in order to increase business. However, there were many prominent, widely certified standards that did not list clear certification body information on their websites. For example, the International Organization for Standardization (ISO) offers multiple quality management system standards that can be used in the food and agriculture industries, such as ISO 22000 and ISO 9001. Many certification bodies listed these standards as services on their websites, but we found no evidence that ISO provides lists of certification bodies approved to offer these services. As a result of these situations, we had to designate a large proportion of matches (34%) as having missing information on the standard side.

Another factor to consider when discussing information on the relationships between certification bodies and standards is the practice of certification bodies working as partners. In our sample, 53 certification bodies advertised that they offered certification services for certain standards “in partnership” with another certification body. In these situations, it appears that one of the organizations is accredited to carry out certification under a certain standard, and another certification body partners with them to offer auditing services for the standard on their behalf. It is not always clear if the organization that partners with the accredited certification body also goes through an accreditation program for the standard in question. For example, the website for Bohemia Certification, a certification body in the Czech Republic, says that the organization certifies the GLOBALG.A.P. scheme for crops “in cooperation” with the certification body IQC. The GLOBALG.A.P. website only lists IQC as an approved certification body.
Though little is known on how these relationships work in the context of accreditation, partnerships appear to benefit both certification bodies involved in these arrangements. A certification body may be able to expand their geographical presence by having another organization conduct audits on its behalf. Or, a certification body may be able to extend the range of services they offer by partnering with an organization to certify a specific standard. In the aforementioned example, IQC is a certification body based in Israel. We hypothesize that they partner with Bohemia Certification to extend their services or expand their capacity in the Czech Republic. Additionally, we hypothesize that it may be easier for Bohemia Certification to conduct GLOBALG.A.P. audits as an IQC partner rather than on their own.

We noted partnership instances in 155 of our 448 standard-to-certification body relationships. For many of the partnership situations, only one of the partners was listed as an approved certification body on the standard website, if certification bodies were listed on the standard website at all. Hence, some of the standard-to-certification body matches that fell into the “inconsistent information” categories may have arisen due to this practice. While we found many cases where certification bodies explicitly state that they certify a standard in partnership with another organization, we also hypothesize that some certification bodies may certify standards as partners, but list the relevant standard on their website without stating that they carry out certification with the approval of another organization.

We include information from all 5 standard-to-certification body relationship categories in the analysis of food safety standard coverage in the following section. Our
use of the 5 standard-to-certification body relationship categories allows for results to be separated by category in future research.

3.6 Certification Bodies that Cover Food Safety Standards

3.6.1 Geographical Coverage for Food Safety Standards

In the previous section, we discussed how the 581 organizations in the Certification Body Database offer certification services for a combined total of 4483 standards, which includes overlap in standards because most standards are certified by multiple certification bodies. We found that 1934 of these 4483 standard-to-certification body coverage relationships involved food safety standards. Given our interest in assessing the potential effects of FSMA on the food system, this section focuses on certification bodies and food safety standards.

Because FSMA establishes a program for certification bodies to conduct food safety audits on imports, we describe the geographical distribution of organizations that offer food safety services as an early step in determining whether there is adequate capacity to implement this program. Also, because many U.S. food producers will have to comply with new food safety practices under FSMA, we assess the availability of food safety certification services in the U.S. to shed light on the types of food safety practices and schemes that producers may currently use.

Of the 425 standards on the Master Standards List, 146 are categorized as food safety standards. In our sample of 581 certification bodies, 358 organizations cover at least one food safety standard. These 358 organizations have office locations in 182 countries. To highlight the highest concentrations of these organizations, Table 9
presents a description of the number of certification bodies with food safety certification services and offices in each country for countries with 20 or more certification bodies present. Figure 14 is a heat map that shows how the offices of certification bodies that offer food safety certification are distributed worldwide.

Note that the data presented are for countries where the certifying bodies have offices. The actual country coverage for certification services may differ from the office coverage. For example, certification bodies still offer services in countries where they have no physical location or they may only offer certification services in a limited number of countries regardless of their office locations.

Table 9: Number of certification bodies that certify food safety standards per country, for countries with 20 or more certification bodies

<table>
<thead>
<tr>
<th>Country</th>
<th># of CBs present</th>
<th>Country</th>
<th># of CBs present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>24</td>
<td>Mexico</td>
<td>47</td>
</tr>
<tr>
<td>Australia</td>
<td>26</td>
<td>Netherlands</td>
<td>26</td>
</tr>
<tr>
<td>Belgium</td>
<td>27</td>
<td>Poland</td>
<td>36</td>
</tr>
<tr>
<td>Brazil</td>
<td>37</td>
<td>Portugal</td>
<td>25</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>26</td>
<td>Republic of Korea</td>
<td>34</td>
</tr>
<tr>
<td>Canada</td>
<td>31</td>
<td>Romania</td>
<td>33</td>
</tr>
<tr>
<td>Chile</td>
<td>29</td>
<td>Russia</td>
<td>23</td>
</tr>
<tr>
<td>China</td>
<td>52</td>
<td>Singapore</td>
<td>23</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>29</td>
<td>South Africa</td>
<td>26</td>
</tr>
<tr>
<td>Egypt</td>
<td>24</td>
<td>Spain</td>
<td>51</td>
</tr>
<tr>
<td>France</td>
<td>42</td>
<td>Sweden</td>
<td>23</td>
</tr>
<tr>
<td>Germany</td>
<td>66</td>
<td>Taiwan</td>
<td>20</td>
</tr>
<tr>
<td>Greece</td>
<td>25</td>
<td>Thailand</td>
<td>21</td>
</tr>
<tr>
<td>Hungary</td>
<td>21</td>
<td>Turkey</td>
<td>59</td>
</tr>
<tr>
<td>India</td>
<td>47</td>
<td>United Arab Emirates</td>
<td>23</td>
</tr>
<tr>
<td>Indonesia</td>
<td>23</td>
<td>United Kingdom</td>
<td>42</td>
</tr>
<tr>
<td>Italy</td>
<td>59</td>
<td>United States</td>
<td>65</td>
</tr>
<tr>
<td>Japan</td>
<td>41</td>
<td>Vietnam</td>
<td>22</td>
</tr>
<tr>
<td>Malaysia</td>
<td>20</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
There are 33 countries with more than 20 certification bodies with food safety certification services in operation. Germany has the most certification bodies that offer food safety certification services in operation, with 66 organizations. The United States has 65 certification bodies that offer food safety certification, and Turkey and Italy each have 59. The 33 countries with more than 20 certification bodies with food safety certification services include Australia, South Africa, all 3 North American countries, 15 countries in Europe, 7 in Asia, 3 in the Middle East, and 3 in South America. Producers in these countries may have better access to food safety certification, given the higher national concentration of certification bodies offering these services.

Figure 14: Heat map for certification bodies (CBs) with food safety offices in operation per country

Source: Created with OpenHeatMap tool
Figure 8 shows that the presence of offices of certification bodies that offer food safety certification is strongest in North America, Australia, most of Europe, and certain parts of Asia. There is relatively little coverage in most of Africa and in some parts of Asia and the Middle East. Several small island countries in the Caribbean and Oceania also have low numbers of certification bodies with food safety certification offices in operation. Producers that export food from countries with a low presence of certification bodies that offer food safety certification services may face more difficulties in achieving certification under FSMA’s Rule on Accredited Third-Party Certification.

3.6.2 GFSI Standards

Within our distribution of food safety standards, some standards are more prominent. There is particularly high coverage of certain Global Food Safety Initiative (GFSI) benchmarked standards. The GFSI is an organization that aims to reduce food risks by specifying recognition requirements for food safety schemes (GFSI, 2016a). The organization designates food safety standards that meet these requirements as “GFSI benchmarked standards,” which are widely accepted by food retailers (Crandall et al., 2012). The GFSI benchmarked schemes include the following standards: PrimusGFS; IFS (PACsecure standard, Food standard, and Logistics standard); Global Aquaculture Alliance Seafood; GLOBALG.A.P. (Integrated Farm Assurance-Crops Scheme and Produce Safety Standard); Global Red Meat Standard; FSSC 22000; SQF; CanadaGAP; and the BRC Global Standard (GFSI, 2016b).

We assessed the number of certification bodies that offer each GFSI benchmarked scheme using our standard-to-certification body match information. The IFS and GLOBALG.A.P. standards are comprised of different schemes, some that are GFSI
benchmarked and others that are not. In the following counts, we only included the certification bodies that offer the GFSI benchmarked schemes, and account for overlap between schemes within standards. Table 10 shows the number of certification bodies that cover each GFSI benchmarked standard and the number of countries in which the certification bodies associated with each standard operate. Table 10 also lists the number of certification bodies that cover each standard that operate in the U.S.

Table 10: Number of certification bodies (CBs) that cover GFSI standards

<table>
<thead>
<tr>
<th>GFSI Standard</th>
<th># of CBs</th>
<th># of countries where CBs present</th>
<th># CBs in U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLOBALG.A.P.</td>
<td>145</td>
<td>174</td>
<td>29</td>
</tr>
<tr>
<td>FSSC 22000</td>
<td>108</td>
<td>175</td>
<td>29</td>
</tr>
<tr>
<td>BRC</td>
<td>104</td>
<td>172</td>
<td>37</td>
</tr>
<tr>
<td>IFS (PACsecure standard, Food standard, and Logistics standard)</td>
<td>81</td>
<td>170</td>
<td>23</td>
</tr>
<tr>
<td>SQF</td>
<td>35</td>
<td>169</td>
<td>28</td>
</tr>
<tr>
<td>PrimusGFS</td>
<td>9</td>
<td>84</td>
<td>7</td>
</tr>
<tr>
<td>Global Aquaculture Alliance</td>
<td>4</td>
<td>140</td>
<td>3</td>
</tr>
<tr>
<td>Global Red Meat Standard</td>
<td>4</td>
<td>164</td>
<td>3</td>
</tr>
<tr>
<td>CANADAGAP</td>
<td>3</td>
<td>140</td>
<td>2</td>
</tr>
</tbody>
</table>

The GFSI benchmarked standard that has the most coverage is GLOBALG.A.P., with 148 certification bodies that offer services in 174 countries. All 148 of these certification bodies offer the GLOBALG.A.P. Integrated Farm Assurance-Crops Scheme, and 3 offer the GLOBALG.A.P. Produce Safety Standard as well.

The GFSI benchmarked standard with the second most coverage is FSSC 22000, which is certified by 108 certification bodies that operate in 175 countries combined. The BRC standard is also prominent. It is offered by 104 certification bodies that operate in a
combined total of 172 countries. These figures indicate that certification services for
GLOBALG.A.P., FSSC 22000, and BRC appear to be available in most countries, and
that these schemes may be the most commonly implemented food safety standards
worldwide.

The GFSI benchmarked standards IFS and SQF have fewer certification bodies
that certify to them but their country coverage is similar in scope to GLOBALG.A.P.,
FSSC 22000, and BRC. PrimusGFS is only covered by 9 certification bodies, but these
organizations have operations in 84 countries combined, because 3 of the 9 certification
bodies have operations in more than 30 countries each. Similarly, the Global Aquaculture
Alliance, Global Red Meat, and CANADAGAP standards are each covered by 4
certification bodies or less, but are represented in many countries because some of the
associated certification bodies have offices in several locations. For example, SGS has
locations in 140 countries and offers the Global Aquaculture Alliance, Global Red Meat,
and CANADAGAP standards.

The GFSI standard with the most coverage in the U.S. is the BRC standard, which
is offered by 37 certification bodies. GLOBALG.A.P. and FSSC 22000 are each offered
by 29 certification bodies, while SQF and IFS are offered by 28 and 23 U.S. certification
bodies respectively. The remaining standards are each covered by 7 or less U.S.
certification bodies. These coverage figures may indicate that BRC, GLOBALG.A.P.,
FSSC 22000, SQF, and IFS are food safety standards that are commonly implemented
among producers in the U.S. Assessing which certification services have the widest
availability in the U.S. provides a basis for determining the extent of current food safety
certification practices in the U.S. and whether producers are prepared for FSMA compliance.

3.7 Conclusions

Certification systems are complex and involve several actors. Though certification in the food and agriculture sectors has become more common in recent years, there is relatively little research on the certification industry. In this chapter, we provided a descriptive analysis of the food certification sector by assessing information on 425 certification standards and 581 certification bodies.

Of the 425 certification standards on our Master Standards List, 241 standards address production process attributes and 146 address food safety attributes. The remaining standards are associated with business management, nutrition, value, and sensory attributes. Additionally, 164 standards focus on a specific product or category of products while 270 standards are not product specific.

The Certification Body Database information shows that the number of certification bodies in operation increased most dramatically in the 1980’s and 1990’s. The 581 organizations in our sample have operations in 191 countries combined, indicating that most countries have certification bodies present. The highest concentrations of these organizations by country are in North American, European, and Asian countries.

We also recorded the names of relevant standards covered by each certification body. We found that information on standard coverage was not always available on both certification standard and certification body websites, or that information was sometimes contradictory across the two sources. Several certification bodies indicate that they certify
standards in partnership with other organizations, which raises questions about how the accreditation practice works in these situations and whether partnership certifications are as effective as traditional certifications. Our standard-to-certification body match data also showed that the food safety certification schemes with the most coverage by certification bodies include the GLOBALG.A.P IFA Crops, FSSC 22000, and BRC standards.

Describing attributes of certification standards and organizational characteristics of certification bodies helps to establish an understanding of current practices, geographical capacity, and areas of concern in the food certification industry. The prevalence of certification bodies that offer food safety certification services in the United States may indicate that food producers have several options for implementing food safety standards on the eve of FSMA, if they have the resources to undergo certification. Also, FSMA will rely on the third-party audits to verify the safety of imported food, and this research is a starting point for assessing the geographical capacity of international certification bodies to conduct audits under FSMA.
CHAPTER 4
AREAS FOR FUTURE RESEARCH

This research has assessed how farm characteristics may influence compliance with the FSMA Final Rule on Produce Safety, and provided preliminary steps in determining the international auditing capacity of certification bodies under the FSMA Final Rule on Accredited Third-Party Certification. There are several potential areas for extended research concerning both topics.

The certification systems piece of this research could be supplemented with international food trade data to more precisely determine the capacity of international food certification bodies to conduct food safety inspections of foreign food facilities. For example, future work could compare the amount of food exported to the U.S. from certain countries with the number of certification bodies offering food safety auditing services in those countries, and conclude whether each country is likely to have adequate or inadequate certification capacity.

Implications for consumer welfare are also an important area for future research on the impacts of FSMA in the context of both the Produce Rule and the Final Rule on Accredited Third-Party Certification. These rules are intended to result in a safer food supply. However, costs of complying with FSMA or achieving food safety certification may be passed on to consumers in the form of higher food prices, so it is critical to determine whether consumers attain any real benefits from food safety efforts.

Assessing the extent to which FSMA and food safety certification systems aid consumers requires additional analysis steps, such as gathering data on food prices and
the frequency of foodborne illnesses in the U.S. before and after FSMA implementation. If foodborne illness outbreaks decline and food prices rise after FSMA implementation, research could determine whether the benefits of illness reduction outweigh the higher cost of food for consumers. As many parts of FSMA have not been fully implemented yet, this research will not be able to be completed for several years.
APPENDIX A

2012 CENSUS OF AGRICULTURE QUESTIONS USED IN ANALYSIS

1. Section 10: Area for which vegetables, potatoes, and melons were harvested in 2012. Acres Harvested.

   Report gross value of vegetables, potatoes, and melons sold from the operation in 2012. Value of Sales (Dollars).

2. Section 11: Acres in bearing and nonbearing fruit orchards, vineyards, and nut trees. Total Acres.

   Report gross value of fruits and nuts sold from this operation in 2012. Value of Sales (Dollars).

3. Acres on which berries were grown in 2012. Acres Grown.

   Report gross value of berries sold from this operation in 2012. Value of Sales (Dollars).

4. Section 32, Question i: At any time during 2012, did this operation – Have an on-farm packing facility for distributing vegetables, potatoes, fruit, nuts, berries or other crops?

5. Section 32, Question c: At any time during 2012, did this operation – Produce and sell value added crops, livestock, or products such as beef jerky, fruit jams, jelly, preserves, floral arrangements, cider, wine, etc.?

6. Section 32, Question i: At any time during 2012, did this operation – Market products directly to retail outlets (including restaurants, grocery stores, schools, hospitals, or other businesses) that in turn sell directly to consumers?

7. Section 33: During 2012, did you produce, raise, or grow any crops, livestock, poultry, or agricultural products that were sold directly to individual consumers for human consumption?

   INCLUDE-sales from:
   • roadside stands
   • farmers markets
   • pick your own
   • door to door, etc.
   • Community Supported Agriculture (CSA)
EXCLUDE

- craft items
- processed products such as cheese, butter, jellies, sausages, and hams
- wine and cider

Gross value of these direct sales:

8. Section 32, Question d: At any time during 2012, did this operation – Market products through a Community Supported Agriculture (CSA) arrangement?

9. Section 27: In 2012, did this operation produce organic products according to USDA’s National Organic Program (NOP) standards or have acres transitioning into USDA NOP production?

10. Section 13: Did you or anyone else have any cattle or calves, including dairy cattle, on this operation in 2012?

11. Section 14: Did you or anyone else have any hogs or pigs on this operation in 2012? Contractors or integrators only report hogs on land you operate.

12. Section 15: Did you or anyone else have any horses, ponies, mules, burros or donkeys on this operation in 2012?

13. Section 16: Did you or anyone else have any sheep, lambs, goats or kids on this operation in 2012?

14. Section 18: Did you or anyone else have any poultry, such as chickens, turkeys, ducks, emus, ostriches, etc., on this operation in 2012? Include poultry grown for others on a contract basis.

15. Section 20: Did you or anyone else have other livestock or livestock products on this operation in 2012?

16. Section 26: Acres of cropland and pastureland on which animal manure was applied.

17. Section 23: How many MIGRANT workers were on this operation in 2012? A migrant worker is a farm worker whose employment required travel that prevented the migrant worker from returning to his/her permanent place of residence the same day. Include hired and contract workers.

18. Section 25, Question 10. b: Report total production expenses paid by this operation in 2012. Contract labor – Include expenses for labor, such as harvesting of fruit, vegetables, berries, etc. performed on a contract basis by a contractor, crew leader, etc.
19. Section 35: At which occupation did the operator spend the majority (50 percent or more) of his/her worktime in 2012? 1. Farm or ranch work 2. Other

20. Section 23: How many HIRED farm or ranch workers, including paid family members and office workers-

   a. Worked less than 150 days on this operation in 2012? Exclude contract labor
   b. Worked 150 days or more on this operation in 2012? Exclude contract labor
APPENDIX B

RARELY CONSUMED RAW AND COVERED PRODUCE

Rarely Consumed Raw Commodities

The final Produce Rule defines the following commodities as rarely consumed raw:

- asparagus, black beans, great Northern beans, kidney beans, lima beans, navy beans, pinto beans, beets, sugar beets, cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill, eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, winter squash, sweet potatoes, and water chestnuts.

Produce commodities included in our analysis as covered produce:

The Produce Rule covers fruit and vegetable commodities that are not defined as rarely consumed raw. The following commodities from the 2012 Census of Agriculture are included in our analysis as covered produce:

- Snap beans, broccoli, brussel sprouts, cabbage, Chinese cabbage, carrots, cauliflower, celery, chicory, Chinese peas (Sugar, Snow), collards, cucumbers, eggplant, escarole, endive, asparagus, garlic, honeydew, kale, lettuce (head), lettuce (leaf), mustard greens, romaine lettuce, dry onions, green onions, okra, parsley, peas (green), peppers (bell), peppers (other than bell), ginseng, radishes, rhubarb, herbs (fresh harvested), raspberries (nonspecified), blackberries, dewberries, blueberries (tame), blueberries (wild), cranberries, currants, strawberries, other berries, apples, apricots, avocados, bananas, temples, Valencia organs, non-Valencia oranges, guava, kiwifruit, mangos, nectarines, olives, papayas, passionfruit, peaches (nonspecified), pears (nonspecified), plums and prunes (nonspecified), pomegranates, other noncitrus fruits, pluots, grapefruit, kumquats, lemons, limes, tangelos, tangerines, other citrus, almonds, chestnuts, macadamia nuts, sweet cherries, pistachios, English walnuts, other nuts, grapes, spinach, tomatoes, turnips, turnip greens, summer squash, winter squash, watermelons, other vegetables

Produce commodities excluded from analysis due to data limitations:

- freestone peaches, clingstone peaches, Bartlett pears, “Other” pears, watercress, artichokes, mustard cabbage, cowpeas, cantaloupe, daikon, loganberries, boysenberries, red raspberries, black raspberries
APPENDIX C

GEOGRAPHIC REGION DEFINITIONS BY COUNTRY

Africa: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cape Verde, Cameroon, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Republic of the Congo, Cote d'Ivoire, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Libya, Madagascar, Malawi, Mali, Mauritania, Mauritius, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe

Central Asia: Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Uzbekistan

Southeast Asia: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Timor-Leste, Thailand, Vietnam

Asia, excluding Central and Southeast Asia and the Middle East: Afghanistan, Bangladesh, Bhutan, Brunei, China, India, Mongolia, North Korea, South Korea, Japan, Maldives, Nepal, Pakistan, Sri Lanka, Taiwan

Middle East: Bahrain, Cyprus, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Palestine, Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates, Yemen

Australia/Oceania: American Samoa, Australia, Cook Islands, Fiji, French Polynesia, Guam, Kiribati, Marshall Islands, Micronesia, Nauru, New Caledonia, New Zealand, Niue, Norfolk Island, Northern Mariana Islands, Palau, Papua New Guinea, Pitcairn Islands, Samoa, Solomon Islands, Tokelau, Tonga, Tuvalu, Vanuatu, Wake Island, Wallis and Futuna

Europe: Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Italy, Kosovo, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Moldova, Monaco, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Russia, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom (UK), Vatican City (Holy See)

North America: Canada, Mexico, United States (including Puerto Rico)

Central America and the Caribbean: Anguilla, Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Costa Rica, Cuba, Curaçao, Dominica, Dominican Republic, El Salvador, Grenada, Guadeloupe, Guatemala, Haiti, Honduras, Jamaica, Martinique, Montserrat, Netherlands Antilles, Nicaragua, Panama, Saint Kitts
and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and the Grenadines, Trinidad and Tobago, U.S. Virgin Islands

**South America:** Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, Uruguay, Venezuela
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