

## PEER-REVIEWED ARTICLE

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# Regulatory and Food Safety Knowledge Gaps Associated with Small and Very Small Food Businesses as Identified by Regulators and Food Safety Educators — Implications for Food Safety Training

## ABSTRACT

The popularity of farmers' markets and locally grown foods has increased the desire for value-added, locally produced products. Many states have cottage food regulations that allow sale of certain foods produced in home kitchens. However, product types permitted, requirements for food safety training, frequency of inspection and types of permits vary by state. The objectives of this study were to survey state regulatory officials and food safety educators nationwide to determine their ratings of the prevalence of practices that contribute to food safety risks associated with products from small and very small businesses with which they work and to determine the prevalence of risky behaviors observed in farmers' markets. By means of using an online survey, participants were asked to rate the prevalence of food safety knowledge factors and practices observed among small food businesses with which they work that could lead to food safety risks for consumers. Mean ratings indicate a lack

of awareness of food safety risks associated with products and how to mitigate those risks, lack of capital for training, lack of understanding of laws that pertain to them, and lack of knowledge of food allergens and mandatory labeling among owner/operators with whom they work. These outcomes have implications for future training needs for small and very small food businesses.

## INTRODUCTION

In recent years, interest in local foods has increased, likely because consumers perceive these products as being fresher, higher in quality and safer than foods from large "factory" farms or imported, as contributing to the welfare of the local economy, as supporting local agriculture, and as being better for the environment (4, 9). Nowhere is this more evident than in the growth of farmers' markets, with an increase of almost 400% in the number of markets listed in the USDA's National Farmers' Market Directory since the early 1990s (4). A study of food safety practices on small farms and in farmers' markets indicated a need for educating farmers

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on small farms selling directly to the public about “best practices” related to produce safety and a need for training farmers’ market managers about the importance of food safety plans for markets and “best practices” for the market related to produce safety (5). Fresh produce is not the only product sold in farmers’ markets; with the growing interest in farmers’ markets and locally grown foods has come an increased interest in value-added local foods and a wider range of locally produced food products, which typically include jams, jellies, pickles, salsas and further processed vegetable products. Small farms engaging in direct-to-consumer sales often engaged in other entrepreneurial activities, such as production of value added or processed products (6, 7).

Also fueling this explosion of small and very small businesses are government agencies such as the U.S. Small Business Administration that encourage people to turn a hobby of cooking and food preparation into a business (2). Allowing entrepreneurs to start food businesses that produce food in home kitchens eliminates the high costs that can be associated with starting a business and fosters growth of businesses that can lead to stronger local economies (3). With increasing numbers of entrepreneurs interested in developing products for sale, states and local governments have the difficult task of establishing standards that protect public health while allowing these businesses, referred to as “cottage food businesses,” to thrive (1). In response, the Association of Food and Drug Officials issued guidance for best practices in cottage food industries for food safety regulatory officials in 2012 (1).

In 2013, the Harvard Food Law and Policy Clinic issued a report on a study of cottage food regulations throughout the U.S. (3). The study found that at that time, 42 states had cottage food laws. Results of a detailed study of the various states indicated that the regulations vary from state to state and in some cases are difficult to find on state government websites or may not be clearly defined (3). Some states restrict the types of products that can be produced in a home kitchen and sold as cottage foods, set limits on the amounts that can be sold, require licenses, permits and inspections, charge application fees, etc. However, these requirements and regulations vary (3). Most states define cottage foods as non-potentially hazardous foods (foods that do not require time-temperature control for safety) prepared in a home kitchen. With that being said, wide variation exists from state to state among what foods are allowed to be produced under these regulations. These factors make it challenging for regulators and educators to develop training for these entrepreneurs, as well as making it difficult for entrepreneurs to understand what food best practices should be in place when preparing a food product in their home as well as any regulatory considerations. The growing interest in local markets and local food production, the increasing interest in making and selling food products, and the variety of regulations

concerning these products have implications for food safety educators and regulators with regard to public health and safety of products in the marketplace.

The objectives of this exploratory study were to survey state food safety regulatory officials and food safety educators nationwide to determine their observations and perceptions of the prevalence of practices that could contribute to food safety risks associated with food products from small and very small businesses, determine their observations and opinions of the prevalence of certain food safety risks in farmers’ markets, and identify food safety training needs of small and very small food business operators.

## **MATERIALS AND METHODS**

### **Questionnaire and research protocol development**

The research protocol and questionnaire were approved for use with human subjects by the Institutional Review Board of the university conducting the research project. The questionnaire was developed for administration using the Qualtrics Online Survey Platform (8). The survey was field-tested prior to widespread administration with a panel of experts, including an instructional designer, two food safety educators, and one state regulatory official. After minor adjustment related to survey flow, the questionnaire was released to generate a link to the on-line form for inclusion in e-mail invitations to prospective survey participants.

### **Recruitment of survey participants**

This exploratory survey used a convenience sample of state regulatory personnel and state food safety educators to determine observed and perceived prevalence of potential food safety risks that could impact training designed for small and very small food businesses. Contact information for state regulatory personnel was obtained by accessing the Directory of State and Local Officials available on the Web site of the Association for Food and Drug Officials (<http://dslo.afdo.org/>). Each state Department of Agriculture list was accessed, and efforts were made to identify those personnel most likely to either be involved with small and very small food businesses or be in a position to pass along the survey invitation and link to the appropriate personnel. Titles of those invited to participate included directors of food safety divisions, associate directors of food safety, retail program managers, manufactured food program managers, directors of marketing divisions, and program managers of marketing divisions. In those states where identification of appropriate individuals based on titles was difficult, additional personnel were contacted. E-mail invitations containing a link to the online survey were sent to each contact identified. In addition, E-mail invitations containing the link to the online survey were forwarded by the National Program Leader for Food Safety at the U.S. Department of Agriculture — National Institute of Food and Agriculture to state food safety contacts. A total of 145 invitations to participate

were issued to regulatory personnel, and approximately 95 invitations were issued to state food safety contacts. In an effort to maximize survey response rates, reminder messages were sent to non-respondents two weeks following the initial contact. Since it was difficult to tell from some states' Web sites who the appropriate contact would be to complete the survey, the reminder message also instructed recipients to share the survey with any colleague who was better suited to complete it, in an effort to ensure that respondents were the appropriate contacts working with small and very small food businesses.

### Administration of the survey

Survey participants first were asked to read and respond to a consent statement allowing their answers to be used for research purposes. Two demographic questions were included to determine whether respondents described themselves as regulatory, educator or both and to determine the length of time they had been in their current position. Next, participants were asked to rate the prevalence of 13 items related to food safety knowledge and practices for the owner/operators of small and very small food businesses with whom they work, using a scale of 1 = Not Prevalent to 7 = Extremely Prevalent. Percentages were included for each scale increment to serve as a quantitative guide for each category (1 = Not Prevalent represented less than 10% of owner/operators; 2 = Slightly Prevalent represented 10 – 24%; 3 = Somewhat Prevalent represented 25 – 39%; 4 = Moderately Prevalent represented 40 – 54%; 5 = Prevalent represented 55 – 74%; 6 = Very Prevalent represented 75 – 90%; and 7 = Extremely Prevalent represented greater than 90% of owners/operators). Response categories were also included to allow respondents to indicate that they had not had an opportunity to observe the item to be rated, that the item was not applicable to the owner/operators of small and very small businesses that they had worked with or, in the case of questions related to observations in farmers' markets, that they had not had an opportunity to observe markets. Responses in these categories where observations were lacking were not included in the analysis of the prevalence ratings.

Specifically with regard to products sold at farmers' markets, participants were asked to respond to a question that asked about the likelihood, if you visit farmers' markets in your area, that you would observe the following practices. Participants were asked to rate the prevalence of eight practices related to lack of appropriate licenses or certificates or practices that may result in food safety risks for consumers. In this situation, the rating scale was the same as described previously. Participants could also select the response that the item would not be considered a food safety risk in their state or that they had not had an opportunity to observe markets. If a respondent selected either of those categories, the selection was excluded in the analysis of prevalence ratings. In addition, participants were asked questions about

regulations in their states related to the sale specifically of "cottage foods — foods made in the kitchen of a private home." Using the scale previously described for small and very small businesses, they were asked to rate the prevalence of four items among owner/operators they have observed related to knowledge of food safety risks, laws that might apply to them, where to find information to help with their food businesses, and willingness to pay for licenses. If respondents reported having had no opportunity to observe these practices, their responses were eliminated from the rating analysis.

### Analysis of data

Data were analyzed using the Qualtrics Online Survey Platform research functions to calculate percentages of responses to certain questions and to calculate mean ratings and standard deviations for questions involving rating scales (8).

### RESULTS

Of the 145 messages sent to regulatory personnel, 20 were non-deliverable. Of the 95 messages sent to educators, 10 were non-deliverable. When non-deliverable E-mails were eliminated, response rates for the two groups averaged 32%. A total of 66 people responded to the survey. Responses of one person who chose not to have their data used for research purposes were excluded from the data analysis, resulting in a total of 65 respondents.

Of the 65 respondents, most (57%) identified themselves as food safety educators; 28% were regulatory officials and 15% considered themselves both as regulators and educators (Fig. 1). The majority had been in their positions for 10 years or more (Fig. 2). Only 40 to 54% of owner/operators were rated as being aware of regulations that may pertain to them and licenses they may need to sell their products (Table 1). Only 10 to 24% perceived themselves as having capital to invest in training themselves or their employees. For specific knowledge categories rated, respondents indicated that a range of 25 to 39% of owner/operators have a good understanding of good agricultural practices, good manufacturing practices, and food safety as it relates to their products and processes, and/or have knowledge of labeling requirements for their products. This is equivalent to a rating of somewhat prevalent. Only 10 to 24% of owner/operators were rated as being able to identify all eight major food allergens and mandatory labeling requirements. Prevalence ratings of attitudes among small and very small business owners/operators about the likelihood of their products causing foodborne illness, presented in Table 2, indicate that 55 to 74% of owner/operators viewed their products as unlikely to cause illness because the products are small, local or organic. This range is equivalent to a rating of prevalent.

Specifically with regard to cottage foods, 70% of respondents (45) indicated that their states have laws that support sale of cottage foods made in the kitchens of private homes;

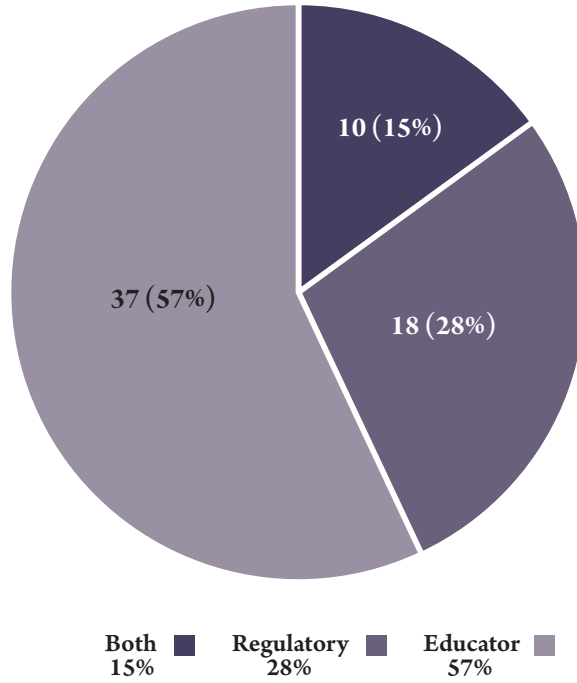


Figure 1. Classification of respondents to a survey about food safety issues and training needs among owner/operators of small and very small food businesses based on self-description of position

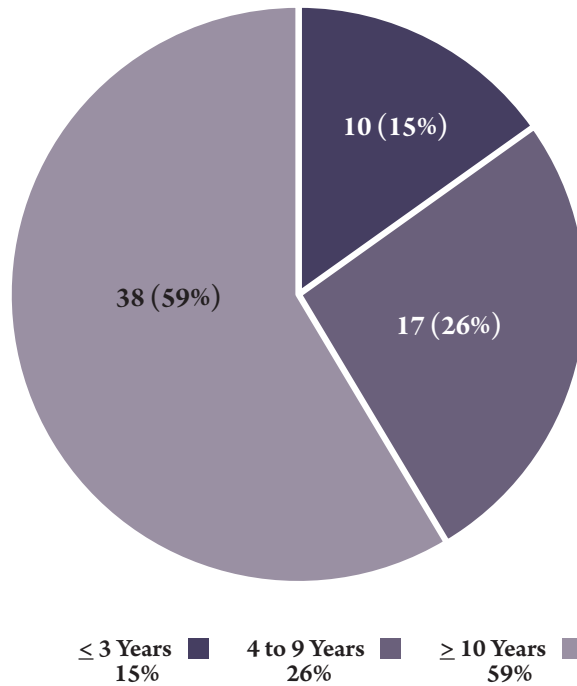


Figure 2. Length of time in positions of respondents to a survey about food safety issues and training needs among owner/operators of small and very small food businesses

**Table 1. Prevalence of knowledge and practices among small and very small food business owners/operators related to regulations and safety of their products as observed and rated by state regulators and food safety educators<sup>1</sup>**

Questions – Rate the prevalence of owner/operators who:	Mean Rating <sup>2</sup>	Std. Dev.
Have capital to send themselves and/or employees to food safety training.	2.78	1.26
Are aware of regulations that may pertain to them.	4.02	1.35
Are aware that they may need licenses or permits to sell their products.	4.53	1.52
Have a good understanding of Good Agricultural Practices.	3.19	1.40
Have a good understanding of Good Manufacturing Practices.	3.45	1.66
Have a good understanding of food safety as it relates to their products and processes.	3.60	1.58
Can adequately identify food safety risks that may impact their products or processes.	3.08	1.38
Are aware of labeling requirements for their products.	3.44	1.60
Are aware of mandatory allergen labeling requirements.	2.79	1.44
Are able to properly identify all eight major food allergens.	2.20	1.30

<sup>1</sup>Respondents were excluded if they indicated the item is not applicable to the owners/operators they have observed or if they indicated they have not had an opportunity to observe this.

<sup>2</sup>Rating scale based on percentages of owner/operators

- 1 = Not Prevalent (less than 10% of owner/operators)
- 2 = Slightly Prevalent (10 – 24% of owner/operators)
- 3 = Somewhat Prevalent (25 – 39% of owner/operators)
- 4 = Moderately Prevalent (40 – 54% of owner/operators)
- 5 = Prevalent (55 – 74% of owner/operators)
- 6 = Very Prevalent (75 – 90% of owner/operators)
- 7 = Extremely Prevalent (greater than 90% of owner/operators)

17% (11) responded no, and 13% (6) indicated they did not know if their states had laws allowing this. Of the 45 who had cottage food laws, 39 responded to the question about the types of products that could be made and sold under these laws (Table 3). Responses indicated that products allowed under cottage food laws are predominantly low-risk foods. However, 13% (n = 5) indicated that sauces and dressings are allowed, and 26% (n = 10) indicated that foods like pickles and salsas are allowed in their locations. Of 41 respondents to a question about whether or not food safety training is required in their state for cottage food manufacturers, 59% (24) said no, 32% (13) said yes and 10% (4) did not know. When asked if mandatory annual inspections are required for cottage food facilities in their states, 63% of 41 respondents (26) said no, 22% (9) said yes, and 15% (6) did not know.

Prevalence ratings were in the moderately prevalent range (40% to 54%) for owner/operators selling foods without the appropriate training to mitigate food safety risks (Table 4). Ratings in the somewhat prevalent range (25–39% of owner/operators) were assigned for owner/operators selling foods without adhering to state and/or federal laws that might apply to them, without knowing where to go to find information they need to help them with their business and without being willing to pay for licenses for their food businesses.

The range of vendors selling meats and low-acid canned foods in farmers' markets without appropriate licenses was rated in the 10% to 24% range, or as slightly prevalent (Table 5). Only the sale of dairy products without the appropriate licenses was perceived to be not prevalent (< 10% of vendors). The range of vendors with cut produce



**Table 2. Prevalence of opinions among small and very small food business owners/operators about the likelihood of their products causing foodborne illnesses as observed and rated by state regulators and food safety educators<sup>1</sup>**

Question — Rate the prevalence of owner/operators who:	Mean Rating <sup>2</sup>	Std. Dev.
View their products as unlikely to cause foodborne illness because they are a small operator.	5.26	1.73
View their products as unlikely to cause foodborne illness because they are organic.	5.08	1.65
View their products as unlikely to cause foodborne illness because they are “local foods.”	5.17	1.61

<sup>1</sup>Respondents were excluded if they indicated the item is not applicable to the owners/operators they have observed or if they indicated they have not had an opportunity to observe this.

<sup>2</sup>Rating scale based on percentages of owner/operators

1 = Not Prevalent (less than 10% of owner/operators)

2 = Slightly Prevalent (10 – 24% of owner/operators)

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4 = Moderately Prevalent (40 – 54% of owner/operators)

5 = Prevalent (55 – 74% of owner/operators)

6 = Very Prevalent (75 – 90% of owner/operators)

7 = Extremely Prevalent (greater than 90% of owner/operators)

**Table 3. Products identified by a sample of state department of agriculture regulatory personnel and food safety educators that are allowed to be made and sold under cottage food laws in their states**

Product Type Allowed	Response Frequency <sup>1</sup>	% of Respondents
Baked goods, except those requiring refrigeration	37	95
Jams and jellies	30	77
Candy	27	69
Dry snacks	27	69
Acidified foods (pickles, salsas, etc.)	10	26
Sauces and dressings	5	13

<sup>1</sup>Total respondents = 39; respondents could select more than one answer.

items not displayed on ice or kept cold was rated in the somewhat prevalent range (25 to 39% of vendors). The prevalence of vendors with no access to handwashing or hand sanitizer and reusing cartons, boxes, bags and/or straw baskets for fresh produce was moderately prevalent (40 to 54% of vendors).

## DISCUSSION

Regulators and food safety educators have observed, among small and very small food business owner/operators, gaps in knowledge and practices related to regulations and safety of their products that may put consumers at risk for

foodborne illnesses. Ideally, the prevalence among owner/operators of small and very small food businesses would be rated in the very prevalent or extremely prevalent range ( $\geq 75\%$  of the owner/operators) for having capital to invest in food safety training, being aware of regulations that may pertain to them, being aware that they may need licenses or permits to sell their products legally, having a good understanding of good agricultural practices and good manufacturing practices, being able to adequately identify food safety risks that could impact their specific products and processes, being aware of labeling requirements for their products, and being aware of all eight major food allergens

**Table 4. Prevalence of knowledge and practices among cottage food operators and owners of small and very small food businesses that could entail food safety risks for consumers who purchase their products, as observed and rated by state regulators and food safety educators<sup>1</sup>**

Questions — Rate the prevalence of individuals/businesses that:	Mean Rating <sup>2</sup>	Std. Dev.
Are selling foods without appropriate training to understand and mitigate food safety risks.	4.29	1.67
Are selling foods and not adhering to state and/or federal laws.	3.82	1.53
Do not know where to go to get the information they need to help them with their food businesses.	3.92	1.66
Are not willing to pay for licenses for their food businesses.	3.17	1.84

<sup>1</sup>Respondents were excluded if they indicated the item is not applicable to the owners/operators they have observed or if they indicated they have not had an opportunity to observe this.

<sup>2</sup>Rating scale based on percentages of individuals/businesses

- 1 = Not Prevalent (less than 10% of owner/operators)
- 2 = Slightly Prevalent (10 – 24% of owner/operators)
- 3 = Somewhat Prevalent (25 – 39% of owner/operators)
- 4 = Moderately Prevalent (40 – 54% of owner/operators)
- 5 = Prevalent (55 – 74% of owner/operators)
- 6 = Very Prevalent (75 – 90% of owner/operators)
- 7 = Extremely Prevalent (greater than 90% of owner/operators)

and the mandatory labeling required for safety. However, regulators and food safety educators have observed that a large percentage of owner/operators do not appear to have knowledge of food safety or capital to invest in training.

Although lack of food safety knowledge was observed by educators and regulators, the number of owner/operators who view their products as unlikely to cause foodborne illness because they are a small operation, they are organic and/or they are “local food” producers was high (55 to 74%). This indicates a potential need for training that includes explanations of how local, organic foods from small operations can cause illness just as those from large, conventional operations can, as well as to creating awareness of food safety risks associated with specific products and handling practices and steps to take to make products safer.

Many states allow only low-risk foods to be sold in cottage food operations. However, some respondents indicated that sauces, dressings and acidified foods such as pickles and salsas are allowed under cottage food rules in their states. A lack of food safety knowledge and a lack of training on understanding and mitigating risks become even more important when the foods being sold include those that must be properly acidified and processed to prevent microbial problems. Although rated as only slightly prevalent, the fact that even 10 to 24% of vendors at farmers’ markets sell

low-acid canned foods without appropriate licenses raises concern. Lack of access to handwashing or hand sanitizer and reuse of cardboard boxes, bags and straw baskets for fresh produce were frequently observed (moderately prevalent). Similar observations made by Harrison et al. (5) also raised concerns about sanitary conditions in farmers’ markets that could lead to increased risk of contamination and cross-contamination of products.

## CONCLUSIONS

The observations of regulators and food safety educators who indicate they work with owner/operators of small and very small food businesses and observe a lack of knowledge about food safety, lack of capital to invest in food safety training and lack of knowledge about where to go to get information raise questions about food safety risks associated with products from local entrepreneurs. This exploratory survey illustrates a need for low-cost, effective training programs for owner/operators and personnel in small food businesses, a need for better connecting the target audience with these programs, and a need for better access to clear information pertaining to locally produced foods on regulatory Web sites. Additional observational studies and intervention programs are needed to better define effective training for this target group.

**Table 5. Prevalence of food safety practices reported to be observed in farmers' markets as rated by state department of agriculture regulatory personnel and food safety educators<sup>1</sup>**

Question — Rate the prevalence of vendors:	Mean Rating <sup>2</sup>	Std. Dev.
With produce displays sitting directly on the ground.	2.73	1.99
With cut produce items not displayed on ice or kept cold.	3.44	1.77
With no access to handwashing or hand sanitizer.	4.34	1.75
Reusing cartons, boxes, bags, and/or straw baskets for fresh produce.	4.94	1.74
Selling meats without the appropriate licenses.	2.10	1.50
Selling low acid canned foods like vegetables, soups, etc. without licenses.	2.18	1.41
Selling dairy products without the appropriate licenses.	1.93	1.25
Selling eggs without the appropriate certificates.	2.17	1.24

<sup>1</sup>Respondents were excluded if they indicated this item would not be considered a food safety risk in their state or if they indicated they have not had an opportunity to observe markets.

<sup>2</sup>Rating scale based on percentages of individuals/businesses

- 1 = Not Prevalent (less than 10% of owner/operators)
- 2 = Slightly Prevalent (10 – 24% of owner/operators)
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