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Understanding the Food Safety Needs of Small and Very Small Processors in the Northeast United States: Food Safety Communicator and Regulator Perspectives

ABSTRACT

A needs assessment was conducted by the Northeast Center to Advance Food Safety (NECAFS) to articulate challenges that small and very small (SVS) food processors face and to identify strategies based on those needs for increasing compliance with the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PCHF) Rule. Food safety communicators (educators, consultants, and individuals in allied industries) and regulators in the NECAFS network states were surveyed to determine their perceptions of PCHF compliance challenges and recommendations for improvements in training and resource development. In alignment with the historical struggles faced by smaller food processors as they adjusted to earlier hazard analysis critical control point regulations and buyer mandates, both survey participant groups identified gaps in processor awareness of the PCHF Rule and its requirements, knowledge of good manufacturing practices, sanitation standards, and core elements of the hazard analysis risk-based approach to food safety, including conducting a hazard analysis and establishing verification and validation procedures. Recommendations included creating awareness materials for distribution to SVS food processors and educational programs and resources tailored to the needs and learning styles of SVS food processors that will increase motivation to engage in the PCHF compliance process.

INTRODUCTION

The 2011 Food Safety Modernization Act (FSMA, public law 111-353) granted new authority to the U.S. Food and Drug Administration (FDA) to establish and enforce risk-based farm-to-fork food safety standards designed to prevent food outbreaks and recalls. Under the law, the FDA issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PCHF) Rule in 2015 *(28)*. The regulation adopted and expanded the hazard analysis critical control point (HACCP) approach for managing food safety risks to a broader hazard analysis risk-based preventive controls (HARPC) approach for addressing potential process, allergen, sanitation, and supply chain hazards *(16)*.

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The risk-based management approach for controlling food safety hazards was introduced in the 1960s through a joint effort by the U.S. National Aeronautics and Space Administration and Pillsbury to ensure pathogen-free food for space travel *(32)*. In 1998, the National Advisory Committee on Microbiological Criteria for Foods published guidelines for developing HACCP plans *(17)*, which have since been adopted throughout the world *(10)*. In the United States, HACCP principles were the basis for a succession of FDA and U.S. Department of Agriculture (USDA) regulations for seafood *(26)*, meat and poultry *(25)*, and juice products *(27)*. Risk-based food safety management approaches rely on research-generated data to proactively identify and evaluate potential food safety hazards and to develop appropriate, effective, and verifiable control measures.

Most commercial food operations that manufacture, process, pack, or hold human food for consumption in the United States are covered under the PCHF Rule, apart from USDA-regulated facilities, retail food establishments, restaurants, and home-based businesses. Businesses that are already covered by FDA HACCP regulations are exempt from the risk-based preventive control parts of the regulation, although they are required to follow good manufacturing practices (GMPs) *(8)*. Company management must ensure that all employees involved in manufacturing, processing, packing, or holding food are trained and therefore qualified to perform their assigned duties. Each fully covered facility is required to have a preventive controls qualified individual (PCQI) in place to evaluate foreseeable hazards; identify and implement appropriate process, allergen, sanitation, and supply chain controls; and oversee monitoring, verification, and recordkeeping activities. To become a PCQI, an individual must be able to demonstrate expertise in risk-based food safety management through on-the-job experience or by attending an FDA-recognized training course, such as that developed by the Food Safety Preventive Controls Alliance (FSPCA). In the United States, more than 1,300 individuals have attained lead instructor status after presenting evidence of expertise in food safety and processing and successfully completing the FSPCA train-the-trainer course, and more than 80,000 members of the food industry in the United States have attained PCQI status by attending the PCHF training course *(15)*.

The regulatory burden placed on smaller food businesses was taken into consideration during the rule-making process. Qualified facility exemptions are available to (1) very small businesses defined in the PCHF Rule as averaging less than $1 million (adjusted for inflation each year) per year in both sales and unsold value of the food over a 3-year period or (2) facilities that have average annual sales over a 3-year period of less than $500,000 (adjusted for inflation each year) and make at least half of the sales to consumers or to local retailers or restaurants within the same state or within 275 miles. Qualified facilities are subject to GMP requirements, as well as the modified requirements described in 21 CFR 117.201. They must also submit an attestation to the FDA that they (1) meet the definition of a qualified facility, (2) have identified potential hazards associated with the food being produced, (3) are implementing preventive controls to address the hazards, and (4) are monitoring the performance of the preventive controls to ensure that the food produced is safe. Qualified facility exemptions may also be granted to operations that attest to full compliance with state or local food safety regulations. Qualified facilities must confirm their status with the FDA every 2 years and maintain records to support the attestations. In addition, mixed-type facility exemptions from the full requirements of the PCHF Rule may be granted for certain lower-risk processing activities conducted on a farm if they meet the definition of either a very small or a small business (defined as having fewer than 500 full-time-equivalent employees) *(8)*.

Early on, as HACCP became a globally accepted food safety management system, several studies reported that awareness of requirements, knowledge of food safety risks and how to control them, and perceived costs for adoption were barriers to implementation *(2, 6, 9, 11, 13, 22, 23, 31, 34)*. Gilling et al. proposed an "awareness to adherence" behavioral model that demonstrated the complex range of potential knowledge-, attitude-, and behavior-related barriers involved in adherence with HACCP regulations *(13)*. Azanza and Zamora-Luna followed up with a cognitive-behavior HACCP implementation model that consisted of a sequence of awareness, familiarity, comprehension, commitment, adoption, and compliance steps *(2)*. Other studies reported that processors believed HACCP jargon was difficult to understand, was time consuming to implement, and had few perceived benefits *(11, 23)*. Subject areas that processors found most difficult to understand and implement were conducting a hazard analysis and establishing verification and validation procedures *(6, 11, 31)*.

There are fewer studies on compliance barriers for the more recent FSMA PCHF Rule, but they suggest that similar compliance issues remain. In a survey of local agricultural producers, small-scale value-added food processors often mentioned that they would not be aware of new regulations until their first inspection or audit *(5)*. Understanding the PCHF Rule, time restrictions, and costs to implement were identified by Grover et al. *(14)* and Barone et al. *(3)* as PCHF compliance barriers. In a 2021 survey of small-scale food manufacturers using shared-use kitchen facilities, Richard et al. noted that processors generally hold positive attitudes toward food safety but that as a group, they still lack sufficient knowledge to comply with the PCHF Rule and need more training on hazard analysis and preventive control concepts *(19)*. In a 2023 follow-up study by Richard et al., food safety and PCHF knowledge increases were measured among attendees at a workshop for small-scale food businesses, although challenges remained on understanding hazards, hazard analysis, and preventive control concepts *(20)*.

Although past research suggests that many smaller food processors struggle to understand and implement the PCHF requirements that apply to them, there is a limited amount of data to quantify the gap. One measure of where processors are falling short comes from a 2020 FDA report that only 440 facilities were registered as qualified facilities with the FDA *(29)*, despite there being an estimated 3,500 food processors in the Northeast that are required to file as such *(4)*. This indicator for low awareness of the modified requirements of the PCHF Rule among small and very small (SVS) food processors raises questions about which parts of the PCHF Rule present the greatest obstacles and what tools might be used to overcome them.

In response to these concerns, the members of the Northeast Center to Advance Food Safety (NECAFS) PCHF Workgroup, a team of subject matter experts, articulated the need to build consensus of observed challenges faced by SVS food processors when adopting food safety programs and practices required by the PCHF Rule and of approaches to overcoming those challenges. NECAFS is one of four USDA-funded regional centers tasked with coordinating and supporting the development of training, education, and outreach activities to assist small and medium-sized farms, beginning and socially disadvantaged farmers, and small processors located in 12 northeastern states and Washington, DC, achieve compliance with the FSMA Produce Safety and PCHF Rules. Therefore, the scope of activities conducted by the PCHF Workgroup is to assist the many smaller processors that are either fully covered by the PCHF Rule or that meet the criteria for either qualified facility or mixed-type facility exemptions.

Anecdotally, the experience of NECAFS PCHF Workgroup members is that the SVS food processors they work with lack awareness of the PCHF Rule and that some existing educational materials, including the national PCHF training curriculum developed and administered by the FSPCA, are overwhelming to processors just getting started with food safety. NECAFS began to address this need by developing the Processors' Food Safety Toolkit (http://www.pchf.necafs.org) to connect educators and SVS food processors with resources to help them implement food safety practices. By further increasing understanding of this audience's food safety needs, NECAFS can improve educational tools and outreach activities aimed at SVS food processors that may not have adequate staff (small businesses) or revenue (very small businesses) to understand the complex issues around understanding PCHF Rule requirements, including modified requirements for qualified facilities and ultimately facilitating greater compliance with the PCHF Rule.

To identify and understand the food safety needs of SVS food processors and strategies to increase compliance across the Northeast region, we surveyed individuals within the NECAFS network in the Northeast United States, as well as FSPCA PCHF course lead instructors. We surveyed the NECAFS network and FSPCA PCHF course lead instructors, rather than contacting processors directly, for two reasons. First, NECAFS is composed of university extension educators, community-based organizations, state and federal regulators, consultants, and allied industry members that work with many different products. Their qualifications through education and training and their experience interacting with processors through educational programming, technical assistance, and conducting third-party audits or PCHF facility inspections provide a broad overview and the necessary context to where processors struggle when learning about and implementing food safety practices. FSPCA PCHF course lead instructors have firsthand knowledge of the requirements of the PCHF Rule and experience providing PCHF education to food processors of all sizes. Second, researchers have historically observed challenges in reaching smaller processors, suggesting that this indirect approach would be more likely to provide a sufficient number of useful responses *(34)*. Therefore, the survey priority was designed to determine the perceptions among the NECAFS network, FSPCA PCHF course lead instructors, and regulators of the challenges and needs that smaller food businesses face with respect to (1) awareness and knowledge of the PCHF Rule, (2) education and resources available about the PCHF Rule, and (3) practical solutions for successfully complying with the PCHF Rule.

MATERIALS AND METHODS

Survey respondent audience and distribution

The NECAFS PCHF Workgroup wrote the initial survey questions framed around four areas: (1) background information on respondents and how they work with SVS food processors, (2) respondent perceptions of SVS food processor awareness of the PCHF Rule and knowledge needed for compliance, (3) respondent perceptions of the challenges that SVS food processors face in meeting the PCHF Rule, and (4) types of information processors seek from respondents and respondents' perceptions of the value of the FSPCA PCHF course and other courses for filling knowledge gaps. The survey used mixed formats, consisting of multiple-choice, checklist, Likert scale, and open-response questions. The entire NECAFS PCHF Workgroup reviewed the survey, made suggestions for improving usability, and provided assurance that questions were crafted in a manner that would provide the desired information.

A link to the survey, administered through Qualtrics software version August 2019 and version June 2021 (Qualtrics, Seattle, WA), was initially sent by email to 426 subscribers to the NECAFS e-newsletter in August 2019, followed by two reminders in September and October. NECAFS e-newsletter subscribers are regulators, educators, technical service providers, growers, and processors primarily in the Northeast who are interested in the FSMA Produce

Safety and PCHF Rules. Separate mailings of the survey link were sent between August and December 2019 on behalf of NECAFS to the FSPCA list of PCHF course lead instructors in the 13 NECAFS network states and district. A total of 75 responses were received; 6 responses were excluded because it was unclear whether they were part of the target audience, and 11 responses were excluded because the respondents did not live or work in the Northeast and thus would not provide an accurate perspective of the target audience. Partially completed surveys were analyzed question by question to determine whether the results merited inclusion.

After completion of the initial survey, we found that a low number of responses from regulators (n = 11) who work directly with SVS food processors provided a limited perspective from this group. Therefore, we conducted a follow-up survey sent exclusively to regulators. The questions included in the survey were identical to those in the first survey except for those asking about challenges observed during inspections and those specifically directed to FSPCA lead instructors. We sent this survey exclusively to state regulators located in NECAFS network states that were listed in the Association of Food and Drug Officials (AFDO) Directory of State and Local Officials *(1)*. Each was asked to participate in the study and/or provide contacts in field offices for others with knowledge of the PCHF Rule and who would be willing to complete the survey. In the United States, most state food safety agencies contract with the FDA to enforce FDA regulations, including all those in the Northeast except for Delaware, New Hampshire, and Rhode Island *(30)*.

The list of contacts was reviewed and refined to 75 individuals confirmed as meeting the required criteria. The link to the survey was initially sent by email in June 2021, followed by four reminders: two in July and then two more in August specifically targeting regulators in states from which we had not received responses or who had been recommended to us after the initial email recruitment campaign was completed. Of the 43 responses received, 6 responses were excluded because they were not actually a regulator or did not live or work in the Northeast, thus yielding 37 usable surveys. Of these, 5 surveys were partially completed and analyzed question by question to determine whether the results merited inclusion.

To avoid duplication of data, regulators who responded to the first survey were removed from the dataset before analysis. Hereafter, respondents to the initial survey are called food safety communicators, whereas those responding to the follow-up survey are called regulators. The University of Vermont Institutional Review Board for Human Participants deemed both surveys to be exempt from review (study 00000460).

RESULTS

Background of survey respondents

Survey responses revealed varying expertise and levels of involvement on PCHF issues among both food safety communicators and regulators. *Table 1* shows professional titles and activities in which food safety communicators and regulators work with SVS food processors. Respondents could select more than one response. Among food safety communicators, more than a third identified as commercial consultants (35%), followed by university extension educators (33%). Shared kitchens and copackers (15%) and, to a lesser extent, retail food operations (6%), buyers or distributors (6%), process authorities (4%), insurance companies (2%), and commercial laboratories (2%) accounted for the remaining categories. Nearly half of respondents (46%) self-identified as lead instructors for the FSPCA PCHF curriculum, of which 43% and 38% coidentified as a consultant or an extension educator, respectively. All 37 regulators responding to the follow-up survey stated they were either currently employed or recently retired from state agencies charged with enforcing food safety regulations, of which 32 stated that they perform facility inspections, reviews, or audits (data not shown).

Most food safety communicators (62%) indicated that they conduct one-on-one or small-group advice or assistance activities to help SVS food processors comply with the PCHF Rule, with about half of those indicating it was their main responsibility *(Table 2)*. Among those who did not advise or assist processors (38%), most indicated that they refer questions to others. Among regulator respondents, a combined total of only 38% indicated that they offer advice and assistance to SVS food processors as their main or partial job responsibility. Among the 62% of regulators who do not provide direct assistance or advice, most forward questions to others with more expertise.

At least one respondent from each of the surveys was located or worked with processors located within each of the 12 NECAFS network states. None of the respondents were from Washington, D.C. Pennsylvania, New York, and Massachusetts were the most frequently reported locations by food safety communicators, and Pennsylvania and Vermont were the most common locations of regulator respondents *(Table 3)*. When food safety communicators were asked in which state or district the food processors they work with are located, Pennsylvania, New York, and Massachusetts yielded the most responses *(Table 4)*. It is apparent that some food safety communicators work with processors in multiple states, as evidenced by a higher number of responses compared with the number of respondents and the written comments mentioning out-of-state work in Ohio, Wisconsin, Utah, Florida, Oregon, Arkansas, Iowa, and California and more broadly in the southern United States, nationally, and internationally. In contrast, regulators worked exclusively with processors in their own states, as would be expected given the boundaries of their state jurisdictions.

Table 5 presents a summary of the types of food products with which food safety communicators and regulators have

TABLE 1. Descriptions of professional activities and how food safety communicators and regulators work with SVS food processors

Respondent	Frequency[a]	%
Food safety communicator (n = 46)		
FSPCA lead instructor[b]	21	46
Consultant	16	35
Extension educator	15	33
Shared kitchen incubator or copacker	7	15
Retail food operation	3	6
Buyer or distributor	3	6
Process authority	2	4
Insurance company	1	2
Commercial laboratory	1	2
Regulators (n = 37)		
State regulator	37	100
Federal regulator	0	0
County regulator	0	0

[a]Respondents checked all answers that applied.

[b]81% coidentified as a consultant (43%) or an extension educator (38%).

TABLE 2. Response to question on whether food safety communicators and regulators conduct one-on-one or small-group advice or assistance activities to help SVS food processors comply with the PCHF Rule

Response	Food safety communicators		Regulators	
	Frequency	%	Frequency	%
Yes, but it is not my main responsibility.	15	33	13	35
Yes, that is my main responsibility.	13	29	1	3
No, but I refer processors to other people who do.	12	27	14	38
No, I do not actively advise or assist food processors.	5	11	9	24
Number of respondents	45		37	

TABLE 3. State or district in which food safety communicators and regulators are located

Location	Food safety communicators		Regulators	
	Frequency	%	Frequency	%
Pennsylvania	14	31	6	17
New York	9	20	3	8
Massachusetts	8	18	1	3
Maryland	3	7	3	8
Maine	3	7	3	8
New Jersey	3	7	3	8
New Hampshire	2	4	1	3
Vermont	1	2	6	17
Delaware	1	2	3	8
Rhode Island	1	2	2	6
Connecticut	0	0	3	8
West Virginia	0	0	2	6
Washington, D.C.	0	0	0	0
Number of respondents	45		36	

TABLE 4. State or district in which SVS food processors were located

Location	Food safety communicators		Regulators	
	Frequency[a]	%	Frequency	%
Pennsylvania	23	50	7	19
New York	18	39	3	8
Massachusetts	10	22	1	3
Other states outside of the Northeast	7	15	0	0
Maryland	7	15	3	8
New Hampshire	7	15	1	3
New Jersey	6	13	3	8
Connecticut	5	11	3	8
Vermont	5	11	6	16
Delaware	5	11	3	8
Maine	4	9	3	8
Rhode Island	4	9	2	5
West Virginia	3	75	2	5
Washington, D.C.	2	4	0	0
Number of respondents	46		37	

[a]Respondents checked all answers that applied.

TABLE 5. Food safety communicator and regulator identification of products with which they work

Product category	Food safety communicators		Regulators	
	Frequency[a]	%	Frequency[a]	%
Fruits and vegetables	25	56	16	43
Ready-to-eat foods	22	49	18	49
Cereals, bread, and baked goods	21	47	19	51
Condiments (e.g., dressing, dips, sauces)	21	47	17	46
Confections, candy, and chocolate	20	44	19	51
Beverages other than 100% juice products	20	44	17	46
Acidified canned foods	19	42	18	49
Dairy products	14	31	22	59
100% juice products (e.g., apple cider)	14	31	17	45
Seafood	11	24	14	38
Oils and fats (e.g., infused oils)	9	20	9	24
Other	9	20	5	13
Spices	8	18	15	41
Mushrooms	8	18	11	30
Soups	8	18	10	27
Alcoholic beverages (wine, beer, hard cider, distilled spirits)	8	18	8	22
Low-acid canned foods	7	16	9	24
Sprouts	2	4	10	27
Number of respondents	45		37	

[a]Respondents checked all answers that applied.

TABLE 6. Food safety communicator and regulator perceptions of the extent to which SVS food processors are aware of PCHF requirements and are knowledgeable of GMP standards and HARPC approaches to writing a food safety plan

Awareness or knowledge[a]	Food safety communicators			Regulators		
	n[b]	Mean rating[c]	SD[d]	*n*	Mean rating	SD
Aware of the requirements in the PCHF Rule	44	3.0	1.2	37	3.2	1.7
Knowledgeable of risk-based preventive control approaches for writing a food safety plan	43	2.9	1.2	37	3.0	1.3
Knowledgeable of the basic food safety and sanitation standards in GMPs	42	3.8	1.3	37	4.1	1.2

[a]Full data are presented in *Table S1*.

[b]Different number of respondents *(n)* indicates some questions were not answered.

[c]Mean ratings were calculated from a 7-point scale: 1 = no awareness or knowledge, 4 = somewhat aware or knowledgeable, 7 = fully aware or knowledgeable.

[d]SD, standard deviation.

experience providing technical support. The top seven selections among food safety communicators were fruits and vegetables (56%); ready-to-eat foods (49%); cereals, bread, and baked goods (47%); condiments (47%); confections (44%); beverages (44%); and acidified canned foods (42%). A similar trend was observed among regulators in the follow-up survey, although dairy products (59%) were more often selected than other food types.

Awareness of the PCHF Rule and food safety knowledge

Both groups of survey respondents reported that they perceive SVS food processors' awareness of PCHF Rule requirements and the knowledge needed for successful compliance to be low (*Table 6* and *Table S1*). Food safety communicators were asked to judge SVS food processors' awareness of the regulation on a 1–7 scale, where 1 = not aware, 4 = somewhat aware, and 7 = fully aware. The mean rating for food safety communicators' perception of awareness was only 3.0 ± 1.2, with roughly two thirds (63%) judging SVS food processors to be less than somewhat aware. Respondents to the regulator survey agreed, giving processors a mean score of 3.2 ± 1.7, and 64% gave scores indicating they believed SVS food processors to be less than somewhat aware. Also scoring low were food safety communicators' perceptions of how knowledgeable SVS food processors are about HARPC approaches for writing a food safety plan (including conducting a hazard analysis and implementing preventive controls). The mean rating for food safety communicators was only 2.9 ± 1.2, with 67% scoring processors as below somewhat knowledgeable. Similarly, the mean rating from regulators was 3.0 ± 1.3, and 70% scored processor knowledge to be below somewhat knowledgeable. Knowledge of GMP standards were slightly less concerning than the other categories, where mean knowledge scores for food safety communicators and regulators were 3.8 ± 1.3 and 4.1 + 1.2, respectively. However, 76% and 70% of food safety communicators and regulators, respectively, thought that SVS food processors were no more than somewhat knowledgeable of GMP standards.

Food safety communicator ratings of challenges faced by SVS food processors, shown in *Figure 1*, confirm the awareness and knowledge deficits summarized in *Table 6*, although some areas were more concerning than others. With the combined percentage of ratings for very and extremely challenging at 72% and 56%, respectively, awareness and understanding of the regulations and a lack of understanding of the financial business risks associated with noncompliance are important challenges *(Table S2)*. However, most respondents (79%) did not indicate that SVS food processors lacked an appreciation of the importance of producing safety foods. More than half of the food safety communicators thought that knowledge of potential hazards (65%), costs of implementation (60%), and expertise in recordkeeping and documentation (56%) were very or extremely important challenges for SVS food processors. Regarding monetary challenges, costs for hiring additional workers (83%), hiring consultants (79%), and upgrading equipment and facilities (71%) were thought to be very or extremely challenging by most food safety communicator respondents. Issues around training were also thought to be important challenges. Ranked very or extremely important by more than half of respondents were lack of time for training (62%) and materials too advanced for learners (55%). Issues around difficulty in finding classes appropriate for adult learners (43%), content that is too general to meet their specific needs (42%), or content that engages adult learners (32%) were perceived by less than half of respondents to be very or extremely challenging.

Lead instructor perceptions of FSPCA PCHF course difficulties and inspector field observations

Food safety communicators who indicated they were lead instructors of the FSPCA PCHF curriculum were then asked how challenging they thought SVS food processors find sections of this course to understand and implement *(Table 7)*. Most topic areas were judged to be at least moderately challenging to course participants, but several topics were thought to be especially challenging. There were four areas that more than half of lead instructor respondents thought were very or extremely challenging: validation procedures (85%), conducting a hazard analysis (75%), verification activities (65%), and supply chain controls (60%). These were followed by developing written operating procedures (50%), process controls (50%), recall plan development (45%), allergen controls (40%), and sanitation controls (35%).

Results for onsite observations of misunderstandings and noncompliance from regulators who perform inspections *(Table 8)* revealed the same top four topic areas of concern that lead instructors reported. More than three quarters of inspectors selected verification procedures (79%), validation procedures (76%), and hazard analysis (76%), with nearly two thirds (65%) identifying supply chain controls as an area where misunderstandings occurred. Inspector noncompliance observations were more evenly distributed and proportionally lower than the lead instructor results. Nevertheless, verification procedures (45%), validation procedures (55%), and hazard analysis (45%) were the top three areas of noncompliance reported by inspectors. Supply chain controls (41%); written operating procedures (38%); adequate process, allergen, and sanitation controls in place (45%, 35%, and 38%, respectively); and a recall plan under development (35%) were reported by between one third and half of inspectors.

To understand the information that processors are seeking, how they want it delivered, and what courses might help them understand the most difficult elements of the PCHF Rule, food safety communicators and regulators were asked to select from a list of the types of information that SVS

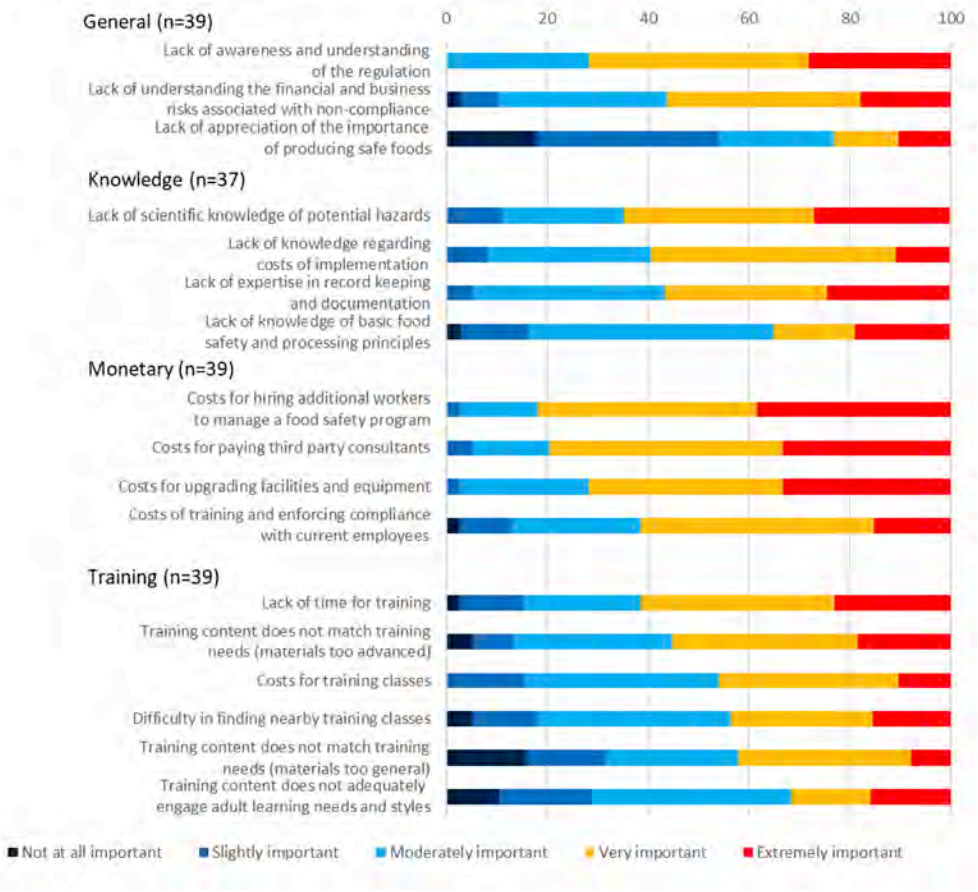

FIGURE 1. Food safety communicator perceptions of general, knowledge, monetary, and training challenges that SVS food processors face and their importance for achieving compliance with the PCHF Rule. All data are available in *TABLE S2*.

TABLE 7. Lead instructor perceptions of how challenging SVS food processors find sections of the FSPCA PCHF course to understand and implement

	Percentage of respondents				
	Not at all	Slightly	Moderately	Very	Extremely or definitely
Validation procedures	0	5	10	60	25
Hazard analysis	0	0	25	50	25
Verification procedures	0	10	25	55	10
Supply chain controls	0	15	25	35	25
Developing written operating procedures	0	10	40	45	5
Process controls	0	10	40	40	10
Recall plan development	5	10	40	40	5
Allergen controls	5	20	35	35	5
Sanitation controls	0	20	45	35	0
Number of respondents	20				

TABLE 8. Inspector perceptions of SVS food processors misunderstandings about PCHF requirements and observations of noncompliance

PCHF requirement	Inspector perception of misunderstandings		Observed noncompliance	
	Frequency[a]	%	Frequency[a]	%
Verification procedures	23	79	13	45
Validation procedures	22	76	16	55
Hazard analysis	22	76	13	45
Supply chain controls	19	65	12	41
Developing written operating procedures	16	55	11	38
Process controls	14	48	13	45
Recall plan development	13	45	10	35
Allergen controls	11	38	10	35
Sanitation controls	7	24	11	38
Number of respondents	29			

[a]Respondents checked all answers that applied.

food processors are looking for when they are contacted for assistance *(Table 9)*. Nearly three quarters (74%) of food safety communicators indicated that processors look for template or model PCHF plans, and more than half indicated that they seek general food safety classes (58%) or private consultant information (53%). These were followed by contact information for a process authority (45%) or university extension (42%), state regulatory contacts (37%) and, to a lesser extent, federal regulator contacts (18%), and legal advice (16%). The top choice among regulators was also where to find template or model PCHF plans (69%), with half or more also selecting state regulator contact information (64%), where to find a PCQI course (56%), process authority or extension contacts (50%), consultant contacts (42%), federal regulators (28%), and legal advice (14%).

Food safety communicators overwhelmingly chose more direct, hands-on approaches to deliver educational programming to SVS food processors, such as one-on-one advice (87%) and training workshops (82%) than did regulators (83% for both) *(Table 10)*. Less than half of the food safety communicators selected printed fact sheets (46%) and webinars or videos (41%), and less than a third chose websites (31%), conferences or meetings (28%), newsletters (13%), or social media (5%). Regulators were similarly less likely to select conferences or meetings (12%) or social media (2%), with none selecting newsletters as a useful information delivery approach.

In the open text responses presented in the Supplement Material, both food safety communicators and regulators reinforce a need for direct education delivery methods, such as hands-on training, visits to smaller processors that have gone through the process of becoming compliant, and combinations of onsite or hands-on trainings with practical application to specific products manufactured (Open Text Responses S1).

Food safety communicators and regulators rated how helpful courses were or would be in helping SVS food processors comply with the PCHF Rule *(Table 11)*. The top four courses chosen by both groups that were considered more than somewhat helpful and very helpful were foundation courses for developing a risk-based food safety program. These included GMP training (97% and 92% for food safety communicators and regulators, respectively), sanitation training (97% and 80%), a general course in HACCP (84% and 74%), and the FSPCA PCHF curriculum (80% and 77%) *(Table S3)*. More than half of the food safety communicators and regulators recommended allergen management training (58% and 56%, respectively), the Produce Safety Alliance curriculum (66% and 69%), and the seafood HACCP curriculum (59% and 67%). Other specialized HACCP courses for meat and poultry (61% and 48%) and juice (51% and 42%) were perceived as less effective in helping SVS food processors comply with the PCHF Rule. Although a higher percentage of regulators considered the Better Process Control School course for acidified and low-acid commercial canned food to be helpful (75%), a higher percentage of regulators also work with acidified canned foods *(Tables 5 and 11)*.

TABLE 9. Types of information on the PCHF Rule that SVS food processors are looking for when they contact a food safety communicator or regulator

Type of information	Food safety communicators		Regulators	
	Frequency	%	Frequency	%
Template or model PCHF food safety plans	28	74	25	69
Where to find general food safety training classes	22	58	19	53
Private consultant contact information	20	53	15	42
Process authority contact information	17	45	18	50
University extension contact information	16	42	18	50
Where to find a PCQI course	15	40	20	56
State regulator contact information	14	37	23	64
Federal regulator contact information	7	18	10	28
Legal advice	6	16	5	14
Number of respondents	38		36	

[a]Respondents checked all answers that applied.

TABLE 10. Food safety communicator and regulator choices for delivery methods that would help SVS food processors understand the requirements of the PCHF Rule and how to write a food safety plan

Delivery method	Food safety communicators		Regulators	
	Frequency	%	Frequency	%
One-on-one advice and consultation	34	87	30	83
Training workshops	32	82	30	83
Printed fact sheets and articles	18	46	21	58
Webinars	16	41	21	58
Videos	16	41	11	31
Websites	12	31	15	42
Conferences or meetings	11	28	18	12
Newsletters	5	13	0	0
Social media	2	5	3	2
Other	2	5	2	1
Number of respondents	39		36	

[a]Respondents checked all answers that applied.

TABLE 11. Food safety communicator and regulator perceptions of how effective courses have been, or would be, in helping SVS food processors comply with the PCHF Rule

Course title or topic[a]	Food safety communicators		Regulators	
	Mean[b] rating	SD[c]	Mean[d] rating	SD
GMP training	4.9	0.4	4.6	0.7
Sanitation training	4.8	0.5	4.5	0.9
HACCP—General	4.6	0.8	4.3	0.9
FSPCA-recognized curriculum	4.4	1.0	4.3	0.9
Allergen management training	4.0	1.0	3.9	1.0
Produce Safety Alliance–recognized curriculum	3.9	1.3	3.9	1.1
Food defense	3.8	1.3	3.4	1.1
HACCP—Seafood	3.7	1.4	3.9	1.2
HACCP—Meat and poultry	3.7	1.4	3.7	1.2
Better Process Control School	3.6	1.4	4.0	0.8
HACCP—Juice	3.6	1.3	3.4	1.1
Serve-Safe restaurant training	3.5	1.3	3.0	1.5
Number of respondents	34		37	

[a]Full data presented in *Table S3*.

[b]Mean ratings were calculated from a 5-point scale: 1 = not helpful, 3 = somewhat helpful, 5 = very helpful.

[c]SD, standard deviation.

[d]Mean ratings were collected using a sliding scale.

Finally, lead instructors reflected on their experiences teaching the FSPCA PCHF course and felt that courses that address the core concepts of risk-based food safety management, along with the basics of food safety and sanitation, would be beneficial preliminary programs for SVS food processors before taking the FSPCA PCHF course *(Table 12)*. Nearly 8 of 10 (79%) respondents felt strongly or very strongly that a risk-based identification of hazards or a GMP course would be beneficial to take before the FSPCA PCHF course. A general course on HACCP was also thought by 68% of respondents to be strongly or very strongly beneficial. However, basic courses in food science and technology or food microbiology were thought to be no more than moderately beneficial by most respondents (58% and 69%, respectively).

DISCUSSION

The goal of this study was to articulate observed challenges that limit PCHF compliance among SVS food processors in the Northeast United States and to find possible solutions. When compared with long-standing challenges smaller food businesses have faced when adopting risk-based food safety management systems, results from this study highlight ongoing challenges, as well as which resources and activities may be most beneficial toward increasing compliance. An appreciation of the challenges and barriers that smaller food processors faced in the past when developing risk-based food safety management systems provides insights for developing strategies to support for PCHF compliance among SVS food processors.

Rather than seeking processors, the approach for this survey was to contact extension educators, consultants, and individuals within allied industries (food safety communicators) and individuals in regulatory agencies (regulators) to understand their perceptions of the challenges that SVS food processors face in complying with the PCHF Rule. Descriptions of professional titles and activities within both respondent groups, and the many types of foods with which they work, illustrate the range of food safety–related experience and expertise within the Northeast United States *(Tables 1–5)*.

In accordance with the HACCP compliance studies of Gilling et al. *(13)* and Azanza and Zamora-Luna *(2)*, the multistep PCHF compliance challenges identified in this study can be categorized as follows: (1) awareness of the PCHF Rule and its requirements, (2) knowledge of hazards and HARPC approaches for controlling them, and

TABLE 12. Lead instructor perceptions of which courses SVS food processors would find to be beneficial before taking the FSPCA PCHF course

Course title or topic	Percentage of respondents				
	None	Slight	Moderate	Strong	Very strong
Risk-based identification of food safety hazards	0	5	16	53	26
GMPs	0	0	21	58	21
General HACCP	0	11	21	47	21
Food science and technology	0	16	42	37	5
Food microbiology	11	16	42	21	11
Number of respondents	19				

(3) motivation to address challenges and engage in PCHF compliance. Survey results also suggest strategies for training SVS food processors on food safety and the PCHF Rule based on preferences for educational resources.

Awareness of the PCHF Rule and its requirements

Food safety communicators and regulators surveyed in this study reported widespread lack of awareness of the PCHF Rule among SVS food processors *(Table 6 and Fig. 1)*. This is an important finding given the studies that recognized awareness as the first of several steps needed to achieve compliance *(2, 9)*.

Small-scale businesses, especially start-up operations, may not be aware of new regulations if they are not involved in food industry or trade associations or if they do not regularly visit online government or university extension sites. Without awareness of the regulations and the specific requirements that apply to SVS food processors, motivation to act on their own or to seek external resources will be hindered. Increased collaborative efforts by food safety communicators and regulators that leverage the expertise and experience within each group will be needed to raise awareness and therefore begin the process of achieving PCHF compliance.

Knowledge of hazards and risk-based food safety approaches for controlling them

Following awareness of the PCHF Rule comes a range of challenges on learning about food safety hazards and developing methods to prevent them from occurring. The results in *Fig. 1* showing that processors appreciate the importance of producing safe foods is consistent with other studies *(19)*. Yet both food safety communicators and regulators agreed that SVS food processors lack knowledge in basic food safety and sanitation standards and, to a greater extent, risk-based food safety management approaches for producing safe foods *(Table 6 and Fig. 1)*. This is not unexpected given the greater complexity of risk-based HACCP and HARPC approaches compared with GMPs. Furthermore, this aligns with earlier studies that found implementation of food safety management programs by smaller food businesses is often hampered by regulations and guidance documents that contain technical jargon that is difficult to understand and that may be judged as overly burdensome and unnecessary *(11, 24)*. The recommended approach of the National Advisory Committee on Microbiological Criteria for Foods to HACCP plan development is to assemble a collaborative multidisciplinary team in which viewpoints and expertise taken from all levels of the company can contribute to a full understanding of risks associated with the process and the product *(17)*. Yet smaller companies with few in-house technical resources often find it challenging to evaluate their own food safety risks *(22)*. This is consistent with the observations of food safety communicators and regulators that SVS food processors most often desire template or model PCHF food safety plans and prefer one-on-one advice and consultations that address the specific products and processes relevant to their operations *(Tables 9 and 10)*.

Lead instructors and regulators who perform inspections agree that three core elements of a risk-based food safety plan, namely, conducting a hazard analysis, verification of monitoring activities, and science-based validation of preventive controls, present the most challenges for SVS food processors *(Tables 7 and 8)*. This was not unexpected given the earlier studies on HACCP implementation that found that conducting a hazard analysis and establishing procedures for verification and validation were the top three subject areas that processors found most difficult to understand and implement *(6, 11, 31)*. The FSPCA PCHF training manual similarly acknowledges the difficulty of conducting a complete and accurate hazard analysis and the complexity of establishing verification and validation procedures *(12)*.

The FDA's stated approach to implementing the FSMA PCHF Rule has been to "educate before and while we regulate." Inspectors often play an important role in interpreting regulatory requirements specific to individual facilities *(7)*. Yet there are limits to the amount of one-on-one advice and assistance inspectors can provide to food businesses given the FSMA directive of inspection frequencies of a minimum of once every 3 to 5 years depending on food risk classification and history of violations *(28)*. Constraints on inspector time at each facility point to a need for food safety communicators and regulators to work together to improve awareness of the PCHF Rule and to provide advice and assistance as needed or refer questions to others in the food safety community.

Motivation to address challenges and engage in PCHF compliance

After SVS food processors are made aware of the PCHF Rule and gained baseline knowledge of its requirements, they face challenges associated with the costs of compliance *(Fig. 1)*. Although SVS food processors and food safety communicators cannot control the costs of compliance, they can identify and emphasize the motivating factors that will foster a personal commitment to adopt food safety practices and accept the associated costs. Greater business opportunities can act as an incentive, whereas fear of legal or regulatory consequences can motivate internal commitment *(34)*.

Costs for hiring consultants, training food safety workers, and upgrading facilities and equipment are among the most challenging barriers to PCHF compliance *(Fig. 1)*. Previous studies have shown that SVS food processors are unmotivated to adopt food safety practices because they consider the risks of enforcement related to noncompliance to be low *(22, 23)*. This is particularly true for SVS food processors that have attested to the FDA that they are qualified facilities because they are not required under the PCHF Rule to develop and implement a food safety plan. Yet long-term adoption of food safety practices can only be successful if there is a written plan for identifying and evaluating potential hazards and continuous reevaluation of risks. In addition, food safety communicators observed that SVS food processors' lack of understanding of financial and business risks associated with noncompliance presents a significant barrier to compliance *(Fig. 1)*.

In addition to the costs of compliance identified in this study *(Fig. 1)*, previously reported challenges to develop a food safety system include shortages of time, staff, and equipment or facilities *(2, 9)*. Despite the monetary challenges that processors face, there are financial benefits to investing in food safety. Most notably, the costs to develop and implement a food safety system can be justified by protecting against litigation *(33)* and maintaining or increasing market access to retailers that may require a food safety plan *(5, 22)*.

In addition to the practical benefits of engaging in PCHF compliance, SVS food processors may be motivated to invest in food safety because of a commitment to producing safe foods. Consistent with the report from Bihn et al. *(5)* that found personal commitment to producing a safer food product was the most common motivation for food producers to learn about food safety, food safety communicators in the present study did not consider lack of appreciation of the importance of producing safe foods to be a challenge to PCHF compliance *(Fig. 1)*. As a result, it is vital for food safety communicators and regulators to educate SVS food processors about how the PCHF Rule is designed to improve food safety and that processors should take steps to comply as part of their personal commitment.

Training improvement opportunities

The results in this study identified several opportunities to improve training and educational resources based on challenges related to content and delivery specific to SVS food processors. The observed knowledge gaps and the perception that some parts of the FSPCA PCHF curriculum are very or extremely difficult show that SVS food processors could benefit from additional training around both basic food safety and sanitation standards and risk-based food safety management approaches for producing safe foods *(Tables 6 and 7)*. This and the reports of food safety communicators that training materials can be both too advanced and too general, not targeted to the specific needs of their products and processes *(Fig. 1)*, point to the diversity of participant background knowledge and preparation needed to develop risk-based management systems.

Respondents' perception of sanitation training highlights SVS food processors' need for introductory training to effectively understand and implement the FSPCA PCHF curriculum. Most lead instructors consider every section of the curriculum to be at least moderately difficult to understand and implement, even the lowest-ranked section, sanitation controls *(Table 7)*. Yet sanitation training is the second most highly recommended course in helping SVS food processors comply with the PCHF Rule *(Table 11)*. The significant gap in the relative difficulty of sanitation training compared with the perceived benefit to processors presents an opportunity for additional training courses to meet processor needs.

Food safety communicators and regulators agreed that GMP training would be the most effective course in helping processors to comply with the PCHF Rule *(Table 11)*. It is also the most broadly applicable course among a range of food businesses that may not be subject to the full requirements of the PCHF Rule, and processors in past studies have expressed greater interest in GMP training than the FSPCA PCHF curriculum *(3, 19, 21)*. Framing GMP training as an effective on-ramping course can provide fundamental training and increase processors' perception that training is accessible and relevant. More generally, Barone et al. *(3)* and Richard et al. *(20)* both commented

on positive outcomes from introductory food safety courses intended as precursors to the FSPCA PCHF curriculum.

Food safety communicators and regulators also provided reflections on processors' preferred education delivery approaches that could be incorporated into training. Processors expressed a preference for information and educational delivery approaches that were hands-on and easy to apply to a business *(Tables 9 and 10)*. In open responses about recommended types of information, one regulator observed that processors want "onsite walk-throughs and facility-specific guidance," which another respondent framed less charitably as "anything they can use without having to think" (Open Text Responses S1). Results suggest that processors are interested in training as a means to compliance, rather than as a holistic learning experience or because they believe it will produce safer foods *(33, 34)*. Although much of this stems from previously outlined motivational issues, training can use this preference by placing greater emphasis on how educational concepts have real-world applications. Given processors' low understanding of risk-based food safety management approaches for producing safe foods, training is also an ideal time to increase awareness and knowledge of how compliance with the regulation can improve the safety of their products *(Table 6) (34)*.

Practically speaking, food safety communicators also have limited time and resources, which should be considered when evaluating how to assess and address processors' educational needs. Results demonstrated an interest in supplementing training by broadening educational formats and delivery methods to address processors' logistical constraints and increase food safety communicators' impact. *Table 10* showed an interest in printed fact sheets and articles, which can offer a less time-intensive introduction to a topic and be tailored to specific topics in which processors are interested. Open text responses about beneficial types of information also encouraged the development of food safety resources in different formats to meet diverse learning needs, such as "more options for different learning styles; more visuals for people who may not have advanced reading skills" and "hands-on SOP [standard operating procedures] and SSOP [sanitation standard operating procedures] writing and other interactive strategies within a workshop" (Open Text Responses S1). Past research has also endorsed broadening types and delivery of food safety education to lower costs and develop online courses *(3, 18)*.

Limitations

This was a mixed-methods study that surveyed food safety communicators and regulators who were relatively convenient to contact. If they were unable to complete the survey, we asked them to pass it on to others in their organization who could. We chose not to pursue statistical analysis but to instead rely on a nonprobability sampling, informed by our knowledge of the topic, to identify preliminary areas of greatest concern. Within the Northeast United States, the number of food safety communicators was skewed toward Pennsylvania, New York, and Massachusetts. This may occur because of more favorable preexisting relationships with the NECAFS PCHF Workgroup or because these are more populous states that are home to a greater number of food processing facilities and thus have more food safety support systems in place. In addition, respondents may not always know the business size category of the processors with which they interact and therefore their exemption status. Because survey participants were recruited only from locations in the Northeast United States, caution should be used when extrapolating the results and insights from this survey to other regions of the United States. Nevertheless, the PCHF Rule is a federal regulation, and requirements apply uniformly across all states and territories. A future study to directly survey a random selection of food processors that addresses these limitations would be beneficial to verify the results presented here.

CONCLUSIONS

Food safety communicators and regulators should collaboratively leverage their expertise and experience to increase compliance among SVS food processors with the PCHF Rule. This study has documented a range of shared challenges that present barriers to advancing PCHF compliance and enhancing food safety practices. Based on the results and the authors' experiences of working with SVS food processors, we conclude these could be addressed through the following: raising awareness, imparting knowledge, motivating SVS food processors, and developing tailored training courses.

Awareness of the PCHF Rule and its requirements

- Develop informative learning materials about the PCHF Rule by applying established principles of plain language interpretation for government communications. Ensure that materials are clear, concise, well organized, and easy to comprehend. Tailor the content to address the unique requirements of smaller food processors, including those that are eligible for qualified facility exemptions or conduct on-farm processing, using appropriate languages and literacy levels to make the information accessible to all.
- Create awareness resources that briefly and succinctly highlight the essentials of the PCHF Rule and provide contact details to food safety communicators for further information, such as procedures for attestation of qualified facility status. Distribute these through direct mailing to SVS food processors or to regulators who can distribute them during inspections.
- Consider establishing stronger relationships between food safety communicators and regulators. For example, organize food safety task forces that include processors, regulators, and educators and aim to address or provide input on specific issues related to processed food products.

Knowledge of hazards and risk-based food safety approaches for controlling them

- Develop step-by-step guidance materials and handbooks in formats that SVS food processors prefer on topics with which they struggle (e.g., GMPs, evaluating food safety risks, verification and validation of preventive controls, creating environmental monitoring programs, managing allergen risks, and developing supply chain controls).
- Food safety communicators must adjust their outreach campaigns beyond traditional channels and reach out to alternative venues in which SVS food processors are involved. These could include extension fruit and vegetable production winter or twilight meetings, pest management workshops, business planning workshops, and other venues where commodity producers might be present as places to deliver presentations and distribute materials to those interested in value-added food processing opportunities.
- Encourage educators to share their materials at food safety conferences and post them on university or trade association websites, social media, and the NECAFS Processor's Food Safety Toolkit. Providing a central repository for all relevant resources specific to SVS food processors makes it more accessible and leverages resources more effectively within the food safety communicator community.

Motivation to address challenges and engage in PCHF compliance

- Undertake research to identify and evaluate how the costs of PCHF compliance and the financial and business risks associated with noncompliance affect SVS food processors' motivation. Leverage this new understanding to develop programming that educates SVS food processors about realistic costs and risk assessments when developing and implementing a food safety plan, such as webinars on passing third-party audits or food safety plan writing workshops that incorporate business planning.
- Partner with organizations that serve SVS food processors (e.g., specialty food associations, shared-use kitchens, food business innovation centers, and wholesale buyer meetings) to deliver guest presentations and distribute materials on risk-based food safety management and the PCHF Rule that describe the benefits of establishing a strong food safety culture and making investments that can allow growth and that protect their customers from illness and their business from liability.
- Create model food safety plans, hazard identification guides, and template production and sanitation verification forms to reduce barriers for SVS food processors to develop their own food safety plans and start adopting risk management food safety practices.

Training tailored to the needs of SVS food processors

- Develop relevant, engaging, and interactive workshops for SVS food processors that focus on key requirements of SVS food processing, including identifying potential hazards, implementing preventive controls to address the hazards, and developing procedures for monitoring the performance of the preventive controls to ensure that the food produced is safe.
- Create new courses or promote existing ones that can serve as precursors to the FSPCA PCHF curriculum, such as general sanitation standards written in GMPs. Courses should be brief and interactive with hands-on exercises, include guest presentations by regulators, and when feasible, include one-on-one support and training.
- Construct evaluation methods to identify predictive indicators of meaningful impact and track the effectiveness of new courses for educating SVS food processors on risk-based management of food safety hazards. Formative and summative data can be used to assess courses, make improvements, and identify the ongoing food safety needs of SVS food processors.
- Pursue continued investment from federal and state grants, industry partnerships, commodity groups, and trade associations to support extension educators who create such training materials to ensure that the development and delivery of education is accessible and affordable.

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REFERENCES

1. Association of Food and Drug Officials. 2023. Directory of state and local officials. Available at: https://www.afdo.org/directories/dslo/. Accessed 21 December 2023.
2. Azanza, M. P. V., and M. B. Zamora-Luna. 2005. Barriers of HACCP team members to guideline adherence. *Food Control* 16:15–22.
3. Barone, N. A., E. DiCaprio, and A. B. Snyder. 2020. A preliminary assessment of food safety training needs and preferences among Ohio food processors of various sizes. *Food Control* 114:107220.
4. Bass, G. 30 March 2022. Status on filed attestations [E-mail: glenn.bass@fda.hhs.gov]. Available from: the author at anne.fitzgerald@uvm.edu.
5. Bihn, E. A., L. Springer, and L. Pineda-Bermúdez. 2019. Local food safety collaborative needs assessment survey report. Cornell University, Department of Food Science, 13 August. Available at: https://foodsafetyclearinghouse.org/sites/default/files/files/listening_session_report_.pdf. Accessed 21 December 2023.
6. Brackett, R. E., W. Ocasio, K. Waters, J. Barach, and J. Wan. 2014. Validation and verification: A practical, industry-driven framework developed to support the requirements of the Food Safety Modernization Act (FSMA) of 2011. *Food Prot. Trends* 34:410–425.
7. Buckley, J. 2015. Food safety regulation and small processing: A case study of interactions between processors and inspectors. *Food Policy* 51:74–82.
8. Center for Food Safety and Applied Nutrition. 2016. Small entity compliance guide: What you need to know about current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food. U.S. Food and Drug Administration. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-what-you-need-know-about-current-good-manufacturing-practice-hazard. Accessed 21 December 2023.
9. Clayton, D. A., C. J. Griffith, P. Price, and A. C. Peters. 2002. Food handlers' beliefs and self-reported practices. *Int. J. Environ. Health Res.* 12:25–39.
10. Codex. 2003. Hazard analysis critical control point (HACCP) system guidelines for its application. Annex to the recommended internal code of practice general principles of food hygiene, CAC/RCP 1-1969, Rev. 4-2003—Annex. FAO/WHO Codex Alimentarius Commission, Rome. Available at: https://downloads.regulations.gov/FDA-2011-N-0143-0375/content.pdf. Accessed 21 December 2023.
11. Fielding, L., L. Ellis, D. Clayton, and A. Peters. 2011. An evaluation of process specific information resources, aimed at hazard analysis, in small and medium enterprises in food manufacturing. *Food Control* 22:1171–1177.
12. Food Safety Preventive Controls Alliance. 2016. Preventive controls for human foods participant manual, 1st ed. Food Safety Preventive Controls Alliance, Bedford Park, IL.
13. Gilling, S. J., E. A. Taylor, K. Kane, and J. Z. Taylor. 2001. Successful hazard analysis critical control point implementation in the United Kingdom: Understanding the barriers through the use of a behavioral adherence model. *J. Food Prot.* 64:710–715.
14. Grover, A. K., S. Chopra, and G. A. Mosher. 2016. Food Safety Modernization Act: A quality management approach to identify and prioritize factors affecting adoption of preventive controls among small food facilities. *Food Control* 66:241–249.
15. International Food Protection Training Institute. 2023. November 6, 2023. Available at: https://www.ifpti.org/fspca-metrics. Accessed 21 December 2023.
16. LaBorde, L. F., 2020. The hazard analysis risk-based preventive controls, p. 205–226. In A. Demirci, H. Feng, and K. Krishnamurthy (ed.), Food safety engineering. Springer, Cham, Switzerland. Available at: https://doi.org/10.1007/978-3-030-42660-6_9. Accessed 21 December 2023.
17. National Advisory Committee on Microbiological Criteria for Foods. 1998. Hazard analysis and critical control point principles and application guidelines. *J. Food Prot.* 61:762–775.
18. Pivarnik, L. F., D. Hicks, M. Jahncke, and K. Gall. 2007. Needs assessment survey of sanitation, good manufacturing and hygienic training practices for food processors, wholesalers and warehouse operators. *Food Prot. Trends* 27:400–408.
19. Richard, N. L., L. F. Pivarnik, C. Von Achen, and A. J. Kinchla. 2021. Knowledge, attitudes, and implementation of food safety practices among small food businesses operating at shared-use kitchens. *Food Prot. Trends* 41:8–20.
20. Richard, N. L., L. F. Pivarnik, C. Von Achen, and A. J. Kinchla. 2023. Increasing food safety preparedness of small and emerging food businesses with targeted food safety training. *Food Prot. Trends* 43:292–303.
21. Syrko, J., and K. Kaylegian. 2015. Developing a contemporary dairy foods extension program: A training and technical resource needs assessment of Pennsylvania dairy foods processors. *J. Extension* 53:1–14.
22. Taylor, E. 2001. HACCP in small companies: Benefit or burden? *Food Control* 12:217–222.
23. Taylor, E., and K. Kane. 2005. Reducing the burden of HACCP on SMEs. *Food Control* 16:833–839.
24. Taylor, E. A., and J. Z. Taylor. 2004. Using qualitative psychology to investigate HACCP implementation barriers. *Int. J. Environ. Health Res.* 14(1):53–63.
25. U.S. Department of Agriculture. 1996. Pathogen reduction; hazard analysis and critical control point (HACCP) systems; final rule. *Fed. Reg.* 61:38805–38989.
26. U.S. Food and Drug Administration. 1995. Procedures for the safe and sanitary processing and importing of fish and fishery products; final rule. *Fed. Reg.* 60:65096–65202.
27. U.S. Food and Drug Administration. 2001. Hazard analysis and critical control point (HACCP): Procedures for the safe and sanitary processing and importing of juice. *Fed. Reg.* 66:6137–6202.
28. U.S. Food and Drug Administration. 2020. FSMA final rule for preventive controls for human food. Available at: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food. Accessed 21 December 2023.
29. U.S. Food and Drug Administration. 2023. Freedom of Information action request, reference number 2023–2432.
30. U.S. Food and Drug Administration. 2023. Human Food Inspection Contract Program. Available at: https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/contracts/human-food-inspection-contract-program. Accessed 21 December 2023.
31. Wallace, C. A. 2014. Hazard analysis and critical control point system (HACCP): Principles and practice, p. 226–239. *In* Y. Motarjemi (ed.), Encyclopedia of food safety, vol. 4. Academic Press, San Diego, CA.
32. Weintroth, M. D., A. D. Belk, and K. E. Belk. 2018. History, development, and current status of food safety systems worldwide. *Animal Frontiers* 8:9–15. https://doi.org/10.1093/af/vfy016.
33. Wilcock, A., B. Ball, and A. Fajumo. 2011. Effective implementation of food safety initiatives: Managers', food safety coordinators' and production workers' perspectives. *Food Control* 22:27–33.
34. Yapp, C., and R. Fairman. 2006. Factors affecting food safety compliance within small and medium-sized enterprises: Implications for regulatory and enforcement strategies. *Food Control* 17:42–51.

SUPPLEMENTAL MATERIAL

TABLE S1. Food safety communicator and regulator perceptions of the extent to which SVS food processors are aware of PCHF requirements and are knowledgeable of GMP standards and HARPC approaches to writing a food safety plan, summarized in *Table 6*

Awareness or knowledge		Food safety communicators		Regulators	
	Rating[a]	Frequency[b]	%	Frequency	%
Awareness of requirements in the PCHF Rule	1	5	11	5	13
	2	11	25	9	24
	3	12	27	10	27
	4	14	32	7	19
	5	1	2	1	3
	6	1	2	2	5
	7	0	0	3	8
Number of respondents		44		37	
Knowledge of GMP standards for basic sanitation practices	1	0	0	0	0
	2	6	14	5	13
	3	11	26	4	11
	4	15	37	17	46
	5	6	14	7	19
	6	2	5	3	8
	7	2	5	1	3
Number of respondents		42		37	
Knowledge of HARPC approaches for writing a food safety plan	1	4	9	3	8
	2	15	35	13	35
	3	10	23	10	27
	4	10	23	7	19
	5	3	7	2	5
	6	1	2	1	3
	7	0	0	1	3
Number of respondents		43		37	

[a]Rating values were based on a 7-point scale: 1 = no awareness or knowledge, 4 = somewhat aware or knowledgeable, 7 = fully aware or knowledgeable.

[b]Different number of respondents *(n)* indicates some questions were not answered.

TABLE S2. Tabulated data of the results represented in *Figure 1*

Category	Percentage of respondents				
	Not at all	Slightly	Moderately	Very	Extremely
General (n = 39)[a]					
Lack of awareness and understanding of the regulation	0[b]	0	28	44	28
Lack of understanding the financial and business risks associated with noncompliance	3	8	33	38	18
Lack of appreciation of the importance of producing safe foods	18	36	23	13	10
Knowledge (n = 37)					
Lack of scientific knowledge of potential hazards	0	11	24	38	27
Lack of knowledge regarding costs of implementation	0	8	32	49	11
Lack of expertise in recordkeeping and documentation	0	5	38	32	24
Lack of knowledge of basic food safety and processing principles	3	13	49	16	19
Monetary (n = 39)					
Costs of hiring additional workers to manage a food safety program	0	3	15	44	39
Costs of paying third-party consultants	0	5	15	46	33
Costs of upgrading facilities and equipment	0	3	26	38	33
Costs of training and enforcing compliance with current employees	3	10	26	46	15
Training (n = 39)					
Lack of time for training	3	13	23	39	23
Training content does not match training needs (materials too advanced)	5	8	32	37	18
Costs of training classes	0	15	39	36	10
Difficulty in finding nearby training classes	5	13	39	28	15
Does not adequately engage adult learning needs and styles	16	16	26	34	8
Does not match training needs (materials too general)	11	18	39	16	16

[a]Different number of respondents *(n)* indicates some questions were not answered.

[b]Values indicate the percentage of respondents selecting each challenge level.

TABLE S3. Tabulated data of the results represented in *Table 11*

Course title or topic		Food safety communicators		Regulators[a]	
	Rating	Frequency	%	Frequency	%
GMP training	1	0	0	0	0
	2	0	0	1	3
	3	1	3	2	5
	4	2	6	10	27
	5	31	91	24	65
Number of respondents		34		37	
Sanitation training	1	0	0	0	0
	2	0	0	2	6
	3	1	3	5	14
	4	4	14	4	11
	5	24	83	25	69
Number of respondents		29		36	
HACCP–General	1	0	0	0	0
	2	0	0	1	3
	3	5	16	8	23
	4	3	10	5	14
	5	23	74	21	60
Number of respondents		31		35	
FSPCA-recognized curriculum	1	0	0	0	0
	2	2	7	2	6
	3	4	13	6	17
	4	6	19	7	20
	5	19	61	20	57
Number of respondents		31		35	
Allergen management training	1	0	0	0	0
	2	1	4	2	6
	3	11	38	13	38
	4	3	10	8	24
	5	14	48	11	32
Number of respondents		29		34	
Produce Safety Alliance–recognized curriculum	1	2	7	0	0
	2	3	10	3	12
	3	5	17	5	19
	4	7	23	8	31
	5	13	43	10	38
Number of respondents		30		26	

Table S3 continued on the next page.

TABLE S3. Tabulated data of the results represented in *Table 11* (cont.)

Course title or topic		Food safety communicators		Regulators[a]	
	Rating	Frequency	%	Frequency	%
Food defense	1	2	7	0	0
	2	2	7	8	24
	3	9	31	11	34
	4	3	10	6	18
	5	13	45	8	24
Number of respondents		29		33	
HACCP–Seafood	1	3	12	2	8
	2	2	8	0	0
	3	5	21	6	25
	4	4	17	6	25
	5	10	42	10	42
Number of respondents		24		24	
HACCP–Meat and poultry	1	3	13	1	5
	2	2	9	2	9
	3	4	17	8	38
	4	5	22	4	19
	5	9	39	6	29
Number of respondents		23		21	
Better Process Control School	1	3	11	0	0
	2	3	11	1	3
	3	6	22	7	22
	4	6	22	14	44
	5	9	33	10	31
Number of respondents		27		32	
HACCP–Juice	1	2	8	1	4
	2	2	8	3	12
	3	8	33	11	42
	4	3	13	5	19
	5	9	38	6	23
Number of respondents		24		26	
Serve-Safe restaurant training	1	3	9	6	21
	2	5	16	5	18
	3	7	22	7	25
	4	8	25	4	15
	5	9	28	6	21
Number of respondents		32		28	

[a]Ratings were collected using a sliding scale, where 1.0 = not helpful and 5.0 = very helpful and rounded to the nearest whole number.

OPEN TEXT RESPONSES S1. Full-text responses to open-ended questions about types of information and resources considered beneficial to SVS food processors

Please list any other types of information you have found to be beneficial for SVS food processors ($n = 24$):

Food safety communicators:
- More options for different learning styles; more visuals for people who may not have advanced reading skills.
- Basic introduction to food safety.
- One-on-one hand holding is huge!
- There seems to be some confusion about nonprofits needing to be compliant.
- Clarity of regulations federal/state/local.
- A one-stop facility providing answers to every question raised by a new food entrepreneur.
- Everything from sourcing ingredients and packaging from reputable suppliers to in-depth GMP training.
- Online templates for developing a food safety plan.
- Recordkeeping, internal auditing, employee training.
- Regulatory guidance documents.
- Hazard guide.
- Current GMPs.

Regulators:
- Production courses for the category of products they are manufacturing.
- Field tickets with a public health statement on them.
- Facility design and equipment construction.
- Onsite walk-throughs and facility-specific guidance.
- Anything they can use without having to think.
- They need the basics. How to identify and control hazards related their products and basic sanitation and food safety. By far more important for them than anything else.
- Internet sites.
- How to get the attestation.
- The FDA food safety plan builder program as a basic starting point for a food safety plan.
- Knowledge of the federal regulations.
- Practical sanitation advice.
- Labeling requirements.

Please list any other resources you have found to be beneficial for small and very small food processors ($n = 8$):

Food safety communicators:
- University extension.
- Site visits to smaller processors that have gone through the process of being compliant.
- Hands-on SOP and SSOP writing and other interactive strategies within a workshop.

Regulators:
- Training that is built into routine inspections.
- AFDO information available for SMEs [small and medium enterprises] to help and assist, as well as extension service.
- Virtual courses.
- Websites.
- State university extension.