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Assessment of Midwest Growers' Needs for Compliance with the Food Safety Modernization Act Produce Safety Rule

ABSTRACT

Increases in outbreaks of foodborne illnesses traced to fruits or vegetables have resulted in a food safety policy shift in the United States (U.S.) from reaction to a focus on prevention of outbreaks. This research assessed the knowledge and educational needs of produce growers in the north central region of the U.S. with regard to the Food Safety Modernization Act (FSMA) Produce Safety Rule, using a modified Delphi approach. The tool gathered information about educational needs and preferred methods of educational delivery from growers over two rounds, with the second round of the assessment survey informed by the first round. Through use of a ranking scale (1 representing the least understood topic and 4 the most understood topic), participants (n = 410) in the second round indicated that the least understood topics were related to biological soil amendments of animal origin (BSAAO) (mean rank 2.18) and agricultural water (mean rank 2.49). Growers preferred to obtain information from extension publications/fact sheets, printed checklists, hands-on/experiential events, and text-based information

rather than from DVDs and flash drives. Based on these results, educational materials in the form of fact sheets that focused on BSAAO and agricultural water were developed for produce growers in the north central region.

INTRODUCTION

Vegetable production is an important sector of the agriculture industry in the United States (U.S.), with 11.7 billion pounds of vegetables produced commercially in 2017 (17). While these foods are an important part of a healthful diet, there are concerns, as fruits, vegetables, and nuts accounted for 23 percent of reported human foodborne illness outbreaks between 2009 and 2015 (5, 6). The farm environment provides opportunities for fruits and vegetables to become contaminated during pre-harvest, harvest, and post-harvest activities (4, 14). Vectors for contamination include biological soil amendments of animal origin (BSAAO); agricultural water; wild and domestic animals; workers with poor hygiene practices; unsanitary harvesting equipment, tools and containers; transport vehicles; and improper storage or packing practices (3, 14).

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The Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR), finalized in 2016 by the U.S. Food and Drug Administration (24), provides minimum standards for safe conditions of growing, harvesting, packing, and holding of fruits and vegetables that are to be consumed by humans. The PSR describes regulations related to pre- and post-harvest agricultural water; BSAAO; sprouts; domesticated and wild animals; workers' training and their health and hygiene; equipment, tools and buildings; and exemptions for produce not typically consumed raw or for small-scale farm operations (25). These new regulations for produce growers necessitated determining what information was needed for them to become compliant with the FSMA PSR.

The Delphi method of data collection, generally credited to Norman Dalkey and Olaf Helmer, is commonly considered a method of achieving consensus of opinions from a group of experts (9, 10, 12, 21). The Delphi technique attempts to collect information through the use of multiple rounds of surveys with controlled feedback and increasingly focused questions. The process ends when a consensus among participants has been reached, as shown when no new information is obtained (12). Qualitative and quantitative data can be collected using the Delphi approach (12).

The objectives of this research were to assess knowledge and identify priority areas of information needs to guide development of materials to assist growers in complying with the PSR in twelve north central states, as well as to identify their preferred methods of delivery of resources. This research was conducted using a modified Delphi approach through two rounds of surveys to growers in the North Central Region (NCR), with a variety of question types and open-ended response options for gathering information and providing feedback. The development of the two rounds of survey tools, along with results of the round one data, can be found in Strohbehn, Enderton, Shaw, Perry, Overdiep, and Naeve (22). This article presents the conclusions of the second round of the needs assessment and describes how the results have been used.

MATERIAL AND METHODS

The needs assessment was developed and implemented with two rounds of surveys targeted to small- and medium-scale growers in the NCR. The survey tools can be found at <https://www.ncrfsma.org/resources-topic>. We chose to deploy two rounds of surveys in order to provide opportunities for subsequent inputs while keeping the survey process within the timeline of the funding source, to allow for creation of relevant educational materials in response to the results. Two rounds of surveys allowed us to reach consensus through careful crafting of the round two survey, which incorporated themes that emerged in responses to open-ended questions in round one.

The following are the steps taken to develop and deploy two rounds of surveys: (1) An expert panel drafted the first

round of the needs assessment survey; (2) a convenience sample of thirty extension educators and produce growers in the NCR pilot tested the instrument; (3) the survey tool was modified on the basis of the reviewers' comments; (4) the modified round one survey was distributed electronically and in paper form to growers within the NCR through various networks; (5) results were analyzed for the top four concern areas related to FSMA and preferred delivery methods; (6) the round two needs assessment survey was developed; (7) a convenience sample of thirty extension educators and produce growers in the NCR pilot tested the instrument; (8) the survey tool was modified on the basis of the reviewers' comments; (9) the final round two survey was distributed to growers within the NCR electronically and in paper form; and (10) results were analyzed.

The round one survey generated both quantitative and qualitative data used to inform development of the second round, a process typical of the Delphi approach. Specifically, the four priority knowledge needs areas identified in round one were used to create a shorter, more focused survey for round two. Those priority needs areas were: biological soil amendment tests and their frequency; agriculture water tests and their frequency; wild and domestic animals; and workers' training, health and hygiene. Additionally, round one findings indicated that growers preferred traditional Extension outreach methods, such as checklists, printed publications, and face-to-face trainings, over online modules, online interactive tools, and social media. We included these top-rated items in the round two survey to identify the most favored methods of delivery. The complete description of the round one phase of the survey is presented elsewhere (22).

The round two survey consisted of two parts. Part one asked respondents for their perceptions related to the PSR and preferences regarding information delivery, while part two included requests for demographic information (gender, age, number of years farming). The perception of understanding of topics were rank ordered using a scale of 1 to 4, with 1 being the least understood topic and 4 being the most understood. Respondents' perceptions of the likelihood of their using various educational resources (online classes, extension publications/fact sheets, printed checklists, DVD/flash drives) were assessed on a 5-point scale (1 = very unlikely to use; 5 = very likely to use). Participants were also asked to identify their two favorite ways of learning new information from a list of approaches such as visual-based messages, verbal communications, and text-based information.

The round two survey was distributed to produce growers in the 12 NCR states (Iowa, Illinois, Indiana, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, South Dakota, Ohio, and Wisconsin) in the fall of 2016. An electronic version, using Qualtrics Survey Software version XM, and paper versions were disseminated by extension educators, grower networks through state and regional produce grower listservs, and at grower conferences and

workshops. There was a concerted effort to distribute the survey to the entire population of produce operators in the NCR. At the time of dissemination, a data base of growers did not exist, so we did not know the size of the population we were inviting to take the survey.

The data collected through use of the round two survey were analyzed as follows: On the advice of statistical advisors, to reduce item non-response bias, we included in the data analysis only surveys with at least one-third of the items completed. Data were analyzed using SPSS Version 12.0, with measures of central tendency (mean, median, and mode), along with levels of dispersion (standard deviation and inter-quartile range) calculated. *T*-tests with significance set at a *P*-value of 0.05 were conducted to determine whether significant differences existed between groups of respondents.

RESULTS AND DISCUSSION

Results

We received 508 round two needs assessment surveys electronically (304 used in data analysis) and 123 in paper form (106 used in data analysis); 410 responses met our inclusion criteria. On average, respondents were 49 years of age and had been farming for ten years ($n = 340$), as shown in *Table 1*. The vast majority (69.7%) of respondents identified themselves as beginning farmers (farming fewer than ten years). Male respondents ($n = 214$) had been farming significantly longer than female respondents ($n = 162$), with means of 12 years and 7 years farming experience, respectively ($P < 0.001$), as shown in *Table 2*. Growers in the region felt the need for more education about BSAAO, as this was perceived as the least understood topic (mean of 2.18, with 1.0 being the least understood topic), followed by agricultural water requirements (mean of 2.49), domestic and

wild animal fecal control (mean of 2.58), and worker training (mean of 2.75), as shown in *Table 3*.

Growers in the NCR reported they were either “Likely” or “Very Likely” (rating of 4 or 5 on the 5-point scale) to use educational materials in these formats: extension publications/fact sheets (76.6%), printed checklists (71.0%), online videos (60.3%), online classes (54.4%), web-based handouts/posters (52.0%), and DVD/flash drives (36.1%), as shown in *Table 4*. Growers identified their top two preferences for ways to learn new information, with the majority (223 of the 410; 56.8%) preferring hands-on/experiential events such as field days and site visits. The second most favored method (189 of 410; 46.1%) was through text-based materials such as extension publications and books, in online and/or print versions. About one-third of respondents indicated visual-based messages (e.g., posters, diagrams), verbal communication (such as webinars or podcasts), and group/social activities like peer-to-peer calls or small group discussions were in the top two preferred methods of receiving new information, as shown in *Table 5*. No significant differences were found between male or female respondents, or by age of responding growers, in their responses regarding likelihood of use of materials or preferred methods of receiving new information.

DISCUSSION

Our results indicated that the average age of our growers is less (48.9 years) than the average of all operators in the U.S., whose age USDA reported at 56.3 years (23). In contrast with farmers nationally, 69.7 percent of our respondents were beginning farmers, compared with 21.7 percent of all operators nationally (23). With a relatively young farmer population in the NCR, integrating food safety into their growing practices and infrastructure may be easier. Research

TABLE 1. Profile of produce grower respondents from the north central region

	Mean	Median	(SD)
Age ($n = 400$)	48.9	49.0	14.0
Years farming ($n = 390$)	10.0	6.0	3.5

TABLE 2. Profile of produce grower respondents in the north central region by gender* ($n = 400$)

Gender	No. (%)	Mean number of years farming	(SD)
Male	214 (53.5%)	12.2	13.0
Female	162 (44.3%)	7.1	8.5

*Significant difference in number of years farming between male and female respondents ($P < 0.001$)

TABLE 3. Mean ranking of topic understanding by respondents to identified priority needs

Topic	Mean ± (SD)	No. (%)
Validation for biological soil amendments of animal origin treatment processes ^a	2.18 (1.09)	
1= least understood		114 (35.3%)
2		91 (28.2%)
3		63 (19.5%)
4 = most understood		55 (17.0%)
Required water tests and their frequency ^a	2.49 (1.10)	
1= least understood		79 (24.5%)
2		86 (26.6%)
3		80 (24.8%)
4 = most understood		78 (24.1%)
Protection of crops from animal fecal contamination ^a	2.58 (1.03)	
1 = least understood		58 (18.0%)
2		94 (29.1%)
3		96 (29.7%)
4 = most understood		75 (23.2%)
Worker training ^a	2.75 (1.16)	
1= least understood		72 (22.3%)
2		52 (16.1%)
3		84 (26.0%)
4 = most understood		115 (35.6%)

^an = 323

has shown that beginning farmers are more likely to utilize technology and seek extension educators to gain knowledge related to farming (1, 8). Also, females constituted a higher percentage of respondents in our sample (44.3%) than in all operators nationwide (30.5%) (23). While others have found female operators to have unique educational needs (2), we found that female respondents had the same top preferences for educational materials and learning styles as male respondents.

Our results showed that BSAAO and agricultural water were the least understood topics of the FSMA PSR. This finding is important, because BSAAO and agricultural water are potential vehicles for contamination from foodborne pathogens such as *E. coli* and *Salmonella* (4, 11), and producers need to know about the action steps that can mitigate the risk. Research has shown that *Escherichia coli* O157:H7 can survive for periods from several weeks to 109 days in surface water samples, depending upon temperature (7, 13, 27). The romaine lettuce outbreak in Arizona linked

contamination of the food to cattle manure in irrigation water (26). BSAAO and agricultural water are also two areas of the PSR that the FDA is still in the process of clarifying, which may partially explain why farmers had the least understanding of these parts of the rule. As of October 2018, the PSR does not have specific, set, or mandatory guidelines with regard to BSAAO application-to-harvest interval or number and frequency of water testing requirements. FDA has placed a reserved space for additional regulation language regarding BSAAO in 21 CFR 112.56(a) (1) (i), which will include a research-based minimum application-to-harvest interval once research has been conducted (18). Additionally, FDA recognizes that application of the agricultural water regulations are difficult to understand, translate, and implement; therefore, plans are under way to simplify the standards, and compliance dates have been extended pending more research to assist in finalizing the rule (19, 25). FDA also collaborated with the Produce Safety Alliance to convene Soil and Water Summits in fall 2017 and spring

TABLE 4. Respondents' likelihood of using listed educational resources

Resource	No. (%)				
	Very unlikely ^a	Unlikely	Neither likely nor unlikely	Likely	Very likely ^a
Extension publication/ fact sheets (n = 403)	17 (4.1%)	15 (3.7%)	59 (14.4%)	135 (32.9%)	179 (43.7%)
Printed checklists (n = 403)	23 (5.6%)	22 (5.4%)	69 (16.8%)	131 (32.0%)	160 (39.0%)
Online videos (n = 403)	100 (24.4%)	20 (4.9%)	38 (9.3%)	100 (24.4%)	147 (35.9%)
Online classes (n = 403)	108 (26.3%)	27 (6.6%)	47 (11.5%)	100 (24.4%)	123 (30.0%)
Web-based handouts/posters (n = 402)	58	34	99	120	93
	(14.1%)	(8.3%)	(24.1%)	(29.3%)	(22.7%)
DVD/flash drives (n = 400)	129 (31.5%)	62 (15.1%)	63 (15.4%)	80 (19.5%)	68 (16.6%)

^aRating scale: 1 = Very unlikely, 5 = Very likely

TABLE 5. Respondents' selections of top two best ways to learn new information (n = 410)*

Learning style	No.	(%)
Hands-on/experiential events (e.g., field days, site visits)	233	56.8
Text-based information (e.g., Extension publications, books-online and/or print)	189	46.1
Visual based messages (e.g., posters, diagrams)	135	32.9
Verbal communication (e.g., webinars, podcasts)	129	31.5
Group/social activities (e.g., peer-to-peer calls, small group discussions)	124	30.2

*Respondents were asked to choose two most preferred ways to learn new information

2018 to gather input from produce growers and experts from various universities and government affiliates on how the BSAAO and agricultural water portions of the FSMA PSR could be clarified (19). Representatives from the NCR were present at the Soil and Water Summits to provide input related to Midwest growers' concerns and lack of knowledge related to these parts of the PSR.

In direct response to the results of this needs assessment, extension educators in the NCR formed working groups to develop educational materials for Midwest produce growers related to BSAAO, record keeping, training guidance for staff and volunteers, domesticated animals on the farm and in the packing shed, and wildlife management. Recognizing that a variety of delivery methods was preferred, these materials were

created as fact sheets, web-based handouts, videos, printable checklists, and flip-charts (15). These can be accessed from the NCR FSMA and National FSMA Clearinghouse websites (see www.ncrfsma.org and www.uvm.edu/extension/necafs/clearinghouse, respectively) (16).

RECOMMENDATIONS

In this study, the researchers used a modified Delphi approach with two rounds of surveys deployed to assess needs of growers in the north central region regarding educational gaps related to the PSR. Analysis of qualitative and quantitative data provided direction in development of educational materials for this audience, using preferred methods of delivery of this information. In this investigation,

the least understood topics (biological soil amendments of animal origin and water requirements, domestic and wild animal fecal controls, and worker training), preferred methods of information delivery (checklists and fact sheets), and ways to receive new information (hands-on learning and text-based information) were determined. The research team used the data to identify resources needed in this specific region, recognizing that the population of growers differs from that of other parts of the country. Future research could include verification of whether growers actually use the developed resources, as well as ascertaining changes in knowledge and reported behaviors. Those involved with

PSR compliance in other parts of the country could conduct their own assessments to determine educational needs and preferred methods of delivery specific to grower population in those areas.

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