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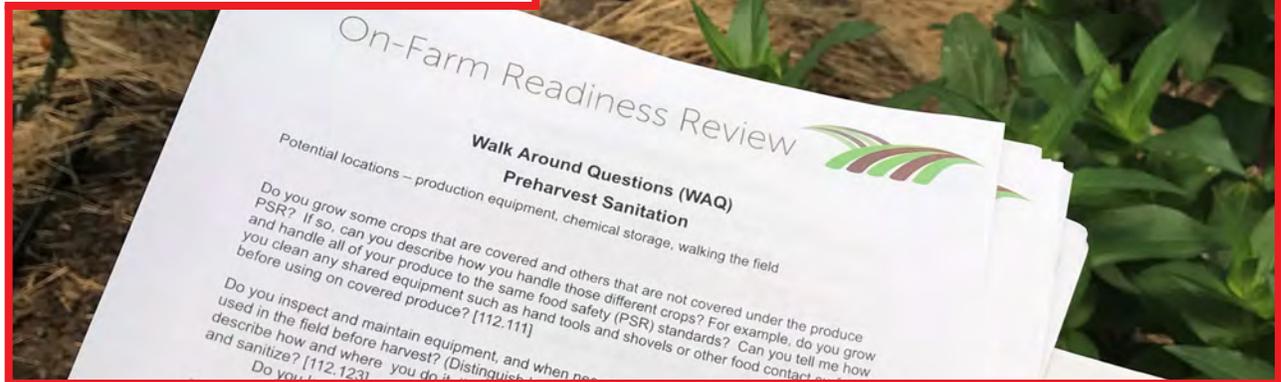
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## On-Farm Readiness Review Tool and Training Curriculum to Help Farmers Assess Their Readiness to Comply with the FSMA Produce Safety Rule

### ABSTRACT

A team of extension professionals and state and national regulatory staff convened by the National Association of State Departments of Agriculture developed the On-Farm Readiness Review (OFRR) to support farm personnel on compliance with the Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR). The OFRR tool was created to align the FSMA PSR provisions with relevant farming practices in time and space; it also linked recommendations for implementation of PSR requirements and offered evaluation criteria to assess PSR compliance before inspection. The developed tool is composed of a decision tree, walk-around questions, and a resource manual. The tool is the foundation of the training curriculum. The tool and curriculum were piloted and evaluated by participants to inform additional development of the final product. OFRR trainings were held nationally, and participants were trained on how to use the tool to conduct a confidential on-farm assessment of a farm's readiness for a FSMA PSR inspection. The tools and training have had a beneficial impact on participants

understanding of the FSMA PSR, have increased the assessors' ability to apply the PSR to the farm, and have developed trained assessor teams that are able to evaluate inspectional readiness in their home state.

### INTRODUCTION

Food Safety Modernization Act (FSMA) Produce Safety Rule (PSR) compliance dates began for farm operations starting in 2018 (9). Fresh produce growers, harvesters, and packers covered by the PSR need to understand the complex PSR requirements and how to apply them to their farm. Attending a training recognized as adequate by the U.S. Food and Drug Administration (FDA) is a PSR requirement (9); a seven-module workshop was developed and is coordinated by the Produce Safety Alliance (PSA) to fulfill this training requirement (10). Following the training, growers are expected to assess their farms and implement practices necessary to be compliant with the PSR. Growers lacked a consultative way to connect the PSA training with practices on their farm. This lack of technical on-farm support is a well-documented hurdle to PSR implementation (1, 4, 5). In

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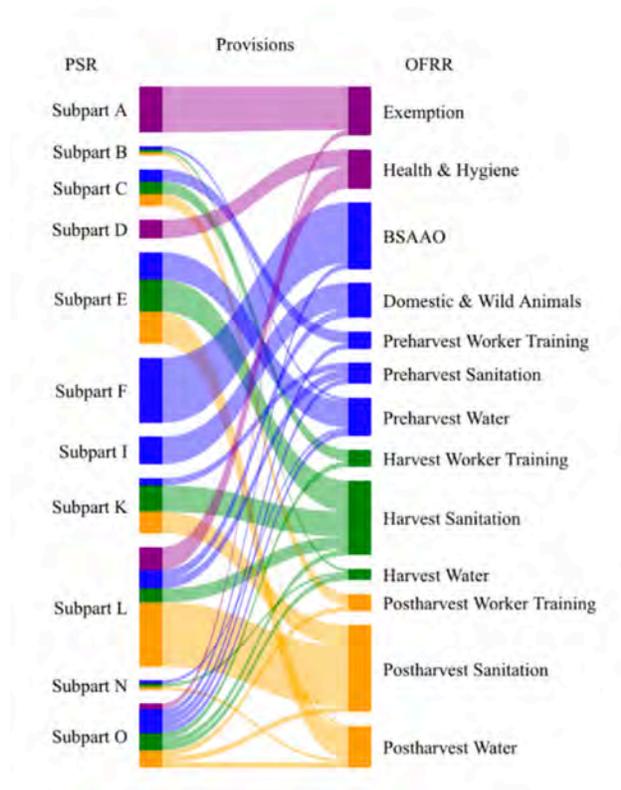
addition, Strohbahn et al. (8) found specialty crop growers prefer one-on-one consultations as opposed to self-guided activities when implementing food safety practices.

To support PSA trainings and PSR implementation requirements, extension, nongovernmental organizations, and state departments of agriculture have recruited new staff or have expanded the job descriptions of existing staff to include produce safety. One of the resulting challenges is that many of the staff hired nationally to serve as PSR educators and inspectors do not have on-farm produce safety experience. Of those with food manufacturing experience, few understand appropriate on-farm etiquette, how to communicate with farmers, and how to assess food safety risks in farm situations; some may have never visited a produce farm. Of those with previous on-farm experience, few have been exposed to food safety concepts and how to communicate food safety principles and mitigation strategies on farms. Lack of these skills, coupled with farmers documented distrust of government regulatory agencies (3, 6), creates additional PSR education and outreach challenges, and the need for technical assistance remains. Stakeholders covered by the PSR need help in determining how to apply PSR requirements taught during the PSA grower training. Assessors needed a way to learn on-farm etiquette, develop a conversational approach to interactions, gain exposure to various farming practices, and see how food safety principles can be applied to these practices.

To address these needs, the On-Farm Readiness Review (OFRR) team was established through a partnership of the National Association of State Departments of Agriculture (NASDA), FDA, state departments of agriculture or health, and university extension divisions. The OFRR team developed a tool to be used in collaboration with stakeholders and assessors during a voluntary, confidential, guided assessment of farming activities aligned with standards of the PSR, as well as a standardized training to teach assessors about the tool and its use on farms. The tool and in-person trainings were offered over a 2-year period and were evaluated with an online post-training participant survey.

## MATERIALS AND METHODS

To assess a farm's readiness for inspection, an impactful OFRR tool was needed to align the PSR language in a way growers could follow chronologically across their farm. The OFRR tool authors broke the PSR-grouped provisions into 12 sections based on when and where covered activities were performed on the farm (Fig. 1). An effective OFRR tool needed a set of recommendations to show how a grower could achieve compliance with each rule provision that an inspector would be evaluating. The tool authors created a resource manual that paired each PSR provision with subject matter expert recommendations for regulatory compliance and evaluation criteria using a table format (Fig. 2); each section was reviewed for accuracy. The resource manual



**Figure 1.** How specific provisions in each subpart of the PSR were realigned into OFRR sections based on growers' activities in time and space. Preharvest OFRR sections are blue, harvest OFRR sections are green, postharvest OFRR sections are yellow, and general health and hygiene and exemption sections applicable for all operations are purple. For example, all water used on a farm, whether it be for growing, harvesting, packing, or cleaning and sanitizing activities, is included in one provision (subpart E). A grower may not perform activities that use preharvest, harvest, or postharvest water. By separating these provisions into where they fell in time and space (preharvest, harvest, and postharvest OFRR sections), growers can better understand how the PSR applied to their farming activities and eliminate asking questions that do not apply to their farm. BSAAO, biological soil amendments of animal origin. Parts of subparts A, B, D, and L and all of subparts P, Q, and R are not included in the OFRR tool.

was designed to be both a tool for assessors and a resource for farmers. Resource manuals are distributed to training participants and farmers receiving an OFRR and are not available online.

The OFRR development team then created specific walk-around questions (WAQs) for each of the identified 12 sections for assessors to use during an OFRR (Fig. 3). These questions facilitated a conversational approach rather than a yes/no checklist while ensuring that the needed topics within the PSR were covered during the visit. The WAQs were tested for appropriateness in a pilot and updated to make them more efficient. Several major changes that were made based on the pilots added rule provision citations to each question, included potential farm locations where the WAQs

**OFRR**

Health and Hygiene Module, cont.

Text of the Regulation	Possible Activities that May Lead to Compliance with the Regulation	Evaluation
<b>§ 112.129(b)(3)</b> Provide for the sanitary disposal of waste and toilet paper.	Ensure that: <ul style="list-style-type: none"> <li>septic systems are well maintained and in good condition,</li> <li>port-a-potties hold waste and toilet paper, and</li> <li>workers are trained to properly use the facilities so that toilet paper does not end up on the floor where it could be tracked back into the field on workers' feet.</li> </ul>	Ask whether employees throw toilet paper into the toilet or in a toilet-side trash can, and whether there is the possibility that toilet paper ends up on the restroom floor.
<b>§ 112.129(c)</b> During growing activities that take place in a fully enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.	Provide employees with adequate, readily accessible hand-washing facilities in close proximity to toilet facilities.	Observe the location of hand-washing stations to ensure they are in sufficiently close proximity to the toilet facilities.
<b>§ 112.130</b> What requirements apply for hand-washing facilities? All of the following requirements apply to hand-washing facilities:		
<b>§ 112.130(a)</b> You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully enclosed building, and during covered harvest, packing, or holding activities.	See § 112.129(c).	See § 112.129(c). Observe the location of hand-washing stations to ensure they are adequate and readily accessible.
<b>§ 112.130(b)</b> Your hand-washing facilities must be furnished with:		
<b>§ 112.130(b)(1)</b> Soap (or other effective surfactant);	Provide soap, or another effective surfactant, to assist in the removal of soil and potential contaminants from workers' hands.	Observe if soap is provided.

Figure 2. One page in the OFRR manual, showing that each section of the OFRR manual is arranged in three columns. The first column lists the PSR provisions pertinent to that section. The second column lists actions recommended for a farm to achieve compliance. The third column provides evaluation criteria that regulatory staff could use when inspecting farms to assess compliance against the provision in the first column.

**OFRR**

## On-Farm Readiness Review

### Walk Around Questions (WAQ) Health & Hygiene

Potential locations – immediately upon arrival if asked to sign an acknowledgment of food safety practices document, employee break area, hand wash station, restroom

The questions in this section refer to the practices employees who handle, harvest and pack produce follow as it pertains to their health and hygiene. The questions outlined will help us understand how the practices the farm is currently following align with the requirements in the PSR.

How do you prevent ill persons or persons you suspect of being sick from coming into contact with produce and food contact surfaces? What is your sick leave policy? [112.31]

What sort of hygiene expectations do you have for each of your employees? Do you have glove, jewelry, or other similar policies? If so, what are they? [112.32]

Can you talk about your visitor policies or procedures related to health and hygiene? [112.33]

What type of toilet facilities and handwashing stations do you provide?

What supplies are included with the toilets and handwashing facilities? [112.130]

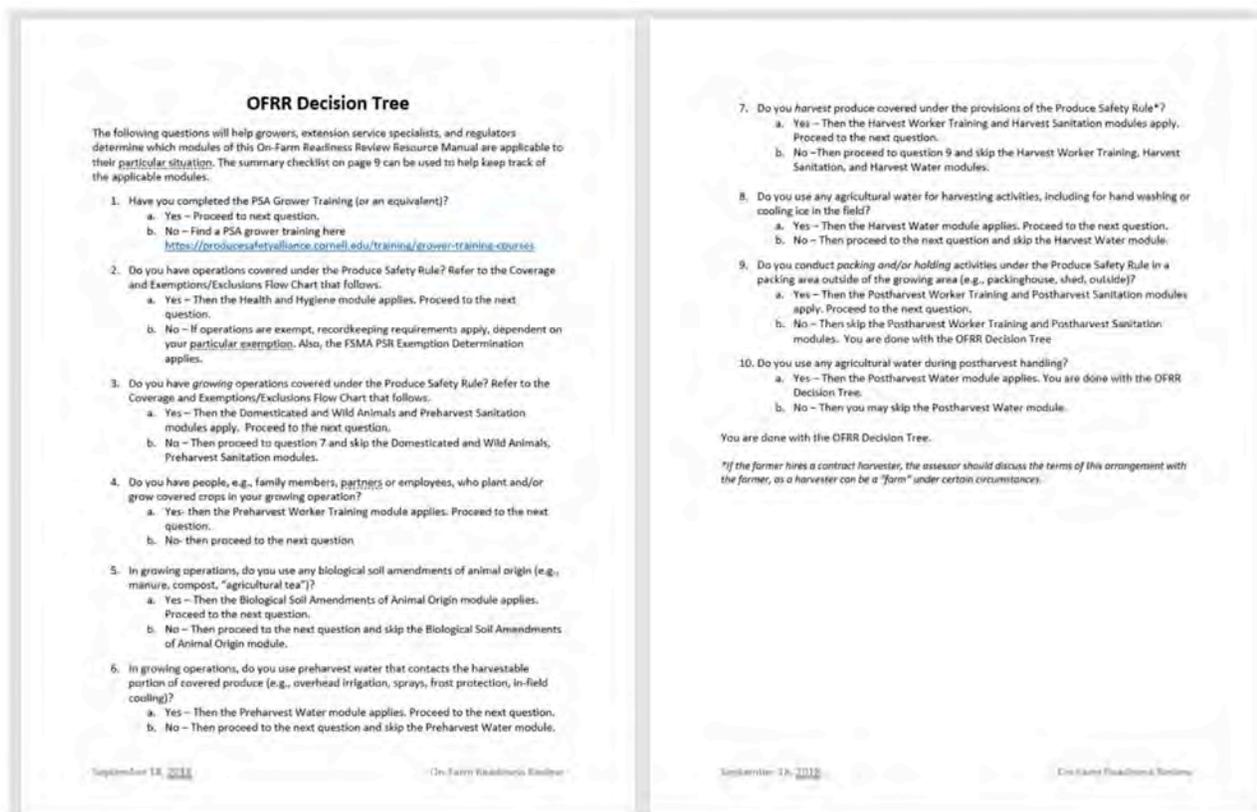
How are they serviced? Do you use a servicing company, or do you service them yourself? [112.129(b)(2)]

What do you do if a portable toilet leaks, tips, or spills? [112.129(b)(1), 112.131(c)]

Where are toilets in relation to the work being done and how many do you have? [112.129(a)]

*Questions on toilet facilities also appear in the Postharvest Worker Training WAQ.*

Figure 3. WAQs were developed focusing on activities of the farm that fall under the PSR. The questions shown here focus on worker health and hygiene. WAQs prompt the user of the tool to ask specific questions about all aspects of that section. The questions are open ended and meant to spur a conversational approach to assessment of compliance.



**Figure 4. OFRR decision tree questions to be used during an assessment. Each couplet of the dichotomous key helps the user focus on only those sections that apply to the farm being assessed.**

should be carried out, and highlighted where records were required by the rule. Growers who hosted the pilots on their farms were included in the postpilot review dialog to better understand the impact to the grower. The creation of the WAQs helped assessors that were unfamiliar with the rule or farming practices to effectively conduct the review.

To be most efficient, the tool needed to be flexible enough to be able to skip aspects of the PSR that did not apply to an individual farm yet broad enough to capture each farm’s applicable activities. A decision tree was created based on grower feedback during the pilots of the first version of the tool. The decision tree allows assessors to identify covered activities taking place at each farm (Fig. 4). This approach prompts the reviewer to ask at the start of the OFRR if the farmer has attended the PSA grower training and if the farm has activities covered by the PSR, as well as to determine the activities taking place on the farm. This decision tree evolved as it was piloted. One notable change recognized the potential for contracted activities throughout the production, harvest, and transportation process. In one scenario, a custom harvest crew, independent of the farm, may be contracted to harvest the crop by the landowner. As a result of these types of situations, the decision tree now asks separately whether a

grower grows a crop and harvests a crop to better identify the practices taking place and the parties responsible for them.

The complete OFRR tool is composed of the decision tree, WAQs specific to the FSMA PSR, and a resource manual. The tool was used as a foundation to develop a training curriculum.

The purpose of the OFRR training curriculum is to teach participants how to use the OFRR tool, to better understand how the FSMA PSR translates onto an individual farm, and to teach a conversational approach to assessing a farm’s readiness for a FSMA PSR inspection. Training PowerPoint presentations were developed focusing on each component of the OFRR tool and discussing why each was developed and how to use them most effectively. Additional presentations were developed to prepare participants who are not familiar with farming on what to expect and how to interact with a farmer in a way that fosters trust and communication. A pilot training program was used to evaluate the effectiveness of the curriculum, resources, and OFRR process. The pilot training program was offered regionally, taking place in the classroom and on a diversity of farms (Fig. 5). PowerPoints, self-assessments, peer-to-peer learning, demonstrations, role playing, and completion of an OFRR on a working farm



**Figure 5. States where the tool and/or training was piloted. The commodities grown on the farms for each pilot are indicated by icons of individual commodities and a farm stand for diversified produce farms ( $n = 7$  pilots). States in purple are states where the OFRR tool was piloted (Florida and North Carolina), states in green hosted a pilot of the training curriculum (New Jersey, Oregon, and Vermont), and states with purple stripes hosted a pilot of the tool separate from a pilot testing the training curriculum (Michigan).**

make up the finalized 2-day, 20-hour training curriculum (Table 1). Each pilot training was followed with an OFRR development team discussion about participant feedback received. Discussions led to the improvement of the training by updating the curriculum and streamlining the use of the resources. For example, numerous questions and concerns were raised around a single slide related to the subject of egregious conditions, specifically what would be considered a human health hazard and what actions should be taken if one was observed. Through group discussions and multiple evolutions, additional slides were added that included photos of working farms. The photos serve as the basis of peer-to-peer learning about human health hazard risks on farms and the question-asking skills required to determine the activities and resulting risks. Postpilot development team discussions also facilitated the standardization of these working farm pictorial scenarios and the conversion of an on-farm etiquette presentation into a think-pair-share learning activity.

Upon completion of the pilot training program, OFRR assessor trainings were held regionally (Fig. 6) across the nation collaboratively between the NASDA and state departments of agriculture in the host training state. FDA Cooperative Agreement Program funds were used by states to pay for participant travel expenses.

Regulators, educators, and other state staff from multiple states attended. Extension educators from the OFRR development team led the training. An eight-question anonymous post-training survey was developed to gather feedback from participants about their role in the agricultural industry, the effectiveness of the training, and their likelihood of using the OFRR tool. Post-training feedback was reviewed annually during OFRR development team meetings to determine whether additional changes to the training curriculum were needed. This survey, Institutional Review Board number Pro2018000502, has been approved for exemption by the Rutgers Office of Research and Regulatory Affairs Institutional Review Board.

## RESULTS AND DISCUSSION

At the outset, the OFRR development team understood a multidisciplinary approach was essential to success. Federal regulatory partners knew the PSR language. Extension partners understood how growers thought. State department of agriculture partners could offer evaluation criteria. Each partner was essential to providing critical information necessary for success. Furthermore, by working together, the group became self-norming, creating a consistent understanding and interpretation of the PSR and its application.

**TABLE 1. The OFRR training program curriculum used varying educational methods, in conjunction with the OFRR tool, to allow for use of the PSR language in differing farm situations**

Title	Format	Purpose
What Do You Already Know about the OFRR?	Self-identification	Participants anonymously identify on a communal poster what they think they already know about the OFRR to facilitate discussion and lay a foundation for the workshop.
What Do You Want to Know about the OFRR?	Self-identification	Participants anonymously identify on a communal poster what they would like to learn about the OFRR to facilitate discussion and set the stage for the workshop objectives.
OFRR: An Introduction	PowerPoint	Overview of how the OFRR was developed, its purpose, and the participants' role during the training.
Expectations of Assessors	PowerPoint	Participants are familiarized with the purpose of an OFRR, the role of the assessors, and the need for continued learning about agricultural practices and the PSR.
Farm Etiquette	Peer-to-peer learning with round-robin discussion	Review of the guiding principle and 17 etiquette points and discussion of previous experiences, proper ways to prepare for and handle oneself during an OFRR, and why.
OFRR WAQs, Process, and Tool	PowerPoint and guided discussion	Walk-through of the decision tree, WAQs, and resource manual use during the OFRR process. Discussion and role play as preparation for when a human health hazard may be found.
Egregious Conditions	Peer-to-peer learning through photographic evidence, with mounting situational context, and round-robin discussion	Egregious condition decision making based on farm production photos. Additional photos and information are provided, adding context and situational awareness to each activity. Question-asking skills are central to this activity.
Farm Visit Logistics	Debrief	Information shared about the farm visit logistics, preparation, and process.
Farm Visit 1	Demonstration	Two course instructors conduct an OFRR on a working farm viewed by the course attendees.
Farm Visit 1 Reflection	Discussion	Participants discuss what they saw during the farm visit, identifying the top three areas of improvement needed, situations that surprised them, what was done well, and what could have been done differently.
Action Scenarios	Role play	Course attendees are broken into smaller groups and use the decision tree and WAQs to practice an OFRR, with a course instructor acting as the farmer and using photos of farms. The activity is repeated with four farm scenarios. Role-play group activity using the decision tree, WAQs, and sample farm photos.
Post-Farm Visit Survey	PowerPoint	Overview of the anonymous post-farm visit survey that is used after each OFRR is conducted.
Farm Visit 2	On-farm using the decision tree and WAQs	Multiple course attendees conduct an OFRR on a working farm viewed by the instructors and remaining course attendees.
Farm Visit 2 Reflection	Discussion	Participants discuss what they saw during the farm visit, identifying the top three areas of improvement needed, situations that surprised them, what was done well, and what could have been done differently.
What Did You Learn about the OFRR?	Self-identification	Participants anonymously identify on a communal poster what they learned about the OFRR during the training to facilitate discussion.
Wrap-up	Debrief	Final question-and-answer session.



**TABLE 2. Examples of post-training survey comments provided by participants**

Subject	Comment
WAQs	“I would have to say this is one of the better trainings I have been to. It was great to get so much hands-on experience and be able to see the walk around questions in action. At first it seemed an intimidating process but the more I worked with the questions and the materials the more comfortable I got.”
	“Great training – walk around questions were awkward. The training was great in that it tested rule knowledge and also prepared me for many different farm situations.”
Role-play farm scenarios	“I was skeptical about the training since I had already observed dozens of OFRRs in my state. I didn’t think I would learn much but I felt the training was very beneficial and I took away some important information. The scenarios were a good way to prepare for the OFRRs we did.”
	“The action scenarios were especially useful. It would have been great to have more time for those. As a volunteer for the student-led OFRR I would have really liked some direct feedback on what our team could improve – specific examples of what we missed or could have done a better job with.”
OFRR demonstration	“Can’t stress enough how valuable it was to go through two OFRR farm visits as a class.”
	“This was the best food safety training I have participated in so far. It provided the missing link between the PSA trainings and actually applying the rule in the field to help growers attain compliance. I especially appreciated the integrated farm visits and the chance to see the OFRR in action. I feel much more prepared to conduct OFRRs now.”
PSR language	“The training was great in that it tested rule knowledge and also prepared me for many different on farm situations.”
	“This training was helpful but made me realize just how uncomfortable I am with the rule. I will definitely be going through it again to see what the ‘musts’ are versus the ‘shoulds.’”
Overall	“I came in the training unsure about what it was all about and left feeling confident. I could conduct an OFRR.”
	“I learned a lot about the approach that the trainers took to design the training and the network building was a wonderful opportunity. Most importantly, I learned a lot about what I don’t know and it was also demonstrated the level of responsibility that we have as OFRR reviewers – we can do a lot of good, but we can also do a lot of harm [or] cause misunderstanding if we are incorrect.”

indicated that although the process may have seemed overwhelming at first, the curriculum design and repetitive use of the WAQs allowed them to build confidence in their ability to assess a farm using the tools (Table 2).

For the OFRR training to have a national reach, the development team recognized that trainings needed to be made available regionally. Collaboration of the NASDA, extension development team members, and host states allowed for regional training locations, with two farms participating in the on-farm portion of each training. Individual states collaborated with the OFRR development team to host 34 in-person trainings in 20 states between 2017 and 2019 (Fig. 6). Between 2017 and 2019, 498 regulators and educators completed the OFRR training and are

qualified to conduct the OFRR (Fig. 7). The regional training locations allowed for greater participation by stakeholders nationally, with all but two states attending. In addition to attendance by most states, participants represented the intended audience, with 57% of the attendees in the role of state or federal regulator (Fig. 8).

The post-OFRR training survey was distributed to the 498 training attendees and had a response rate of 32%. Of the 161 surveys received, 54% of participants indicated that they expected to conduct inspections, 25% thought that they might conduct inspections, and 21% did not expect to conduct inspections. We expect educators, state grant administrators, and nonprofit service organizations answered “no” to this question. OFRR training participants indicated in the online



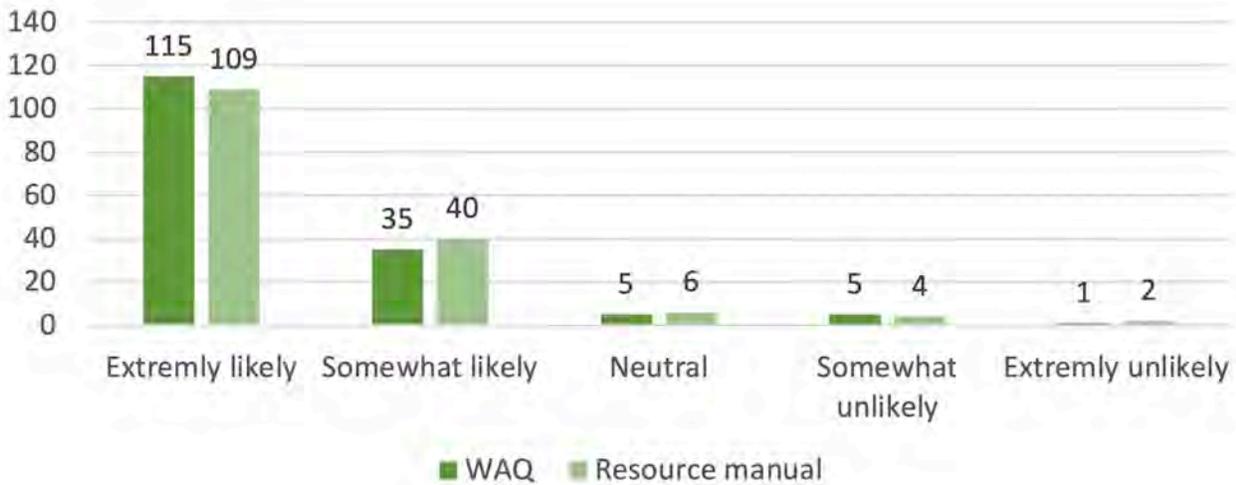


Figure 9. Training participants response of their likelihood of using the OFRR WAQs and resource manual during a future OFRR.

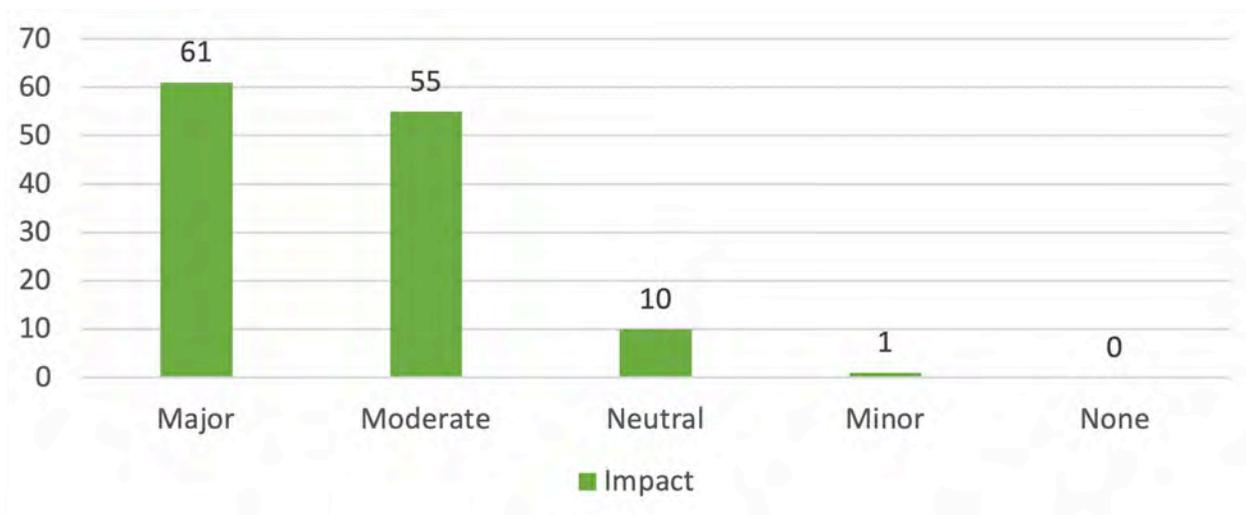


Figure 10. Participants who indicated that they would or may be inspecting for the FSMA PSR indicated the impact of the OFRR training on their ability to conduct an OFRR PSR assessment on a farm.

survey that they are extremely likely to use both the WAQs and the resource manual (Fig. 9). Of the participants who expect to conduct FSMA PSR inspections and completed the survey, 91% felt that the training positively affected their ability to do so (Fig. 10).

The OFRR tool and training bring together PSR language, on-farm application, and regulatory evaluation. When used effectively, a user can assess a farm's readiness for FSMA PSR inspection and provide clear recommendations on how to apply specific PSR provisions on individual farms, offering growers a path to compliance. Many of those serving as PSR educators and regulators have little experience on farms and

communicating with farmers. The OFRR tool and training aim to bridge that gap.

The OFRR training participants demonstrated by engaging in role play, discussions, group activities, and anonymous survey responses that they gained new knowledge about the FSMA PSR, increased their understanding of produce food safety risks, learned how to have insightful and meaningful conversations with farmers about their practices, and are better able to assess for compliance with the FSMA PSR. This gained knowledge and skillset improve the assessor's ability to provide technical assistance to growers to support their compliance with the FSMA PSR.

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