

**Request for Approval under the “Generic Clearance for Quantitative Testing
for the Development of FDA Communications”
(OMB Control Number: 0910-0865)**

TITLE OF INFORMATION COLLECTION: Pre-/Post-Training Test for the Development and Improvement of FDA International On-Farm Readiness Review (OFRR) Training

1. STATEMENT OF NEED

The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. As part of the agency’s ongoing efforts to implement FSMA, the Produce Safety Rule (PSR) established science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. The final rule went into effect January 26, 2016. The standards apply to fresh produce grown domestically, as well as fresh produce imported to the United States from foreign countries.

The FDA has established the Produce Safety Network to support the efforts of farmers and other key stakeholders with complying with the Produce Safety Rule. One of the resources available to farmers is the On-Farm Readiness Review (OFRR) program. OFRR provide farmers real-time feedback on their current operations and facilities. These reviews can help farmers address any areas in need of improvement before a regulatory inspection takes place in the future. As part of this program for advance, readiness reviews, food safety professionals conduct voluntary, non-regulatory visits to farms and packinghouses. Their goal is to observe current practices and provide feedback on how those practices can be strengthened to better align with regulatory expectations. These reviews are not inspections.

Given the significant volume of imported produce, FDA uses this On-Farm Readiness Review tool for farms exporting fresh produce to the United States, to support farmers in achieving compliance with the PSR. In Latin America, FDA is providing OFRR training to foreign government personnel and university personnel. The training uses traditional classroom training, and on-farm training, to inform and educate foreign government and university personnel about the PSR, and how to provide OFRRs to farmers.

FDA developed a Pre-/Post-Training Test, in a survey format, to support the delivery of FDA-sponsored international OFRR trainings. The test contains multiple-choice questions regarding the PSR and OFRRs and is intended to be administered to respondents both before and after the training. The pre-/post-training test will serve as a formative testing. Results of the test can provide valuable information on the effectiveness of the educational messages delivered during the training. By analyzing and comparing the pre- and post-training test results, FDA can identify topic areas needing improvements and make necessary changes to future OFRR training educational materials.

2. TYPE OF COLLECTION

[Check one box.]

Experiment

Survey

3. PARTICIPANT UNIVERSE AND SAMPLING PLAN

Respondents will be trainees of international OFRR trainings - foreign government and university personnel who are over 18 years old. Responding to the International OFRR Pre-/Post-Training Test will be completely voluntary.

A 3rd party contractor (University Extension Services) will help to administer the survey and collect data. Attendees of the international OFRR training will be notified at the beginning of their training about the data collection. Trainees who are willing to voluntarily take the survey will be recruited. Respondents will be instructed to complete the pre-training test before the first training session, and will be instructed to complete the post-training test after the last training session.

Identical survey instruments will be used for both the pre- and post-training tests.

Respondents will complete the pre- and post-training tests anonymously. No Personally Identifiable Information (PII) will be collected.

Data collection dates: ongoing, beginning with OMB’s approval of this collection of information. For Fiscal Year 2020, the anticipated dates for trainings are November 12-15, 2019 (training will be provided in Chile) and March 16-20, 2020 (training will be provided in Mexico). These dates are contingent on corresponding approvals.

The International OFRR Pre-/Post-Training Test will be translated and administrated in the official language of the country where the training will be provided. For the FY 2020 trainings in Chile and Mexico, the test will be translated and administrated in Spanish.

The following language will be included on the survey:

“Your participation / nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection’s data will be kept secure to the fullest extent allowed by law.”

4. INCENTIVE

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? Yes No

[If yes, describe the incentive and provide a justification for the amount.]

5. DATA ANALYSIS PLAN

Frequencies and percentages will be generated from the questions. T-tests for respondents’ pre- and post- test scores on each question will be conducted.

6. BURDEN HOURS

Activity: Survey

No. of Respondents: 150.

Participation Time: 10 minutes for pre-training test; 10 minutes for post-training test; total of 20 minutes.

BURDEN HOUR COMPUTATION (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

Activity	No. of Respondents	Participation Time (minutes)	Burden (hours)
Pre-training Test	150	10	25
Post-training Test	150	10	25
Totals			50

7. CERTIFICATION:

In submitting this request, I certify the following to be true:

- a) The collections are voluntary;
- b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
- c) The collections are noncontroversial;
- d) Personally identifiable information (PII) is collected only to the extent necessary¹ and is not retained; and
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.²

¹ For example, collections that collect PII in order to provide remuneration for participants of cognitive interviews will be submitted under this request. All privacy act requirements will be met.

² As defined in OMB and agency Information Quality Guidelines, “influential” means that “an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.”

REQUESTED APPROVAL DATE: November, 2019.

8. NAME OF PRA ANALYST & PROGRAM CONTACT:

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