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### **Food Defense Plan Builder Usability Study Participant Questionnaire**

The target audience for the Food Defense Plan Builder is food industry stakeholders who have the responsibility of developing or assisting with the development of a food defense plan within a food facility.

#### Recruiting Goals

- Four Usability Study groups of up to 20 participants in each group will be conducted (60 participants in 3 groups total). The Usability Study groups will be conducted in several locations.

#### Study Protocol

- Each group will last approximately 240 minutes (including time needed for signing in before the group starts and signing out after the group ends).
- Participants would be asked to bring their own laptop computer to the session.
- A moderator will guide participants through the entire process starting from installing the tool, walking participants through each section of the tool and allowing time for participants to use and play with each section of the tool.
- The moderator will ask specific questions about the tool's content, functionality, ease of use, etc. and solicit feedback from participants on how to improve or changes to be made to the tool.
- Notes will be taken by FDA/CFSAN staff during the discussion portions of the usability study group.
- There will be an internal report generated on the usability study group findings but no official analysis or report will be conducted.
- Participants do not have to answer any questions that they do not want to, but are encouraged to participate.

## PARTICIPANT QUESTIONNAIRE

Thank you for taking the time to join us today. I am \_\_\_\_\_ from the U.S. Food and Drug Administration. The purpose of this focus group is to get your thoughts on Version 2.0 of the Food Defense Plan Builder software tool. Your feedback is very important to us and may ultimately be used to help improve this tool for the food industry. Our discussion will last 4 hours.

Many of you may have used Version 1.0 of the Food Defense Plan Builder, which was launched in May 2013. Version 1.0 was developed based on existing FDA tools, guidance, and resources under the voluntary food defense framework. Since then FDA has issued a proposed rule and now a final rule entitled “Mitigation Strategies to Prevent Food from Intentional Adulteration,” which requires covered food facilities to develop and implement a food defense plan. During the course of rulemaking, we heard from the industry that they would like FDA to update the Food Defense Plan Builder so that it can be used by industry to meet the requirements of the final rule.

We have many enhancements and updates to the Food Defense Plan Builder and we hope that you will help us by providing feedback to help us improve the tool.

Hopefully you’ve all had a chance to go through the tool and test it out. Now we will go through each section and discuss what you like/dislike and any recommendations that you have to improve the tool. This is meant to be a discussion so feel free to chime in.

### Q1 . General

- a. What are your overall impressions of the FDPB?
- b. What did you like about the FDPB?
- c. What did you not like about the FDPB?
- d. How user friendly is the tool? Could you have gone through the tool on your own without?

### Q2. Facility Information

- a. What did you like about this section?
- b. Were there any functions that didn’t work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added?

### Q3. Facility-Wide Security Measures

- a. What did you like about this section?
- b. Were there any functions that didn’t work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

### Q4. Vulnerability Assessments

- a. What did you like about this section?
- b. Were there any functions that didn’t work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

### Q5. Mitigation Strategies

- a. What did you like about this section?
- b. Were there any functions that didn’t work for you?

- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

Q6. Monitoring Procedures

- a. What did you like about this section?
- b. Were there any functions that didn't work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

Q7. Corrective Action Procedures

- a. What did you like about this section?
- b. Were there any functions that didn't work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

Q8. Verification Procedures

- a. What did you like about this section?
- b. Were there any functions that didn't work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

Q9. Emergency Contacts

- a. What did you like about this section?
- b. Were there any functions that didn't work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added?

Q10. Action Plan

- a. What did you like about this section?
- b. Were there any functions that didn't work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

Q11. Food Defense Plan

- a. What did you like about this section?
- b. Were there any functions that didn't work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

Q12. Supporting Documents

- a. What did you like about this section?
- b. Were there any functions that didn't work for you?
- c. What suggestions do you have for how to improve this section? Is there anything that you would like to be added or deleted?

Conclusion

Thank you for your time and feedback. We will take all of your comments into consideration to make edits and enhancements to the FDPB.