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Food Defense Plan Builder Usability Study Moderator’s Guide

Welcome [5 minutes]

Thank you for taking the time to join us today. I am _____ from the U.S. Food and Drug Administration. The purpose of this usability study group, which is being sponsored by the FDA, 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.

Ground Rules

- A. You have been asked here to offer your views and opinions; everyone’s participation is important
- B. Audio/video/observers
- C. Speak one at a time
- D. No side conversations
- E. No right or wrong answers
- F. It is OK to be critical. If you dislike something or disagree with something that is said, I want to hear about it.

Participant Introductions [10 minutes]

To begin, I would like to have you go around the table and introduce yourselves. Please tell me:

1. Your name.
2. Your company/organization.
3. Your role in that company/organization.
4. Your experience in development food defense plans.
5. Whether you used Version 1.0 of the Food Defense Plan Builder.

Overview of the Intentional Adulteration Final Rule [15 minutes]

One of the main purposes of the FDPB is to help industry to develop a food defense plan that includes the requirement elements of the final rule. In case you are not familiar with those requirements, I will give a quick overview.

FDPB Background and Walkthrough [20 minutes]

[Provide a presentation that includes a background on FDPB and an overview/walk through of FDPB Version 2.0]

- Facility Information
- Facility-Wide Security Measures
- Actionable Process Steps- Key Activity Types and Vulnerability Assessments
- Mitigation Strategies
- Monitoring Procedures
- Corrective Action Procedures
- Verification Procedures
- Emergency Contacts
- Action Plan
- Supporting Documents
- Food Defense Plan
- Signature

Break [15 minutes]

Let's take a 15 minute break. After the break you'll have some hands on to use the tool.

FDPB User Time [1.5 hour]

Now you'll have some time to use the tool and work through each of the sections on your own. As you go through each section, feel free to ask any questions. Also, write down any comments and suggestions so we can discuss them during the feedback session. You'll have an hour and a half to go through the tool.

Break [10 minutes]

Let's take a 10 minute break. After the break I'd like to get your feedback on the tool.

Feedback Session [1 hour]

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 on

General

1. What are your overall impressions of the FDPB?
2. What did you like about the FDPB?
3. What did you not like about the FDPB?
4. How user friendly is the tool? Could you have gone through the tool on your own without?

Facility Information

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

Facility-Wide Security Measures

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

Vulnerability Assessments

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

Mitigation Strategies

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

Monitoring Procedures

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

Corrective Action Procedures

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

Verification Procedures

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

Emergency Contacts

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

Action Plan

1. What did you like about this section?
2. Were there any functions that didn't work for you?

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

Food Defense Plan

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

Supporting Documents

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

Conclusion [15 minutes]

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