Mitigation Strategies to Protect Food Against Intentional Adulteration Implementation Update

PRESENTED TO

8th Annual American Food Sure Summit

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INTENTIONAL ADULTERATION REGULATION "REFRESHER"

BACKGROUND

- Last of 7 foundational FSMA rules
- Final rule: May 27, 2016
- Establishes requirements to prevent or significantly minimize acts intended to cause wide-scale public health harm
- Uses a HACCP-type approach, with important differences from the Preventive Controls for Human Food rule
- Is risk-based and flexible

WHO IS COVERED BY THE IA RULE?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the Food, Drug, and Cosmetic Act (FD&C) Act
  - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply – see the IA Fact Sheet
  - https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM503566.pdf

EXEMPTIONS

- Very small businesses*
- Holding of food, except holding of food in liquid storage tanks
- Packing, repacking, labeling, or relabeling of food where the container that directly contacts the food remains intact
- Activities of a farm subject to the Produce Safety Rule
- Manufacturing, processing, packing, or holding food for animals
- On-farm manufacturing/processing, packing, or holding by a small or very small business, of eggs (in-shell, other than RACs)

EXEMPTION: VERY SMALL BUSINESSES

- The rule does not apply to very small businesses (VSBs)
  - Averaging less than $10,000,000 per year, in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, e.g., held for a fee
- VSBs are required to provide for official review, upon request, documentation sufficient to show that the facility qualifies for this exemption

WHAT IS REQUIRED?

- Food defense plan
  - Vulnerability assessment
  - Mitigation strategies
  - Procedures for food defense monitoring
  - Food defense corrective action procedures
  - Food defense verification procedures
- Reanalysis
- Records
- Training

FOOD DEFENSE PLAN – VULNERABILITY ASSESSMENT

- For each point, step, or procedure, a facility must consider, at a minimum:
  - Potential public health impact
  - Degree of physical access to product
  - Ability of an attacker to successfully contaminate the product

FOOD DEFENSE PLAN – VULNERABILITY ASSESSMENT

- Must consider the possibility of an inside attacker
- Outcome of assessment must be written
- Key Activity Types are considered an appropriate method to conduct a vulnerability assessment

FOOD DEFENSE PLAN – MITIGATION STRATEGIES

- Measures to ensure strategies are implemented at each actionable process step to ensure significant vulnerabilities are significantly minimized or prevented
- Must include written explanation for how strategy minimizes vulnerability

FOOD DEFENSE PLAN – MITIGATION STRATEGY MANAGEMENT COMPONENTS

- Food defense monitoring
- Food defense corrective actions
- Food defense verification
  - As appropriate to ensure the proper implementation of the mitigation strategies, taking into account the nature of the mitigation strategy and its role in the facility's food defense system

FOOD DEFENSE PLAN – FOOD DEFENSE MONITORING

- Facility must have written procedures for monitoring the mitigation strategies
- Monitoring must be documented in records subject to verification

FOOD DEFENSE PLAN – FOOD DEFENSE CORRECTIVE ACTIONS

- Facility must have written procedures for steps to be taken when mitigation strategies are not properly implemented
  - Identify and correct a problem
  - Reduce likelihood of occurrence
- Corrective actions must be documented in records subject to verification

FOOD DEFENSE PLAN – FOOD DEFENSE VERIFICATION

- Includes (as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system):
  - Verification of monitoring and corrective actions
  - Verification that mitigation strategies are properly implemented through records review or other activities
- Verification must be documented in records

REANALYSIS OF FOOD DEFENSE PLAN

- At least every three years
- Whenever there is a significant change
- When there is new information about potential vulnerabilities

REANALYSIS OF FOOD DEFENSE PLAN

- When a mitigation strategy is not properly implemented
- Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats, or developments in scientific understanding

TRAINING

- Food defense awareness
- Proper implementation of mitigation strategies at actionable process steps*
- Certain components of the food defense plan*

RECORDS

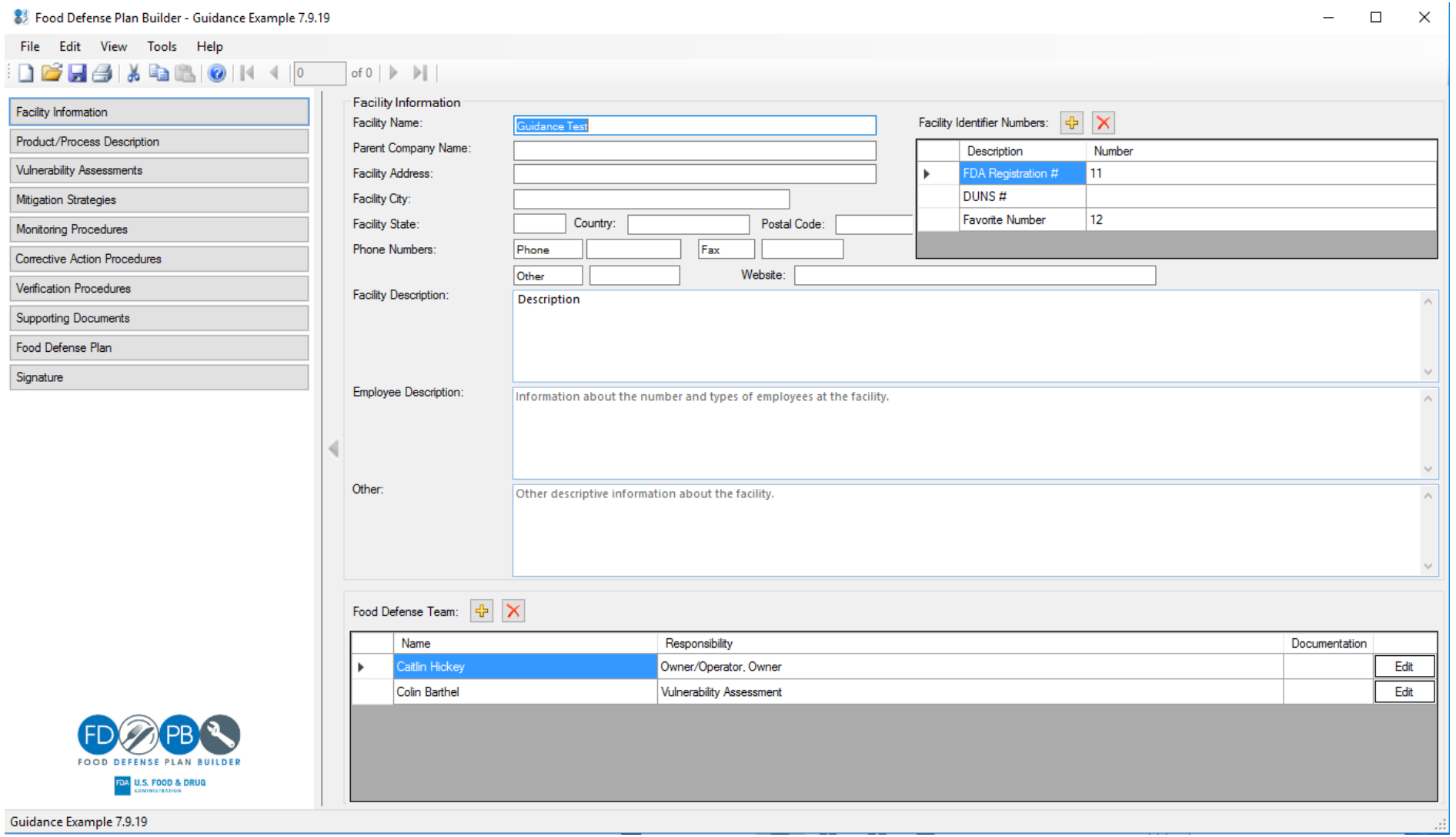
- Establish and maintain certain records, including
  - Food defense plan
  - Food defense monitoring, corrective action, and verification records
  - Documentation related to training of personnel
- Use of existing records

COMPLIANCE DATES

- Businesses that are not small or very small: July 26, 2019
- Small businesses (a business with fewer than 500 full-time equivalent employees): **July 27, 2020**
- Very small businesses (modified requirements): **July 26, 2021**

Food Defense Plan Builder

- Released Sept. 19, 2019
- Aligns with IA rule requirements
- Includes signature & date stamping
- Includes VA wizard with scoring tables and calculators
- Can search FDA Mitigation Strategies Database


Food Defense Plan Builder - Guidance Example 7.9.19
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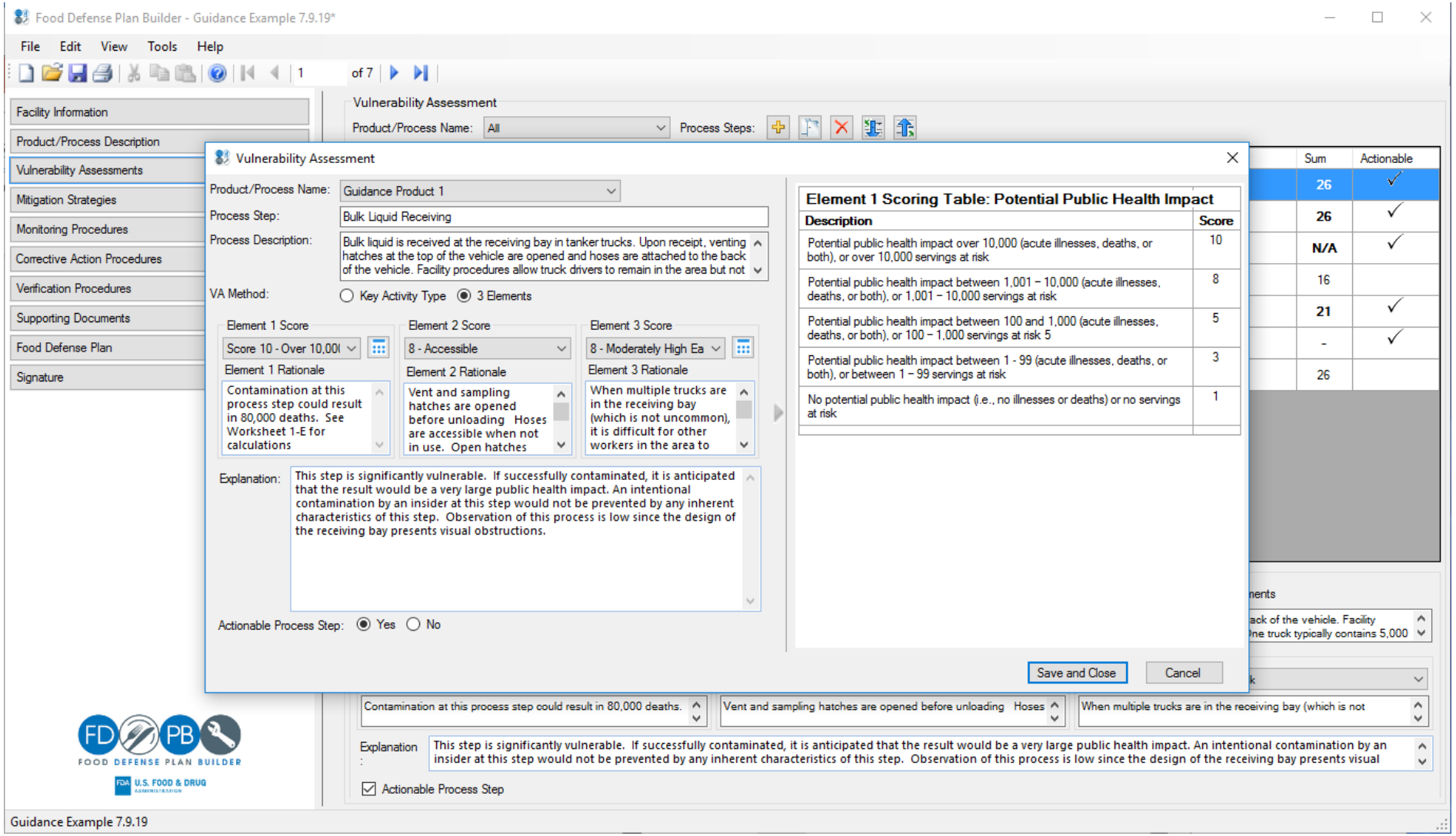
Facility Information
Product/Process Description
Vulnerability Assessments
Mitigation Strategies
Monitoring Procedures
Corrective Action Procedures
Verification Procedures
Supporting Documents
Food Defense Plan
Signature
Facility Information
Facility Name:
Guidance Test
Parent Company Name:
Facility Address:
Facility City:
Facility State:
Country:
Postal Code:
Phone Numbers:
Phone
Fax
Other
Website:
Facility Identifier Numbers:
Description
Number
FDA Registration #
11
DUNS #
Favorite Number
12
Facility Description:
Description
Employee Description:
Information about the number and types of employees at the facility.
Other:
Other descriptive information about the facility.
Food Defense Team:
Name
Responsibility
Documentation
Caitlin Hickey
Owner/Operator, Owner
Edit
Colin Barthel
Vulnerability Assessment
Edit
FOOD DEFENSE PLAN BUILDER
U.S. FOOD & DRUG
Guidance Example 7.9.19


Food Defense Plan Builder - Guidance Example 7.9.19*
File Edit View Tools Help
Facility Information
Product/Process Description
Vulnerability Assessments
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Verification Procedures
Supporting Documents
Food Defense Plan
Signature
Vulnerability Assessment
Product/Process Name: All
Process Steps:
Vulnerability Assessment
Product/Process Name: Guidance Product 1
Process Step: Bulk Liquid Receiving
Process Description: Bulk liquid is received at the receiving bay in tanker trucks. Upon receipt, venting hatches at the top of the vehicle are opened and hoses are attached to the back of the vehicle. Facility procedures allow truck drivers to remain in the area but not
VA Method: Key Activity Type 3 Elements
Element 1 Score
Score 10 - Over 10,00
Element 1 Rationale
Contamination at this process step could result in 80,000 deaths. See Worksheet 1-E for calculations
Element 2 Score
8 - Accessible
Element 2 Rationale
Vent and sampling hatches are opened before unloading Hoses are accessible when not in use. Open hatches
Element 3 Score
8 - Moderately High Ea
Element 3 Rationale
When multiple trucks are in the receiving bay (which is not uncommon), it is difficult for other workers in the area to
Explanation: This step is significantly vulnerable. If successfully contaminated, it is anticipated that the result would be a very large public health impact. An intentional contamination by an insider at this step would not be prevented by any inherent characteristics of this step. Observation of this process is low since the design of the receiving bay presents visual obstructions.
Actionable Process Step: Yes No
Element 1 Scoring Table: Potential Public Health Impact
Description | Score
Potential public health impact over 10,000 (acute illnesses, deaths, or both), or over 10,000 servings at risk | 10
Potential public health impact between 1,001 – 10,000 (acute illnesses, deaths, or both), or 1,001 – 10,000 servings at risk | 8
Potential public health impact between 100 and 1,000 (acute illnesses, deaths, or both), or 100 – 1,000 servings at risk 5 | 5
Potential public health impact between 1 - 99 (acute illnesses, deaths, or both), or between 1 – 99 servings at risk | 3
No potential public health impact (i.e., no illnesses or deaths) or no servings at risk | 1
Save and Close
Cancel
Sum
Actionable
26
26
N/A
16
21
-
26
Contamination at this process step could result in 80,000 deaths.
Vent and sampling hatches are opened before unloading Hoses
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Actionable Process Step
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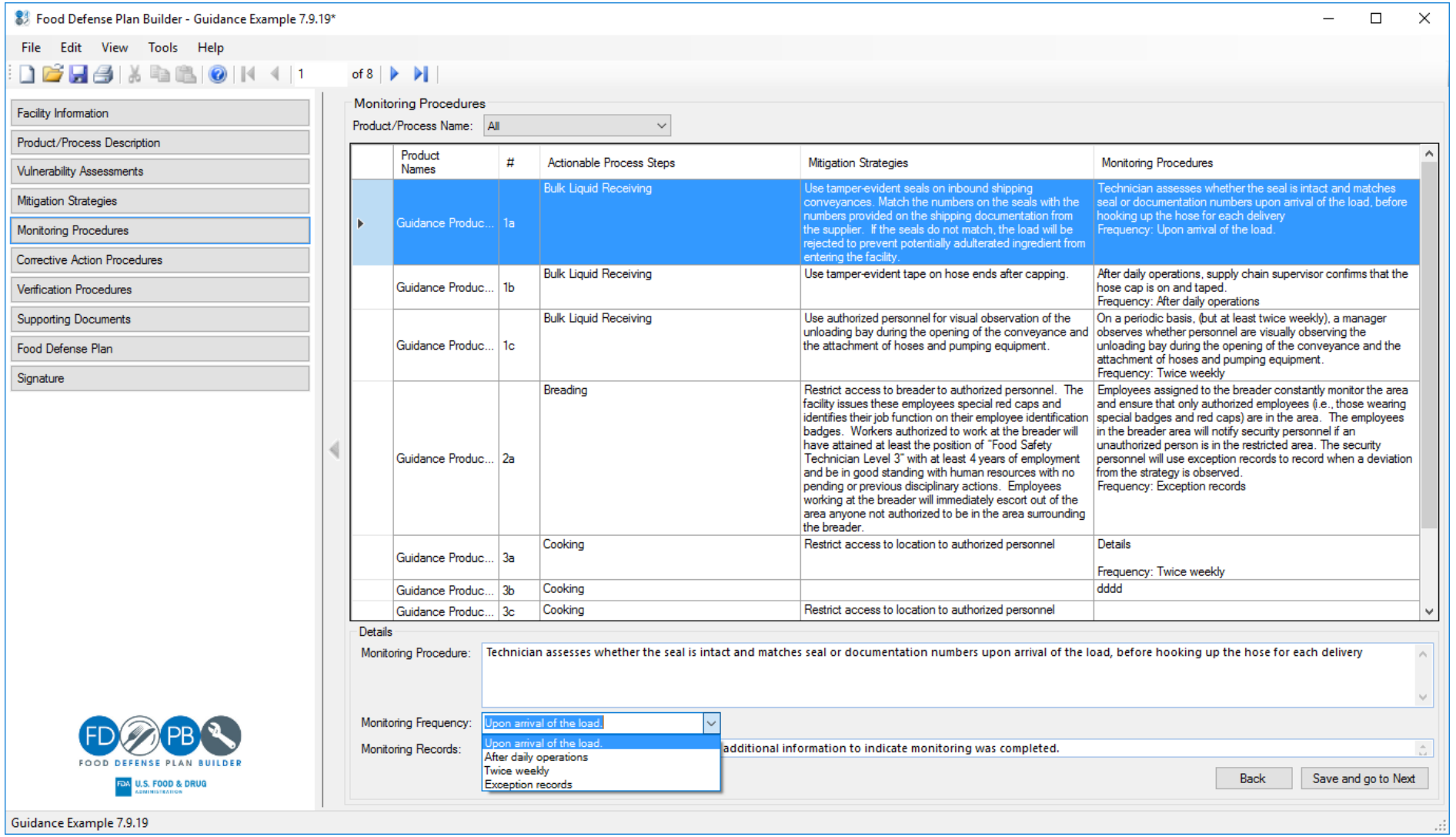
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Facility Information
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Monitoring Procedures
Product/Process Name: All
Product Names
#
Actionable Process Steps
Mitigation Strategies
Monitoring Procedures
Guidance Produc... 1a Bulk Liquid Receiving
Use tamper-evident seals on inbound shipping conveyances. Match the numbers on the seals with the numbers provided on the shipping documentation from the supplier. If the seals do not match, the load will be rejected to prevent potentially adulterated ingredient from entering the facility.
Technician assesses whether the seal is intact and matches seal or documentation numbers upon arrival of the load, before hooking up the hose for each delivery
Frequency: Upon arrival of the load.
Guidance Produc... 1b Bulk Liquid Receiving
Use tamper-evident tape on hose ends after capping.
After daily operations, supply chain supervisor confirms that the hose cap is on and taped.
Frequency: After daily operations
Guidance Produc... 1c Bulk Liquid Receiving
Use authorized personnel for visual observation of the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.
On a periodic basis, (but at least twice weekly), a manager observes whether personnel are visually observing the unloading bay during the opening of the conveyance and the attachment of hoses and pumping equipment.
Frequency: Twice weekly
Guidance Produc... 2a Breading
Restrict access to breader to authorized personnel. The facility issues these employees special red caps and identifies their job function on their employee identification badges. Workers authorized to work at the breader will have attained at least the position of "Food Safety Technician Level 3" with at least 4 years of employment and be in good standing with human resources with no pending or previous disciplinary actions. Employees working at the breader will immediately escort out of the area anyone not authorized to be in the area surrounding the breader.
Employees assigned to the breader constantly monitor the area and ensure that only authorized employees (i.e., those wearing special badges and red caps) are in the area. The employees in the breader area will notify security personnel if an unauthorized person is in the restricted area. The security personnel will use exception records to record when a deviation from the strategy is observed.
Frequency: Exception records
Guidance Produc... 3a Cooking
Restrict access to location to authorized personnel
Details
Frequency: Twice weekly
Guidance Produc... 3b Cooking
dddd
Guidance Produc... 3c Cooking
Restrict access to location to authorized personnel
Details
Monitoring Procedure: Technician assesses whether the seal is intact and matches seal or documentation numbers upon arrival of the load, before hooking up the hose for each delivery
Monitoring Frequency: Upon arrival of the load.
Upon arrival of the load.
After daily operations
Twice weekly
Exception records
Monitoring Records:
additional information to indicate monitoring was completed.
Back
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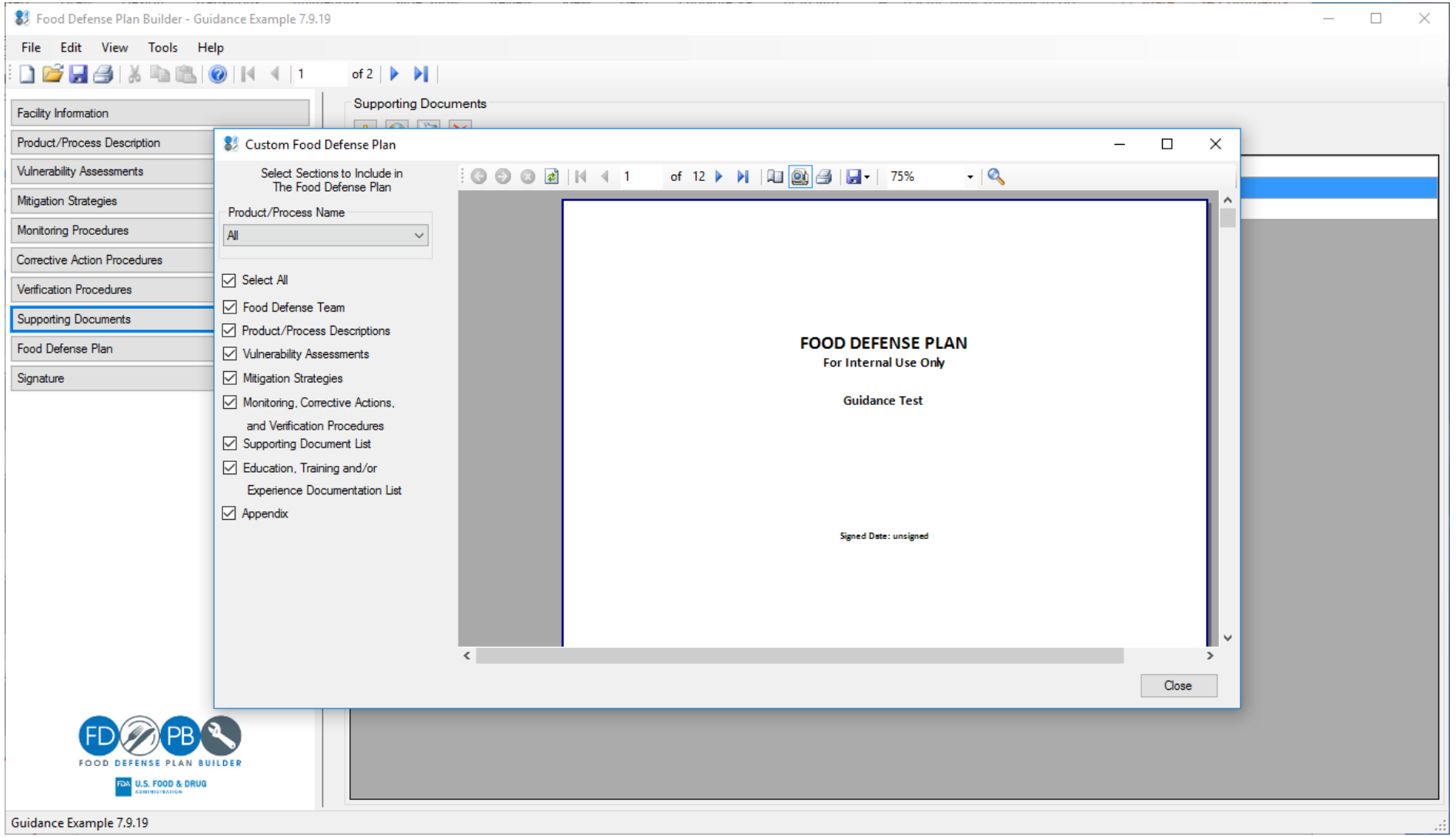
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Signature
Supporting Documents
Custom Food Defense Plan
Select Sections to Include in The Food Defense Plan
Product/Process Name
All
Select All
Food Defense Team
Product/Process Descriptions
Vulnerability Assessments
Mitigation Strategies
Monitoring, Corrective Actions, and Verification Procedures
Supporting Document List
Education, Training and/or Experience Documentation List
Appendix
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FOOD DEFENSE PLAN
For Internal Use Only
Guidance Test
Signed Date: unsigned
Close
FOOD DEFENSE PLAN BUILDER
U.S. FOOD & DRUG
Guidance Example 7.9.19

INSPECTION STRATEGIES

INSPECTION FRAMEWORK

- Two-level inspectional approach
  - **Food defense plan Quick-Check inspection**
    - Conducted on covered facilities during food safety inspections
    - High level review of Food Defense Plan (FDP)
  - **Comprehensive food defense inspections**
    - Conducted only at a limited number of prioritized facilities
    - Conducted by specially trained investigators
    - Critical evaluation of FDP, conclusions, rationale

INSPECTIONAL APPROACH

QUICK CHECK IA INSPECTIONS

- High level oversight of the IA regulation
- Will be conducted through a short inspectional protocol of approximately a dozen questions that are relevant to the requirements of a food defense plan.
- 60-90 minute regulator training prior to the rollout of the Quick-Check inspections
- Will be included in contract inspection conducted by our state partners in the future.

COMPREHENSIVE FOOD DEFENSE INSPECTIONS

- Conducted on prioritized facilities identified through food defense specific analysis
  - Limited number of inspections focused on facilities with increased food defense risk – "Level 1 Facilities"
- Detailed review of food defense plan and inspection to determine status of plan implementation in the facility
- Conducted by investigators with specialized food defense training
  - CFSAN Food Defense SMEs available for real-time consultation & technical support

STAGED IMPLEMENTATION

- Stage 1: Outreach and Baseline-Collection
  - Initiate food defense plan Quick-Check
  - Communicate IA rule requirements to industry
  - Gather baseline industry, facility, and compliance data
  - Enhance cooperative working environment with industry
  - Build food defense expertise of regulators and industry
  - Provide some oversight of the regulation

STAGED IMPLEMENTATION

- Stage 2: Build comprehensive food defense inspection program
  - Identify and train food defense investigators
  - Develop facility identification method and process
    - Identify “Level 1” facilities and prioritize for food defense inspections
  - Initial Phase of comprehensive food defense inspections begin
    - Continue to expand regulator expertise and refine inspection approach for consistent IA rule implementation
    - Acknowledgement of information protection concerns

STAGED IMPLEMENTATION

- Stage 3: Established IA rule compliance program
  - Conduct food defense Quick-Check on covered facilities during routine food safety inspections, as appropriate
  - Comprehensive food defense inspections on identified prioritized facilities
  - Continue to refine implementation approach, as appropriate
  - Anticipate that, like now, food defense assignments may be developed as needed
    - Event-based assignments
      - Such as political conventions, presidential inaugurations, other national special security events
    - Need-based assignments
      - Such as in response to a credible threat to the food supply

TIMING OF INSPECTIONS

- First Compliance Date: July 26, 2019
  - Businesses with > 500 employees and > $10 million in annual food sales
- Begin Quick Checks: **Mid 2020**
  - Enable industry time to refine food defense plans with the benefit of recently released or pending guidance, training, and tools.
  - Educate while we regulate
- Begin Comprehensive Food Defense Inspections: **Mid-2020's**
  - Build baseline data, develop prioritization, training

TRAINING AND TECHNICAL ASSISTANCE - DOMESTIC

- Established the Intentional Adulteration Subcommittee within the Food Safety Preventive Controls Alliance to create training and technical assistance programs
- The FDA FSMA Technical Assistance Network has been established

FOR MORE INFORMATION

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- To contact FDA about FSMA and find the online form for submitting questions: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

INTERACTING WITH YOUR LOCAL FDA DISTRICT/DIVISION

OHAFO 6 EAST

- Food Inspection in IL IN MI
- Manages outbreaks and response
- Utilizes partnerships extensively
- Is a virtual group
- Is part of OHAFO East and then the greater OHAFO
- Does not handle produce, grade A dairy, or shellfish inspection

CORRESPONDING WITH YOUR DIVISION

- Who is my contact
  - Districts will be listed on the 482/484
  - Divisions will be provided by the investigator
- 15 days explained
- Electronic correspondence is preferred
  - orahafeast6recalls@fda.hhs.gov
  - orahafeast6firmresponses@fda.hhs.gov

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PRIMARY CONTACTS

- Joe Cooper, ERC IL 312 596 4252 cell 312 218 9509
- Lisa Joseph ERC MI/IN 313 393 8169 cell 240 742 0023
- William Weissinger, Dir. 312 596 4202
- IL Consumer Complaints 312 353 7840
- MI/IN Consumer Complaints 313 393 8100
- Product Recalls 313 393 8118
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- Firm Responses orahafeast6firmresponses@fda.hhs.gov
- Media/Public Inquires 312 596 6514
  orainfo@fda.hhs.gov


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