Revised Draft Guidance for Mitigation Strategies to Protect Food Against Intentional Adulteration: Public Meeting

April 17, 2019

Why should we protect against IA?

- Intentional adulteration has the potential to cause:
  - Significant public health consequences
  - Widespread public fear
  - Devastating economic impacts
  - Loss of public confidence in the safety of food and effectiveness of government
  - Disruption of trade

IA Rule Background

- Last of 7 foundational rules
- Establishes requirements to prevent or significantly minimize acts intended to cause wide-scale public health harm
- Coverage
  - Facilities that manufacture, process, pack or hold human food
- Exemptions

IA Rule Background

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

IA Rule Background

- Compliance dates
  - **Very small businesses**: Five years (July 26, 2021)
  - **Small businesses** (a business with fewer than 500 full-time equivalent employees): Four years (July 27, 2020)
  - **All other businesses**: Three years (July 26, 2019)

Guidance Overview

- Substantial interaction with stakeholders
  - History of food defense collaboration
  - Dialogue with stakeholders since rule publication
  - Significant compliance cost has been raised in the context of
    - Need for more flexibility
    - Counting existing activities toward compliance
    - Industry-estimated costs
    - Paperwork burden

Guidance Overview

- FDA incorporating stakeholder input, when/where appropriate
  - Committed to making implementation for industry as practical and flexible as possible, while also achieving public health goal
  - Protecting against an inside attacker
  - Addressing misconceptions (flexibility, food safety vs food defense priorities, high-cost mitigation strategies, existing measures)

Guidance Overview

- FDA incorporating input - Examples of flexibility
  - Vulnerability Assessment
    - Key Activity Types (KATs), 3 Fundamental Elements, Hybrid Approach
    - Element 1 approaches include volume of food at risk or contaminant-based approaches
    - Scoring flexibility in 3 Fundamental Elements
    - Writing explanations

Guidance Overview

- FDA incorporating input - Examples of flexibility
  - Mitigation strategies
    - Numerous options
    - Facility-wide security measures?
    - Existing measures?
  - Food defense monitoring
    - Incorporate into existing responsibilities
    - Leverage food safety activities?
    - Exception records
  - Education, training, or experience

Guidance Overview

- FDA incorporating input – Other examples
  - Protection against insiders
    - How can industry assess this?
      - Assumptions to bound assessment
    - How can industry protect against this?
      - Reducing risk by implementing mitigation strategies

Guidance Overview

- FDA incorporating input – Other examples
  - Very costly mitigation or monitoring activities?
    - No need to reengineer facilities
    - No need to hire additional employees solely for peer monitoring
    - Build monitoring into existing responsibilities
    - Exception records

Guidance Overview

- 10 chapters, 4 appendices published in 3 rounds (Round 1 published June 2018)
- Rounds 1 - 2 are intricately connected, with sections of the VA chapter published in both rounds
- Round 2 is incorporated into one document with Round 1, issued as Revised Draft published March 2019
- Inter-chapter themes: risk-based, flexible, and practical

Guidance Overview

- Introduction[1]
- Ch 1 The Food Defense Plan[1]
- Ch 2 Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps[1 - 2]
  - Sections 2A-E, including background and Key Activity Types as a Method for Conducting a VAs [1]
  - Sections 2F-H , including Evaluating the Three Fundamental Elements, Identifying Significant Vulnerabilities and Actionable Process Steps Using the Three Fundamental Elements, and Identifying Actionable Process Steps Using the Hybrid Approach[2]
- Ch 3 Mitigation Strategies for Actionable Process Steps[1]
- Ch 4 Mitigation Strategies Management Components: Food Defense Monitoring[1]
- Ch 5 Mitigation Strategies Management Components: Food Defense Corrective Actions[3]
- Ch 6 Mitigation Strategies Management Components: Food Defense Verification[3]
- Ch 7 Reanalysis[3]
- Ch 8 Education, Training, or Experience[2]
- Ch 9 Records[3]
- Appendix 1. Food Defense Plan Worksheets[1 - 2]
- Appendix 2. Mitigation Strategies in the Food Defense Mitigation Strategies Database[3]
- Appendix 3. Calculating Small Business and Very Small Businesses Sizes[3]
- Appendix 4. Vulnerability Assessment Examples[2]

1 = Installment 1, 2 = Installment 2, 3 = Installment 3

Guidance Overview

- 1st installment
  - Background and definitions
  - Relatively simple and cost-effective method to identify vulnerable points (i.e., KAT Method)
  - Numerous ways to reduce vulnerabilities
  - Numerous ways to check that strategies are functioning as intended
  - Worksheets to assist industry in thinking through, and documenting, requirements

Guidance Overview

- 2nd installment
  - Identifying vulnerabilities in a way that includes an in-depth analysis and can be tailored to a facility (i.e., 3 Fundamental Elements)
  - Identifying vulnerabilities in a way that combines strengths of KAT and 3 Element approaches (i.e., Hybrid Approach)
  - Education, training, or experience
  - Additional examples of worksheets
  - VA examples

Guidance Overview

- 3rd installment
  - Food defense corrective actions
  - Food defense verification
  - Reanalysis
  - Records
  - Appendices

Guidance: Introduction

Guidance: Introduction

- Purpose of guidance
- Scope of rule and guidance
- Glossary of terms and abbreviations
- Exemptions

Guidance: Introduction - 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
- Alcoholic beverages at certain facilities (under specified conditions)
- On-farm manufacturing/processing, packing, or holding by a small or very small business, of eggs (in-shell, other than RACs) or certain types of game meats, if such activities are the only activities conducted by the business subject to section 418 of the FD&C Act

Guidance: Food Defense Plan (FDP)

- Set of written documents that is based upon food defense principles and incorporates a VA, includes mitigation strategies, and delineates food defense monitoring, corrective action, and verification procedures to be followed

Guidance: FDP - Components

- Must include:
  - Vulnerability assessment
  - Mitigation strategies and explanations
  - Food defense monitoring procedures
  - Food defense corrective actions procedures
  - Food defense verification procedures
  - Owner/operator signature

Guidance: FDP

- Individuals to assist with developing a FDP
  - Food Defense Qualified Individuals
  - Food Defense Team
    - Flexibility - personnel from security, maintenance, food production (including equipment experts), sanitation, food safety quality assurance or quality control, engineering, purchasing, human resources, or laboratory.
    - Others

Guidance: Food Defense Plan

- Formatting the FDP
  - Flexibility - no standardized or required format
  - FDA provides sample worksheets in Appendix 1
- Changing the FDP
  - Reanalysis
- Maintaining the FDP
  - FDP is a record
  - Owner/operator must sign FDP
  - Sensitive nature of FDP

Guidance: Vulnerability Assessment (VA) - Purpose and Scope

Guidance: VA - Purpose and Scope

- Purpose
  - Assess each point, step, or procedure (PSP) to identify those points at highest risk, i.e., actionable process steps (APSs)
- Scope
  - Only include PSPs related to manufacturing, processing, packing, or holding of the food product
  - Do not include mail handling procedures, human resources procedures, utilities and processing aids that do not come into contact with or that are not incorporated into the food, facility emergency evacuation procedures

Guidance: VA - Requirements

- For each PSP, a facility must consider, at a minimum these fundamental elements:
  1. Potential public health impact
  2. Degree of physical access to product
  3. Ability of an attacker to successfully contaminate the product
- Must consider the possibility of an inside attacker
- Write explanation for decision at each PSP

Guidance: VA - Preliminary Steps

- Assemble a food defense team – flexibility
- Describe product
- Develop/use process flow diagram - flexibility
- Describe process steps

Guidance: VA - Methods

- Flexibility
  - Key Activity Types
  - 3 Fundamental Elements
  - Hybrid Approach

Guidance: VA - Key Activity Type Method

Guidance: VA - Key Activity Type Method

- KATs
  - General categories of manufacturing/processing identified as most vulnerable, regardless of commodities
  - How were the KATs created?
    - Homeland Security Presidential Directive 9
    - Collaboration with government partners, academia, and industry
    - “FDA has done most of the work for you”

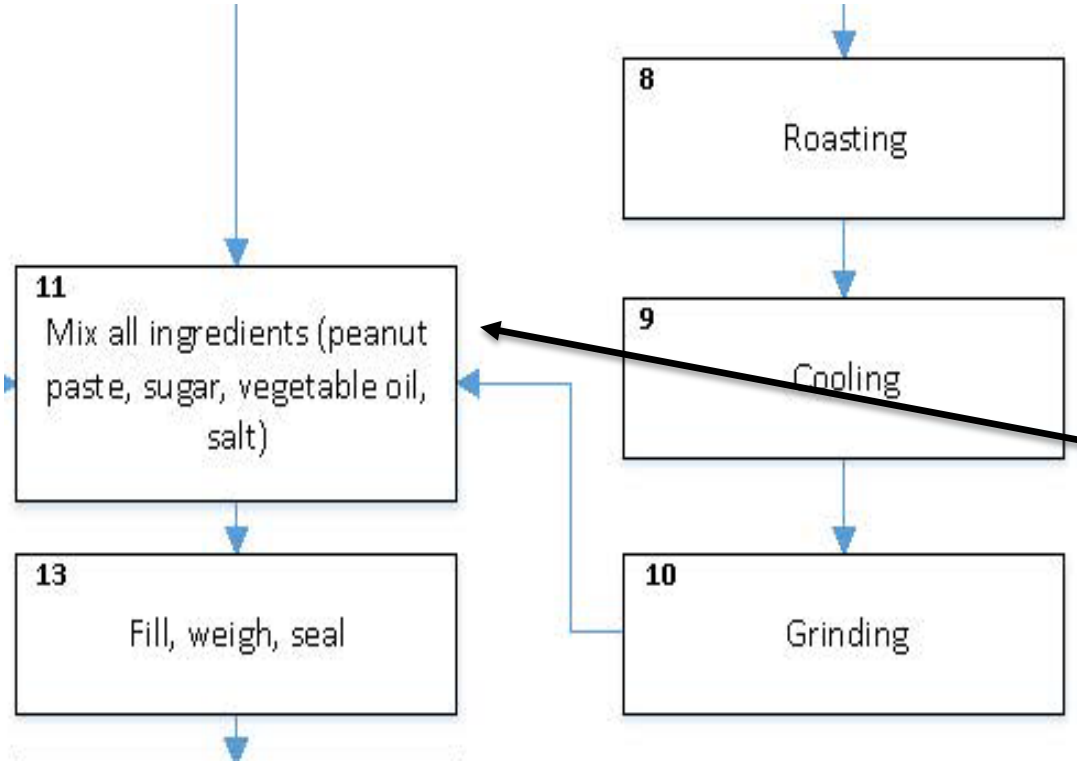
Guidance: VA - Key Activity Type Method

- What are the KATs?
  - Bulk liquid receiving and loading
  - Liquid storage and handling
  - Secondary ingredient handling
  - Mixing and similar activities

Guidance: VA - Key Activity Type Method

- Identifying APSs using the KAT Method
  - Assess each PSP to determine whether they fit within a KAT

Guidance: VA - Key Activity Type Method



KATs

- Bulk liquid receiving & loading
- Liquid storage & handling
- Secondary ingredient handling
- Mixing & similar activities

Guidance: VA - Key Activity Type Method

- Identifying APSs using the KAT Method
  - Points that align are APSs
  - Write explanation describing your decision

Guidance: VA - 3 Fundamental Elements

Guidance: VA - 3 Fundamental Elements

- 3 Fundamental Elements
  - Most important factors to identify vulnerable points at a facility level
- How were the 3 elements created?
  - Homeland Security Presidential Directive 9
  - Collaboration with government partners, academia, and industry

Guidance: VA - 3 Fundamental Elements

- What are the 3 elements?
  1. Potential public health impact
  2. Degree of physical access
  3. Ability of an attacker to contaminate the product

Guidance: VA - 3 Fundamental Elements

- 2 considerations to be evaluated when analyzing each element
  - Inside attacker
  - Inherent characteristics

Guidance: VA - 3 Fundamental Elements

- Inside attacker - scenario of highest risk
  - Legitimate access to facility
  - Basic knowledge of facility operation and products
  - Ability to acquire/deploy contaminant that is highly lethal, capable of withstanding food production process, and undetectable via simple observation if added to food
  - Intend to cause wide scale public health harm

Guidance: VA - 3 Fundamental Elements

- Inherent characteristics
  - Conditions, activities, practices, or characteristics that are integral to the operation of a PSP
  - PSP could not properly operate without these inherent characteristics in place
  - Not easily changed or altered

Guidance: VA - 3 Fundamental Elements

- Inherent characteristics examples - flexibility
  - Type and nature of equipment
    - Enclosed or pressurized?
  - Nature of processing
    - High rate of speed? Homogenous mixing?
  - Worker safety mechanisms built into equipment
  - Required presence of employees in immediate area

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact
  - Assigning a score for each PSP
  - 3 approaches to evaluate potential public health impact - flexibility
    - Volume of food at risk
    - Representative contaminant approach
    - Contaminant-specific approach
  - Additional factors for consideration - flexibility

Guidance: VA - 3 Fundamental Elements

- Element 1 – assign a score

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
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

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Volume of food at risk
    - Calculate volume of food in batch process or continuous flow process to use as proxy for public health impact

Worksheet 1-D: Calculating Volume of Food at Risk

A Process Step	**B** Batch Size	**C** Amount of Product (Ingredient) in Final Serving	**D** Servings per Batch **B ÷ C**	**E** Score from Table 1	**F** Notes

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Volume of food at risk
    - Match calculated number with description in previous table and assign corresponding score for each PSP

Worksheet 1-D: Calculating Volume of Food at Risk

A Process Step	B Batch Size	C Amount of Product (Ingredient) in Final Serving	D Servings per Batch B ÷ C	E Score from Table 1	F Notes
			9,000	8	

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
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

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Volume of food at risk
    - Beneficial to include written rationale for score
    - Simplest, but also least specific, of three approaches

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Representative contaminant approach
    - Not an actual contaminant, but based on amalgam of characteristics from actual contaminants
    - Incorporates characteristics that would allow attacker to achieve goal of causing wide scale public health harm
      - Acquisition is possible, and in some cases, readily so
      - Highly lethal
      - Survives food production process
      - Undetectable via simple observation if added to the food

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Representative contaminant approach
    - Calculate volume of food at risk, incorporate LD50
    - Match calculated number with description in previous table and assign corresponding score for each PSP
    - Beneficial to include written rationale for score
    - More calculations than volume of food at risk approach, but also more specific
    - Since calculations are not based on actual contaminant, results are not as sensitive

Worksheet 1-E: Calculating Potential Public Health Impact using a Representative Contaminant

Element 1 Calculations using Representative Contaminant								Element 3 Calculations	
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
Process Step	Batch Size	Amount of Product (Ingredient) in Final Serving	Servings per Batch **B ÷ C**	Mortality Rate of Contaminant *(FDA provided value = 50%)*	Number of Potential Deaths **D x E**	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving *(FDA provided value = 40 milligrams)*	Amount of Representative Contaminant Needed per Batch **D x I**

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Contaminant-specific approach
    - Should use multiple biological, chemical, and radiological contaminants for each PSP
    - At a minimum, contaminants should have similar characteristics to representative contaminant

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Contaminant-specific approach
    - Uses same calculations in representative contaminant approach but replaces amalgam values with actual contaminant values

Element 1 Calculations using Contaminant-Specific Approach								Element 3 Calculations	
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
Process Step	Batch Size	Amount of Product (Ingredient) in Final Serving	Servings per Batch **B ÷ C**	Mortality Rate of Contaminant	Number of Potential Deaths **D x E**	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving	Amount of Representative Contaminant Needed per Batch **D x I**

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Contaminant-specific approach
    - Use largest public health impact to assign score
    - Match calculated number with description in previous table and assign corresponding score for each PSP
    - Beneficial to include written rationale for score

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact approaches
  - Contaminant-specific approach
    - More calculations than volume of food at risk approach, but also more specific
    - Calculations are based on actual contaminant, so results may be sensitive
    - Number of contaminants and data gaps are problematic

Guidance: VA - 3 Fundamental Elements

- Element 1 – potential public health impact
  - Additional factors for consideration - flexibility
    - End use of food
      - Ingredient vs finished product
    - Consumer packaging
      - Servings per distribution unit

Guidance: VA - 3 Fundamental Elements

- Element 2 – degree of physical access to product
  - Assigning a score for each PSP
  - Evaluate barriers, or lack thereof, to food
    - Inherent characteristics
    - Inside attacker

Guidance: VA - 3 Fundamental Elements

- Element 2 – assign a score

Table 2. Degree of Physical Access to the Product	
Description	**Score**
Easily Accessible. • Inside attacker has access to the product (e.g., attacker can physically touch the product). • There are no inherent characteristics that would make access to the product difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is open and unsecured by packaging, equipment, or other physical access barriers. • Product is handled, staged, or moved in an easily accessible manner.	10
Accessible. • There are limited inherent characteristics that would make access to the product difficult (e.g., enclosed systems, pressurized equipment, railings, equipment safety features, or shields). • Product is in equipment that can be accessed without tools or specialized supplies. • Access to the food is not difficult (e.g., there are minimal physical space constraints that limit access to food) but may require opening equipment, access points, or non-tamper-evident packaging.	8
Partially Accessible.	5

Guidance: VA - 3 Fundamental Elements

- Element 2 – degree of physical access to product
  - Match degree of physical access of PSP with description in previous table and assign corresponding score
    - Every condition in description need not be present to assign score - flexibility
  - Beneficial to include written rationale for score
  - Easiest element to evaluate, recommend beginning with this

Guidance: VA - 3 Fundamental Elements

- Element 3 – ability of an attacker to contaminate product
  - Assigning a score for each PSP
  - Evaluate ability of attacker to contaminate product – flexibility
    - Inherent characteristics
    - Inside attacker
    - Level of observation at PSP?
    - Sufficient volume of contaminant added?
    - Workers in the area?

Guidance: VA - 3 Fundamental Elements

- Element 3 – ability of an attacker to contaminate product
  - Considerations when using a contaminant-specific approach in Element 1
    - Amount of contaminant needed

Worksheet 1-E: Calculating Potential Public Health Impact using a Representative Contaminant

Element 1 Calculations using Representative Contaminant								Element 3 Calculations	
A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
Process Step	Batch Size	Amount of Product (Ingredient) in Final Serving	Servings per Batch **B ÷ C**	Mortality Rate of Contaminant *(FDA provided value = 50%)*	Number of Potential Deaths **D x E**	Score from Table 1	Notes	Representative Contaminant Dose Needed per Serving *(FDA provided value = 40 milligrams)*	Amount of Representative Contaminant Needed per Batch **D x I**

Guidance: VA - 3 Fundamental Elements

- Element 3 – ability of an attacker to contaminate product
  - Considerations when using a contaminant-specific approach in Element 1
    - Concentration or dilution
    - Removal
    - Neutralization

Guidance: VA - 3 Fundamental Elements

- Element 3 – assign a score

Table 3. The Ability of an Attacker to Successfully Contaminate the Product	
Description	**Score**
Highest Ease of Successful Contamination. • The process step is in an isolated area, or obscured from view, enabling an inside attacker to work unobserved with little or no time limitations. • It is easy to successfully add sufficient volume of contaminant to the food. • Inherent characteristics of the point, step, or procedure (e.g., uniform mixing) would evenly distribute the contaminant into the food. • It is highly unlikely the inside attacker would be detected adding a contaminant to the food; an attacker would need to act with little to no stealth to introduce the contaminant. • There are no, or few, workers in the area, and it is highly unlikely that they would notice a contamination attempt by an inside attacker. • There is a low likelihood of the contaminant being removed (e.g., by washing, screening, vibration), diluted, or neutralized at this or later points, steps, or procedures in the process.	10
Moderately High Ease of Successful Contamination. The p… is seld… …ved, en… …inside a… …work … …d with	8

Guidance: VA - 3 Fundamental Elements

- Element 3 – ability of an attacker to contaminate product
  - Match ability of attacker to contaminant product at PSP with description in previous table and assign corresponding score
    - Every condition in description need not be present to assign score – flexibility
  - Beneficial to include written rationale for score

Guidance: VA - 3 Fundamental Elements

- Identifying APSs using the 3 Elements
  - What is wide scale public health harm?
    - Elevated presence of Element 1 and Element 2 and Element 3
    - In context of this rule, threshold of morbidity and mortality is not the only determinative factor
  - If a step has a significant vulnerability, all three elements will have some elevated presence
    - When a PSP has an element with a score of 1, then "automatically" not an APS

Guidance: VA - 3 Fundamental Elements

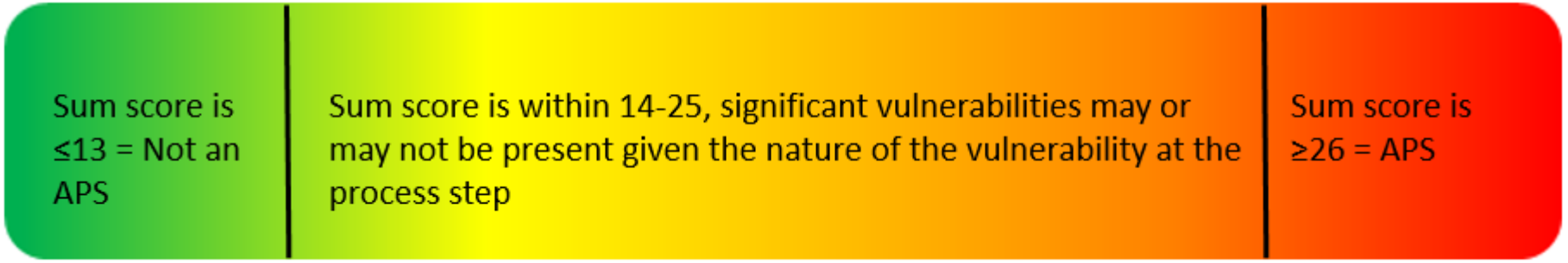
- Identifying APSs using the 3 Elements
  - Summing element scores
  - Ranking summed scores

Guidance: VA - 3 Fundamental Elements

Process Step	Element 1 Score	Element 2 Score	Element 3 Score	Sum
Bulk Liquid Receiving	10	8	8	26
Breading	8	10	8	26
Mixer	8	8	8	24
Belt Conveying	5	8	3	16
Rolling	5	5	3	13
Packaged Ingredient Receiving	5	3	3	11
Cooling	3	3	3	9
Packaging	3	3	3	9
Bulk Dry Ingredient Receiving	10	8	1	N/A[i]
Bulk Dry Storage	Not assessed	10	1	N/A
Water	Not assessed	1	Not assessed	N/A
Vitamin Application	Not assessed	1	Not assessed	N/A

Guidance: VA - 3 Fundamental Elements

- Identifying APSs using the 3 Elements - flexibility



Guidance: VA - 3 Fundamental Elements

- Identifying APSs using the 3 Elements
  - Writing explanations for determination as to whether each step is, or is not, an actionable process step – flexibility
    - "This step is significantly vulnerable because the score > 25."
    - "Relatively low public health impact. Step is hardly accessible. Low ease of attack. Minimal timeframes for contaminant introduction and surrounding workers prevent an inside attacker from working unobserved for enough time to contaminate any significant amount of product."

Guidance: VA Example Worksheet - 3 Fundamental Elements

Process Step	Process Step Description	Element 1: Score and Rationale	Element 2: Score and Rationale	Element 3: Score and Rationale	Sum	Explanation[i]	Actionable Process Step
Bulk Dry Ingredient Receiving	Trucks arrive, enter a receiving bay, and dump bulk dry ingredients into a collector where an auger conveyor moves the ingredients into the storage silo. Usually one employee performs unloading activity. The entire receiving process takes approximately fifteen minutes. Facility procedures allow truck drivers to remain in the area, but not to participate in unloading activity.	Not assessed because Element 3 score = 1	Not assessed because Element 3 score = 1	Score = 1 The amount of a representative contaminant was determined using Worksheet 1-E.[2] It is not feasible to introduce the amount of agent required to contaminate the entire batch undetected. The auger conveyor does not mix the ingredient. Any contaminant would be conveyed as a concentrated slug and would not be distributed throughout the product.	N/A	No significant vulnerability is present because Element 3 = 1.	**No**
Bulk Liquid Receiving	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 to participate in unloading activity. The entire receiving process takes approximately thirty minutes. One truck typically contains 5,000 gallons of liquid ingredient.	Score = 10 Contamination at this process step could result in 80,000 deaths. See Worksheet 1-E for calculations.	Score = 8 Vent and sampling hatches are opened before unloading Hoses are accessible when not in use. Open hatches provide a means of access to the food. This area is accessible by anyone already in the facility.	Score = 8 When multiple trucks are in the receiving bay (which is not uncommon), it is difficult for other workers in the area to observe opening of vent hatches and hooking-up of hoses. A contaminant added to either the vent or the hose itself would mix with the food during unloading and pumping to the storage tank.	26	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.	**Yes**

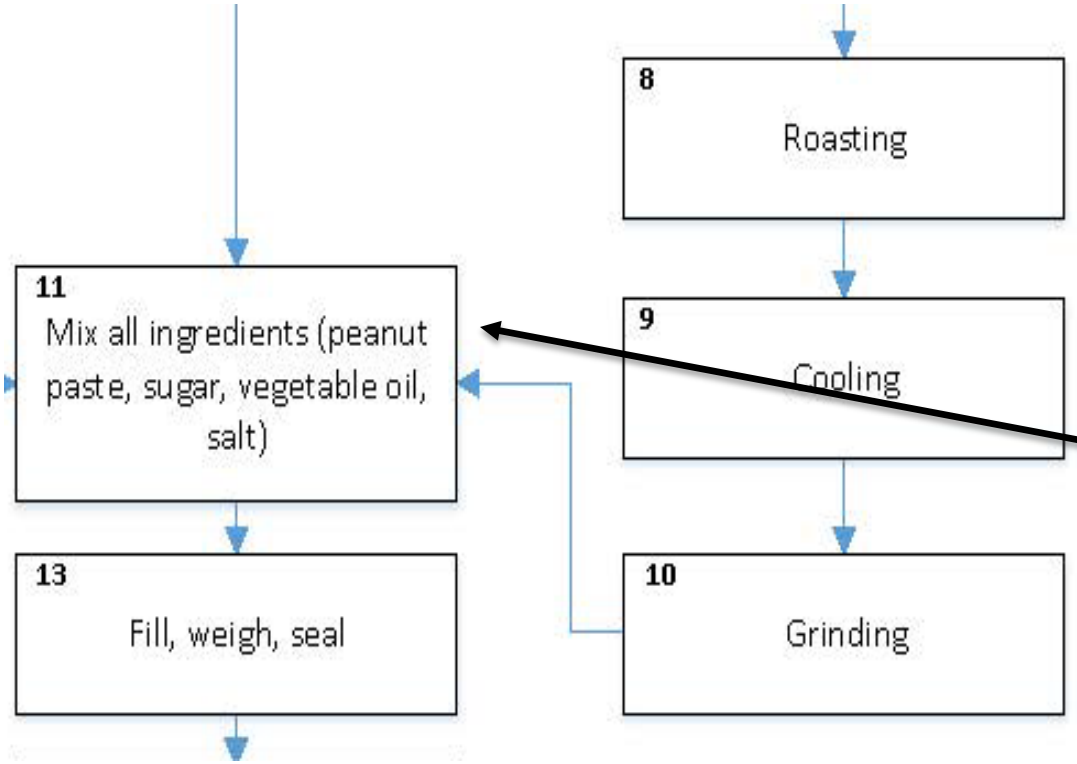
Guidance: VA - Hybrid Approach

- What is the Hybrid approach?
  - Combination of KAT and 3 Elements methods
  - Includes benefits of both methods

Guidance: VA - Hybrid Approach

- Identifying APSs using the KAT Method
  - Assess each PSP to determine whether they fit within a KAT

Guidance: VA - Hybrid Approach



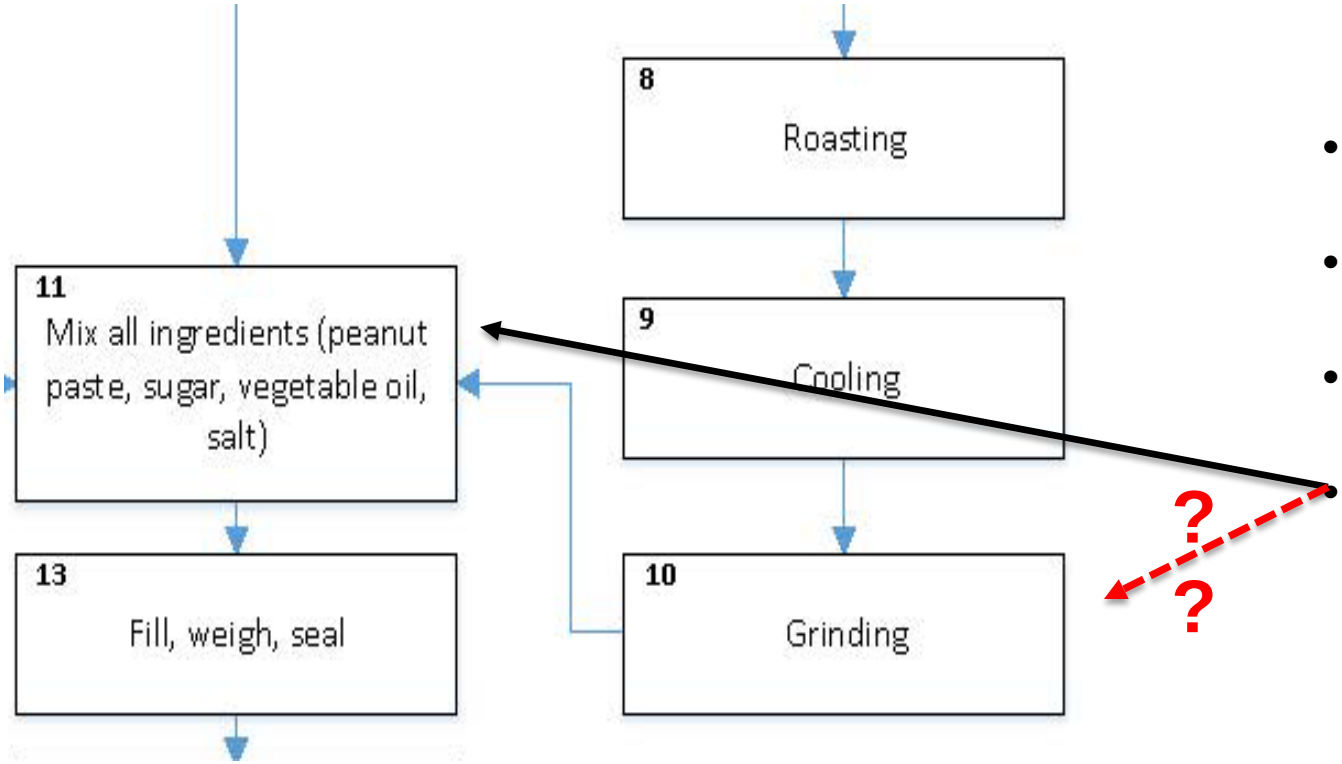
KATs

- Bulk liquid receiving & loading
- Liquid storage & handling
- Secondary ingredient handling
- Mixing & similar activities

Guidance: VA - Hybrid Approach

- Identifying APSs using the Hybrid approach
  - Decision to use 3 Elements for some steps (that align with KATs) is due to factors present at the steps (e.g., inherent characteristics) that would further inform the analysis as to whether a significant vulnerability exists

Guidance: VA - Hybrid Approach



KATs

- Bulk liquid receiving & loading
- Liquid storage & handling
- Secondary ingredient handling
- Mixing & similar activities

Guidance: VA - Hybrid Approach

- Identifying APSs using the Hybrid approach
  - Then, use 3 Elements to conduct a more in-depth evaluation of some of the steps
  - Write explanation describing your decision as to whether each PSP is an APS

Guidance: Mitigation Strategies

Guidance: Mitigation Strategies

- Overview of requirement
  - You must identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented
- Mitigation strategies are:
  - Risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified at actionable process steps, and that are consistent with the current scientific understanding of food defense at the time of the analysis

Guidance: Mitigation Strategies

- Mitigation Strategies are
  - Customized to the process step at which they are applied;
  - Tailored to existing facility practices and procedures; and
  - Directed toward the actionable process step's vulnerability, including vulnerability to an inside attacker
  - Facilities have flexibility to identify and implement appropriate strategies
- Key Term
  - **Significantly minimize** means to reduce to an acceptable level, including to eliminate

Guidance: Mitigation Strategies

- What Mitigation Strategies are supposed to do
  - Minimize accessibility of the product to an inside attacker (Element 2)
  - Reduce ability of an inside attacker to contaminate the product (Element 3)
- Categories of strategies
  - Personnel and operations-based strategies
  - Technology-assisted strategies

Guidance: Mitigation Strategies

- Facility-wide security measures
  - General, non-targeted practices to protect personnel, property, or product
  - Generally not targeted to particular processing steps but are rather practices that address the security of the facility as a whole (e.g., perimeter security) or are practices internal to the facility but that are conducted broadly throughout the facility (e.g., visitor sign-in and escort)

Guidance: Mitigation Strategies

- Facility-wide security measures
  - These measures do not require a VA to inform their identification and implementation – not directed toward individual points, steps, or procedures
  - May serve as a foundation to a mitigation strategy (e.g., using existing badging to identify authorized personnel around an APS) – flexibility
  - There are cases when a facility-wide security measure could be identified as a mitigation strategy if it specifically addresses a significant vulnerability at an actionable process step – flexibility

Guidance: Mitigation Strategies

- Existing measures
  - There may be measures in place, for reasons other than food defense (e.g., quality control, worker safety), at a particular process step that also could serve as mitigation strategies – flexibility
  - Generally, such measures are not inherent characteristics of the step's operation and the VA should not consider these practices when identifying whether the process step is an actionable process step
  - These measures should be evaluated when determining whether they could serve as a mitigation strategy in current or altered form and whether an additional mitigation strategy is needed to augment the existing practice

Guidance: Mitigation Strategies

- Existing measures examples
  - A process step where a worker is a senior employee or an employee who has undergone additional vetting to establish increased trustworthiness. For example, the more trusted employee may be posted at the step because an ingredient is costly or is a trade secret
  - A process step where you require a buddy system for worker safety. For example, your cold storage facility uses buddy systems to prevent workplace injury when working in an area

Guidance: Mitigation Strategies

- Examples in the guidance for minimizing accessibility to the product
  - Restricting the area to only authorized personnel
  - Use tamper-evident tape or seals for partially used ingredient containers
  - Install locking mechanisms on equipment access points
  - Block access pathways to equipment (e.g., ladder cages, locking gates on access gangways)

Guidance: Mitigation Strategies

- Examples in the guidance for reducing the ability to successfully contaminate the product
  - Increase observation of highly vulnerable areas
  - Require workers at actionable process steps to wear uniforms or clothing without pockets or other means of concealing items
  - Install access indicators that would notify other workers that a piece of equipment has been opened

Guidance: Mitigation Strategies

- Examples in the guidance for using cameras and closed circuit TV systems (CCTV)
  - Cameras can facilitate remote observation of an APS
  - The mitigation strategy is the act of observation and CCTV or other technologies can be used to facilitate the increased observation
  - Observation does not need to be constant or dedicated (e.g., workers might oversee several processing activities from a control room, including observing an APS via a CCTV screen)

Guidance: Mitigation Strategies

- Using multiple Mitigation Strategies
  - Layering two or more mitigation strategies together at an APS may be needed to achieve sufficient protection of an APS – flexibility
  - Two or more inexpensive mitigation strategies may be more cost effective than a single expensive one (e.g., one that requires capital investment or installation of protective equipment)

Guidance: Mitigation Strategies

- Explanations
  - Each strategy must include an explanation of how it significantly minimizes or prevents the significant vulnerabilities associated with the actionable process step
  - The written explanations help facilitate proper application of mitigation strategies management components

Guidance: Mitigation Strategies

- Example mitigation strategy and explanation

Actionable Process Step	Mitigation Strategy	Explanation
Liquid food storage tank	Inspect liquid food storage tank prior to use. Immediately prior to reintroducing food, the tank will be visually inspected by the quality control manager using high intensity flashlights and ultraviolet lights to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning.	The use of both high intensity flashlights and ultraviolet lights will enable the quality control manager to make a thorough inspection of the tank to ensure no contamination occurred. The hatch is wide enough to provide a clear view of both the walls and floor of the tank, enabling inspection of all surfaces of the tank interior.

Guidance: Food Defense Monitoring

Guidance: Food Defense Monitoring

- Overview of requirement
  - Conduct a planned sequence of observations or measurements to assess whether mitigation strategies are operating as intended
  - Must establish and implement written procedures, including the frequency with which they are to be performed
- Difference between food safety and food defense
  - Food safety monitoring more likely to document a minimum or maximum value for a parameter is met, and is frequently continuous
  - Food defense monitoring observes whether the strategy is operating as intended and often occurs less frequently

Guidance: Food Defense Monitoring

- What and how to monitor
  - Flexibility to determine
    - What to monitor
    - How often the monitoring will occur
    - Who will monitor the mitigation strategy
  - As long as procedures allow you to assess whether the strategies are operating as intended

Guidance: Food Defense Monitoring

- What and how to monitor
  - How often the monitoring will occur
    - Less frequently than food safety monitoring
    - Periodic basis but at irregular intervals can be beneficial
      - More difficult for an inside attacker to anticipate, and
      - Requires less human and other resources than more frequent monitoring

Guidance: Food Defense Monitoring

- What and how to monitor
  - Flexibility
    - Develop a new procedure to monitor a strategy, or
    - Assign an employee to observe whether the strategy is operating as intended, or
    - Use an electronic monitoring access control device
    - Build monitoring into employee's existing responsibilities

Guidance: Food Defense Monitoring

- Examples in guidance
  - Mitigation strategy: secure access hatch on ingredient storage tank with lock
  - Monitoring procedure
    - Employee observes whether lock is in place and locked at the beginning/end of the tank's 48-hour cleaning cycle
  - Example where monitoring frequency depends on mitigation strategy – depends on cleaning cycle

Guidance: Food Defense Monitoring

- Examples in guidance
  - Mitigation strategy: tamper-evident seals on conveyances
  - Monitoring procedure
    - Check seals for integrity or indications of tampering and match seal or documentation numbers upon arrival of the load
  - Example of monitoring conducted concurrently with mitigation strategy's implementation
  - Example where monitoring frequency depends on mitigation strategy frequency – depends on frequency of inbound shipments

Guidance: Food Defense Monitoring

- Specific example of Cameras / CCTV
  - Mitigation strategy: Increase observation of liquid storage tank, via use of camera (camera facilitates observation; camera, itself, is not the strategy). Assigned employee, who is already observing other feeds, periodically observes camera feed from liquid storage tank area
  - Monitoring procedure
    - Once per shift, manager observes whether employee assigned to observe feeds is doing so on the pre-determined frequency (i.e., the employee is periodically observing the camera feed). Manager documents monitoring by recording either a 'Yes" if the employee is observing the feed or "No" if the employee is not observing the feed

Guidance: Food Defense Monitoring

- Monitoring records
  - Document monitoring in records that are subject to verification
  - Record information at time of observation
  - Should capture observations/actual values, along with the time and date observation was made, and person's signature or initials who made observation

Guidance: Food Defense Monitoring

- Monitoring records
  - Exception records – flexibility
    - Demonstrating a deviation--document monitoring with record of when the strategy is not functioning, or operating, as intended
    - Compared to affirmative records, which demonstrate that mitigation strategy is functioning as intended
    - Exception records are adequate in some, but not all, circumstances
- Continuation of Chapter 3 scenarios

Guidance: Food Defense Monitoring

- Monitoring records
  - Exception records example
    - Automated monitoring system alarm indicates that a gate around an APS is not secured. Whenever the system alarms, an automatically generated exception record documents the instance where the mitigation strategy was not operating as intended
    - Responsibilities of personnel working in area around an APS are modified to include monitoring the area for personal items. An exception record is generated when an unauthorized personal item is discovered in the area by these employees (who are monitoring for personal items in the restricted area)

Guidance: Food Defense Monitoring

- Example food defense monitoring written procedure

Actionable Process Step	Mitigation Strategy	Food Defense Monitoring Procedure and Frequency	Food Defense Corrective Action Procedures	Food Defense Verification Procedures	Food Defense Records
Liquid food storage tank	Inspect liquid food storage tank prior to use. Immediately prior to reintroducing food, the tank will be visually inspected by the quality control manager using high intensity flashlights and ultraviolet lights to ensure that no contaminant has been added to the tank while it was open and accessible after cleaning.	QA technician signs and dates log immediately prior to the liquid food being added to the tank after the monthly cleaning cycle.	*Guidance forthcoming*	*Guidance forthcoming*	Storage tank cleaning sign–off form kept with records for Preventive Controls for Human Food requirements

Guidance: Education, Training, or Experience

Guidance: Education, Training, or Experience

- Overview of requirement
- Qualified Individuals
- Individuals assigned to APSs
  - Food defense awareness – flexibility
  - Proper implementation of mitigation strategy – flexibility
- Food Safety Preventive Controls Alliance (FSPCA)

Guidance: Education, Training, or Experience

FSPCA Training Course	Delivery Method	Intended Audience
Food Defense Awareness		• Workers at Actionable Process Steps (e.g., front line food workers) • Supervisors of Workers at Actionable Process Steps • Satisfies requirement in § 121.4(b)(2)
Overview of IA Rule		• Any stakeholder interested in learning more about the IA rule requirements • This course is not associated with any IA rule training requirement

Food Defense Qualified Individuals

- Requirement for special qualifications for individuals who do or oversee the following activities, which require the most food defense expertise:
  - Preparation of the FDP
  - Conduct of the VA
  - Identification and explanation of mitigation strategies
  - Performance of the reanalysis

Food Defense Qualified Individuals

Such an individual must meet the following requirements:

1. Education, training, or experience (or a combination thereof) necessary to properly perform the activities; **and**
2. Successful completion of training for the specific function that is at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, **or**
3. Be otherwise qualified through job experience to conduct the activities.
   a) Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through a standardized curriculum recognized as adequate by FDA.

Guidance: Education, Training, or Experience

FSPCA Training Course	Delivery Method	Intended Audience – Food Professionals who do the following:
Conducting Vulnerability Assessments (VAs) using Key Activity Types (KAT)	ONLINE TRAINING	• Conduct VAs using the KAT Method only
Conducting Vulnerability Assessments		• Conduct VAs using the 3 Fundamental Elements • This 1-day course must be taught by trained FSPCA VA Lead Instructors
Identification and Explanation of Mitigation Strategies	ONLINE TRAINING	• Identify Mitigation Strategies to implement at Actionable Process Steps
Food Defense Plan Preparation and Reanalysis	ONLINE TRAINING	• Prepare the Food Defense Plan • Conduct Reanalysis activities

*These courses satisfy the training requirements in § 121.4 of the IA Rule.

Food Defense Qualified Individuals

- Preparation of the FDP
- Conduct of the VA
- Identification and explanation of mitigation strategies
- Performance of the reanalysis

You have flexibility to determine how many and which people will be food defense qualified individuals at your facility

FDA Food Defense Plan Builder v1.0

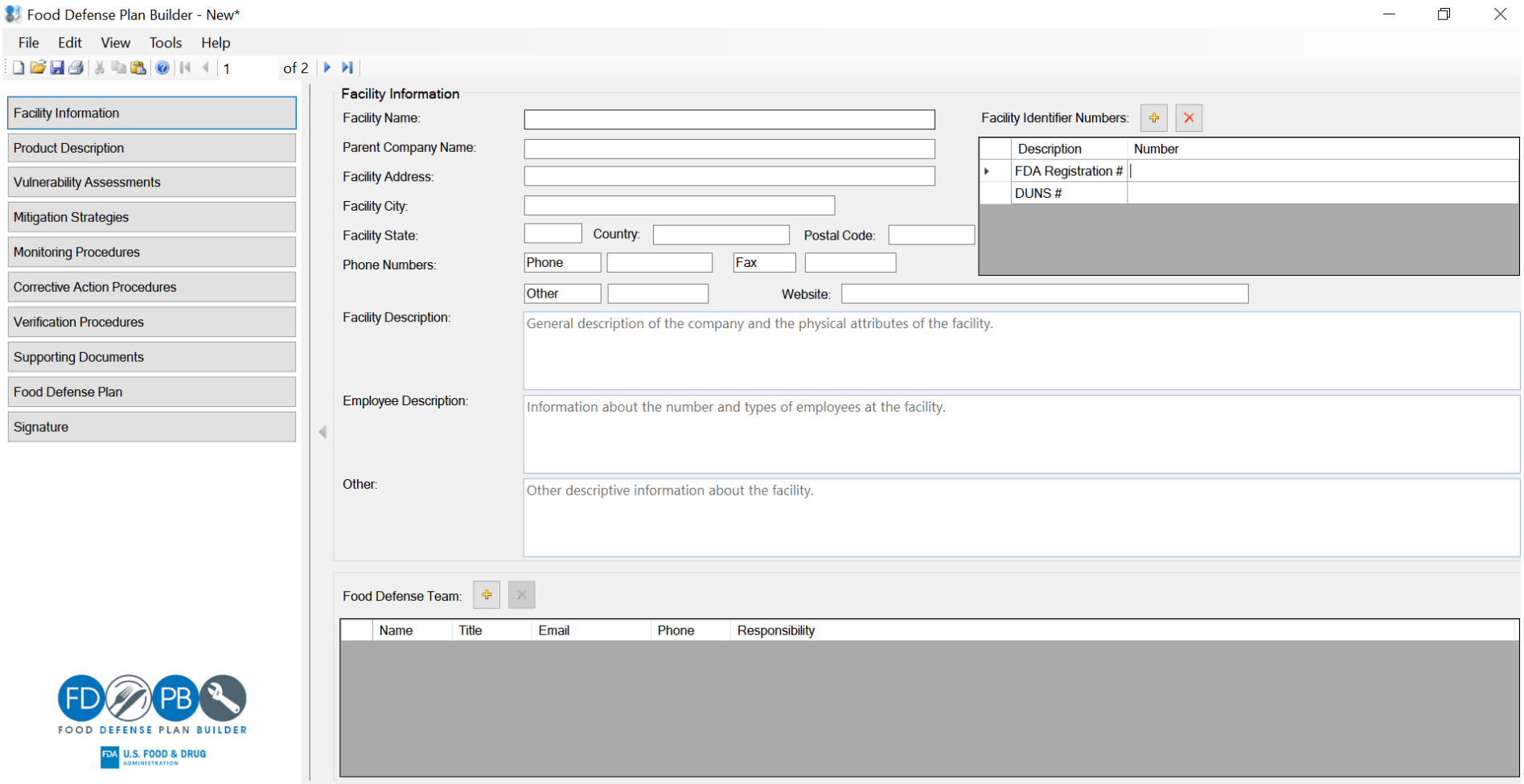
FDA Food Defense Plan Builder v1.0

- User-friendly desktop software tool to assist food industry with developing a food defense plan
- Released in 2013
- Developed under on voluntary food defense framework
- Over 56,500 downloads

FDA Food Defense Plan Builder v2.0

- Updated FDPB content and functionality to align with FDP requirements of the IA Rule
- Conducted usability study with food industry participants April 4-5, 2019
- New sections for monitoring, corrective actions, verification procedures, signature, etc.
- Coming soon!

Facility Information



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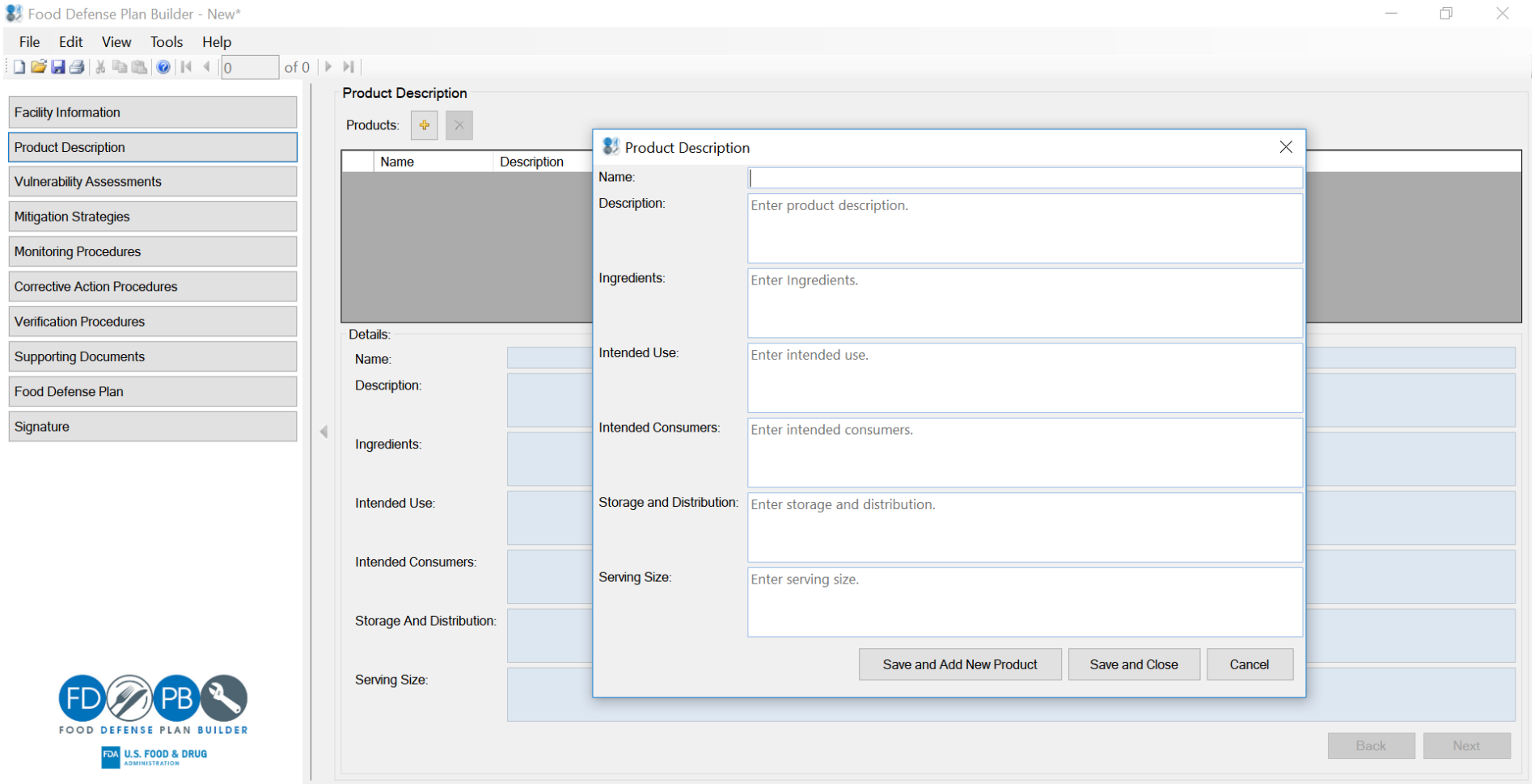
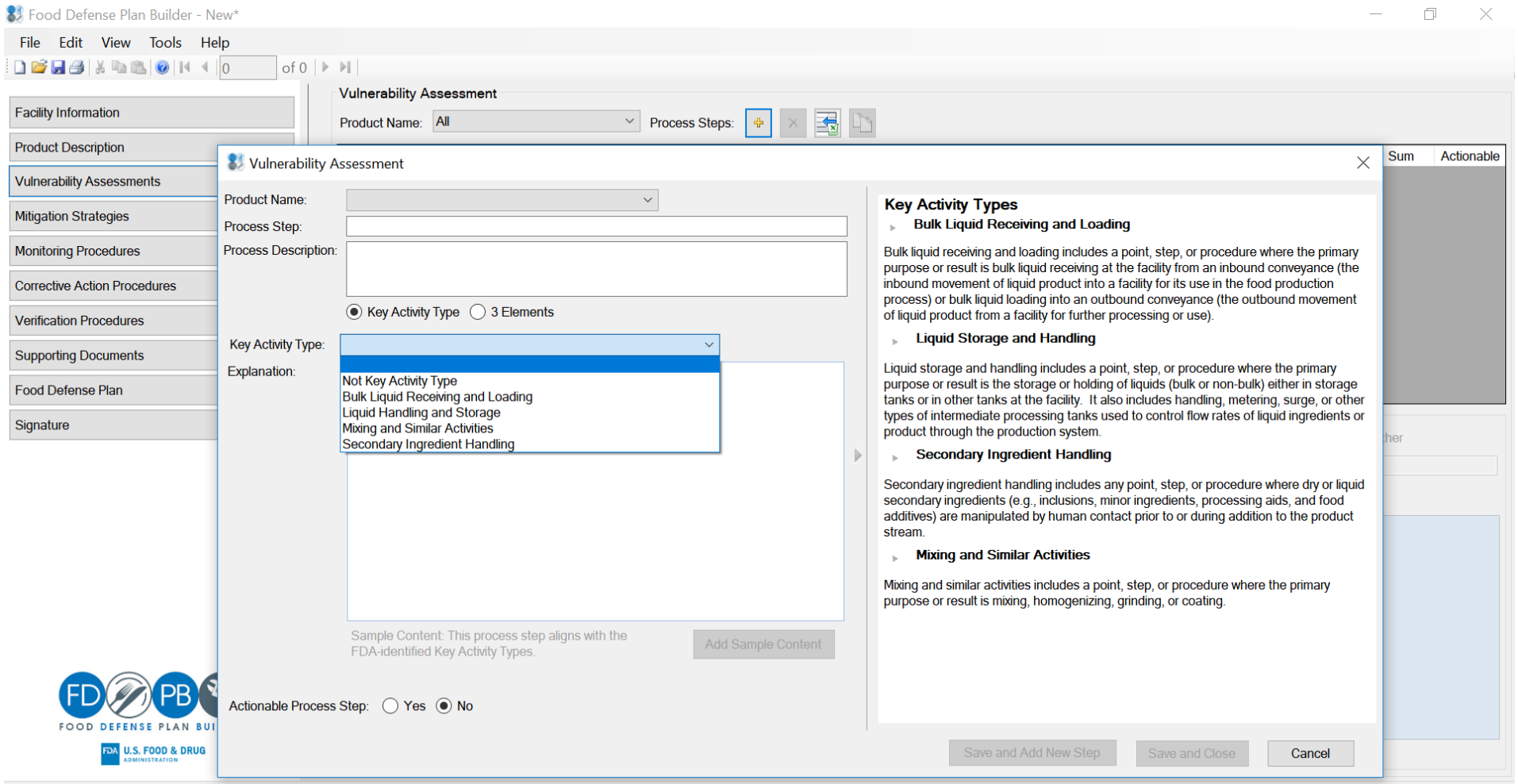
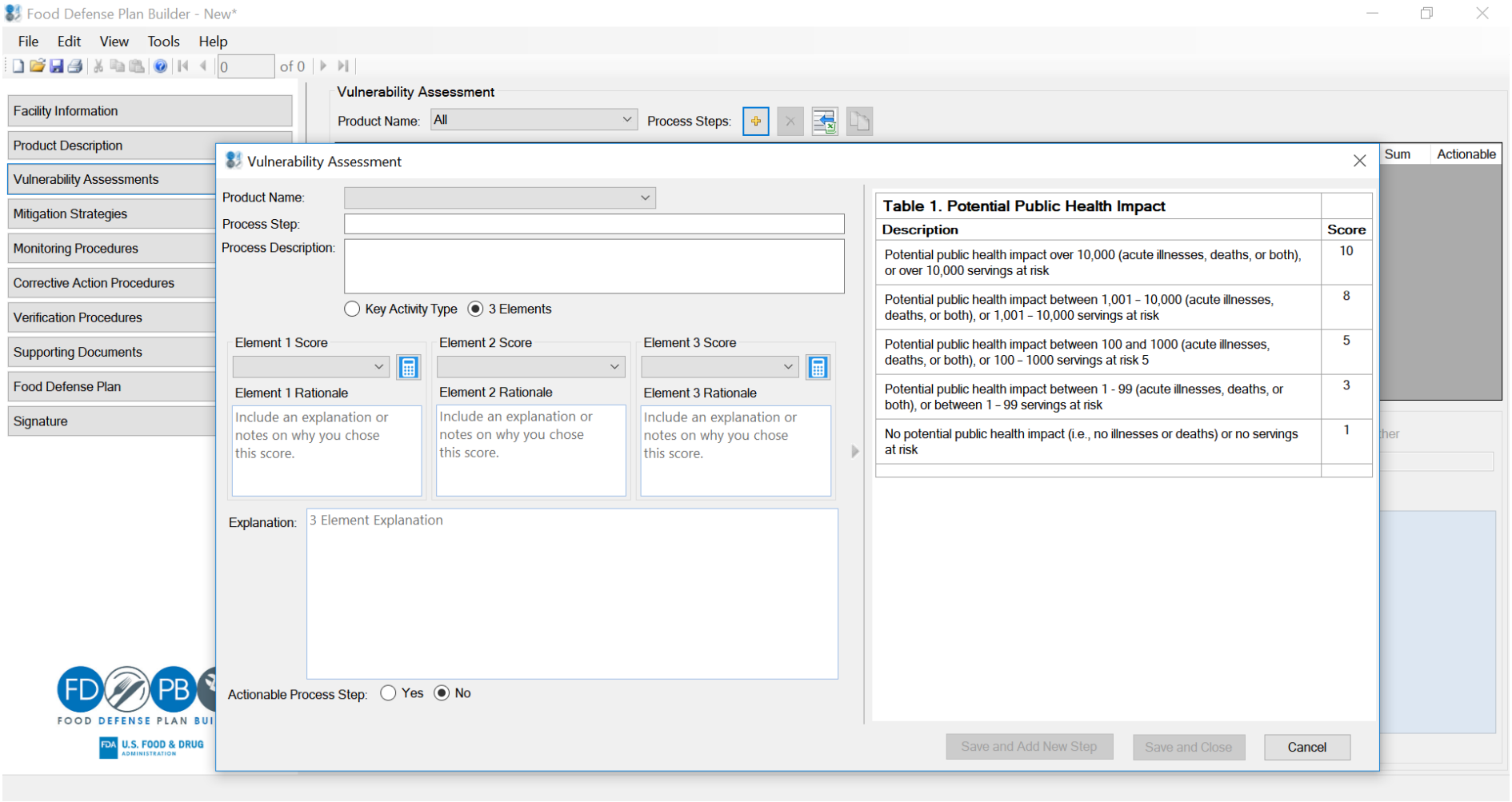


Vulnerability Assessment



Vulnerability Assessment



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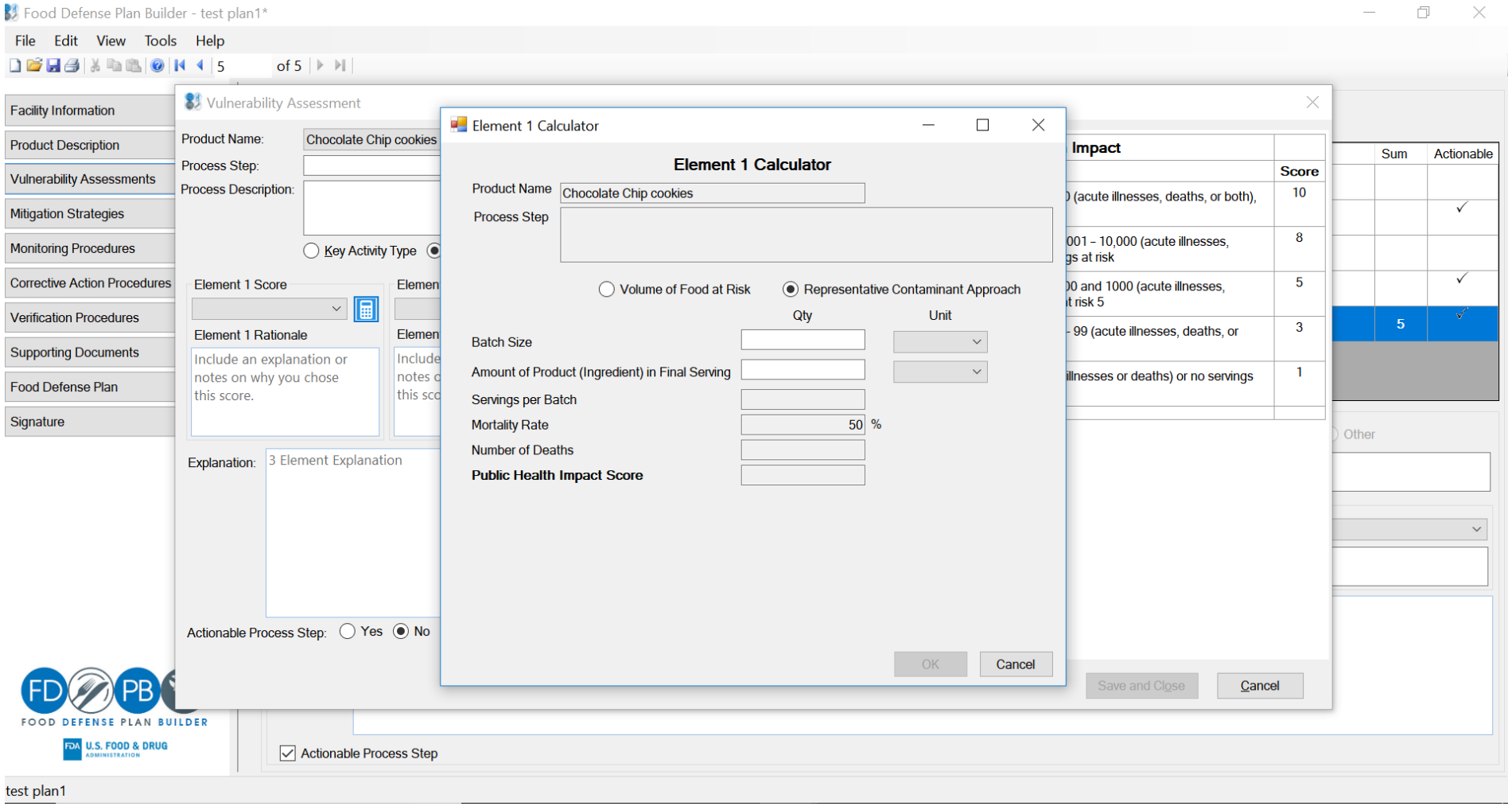

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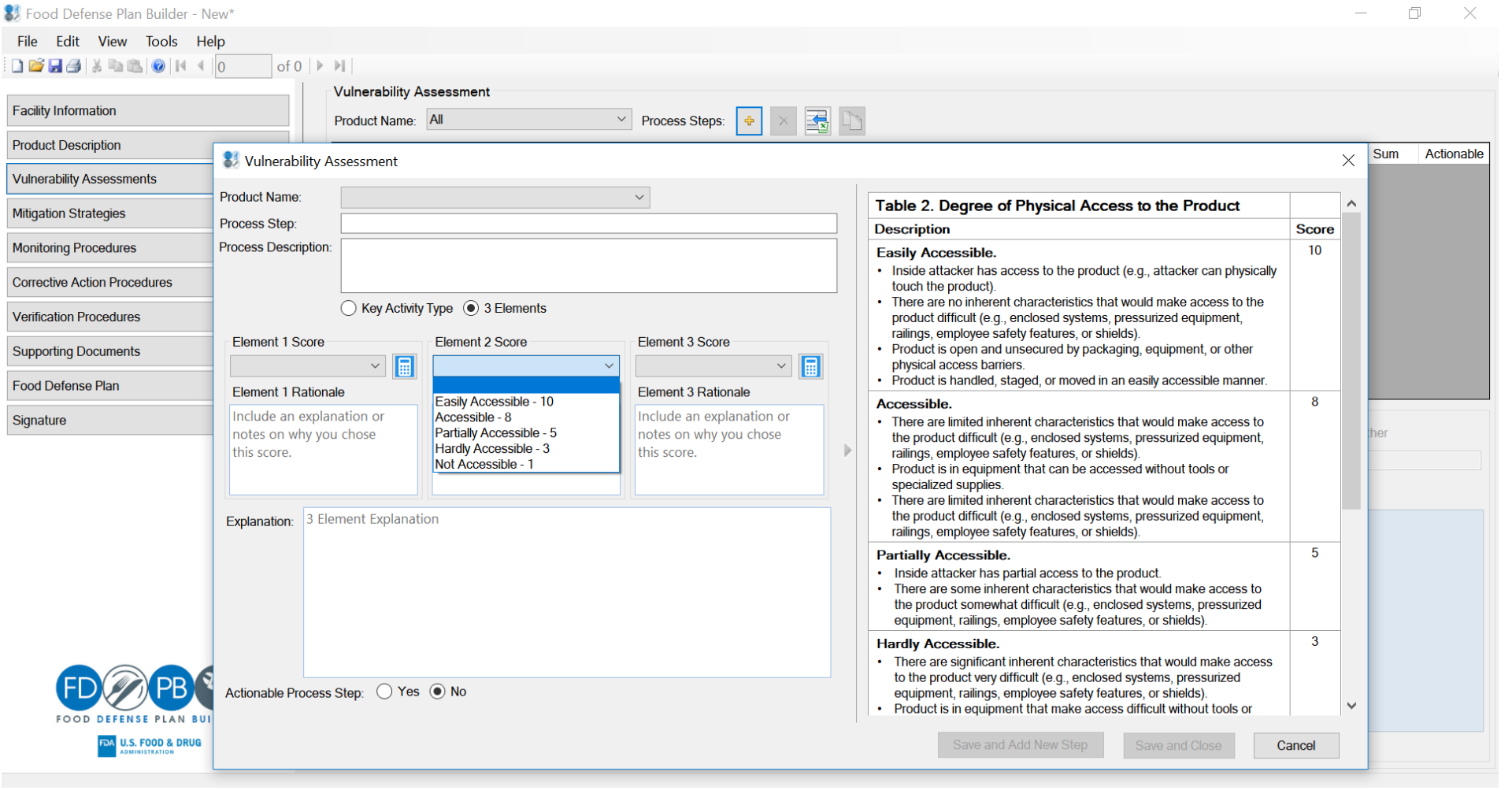

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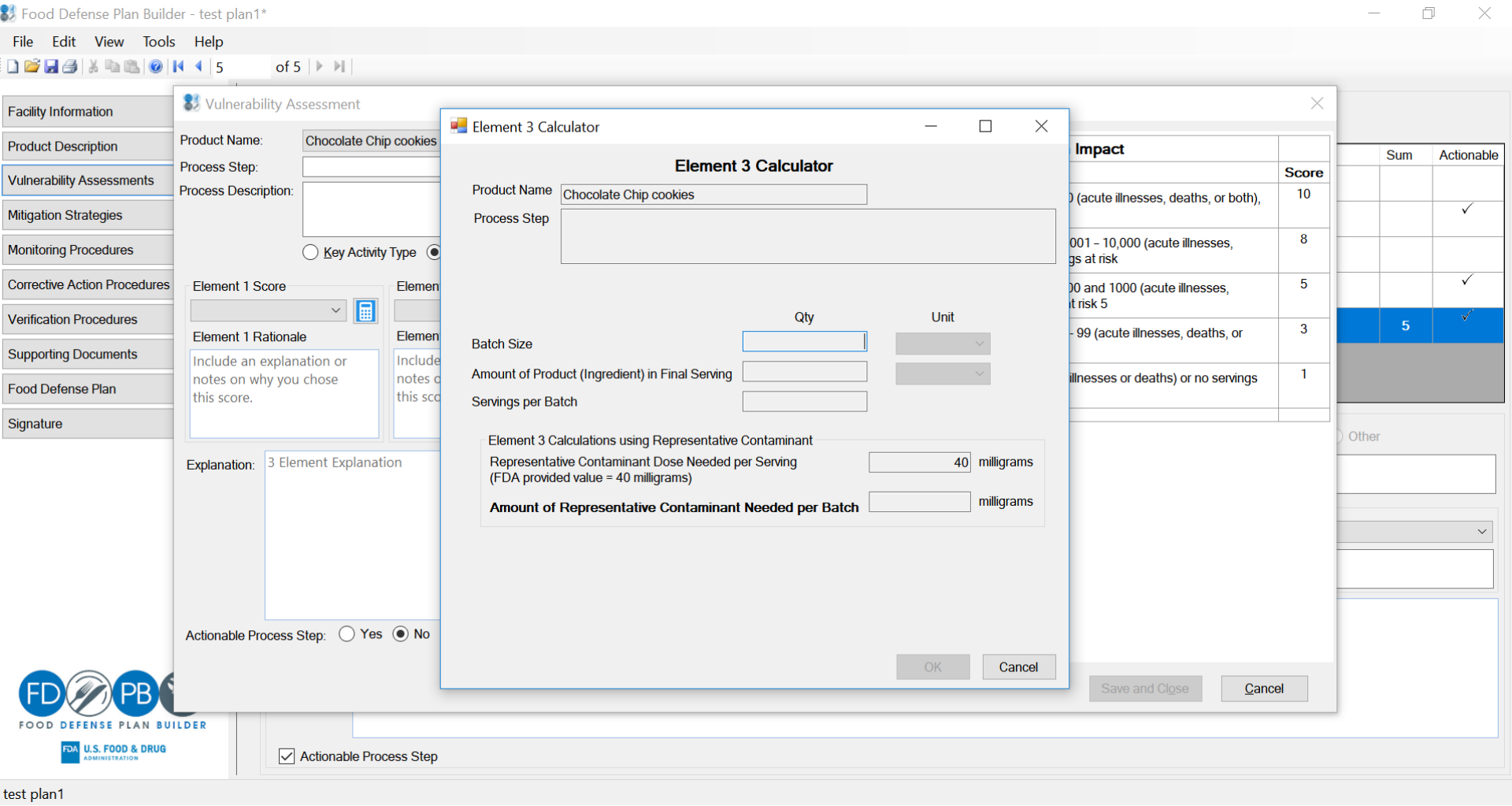
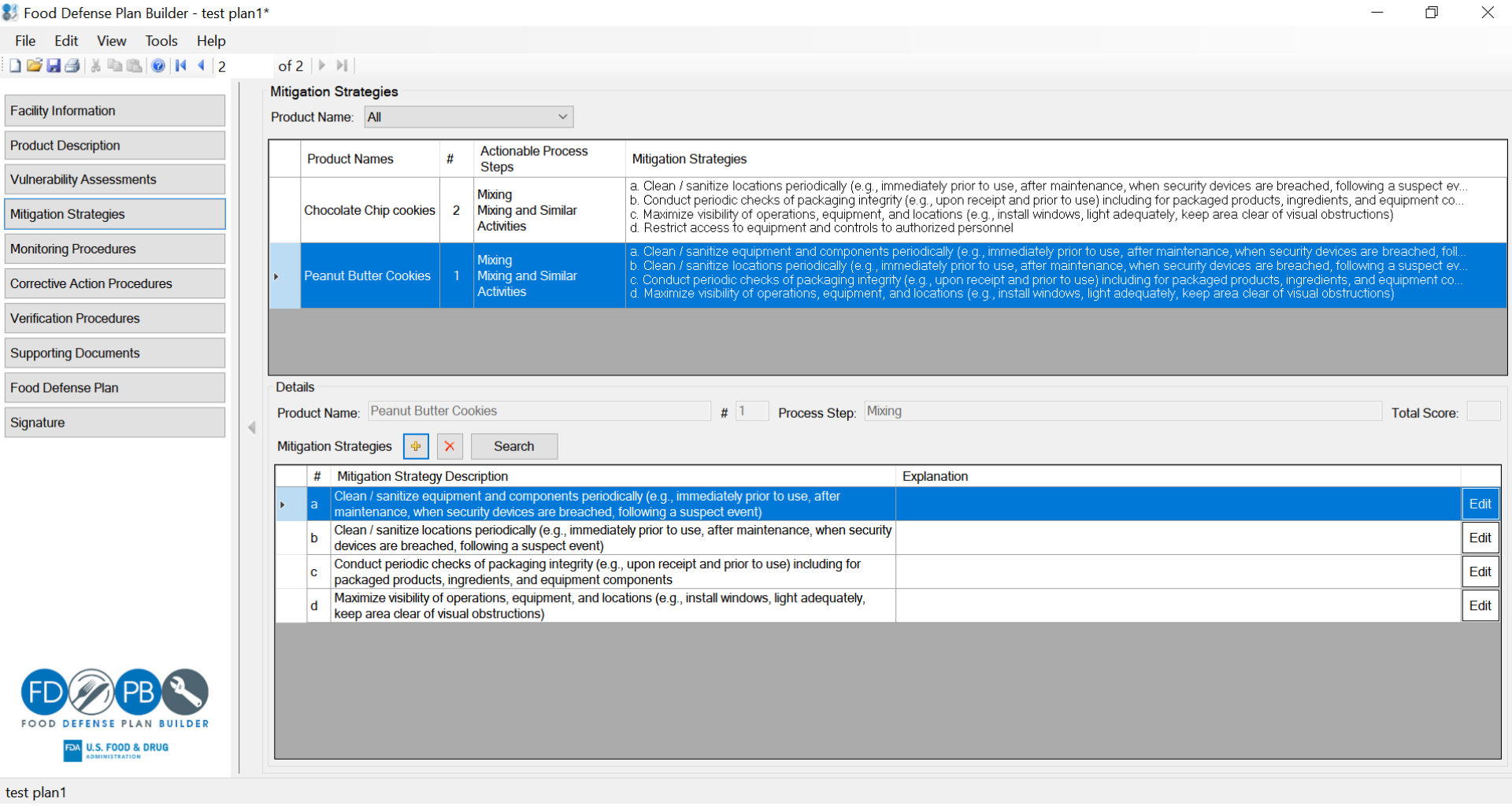


Mitigation Strategies



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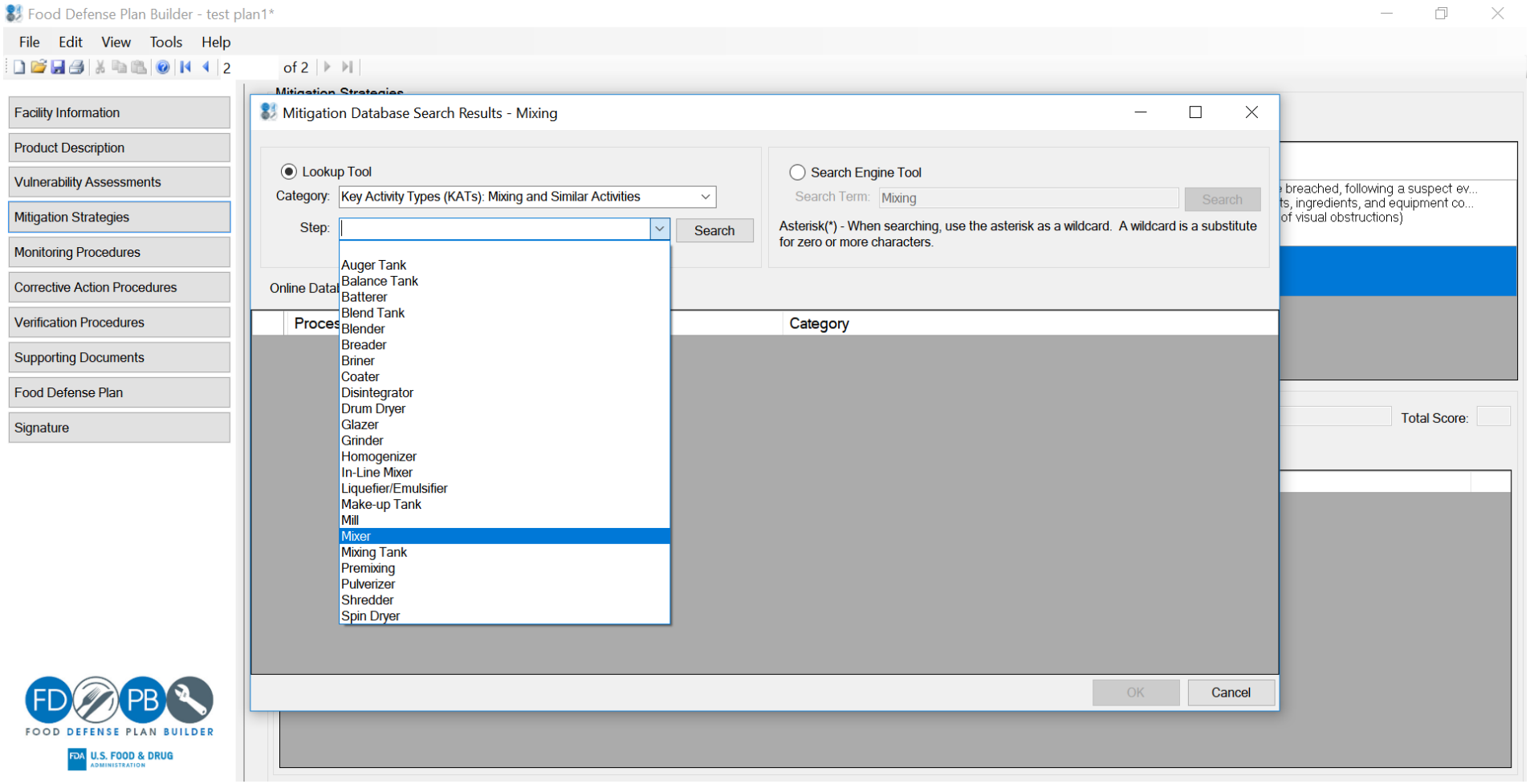

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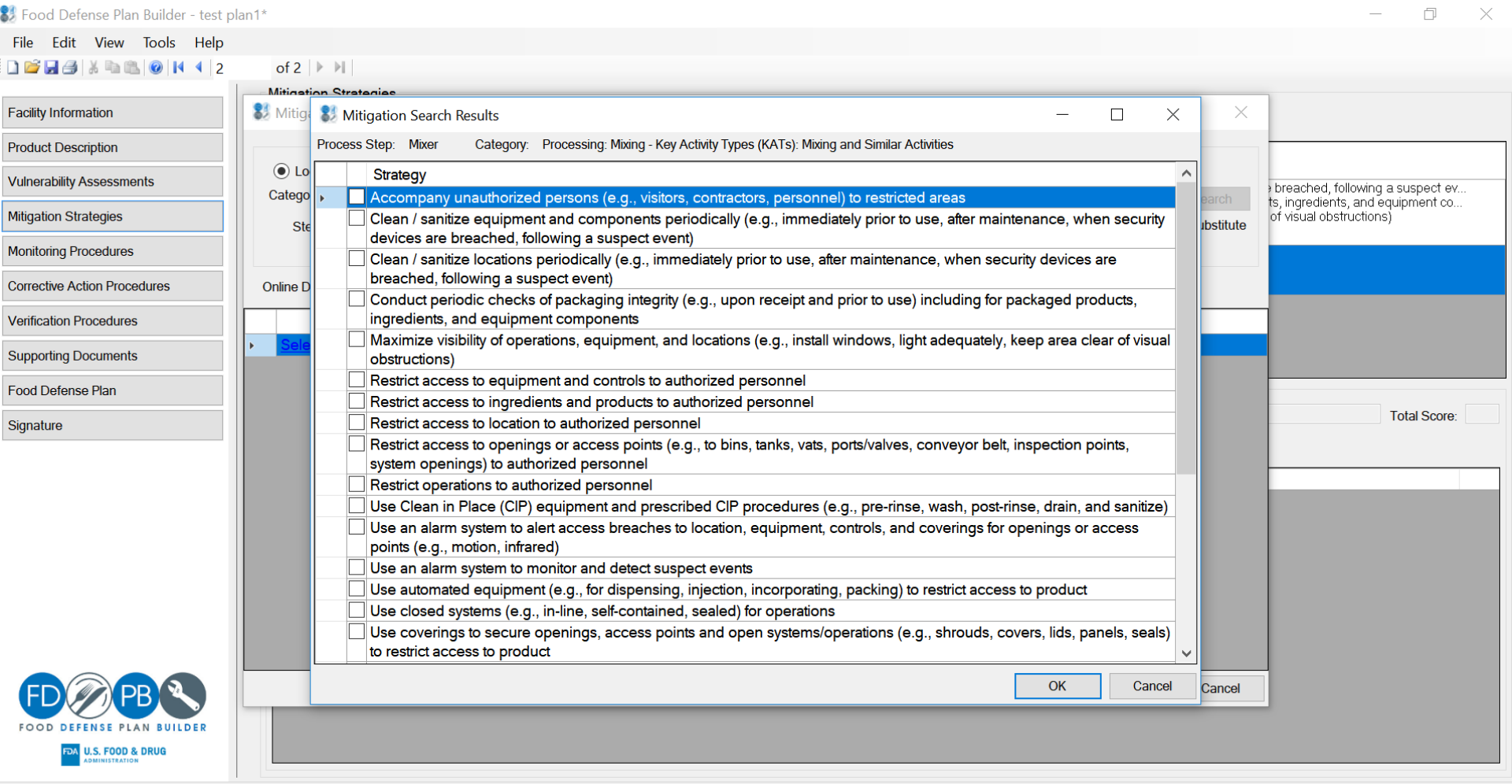

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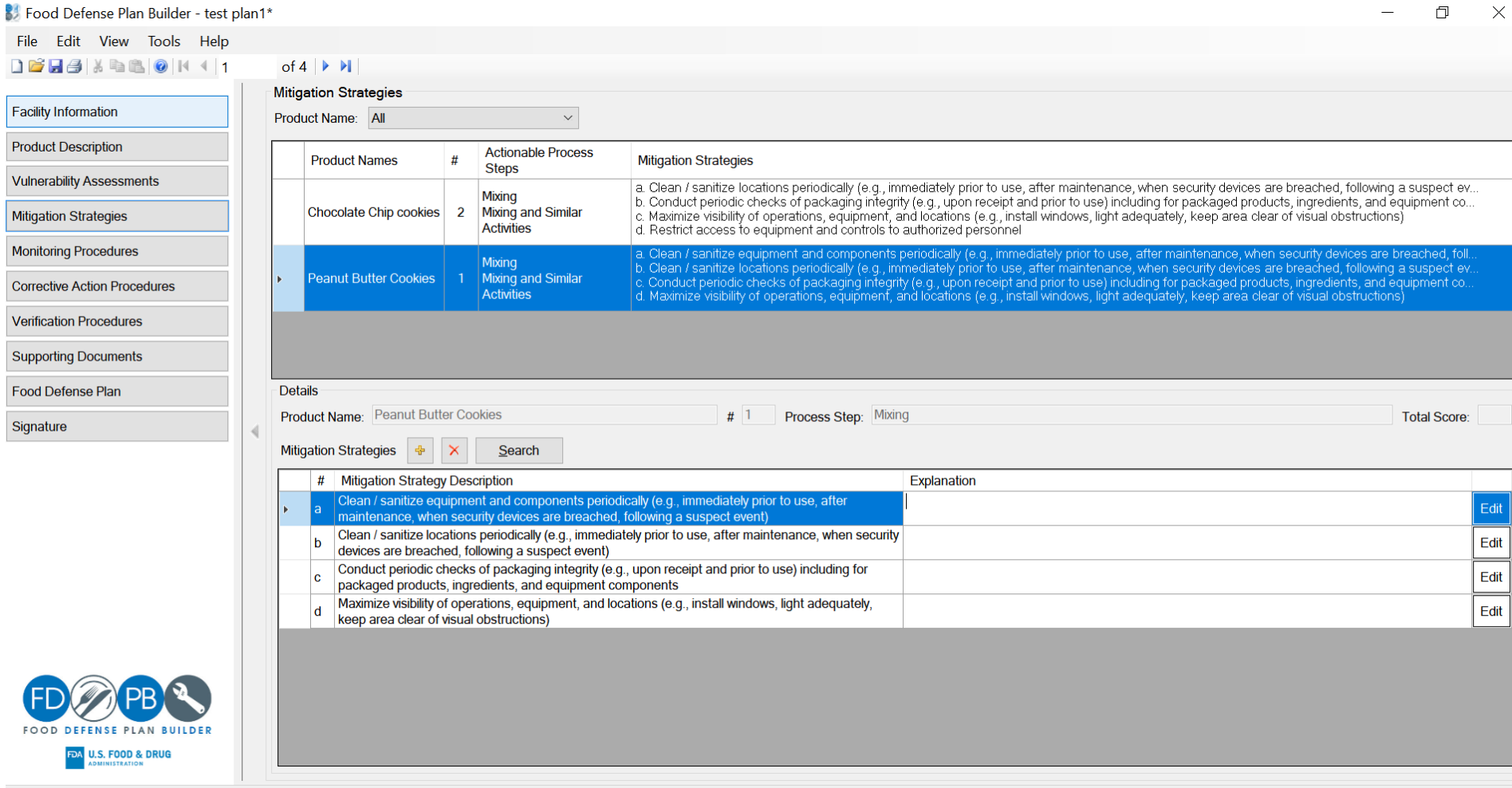
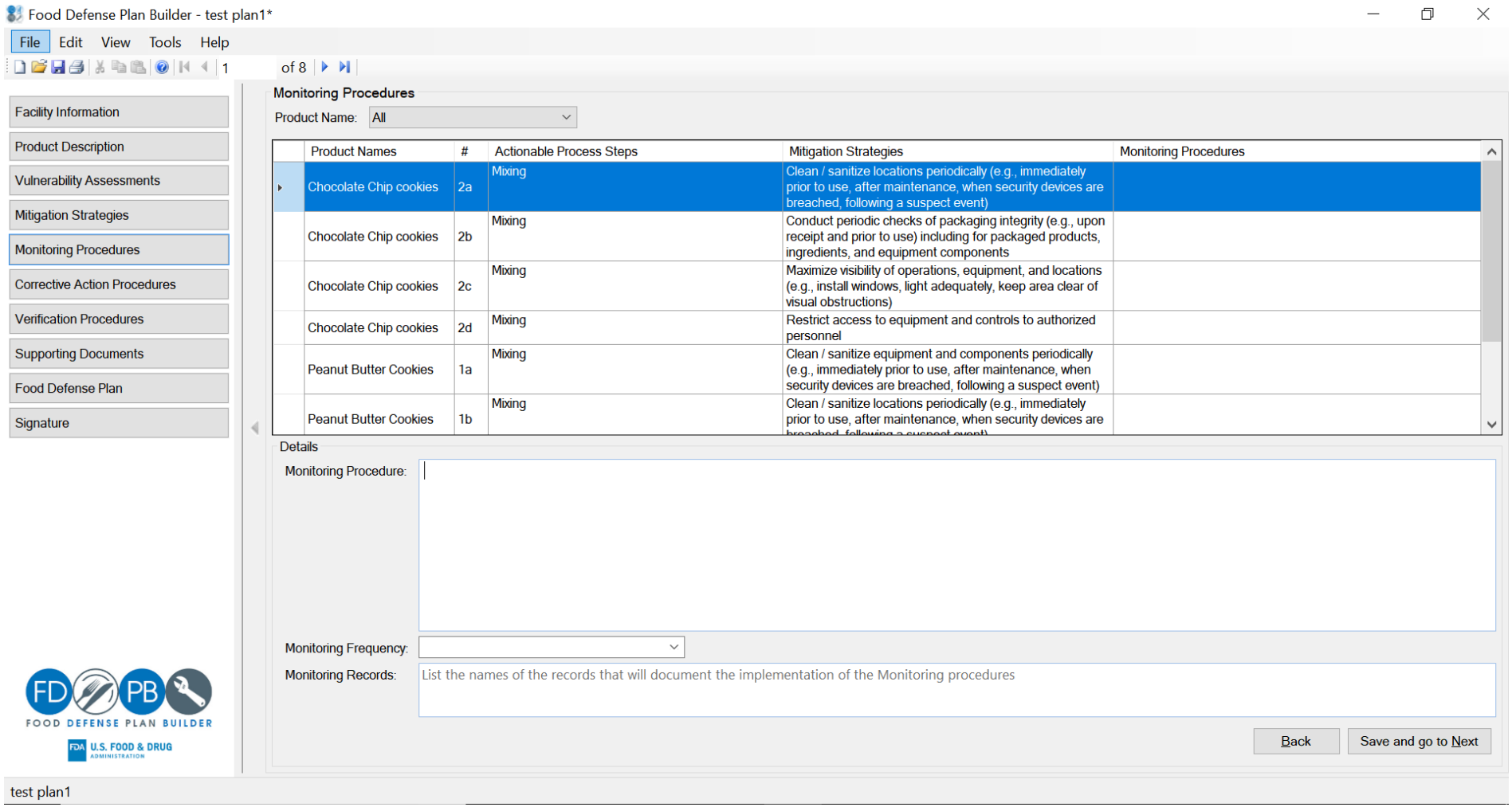
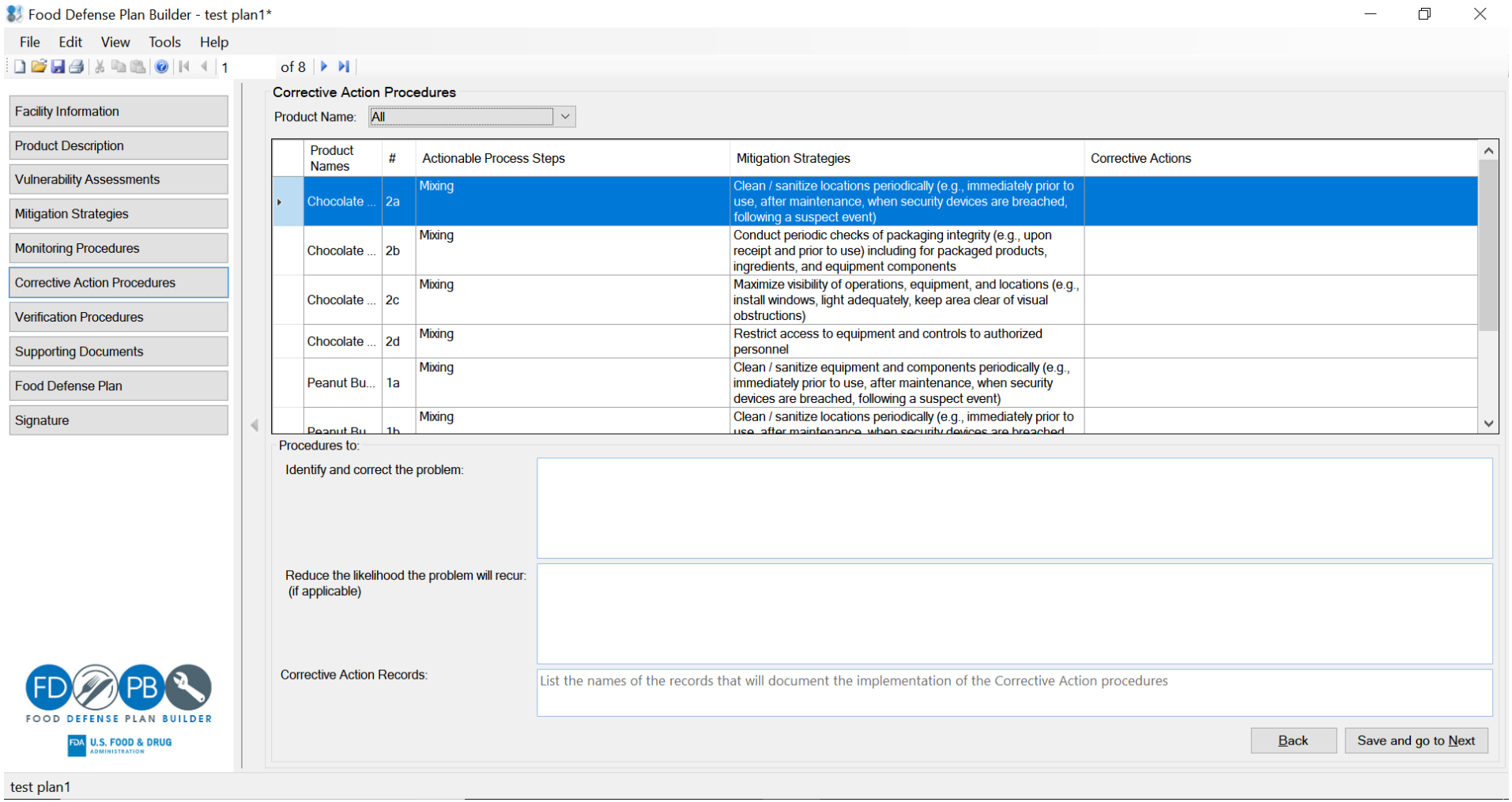


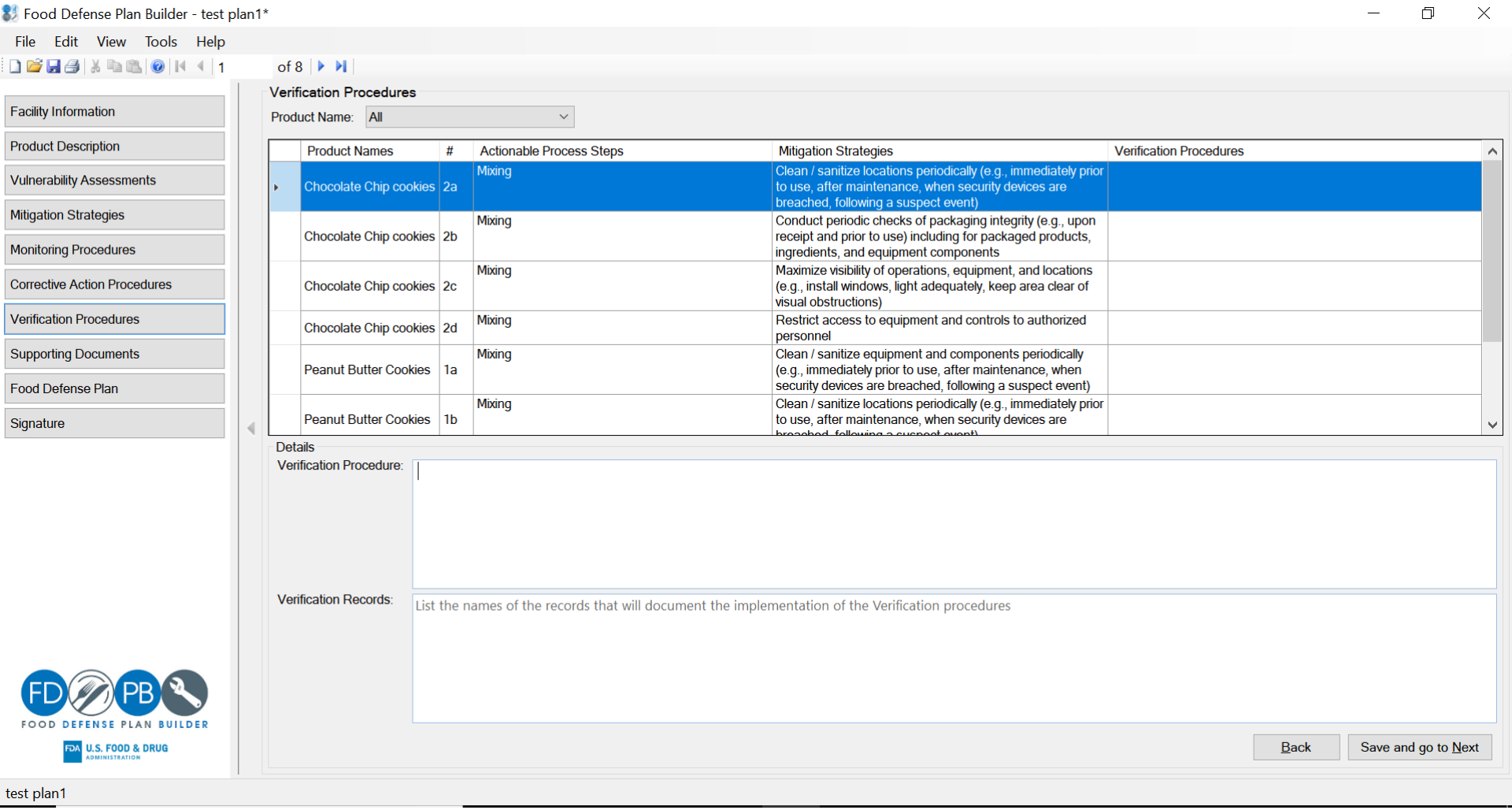
Monitoring Procedures



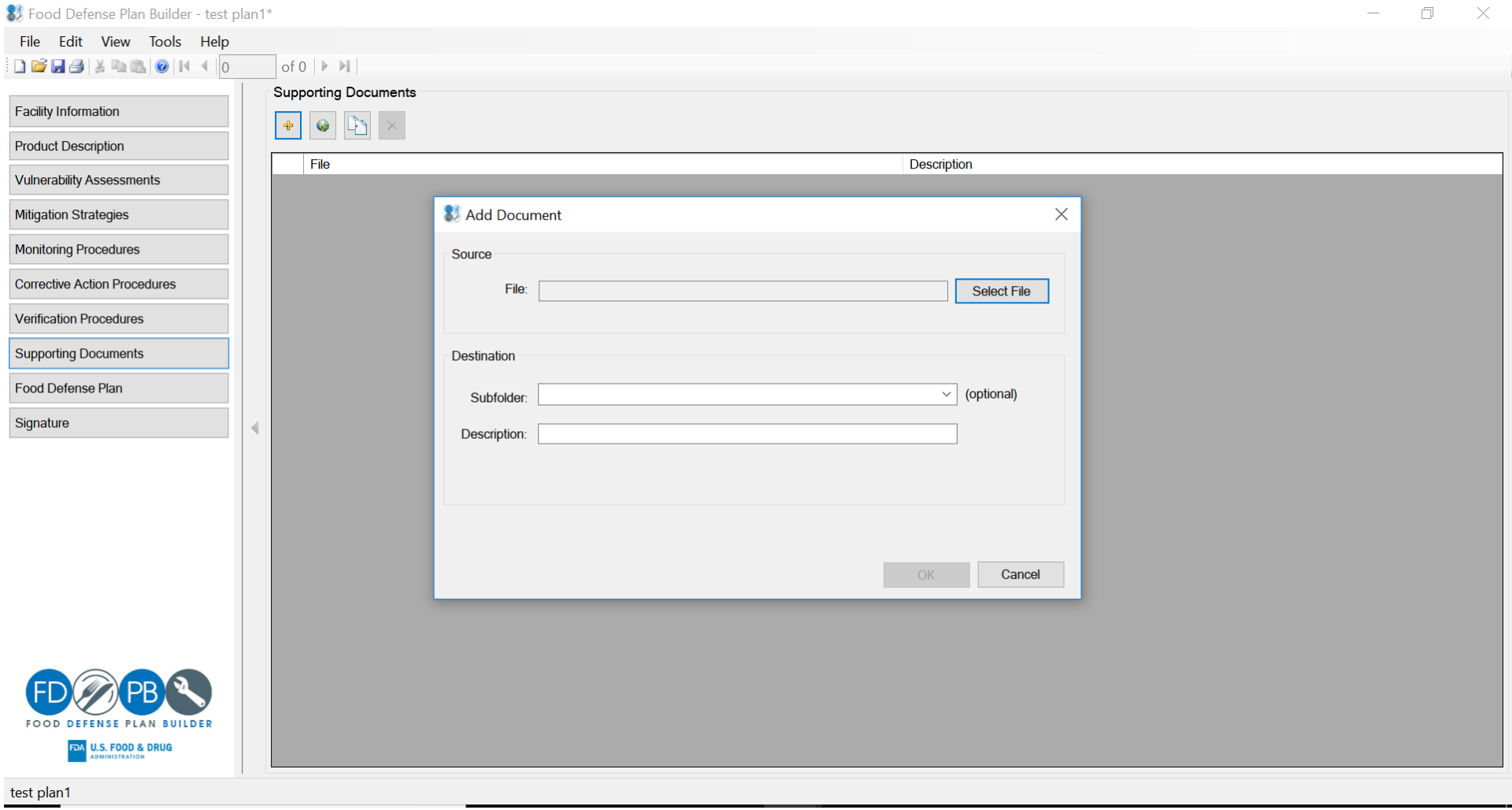
Corrective Action Procedures



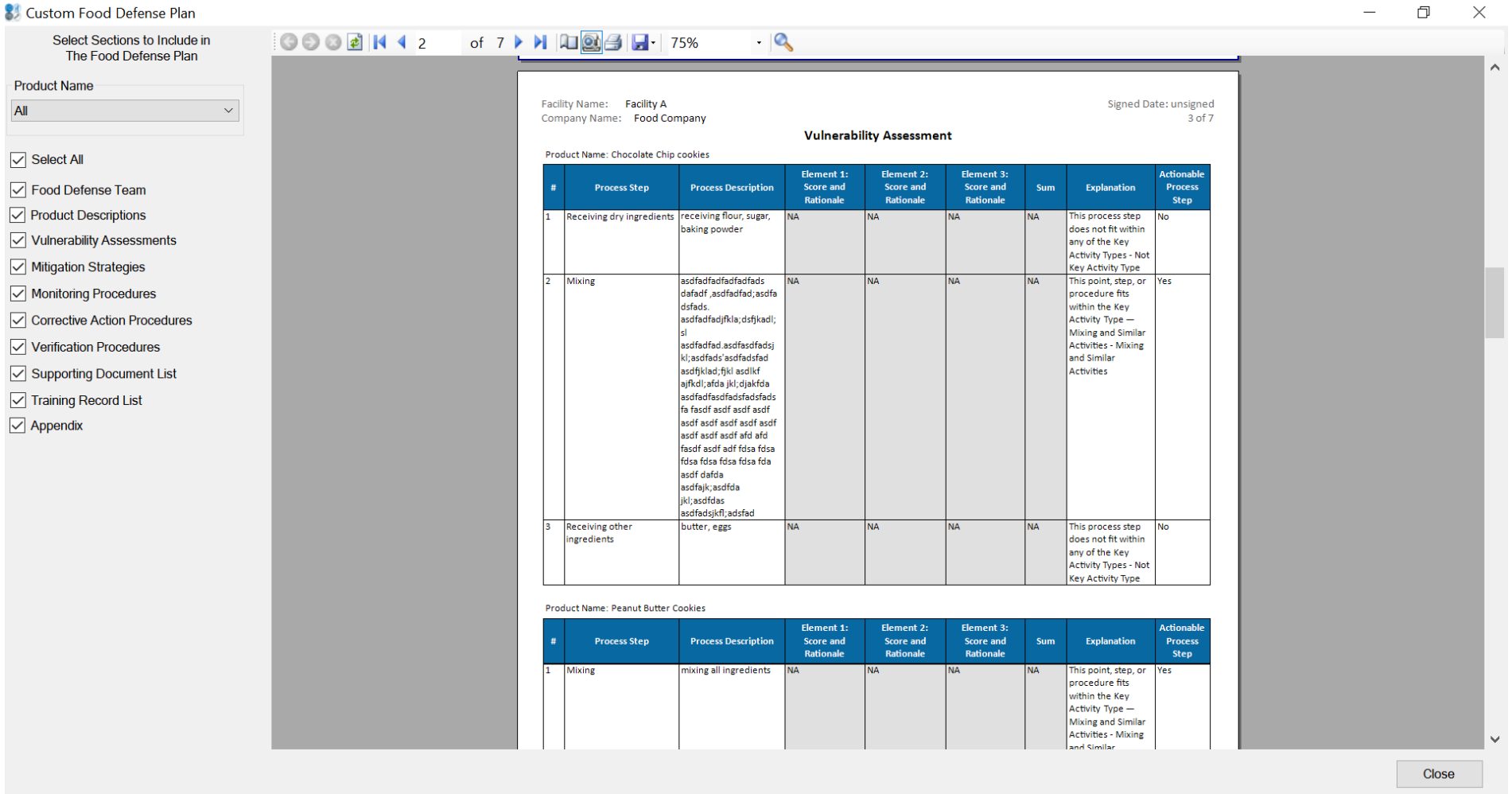
Verification Procedures



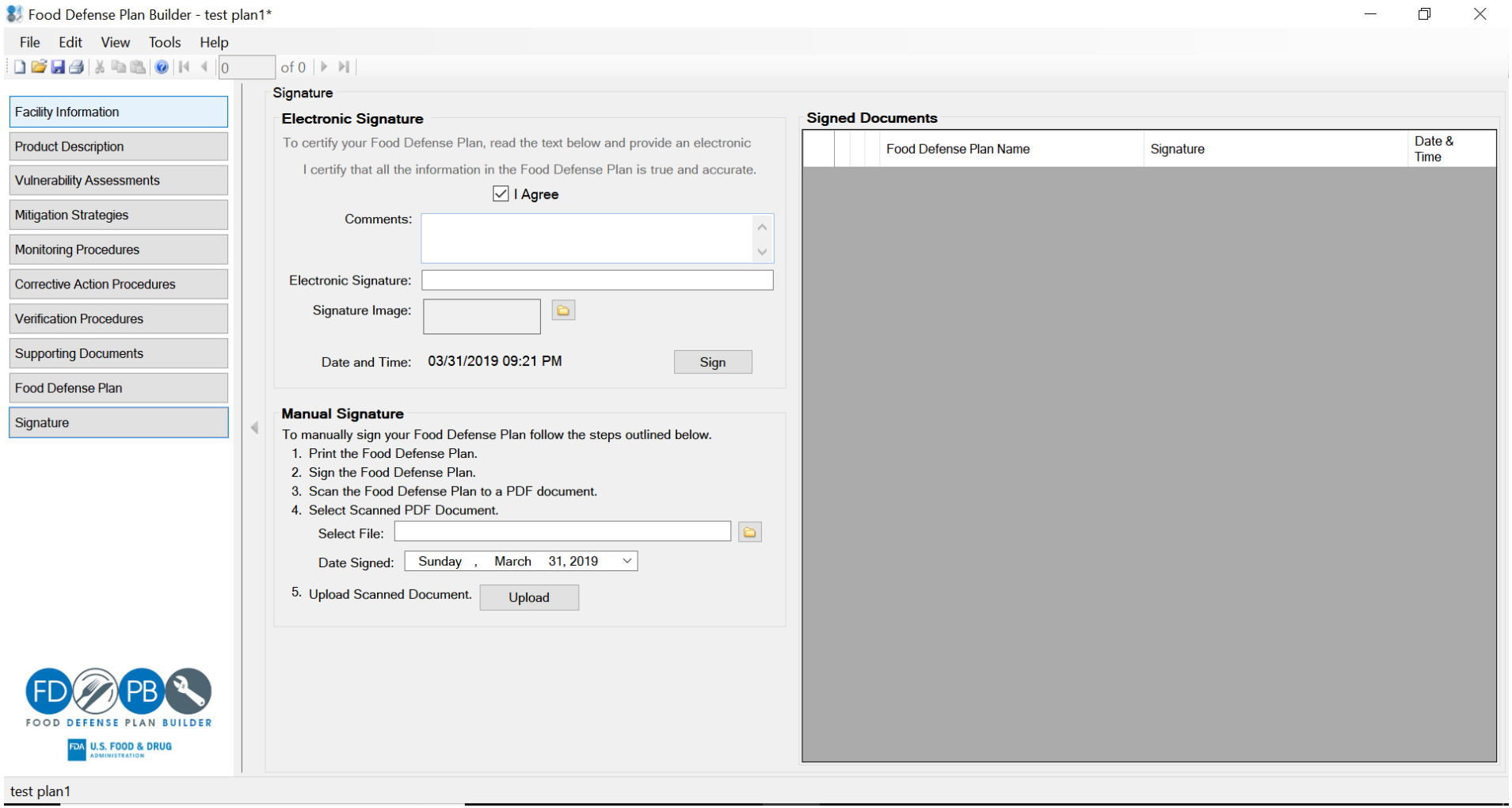
Supporting Documents



Food Defense Plan



Signature


Food Defense Plan Builder - test plan1*
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Facility Information
Product Description
Vulnerability Assessments
Mitigation Strategies
Monitoring Procedures
Corrective Action Procedures
Verification Procedures
Supporting Documents
Food Defense Plan
Signature
Signature
Electronic Signature
To certify your Food Defense Plan, read the text below and provide an electronic
I certify that all the information in the Food Defense Plan is true and accurate.
I Agree
Comments:
Electronic Signature:
Signature Image:
Date and Time:
03/31/2019 09:21 PM
Sign
Manual Signature
To manually sign your Food Defense Plan follow the steps outlined below.
1. Print the Food Defense Plan.
2. Sign the Food Defense Plan.
3. Scan the Food Defense Plan to a PDF document.
4. Select Scanned PDF Document.
Select File:
Date Signed:
Sunday , March 31, 2019
5. Upload Scanned Document.
Upload
Signed Documents
Food Defense Plan Name
Signature
Date & Time
FOOD DEFENSE PLAN BUILDER
U.S. FOOD & DRUG ADMINISTRATION
test plan1

Questions and Answers Session

Public Comments Session

Closing Remarks