

Revised Draft Guidance for Mitigation Strategies to Protect Food Against Intentional Adulteration

June 5, 2019

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)

Draft Guidance Overview

Guidance Overview

- 1st installment – June 2018
 - 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 – March 2019
 - 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

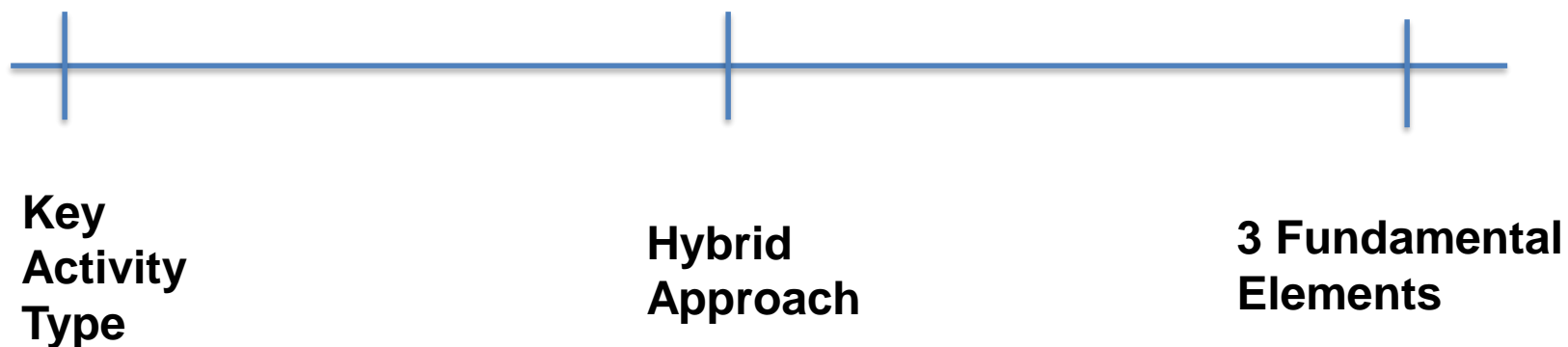
- 3rd installment – forthcoming
 - Food defense corrective actions
 - Food defense verification
 - Reanalysis
 - Records
 - Appendices

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 - Methods

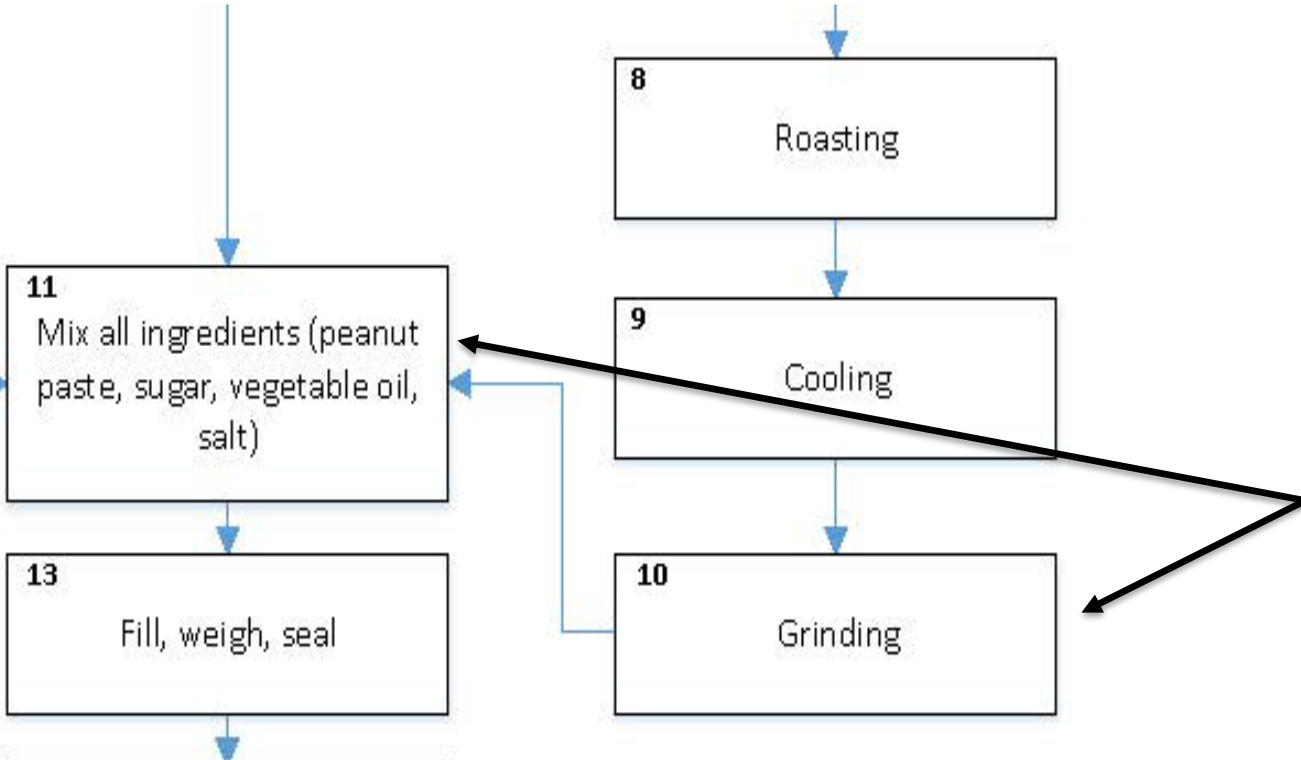
- Flexibility



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



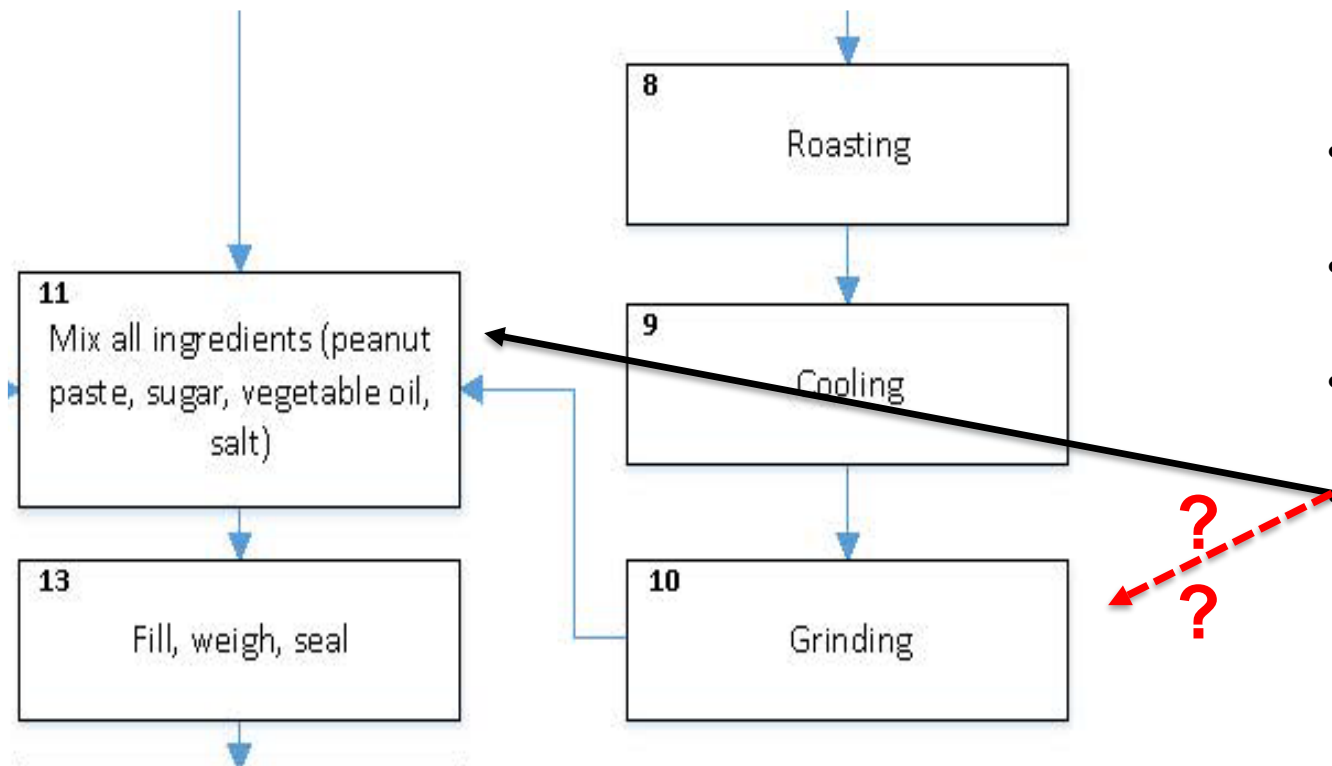
KATs

- 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: 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

- 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

Education, Training, or Experience

Guidance: Education, Training, or Experience

FSPCA Training Course	Delivery Method	Intended Audience
Food Defense Awareness		<ul style="list-style-type: none"> 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		<ul style="list-style-type: none"> Any stakeholder interested in learning more about the IA rule requirements This course is not associated with any IA rule training requirement

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)		<ul style="list-style-type: none"> • Conduct VAs using the KAT Method <u>only</u>
Conducting Vulnerability Assessments		<ul style="list-style-type: none"> • 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		<ul style="list-style-type: none"> • Identify Mitigation Strategies to implement at Actionable Process Steps
Food Defense Plan Preparation and Reanalysis		<ul style="list-style-type: none"> • 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

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

Timing of Inspections



- **First Compliance Date: July 26, 2019**
 - Businesses with > 500 employees and > \$10 million in annual food sales
- **Begin Quick Checks: March 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**
 - Build baseline data, develop prioritization, training

FDA Food Defense Plan Builder v2.0

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 voluntary food defense framework
- Over 57,000 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!





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