

FSMA Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance and Implementation

July 2018

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

Coverage and Exemptions

- Facilities that manufacture, process, pack or hold human food
- Facilities required to register with FDA under sec. 415 of FD&C Act
- Applies to domestic and imported food
- Exemptions
 - Very small businesses (<\$10 million in sales of human food)
 - Activities under FSMA Produce Rule
 - Animal food
 - Others

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

Compliance Dates

- Very small businesses (modified requirements):
July 26, 2021
- Small businesses (a business with fewer than 500 full-time equivalent employees): July 27, 2020
- All other businesses: July 26, 2019



Commissioner's Blog and Rule Guidance

Commissioner Blog



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION FDA Voice by Commissioner Scott Gottlieb, M.D.

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We're Committed to Guarding Against the Intentional Adulteration of Food and Implementing the New Rule Efficiently

Posted on [March 28, 2018](#) by [FDA Voice](#)

By: Scott Gottlieb, M.D.

The U.S. food supply is among the safest in the world. But to keep it safe we must recognize that our foods are vulnerable – not just from unintended contamination, but from those who would seek to deliberately do us harm.



Ensuring that we're prepared to minimize the risk of an intentional attack on our food supply is a goal that we share with the food industry and consumers.

The [FDA Food Safety Modernization Act \(FSMA\)](#) charges FDA with addressing the burden of foodborne illness by requiring that producers, importers and distributors of food take systematic steps to prevent contamination. Congress passed FSMA with a view of the unique risks posed by a global food supply. Six of FDA's seven "foundational rules" for FSMA focus on the safe production, storage, and transport of human and animal

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Commissioner Blog



- Commissioner Gottlieb blog – March 28, 2018
- Emphasizing our commitment to guarding against intentional adulteration AND implementing the rule efficiently
- Main themes
 - Addressing misconceptions
 - Protecting against an inside attack
 - Food and worker safety are priorities
 - Upcoming guidance

- Guidance
 - Three part draft guidance process
 - 1st part – simple, cost-effective way to identify the most vulnerable parts of the production process, outlines numerous ways to guard against deliberate contamination, as well as ways to monitor the operation – **Published June 19**
 - 2nd part – additional, detailed, and flexible method to identify a facility's most vulnerable points
 - 3rd part – corrective actions, verification, reanalysis, and recordkeeping
 - All guidance will be available for public comment
 - Public meeting to be held after part 2 is published

Guidance

Guidance Chapters – Published in 3 Rounds

- **Introduction¹**
- **Ch 1 Food Defense Plan¹**
- **Ch 2 Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps¹**
 - Section 2C Key Activity Types as a Method for Conducting a Vulnerability Assessment to Identify Significant Vulnerabilities and Actionable Process Steps¹
 - Section 2F Evaluating the Three Fundamental Elements to Identify Significant Vulnerabilities and Actionable Process Steps²
- **Ch 3 Mitigation Strategies for Actionable Process Steps¹**
- **Ch 4 Mitigation Strategies Management Components: Food Defense Monitoring¹**
- **Ch 5 Mitigation Strategies Management Components: Food Defense Corrective Actions³**
- **Ch 6 Mitigation Strategies Management Components: Food Defense Verification³**
- **Ch 7 Reanalysis³**
- **Ch 8 Education, Training, or Experience²**
- **Ch 9 Records³**
- **Appendix 1. Food Defense Plan Worksheets¹**
- **Appendix 2. Mitigation Strategies in the Food Defense Mitigation Strategies Database³**
- **Appendix 3. Calculating Small Business and Very Small Businesses Sizes³**

1 = Round 1, 2 = Round 2, 3 = Round 3

Round 1 – Major Components & Themes

- Background and definitions
- Relatively simple and cost-effective method to identify vulnerable points
- 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
- Inter-chapter themes: risk-based, flexible, and practical

Introduction & Food Defense Plan Chapters

- Glossary
- Exemptions
- Description of food defense plan
- Individual(s) developing the plan
- Formatting, changing, and maintaining the plan

Chapter 2 – Vulnerability Assessment (VA)

- Overview of requirement
- Scope of things to consider in VA, grouping of products
- Preliminary steps before conducting the VA
- Key Activity Types (KATs)
- Using KATs to identify vulnerable points

Chapter 3 – Mitigation Strategies

- Overview of requirement
- Description of what mitigation strategies do and categories of strategies
- Facility-wide security measures
- Existing measures
- Explanations
- Scenarios

Chapter 4 – Monitoring

- Overview of requirement
- Difference between food safety and food defense
- What and how to monitor
- Monitoring records
- Continuation of Chapter 3 scenarios

Appendix 1 - Worksheets

- Food Defense Plan Cover Sheet
- Food Defense Plan Product Description
- Food Defense Plan VA
- Food Defense Plan Mitigation Strategies
- Food Defense Plan Management Components

Inspection Strategies

Inspection Framework

- Two-level inspectional approach
 - Level 1:
 - Food defense plan Quick-Check inspection
 - Conducted on covered facilities during food safety inspections
 - High level review of Food Defense Plan (FDP)
 - Checks for required sections, plan is current and signed
 - Does not look at details of plan components
 - Conducted by federal and state investigators
 - Anticipated to be conducted for numerous years prior to Level 2 inspections

Inspection Framework

- Two-level inspectional approach
 - Level 2:
 - Comprehensive food defense inspections
 - Conducted only at a limited number of prioritized facilities
 - Conducted by specially trained investigators
 - Critical evaluation of FDP, vulnerability assessment, mitigation strategies, management components, etc.
 - Generates significantly more detailed compliance information
 - Pilot with federal investigators – then reassess program for federal and state investigators

Training

Training

- Established the Intentional Adulteration Subcommittee within the Food Safety Preventive Controls Alliance to create training and technical assistance programs
- Courses for industry are well into development and implementation
- Specific “Regulator Courses” – for the IA Quick-Check and the Comprehensive Inspections are in planning stages

Role of Individual	Method of Training – <i>Current thinking and subject to change</i>
<ul style="list-style-type: none"> Individuals assigned to an actionable process step (including temporary and seasonal personnel) 	Online course – Food Defense Awareness
<ul style="list-style-type: none"> Supervisors of those individuals assigned to an actionable process step (including temporary and seasonal personnel) 	Online course – Food Defense Awareness
<p>Individual(s) conducting or overseeing:</p> <ul style="list-style-type: none"> the preparation of the food defense plan or reanalysis 	Online course – Food Defense Plan Preparation and Reanalysis
<p>Individual(s) conducting or overseeing:</p> <ul style="list-style-type: none"> the vulnerability assessment 	In-person one day training – Conducting Vulnerability Assessments
<p>Individual(s) conducting or overseeing:</p> <ul style="list-style-type: none"> the vulnerability assessment using only Key Activity Types 	Online course – Key Activity Types
<p>Individual(s) conducting or overseeing:</p> <ul style="list-style-type: none"> the identification and explanation of mitigation strategies 	Online course – Mitigation Strategies



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



Menu ▾

Intentional Adulteration

Training & Materials

[FSPCA Food Defense Awareness for the IA Rule](#)

[FSPCA IA Rule Overview](#)

FSPCA IA Key Activity Types Course (coming soon)

FSPCA IA Identification and Explanation of Mitigation Strategies Course (coming soon)

FSPCA IA Vulnerability Assessments Course (coming soon)

FSPCA IA Food Defense Plan Preparation and Reanalysis Course (coming soon)

FSPCA FOOD DEFENSE AWARENESS FOR THE IA RULE

Course Description

The FDA's Food Safety Modernization Act rule: Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121) (IA Rule) requires that covered facilities develop and implement a food defense plan that protects the facility's most vulnerable points from acts of intentional adulteration intended to cause wide scale public health harm. The points in a facilities operation that have these significant vulnerabilities are called "actionable process steps". According the IA rule, individuals assigned to work at actionable process steps and their supervisors, are required to receive training in food defense awareness (21 CFR 121.4(b)(2)). This "Food Defense Awareness for the Intentional Adulteration Rule" is designed specifically for those individuals who will be responsible for...

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- + THE ALLIANCE
- COURSES
 - + FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP)
 - **INTENTIONAL ADULTERATION**
 - FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD
 - FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD
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