

**“Complying with FSMA Food Defense Rule”**

**Pest Invasion – Premier Food Industry Pest  
Management Seminar**

**Dr. Craig Henry, Intro Inc.  
April 2017**

# Key Topics

- 1. Things to Consider about Food Defense**
- 2. Key Components of a Food Defense Plan**
- 3. Food Imports**
- 4. Accessibility and Vulnerability**
- 5. Accessibility and Vulnerability Examples**
- 6. FDA Approach to FSMA Implementation**
- 7. FDA FSMA Intentional Adulteration Rule  
Overview and Exemptions**
- 8. Resources – How to get it done!**
- 9. Key Industry Considerations**

# Things to consider about Food Defense

**Food Defense is not new to the US food industry but in fact little experience has been gained by industry from ACTUAL events threatening the public or a business.**

Three key components of any food defense plan:

1. PREVENTION
2. RESPONSE
3. RECOVERY

Important to differentiate some key terminology:

- Food Security
- Food Safety
- Food Defense
- Economically Motivated Adulteration

# Key Components for a Food Defense System

1. Assess vulnerabilities
2. Evaluate mitigation strategies
3. Document the Food Defense plan
4. Implement focused strategies to mitigate the vulnerabilities

## Food Importation and YOU!

- ✓ **20% of ALL food consumed by the US is IMPORTED**
- ✓ **67% of ALL fruits and vegetables consumed by the US is IMPORTED**
- ✓ **80% of ALL seafood consumed by the US is IMPORTED**
- ✓ **FDA is only able to inspect about 1% of imports**
- ✓ [https://www.accessdata.fda.gov/scripts/FDTraining/course\\_01/module\\_01/lesson\\_02/FD01\\_01\\_02\\_020.cfm](https://www.accessdata.fda.gov/scripts/FDTraining/course_01/module_01/lesson_02/FD01_01_02_020.cfm)

# Accessibility vs. Vulnerability

FDA states:

**Accessibility** is the measure of the ease with which an attacker can physically access the intended target to intentionally contaminate the food.

**Vulnerability** is the measure of the ease with which a contaminant can be introduced in sufficient quantities to achieve the attacker's purpose, once the target has been accessed.

Facilities must consider multiple points of access to create harm.

1. Exterior access
2. Forced entry
3. Covert entry
4. Insider compromise

# FDA - Potential Vulnerabilities in Process – PRODUCE EXAMPLE

Bagged leafy greens have a short shelf-life and may be accessible to intentional contamination during many stages of the food process. Potential access points in the bagged leafy greens food process include:

1. During harvesting
2. During storage or transport of the harvested leafy greens
3. During washing and packaging
4. During storage or transport of the final product
5. During distribution to the public (retail stores, restaurants, etc)

# FDA - Potential Vulnerabilities in Process – PROCESSED EXAMPLE

Juices have multiple stages of processing and may be accessible to intentional contamination during the stages of the food process. Potential access points in the juice food process include:

1. During harvesting
2. During storage or transport of the harvested fruit or vegetable
3. During multiple processing steps and bottling
4. During storage or transport of the final product
5. During distribution to the public (retail stores, restaurants, etc)



# Use of Pesticides to Poison Foods – FDA Example

In 2003, a supermarket employee mixed a **nicotine-based insecticide** into meat in an attempt to get his supervisor in trouble.

As a result, 1,700 pounds of ground beef was recalled after **111 people became ill** with nicotine poisoning.

Although it was determined that the amount of insecticide in a quarter-pound burger made from the contaminated meat could have been lethal, no fatalities or long-term health effects occurred.

**The employee was imprisoned and ordered to pay restitution fees.**

# **FDA Approach to FSMA Implementation**

# Observed Challenges with FSMA Food Defense Compliance

1. High Paperwork Demand: As written facilities must document each step or process justifying a risk or lack thereof.
  - a) Some facilities including storage and distribution may involve hundreds of process steps.
  - b) Not all steps will be actionable within a FD plan.
  - c) Significant manpower requirement, at least initially.
2. Critical requirement to identify mitigation strategies based upon a complete vulnerability assessment supported with written justifications
3. Facilities must consider external AND internal threats such as disgruntled employees and true terrorism etc.
4. Once the FD plan is established it must be maintained and kept current similar to the FSMA Preventive Control Program.
5. Remember FDA is focused on PREVENTION.
6. Overall cost impact.

# Intentional Adulteration Compliance Timeline

- **The IA Rule effective date is May 27, 2016.**
- Compliance for:
  - July 26, 2019 - businesses with **500 or more full-time equivalent employees** (FTE's), which is 3 years after the effective date.
  - July 27, 2020 - businesses with **fewer than 500 full-time equivalent employees** (but that are larger than a “very small business,” as defined in the exemptions discussion above), which is 4 years after the effective date.

# FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration

<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM503566.pdf>

- Applies to both domestic and foreign companies that are required to register with the FDA as food facilities under the Federal Food, Drug, and Cosmetic (FD&C) Act
- **It does not cover farms.**
- **Designed to primarily cover large companies whose products reach many people, exempting smaller companies.**
- There are 3,400 covered firms that operate 9,800 food facilities.
- Design for preventing intentional adulteration from acts intended to cause wide-scale harm to public health, **including acts of terrorism** targeting the food supply.
- Such acts, while not likely to occur, could cause illness, death, economic disruption of the food supply absent mitigation strategies.

# Facility Intentional Adulteration Requirements

Each covered facility is required to:

1. Prepare and implement a **written food defense plan**.
2. Must identify vulnerabilities and actionable process steps,
3. mitigation strategies,
4. and procedures for food defense monitoring, corrective actions and verification.
5. A **re-analysis is required every three years or when certain criteria are met**, including mitigation strategies that are determined to be improperly implemented.
6. **Facilities must ensure that personnel assigned to the vulnerable areas receive appropriate training;**
7. **Facilities must maintain records** for food defense monitoring, corrective actions, and verification activities.

# FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration - Exemptions

- **Very small business**. While exempt, the business would be required to provide to FDA, upon request, documentation to demonstrate that the business is very small.
- The **holding of food, except the holding of food in liquid storage tanks**
- The packing, re-packing, labeling or re-labeling of food where the container that directly contacts the food remains intact
- Activities that fall within the definition of “**farm**”
- Manufacturing, processing, packing, or holding of **food for animals**
- **Alcoholic beverages** under certain conditions

## FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration - Exemptions (cont'd)

On-farm manufacturing, processing, packing, or holding by a small or very small business of certain foods identified as having low-risk production practices. The exemption applies if such activities are the only activities conducted by the business subject to the rule. These foods include certain types of eggs, and certain types of game meats.



# FSMA Implementation

Public FSMA Implementation Meeting – April 23-24, 2015			
Document/Action			
<b>Two Tier Inspection</b>	Tier 1 - FDA visits to Corporate Headquarters	Why? – To review food safety programs associated with FSMA	Unless corporate is registered under the Bioterrorism Act, it is not amenable to inspection
	Tier 2 – FDA visits to registered facilities		
<b>Two Types of Inspection</b>	Adequacy	Multiple CFSAN subject matter experts involved	<b>“You are what your records say you are” – Joe Levitt Esq. – Hogan &amp; Lovels</b>
	Implementation	FDA Office of Regulatory Affairs staff	

# “Phased-In” FDA Inspection Plan

1. At the 2016 Food Safety Summit, Kathy Gombas, Senior Advisor for Food Safety FDA, expects FDA will **“phase in”** FSMA inspection.
2. FDA plans to begin facility inspections with 30 fully trained FDA investigators and State inspectors.
3. The FDA inspection team MAY include **one FDA Investigator, one State Inspector** and **one FDA CFSAN Subject Matter Expert**.
4. FDA **MAY conduct their own hazard analysis of the facility BEFORE they arrive.**
5. There is no indication as to how long the inspection will last.
6. Inspections can spend **80% of the time on Preventive Control Food Safety Program documentation evaluation and 20% on cGMP assessment onsite.**

# Resources

# **NACCHO – August 2016 Report - *Strengthened Food and Agriculture Sector Defense Posture through Improved Private Sector Information Sharing Practices***

## **NACCHO – National Association of City and County Health Officials**

The first and largest bioterrorism event in the U.S. was a targeted attack in 1984, when the Rajneeshee cult **deliberately contaminated salad bars** with salmonella in The Dalles, Oregon as a political ploy, leading to **over 750 people falling ill.**

To increase the preparedness and resiliency of the FAS, committees and communication channels have been established. The **Food and Agriculture Government Coordinating Council (GCC)**, comprised of Federal, state, local, territorial, and tribal government representatives, provides coordination and communication across the government and the sector on security and resilience strategies and activities.

The **Food and Agriculture Sector Coordinating Council (SCC)**, with representation from industry, “provides a forum for members of the private sector to discuss infrastructure security and resilience issues among themselves or to communicate with the government through the GCC.<sup>1</sup>

# **NACCHO – August 2016 Report - *Strengthened Food and Agriculture Sector Defense Posture through Improved Private Sector Information Sharing Practices – (cont'd)***

The following study provides a baseline of current threat information - threat information for this study refers to both impending, actionable threats, and research-identified threats - sharing practices, and an understanding of barriers that still exist and recommendations for improvement.

## **Methods:**

NACCHO first formed an ad hoc research advisory group to act as a sounding board throughout the project. This group was made up of 24 representatives from local health departments, federal government, nonprofit organizations, and industry. Duties for this group included providing input and feedback on the approach, drafts of interview and assessment questions, and providing recommendations, based on their own experiences to inform actionable next steps.

# **NACCHO – August 2016 Report - Strengthened Food and Agriculture Sector Defense Posture through Improved Private Sector Information Sharing Practices – (cont'd)**

1. **Recommendation:** Create a central repository for tools, training, and resources available to the food and agriculture sector.
2. **Recommendation:** Create a factsheet of available information sharing platforms.
3. **Recommendation:** Continue to expand and build partnerships between public and private entities.
4. **Recommendation:** Federal government members of the Food and Agriculture Sector – mainly from DHS and FBI as they are primarily responsible for intel – host a webinar on the types of information shared, with whom, at what classification, Sensitive But Unclassified information, and the process of declassification.

# FDA Food Defense Tools and Resources

**FDA guidance -<https://www.fda.gov/Food/FoodDefense/>**

## Tools & Resources

[Food Defense 101 \(including ALERT\)](#)

[Food Defense Plan Builder](#)

[FREE-B](#)

[Employees FIRST](#)

[See Something, Say Something™ Campaign](#)

[Mitigation Strategies Database](#)

[More...](#)

# FDA Food Defense Plan Builder and FREE-B Tools

## FDA Food Defense Plan Builder:

A comprehensive tool that walks the user through all the steps of developing a Food Defense Plan.

After completing the steps in the tool, it will automatically generate a Food Defense Plan.

The Plan Builder prompts the user to think about broad mitigation strategies, conduct a vulnerability assessment, identify focused mitigation strategies, and develop a response plan and an action plan.

## FREE-B:

The Food Related Emergency Exercise Bundle (FREE-B) is a compilation of scenarios based on both intentional and unintentional food contamination events.



# FDA Food Defense 101 (including ALERT)

Food Defense 101 is comprised of four courses:

1. Food Defense Awareness for the Food Professional;
2. Food Defense Awareness for the Front-line Employee;
3. Food Defense Regulations; and,
4. ALERT, for owners and operators of food facilities

# **Food Defense 101 (including ALERT) Abstracts**

## **Food Defense Awareness for the Food Professional**

This course provides an understanding of food defense and guidance for professionals in the food industry. The course modules progress through food defense planning including broad mitigation strategies, vulnerability assessments, focused mitigation strategies, and food defense plans.

## **Food Defense Awareness for Front-line Employees**

This course provides guidance specific to front-line workers and simple procedures for these employees to follow in food defense. The FIRST initiative, which emphasizes that Employees are the FIRST Line of Food Defense, is provided in both English and Spanish.

## **FDA Regulations**

This course presents the three FDA Regulations that have been developed to address the safety of our nation's food supply and their impact on the food industry.

## **ALERT**

This course was developed by the FDA to help stakeholders better understand food defense and how food defense applies to the food industry. ALERT has been updated to include FSMA guidance and provides specific examples on ways to protect a firm from the threat of intentional contamination. ALERT brochures, wallet cards and posters are available in English, Spanish, Chinese, French, Korean, Portuguese and Vietnamese.

# FDA – “ALERT ”

An **ALERT** for owners and operators of food establishments about the security of your facilities...



In today's world it is important to be **ALERT** to protect your business.

**A**

How do you **ASSURE** that the supplies and ingredients you use are from safe and secure sources?

**L**

How do you **LOOK** after the security of the products and ingredients in your facility?

**E**

What do you know about your **EMPLOYEES** and people coming in and out of your facility?

**R**

Could you provide **REPORTS** about the security of your products while under your control?

**T**

What do you do and whom do you notify if you have a **THREAT** or issue at your facility, including suspicious behavior?

**Can you answer these questions?**



The ALERT initiative has been incorporated into Food Defense 101, a training program providing awareness and guidance in food defense planning. Food Defense 101 can be accessed from FDA's Food Defense webpage.

[www.fda.gov/FoodDefense](http://www.fda.gov/FoodDefense)



For more information contact us at: [FoodDefense@fda.hhs.gov](mailto:FoodDefense@fda.hhs.gov)

# FDA online Food Defense Awareness for the Food Professional Course

**Food Defense Awareness for the Food Professional: as of March 2017:**

**BEAWARE:**

FDA issued a final rule on [Mitigation Strategies to Protect Food Against Intentional Adulteration](#) in May 2016. This training contains useful awareness-level information **but does not satisfy the training requirements within the final rule at this time.** The agency intends to update its tools and educational materials to align with the relevant provisions of the final rule.

# FDA Mitigation Strategies Database

The Food Defense Mitigation Strategies Database (FDMSD) is a tool designed to assist:

owners, operators or agents in charge of companies that produce, process, store, package, distribute, and/or transport food with identifying preventive measures to protect the food against intentional adulteration.

The FDMSD provides a range of mitigation strategies for individuals to consider implementing at points, steps or procedures to minimize the vulnerability to an intentional attack.

# USDA and Food Defense Resource

[http://www.fsis.usda.gov/Food\\_Defense\\_&\\_Emergency\\_Response/Guidance\\_Materials/index.asp](http://www.fsis.usda.gov/Food_Defense_&_Emergency_Response/Guidance_Materials/index.asp).

**CARVER+SHOCK Primer:** This tool can be used to assess the vulnerabilities within a system or infrastructure to an intentional attack. By doing this assessment you can determine the most vulnerable points in your system and focus your resources on enhancing food protection at those points.

**Developing a Food Defense Plan for Meat and Poultry Slaughter and Processing Plants:** This guide provides an easy, practical, and achievable three-step method for creating a food defense plan. Upon completion, you will have a plan specific for your operation.

**Elements of a Functional Food Defense Plan:** This information serves as a guideline for completing the food defense plan profile extension questions.

**Food Defense Risk Mitigation Tool:** This online tool is part of an ongoing effort by FSIS to help protect the nation's supply of meat, poultry, and egg products from intentional contamination

# Economic Adulteration Vulnerability Tools – Battelle

<http://www.battelle.org/our-work/national-security/cbrne-defense/threat-assessment/emaalert>

## Battelle

The Business of Innovation

[About Us](#) [Media](#) [Careers](#) [Contact Us](#)

Search



Our Work

Doing Business with Us

[Back to Our Work](#)

[National Security](#) > [CBRNE Defense](#) > [Threat Assessment](#) > [EMAAlert™ Food Fraud Vulnerability Tool](#)

EMAAlert™ Food Fraud Vulnerability Tool

Food & Beverage Characterization & Analysis

PRIA™ Poultry and Meat Risk Mitigation Software



## Fighting Food Fraud with EMAAlert™

Wood pulp in shredded Parmesan cheese. Melamine in baby formula and pet food. Asian catfish sold as grouper. Pomegranate juice cut with grape juice. These are examples of food fraud, more formally known as Economically Motivated Adulteration (EMA), an established threat to grocery manufacturers.

To help combat this issue, Battelle and the **Grocery Manufacturers Association** have partnered to provide EMAAlert™, a secure, comprehensive and intuitive software tool that enables food manufacturers to rapidly analyze and understand EMA vulnerabilities. EMAAlert produces quantitative vulnerability results, allowing for the prioritization of mitigation efforts associated with EMA threats.

Contact us today for more information.



SIGN UP for CBRNE Defense updates

**EMAAlert™**  
GMA + Battelle Partnership

# FOOD DEFENSE Summary



# Key Industry Considerations

1. **Protect the Public** – Primary task is to protect the public first
2. **Protect the Brand** – Secondary task is to protect the brand.
3. **FDA Expectations** – FDA and industry will learn together during implementation of FSMA. PREVENTION is the focus and requires active and OBVIOUS management.
4. **Embrace FOOD DEFENSE strategies rigorously** - Based upon written programs, industry must focus more heavily on DOCUMENTATION to establish a valid food defense plan to present during an inspection.
5. **Accessibility** – Utilize trained professionals from law enforcement who have hands on experience within the food industry with food defense plan assessments and facility security.
6. **Response** – As many facilities conduct mock recalls, execute mock intentional adulteration events regularly. FIND THE PROCESS GAPS.
7. **Recover** – Be prepared to COMMUNICATE internally and externally with legal counsel involved, at a moments notice.

Thank you

**Craig Henry Ph.D.**  
**Intro Inc.**  
**foodprotector@aol.com**