

Preventive Control vs. Pre-requisite programs for Warehouse/DCs & Transportation

What is the difference and how do I tackle and sustain?

Food Safety Summit – Jorge Acosta

May 9, 2017



Preventive Controls vs PRP's



Definitions

- Prerequisite programs
 - Procedures, including Good Manufacturing Practices (GMPs), that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.

(FSPCA Definition)

Definitions

- Preventive Controls
 - “Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understand of safe food manufacturing, processing, packaging, or holding at the time of the analysis.”
 - 21 CFR 117.3 Definitions

PRP Components

- The regulation (21 CFR 117 Subpart B) lists these components that establish the conditions and practices the food industry must follow for processing safe food under sanitary conditions:
 - Personnel
 - Plant and grounds
 - Sanitary operations*
 - Sanitary facilities and controls
 - Equipment and utensils
 - Processes and controls*
 - Warehousing and distribution
 - Holding and distribution of human food by-products for use as animal food, and
 - Defect action levels

*Some components may be preventive controls based on hazard analysis

Preventive Controls

- Process preventive controls
- Food allergen preventive controls
- Sanitation preventive controls
- Supply-chain program
- Recall plan
- Other preventive controls

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Potential Preventive Controls

Biological hazards

- Process controls that prevent growth; e.g.,
 - Temperature controls for stored products
- Supply-chain programs for sensitive ingredients used without a kill step
- Sanitation controls that prevent recontamination – tank washer

Chemical hazards

- Supply-chain programs
- Allergen labeling
- Sanitation controls to prevent allergen cross-contact – tank washer

Physical hazards

- Process controls such as
 - Filtering/straining at loading of bulk liquid containers

How do I tackle and sustain?

- Preventive Controls are risk based
 - Sanitation Preventive Controls as well as all other preventive controls (Process, Allergen, and Supply Chain) are risk-based, and require documented procedures and written cleaning programs
 - Sanitation Preventive Controls require verification
 - Documented corrective actions
 - Process Preventive Controls must be validated

How do I tackle and sustain?

- Employees must be trained
 - Individuals must be qualified by education, training, or experience to manufacture, process, pack or hold food
 - Individuals must receive food hygiene and food safety training
 - Supervisors responsible for ensuring compliance must have appropriate knowledge, training or experience

How do I tackle and sustain?

- Monitor
- Verify
- Validate as applicable
- Internal Audits
- Re-train

THANK YOU



SANITATION AS A PREVENTIVE CONTROL FOR WAREHOUSE/DCS & TRANSPORTATION

FOOD SAFETY SUMMIT

ROSEMONT, ILLINOIS

MAY 2017

§ 117.35 - SANITARY OPERATIONS

- (A) *GENERAL MAINTENANCE*
- (B) *SUBSTANCES USED IN CLEANING AND SANITIZING; STORAGE OF TOXIC MATERIALS*
- (C) *PEST CONTROL*
- (D) *SANITATION OF FOOD-CONTACT SURFACES*
- (E) *SANITATION OF NON-FOOD-CONTACT SURFACES*

KEY DEFINITIONS

Preventive controls: These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.

Cleaning: The removal of soil, food residue, dirt, grease or other objectionable matter.

Sanitize: To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Allergen cross-contact: The unintentional incorporation of a food allergen into a food

Cross-contamination is the physical movement or transfer of harmful bacteria from one person, object or place to another.

CHALLENGES IN WAREHOUSES / DISTRIBUTION CENTERS

- TYPICALLY VERY LARGE BUILDINGS
- HIGH SPEED OPERATIONS / PICKING
- MULTIPLE TYPES OF FINISHED GOODS
- WEEPAGE FROM TEMPERING AND/OR STORAGE OF MEAT AND POULTRY.
- WATER FROM ICEPACKED PRODUCT (EX: SEAFOOD, PRODUCE) INCREASING THE CHANCE OF CROSS-CONTAMINATION AND ENVIRONMENTAL CONTAMINATION RISKS
- RISKS DUE TO SPILLS
- LACK OF EMPLOYEE TRAINING / LACK OF KNOWLEDGE ON WHAT ITEMS ARE BEING HANDLED

Types of Cleaning



WET CLEANING - Water-based and/or wet chemical cleaning solutions.

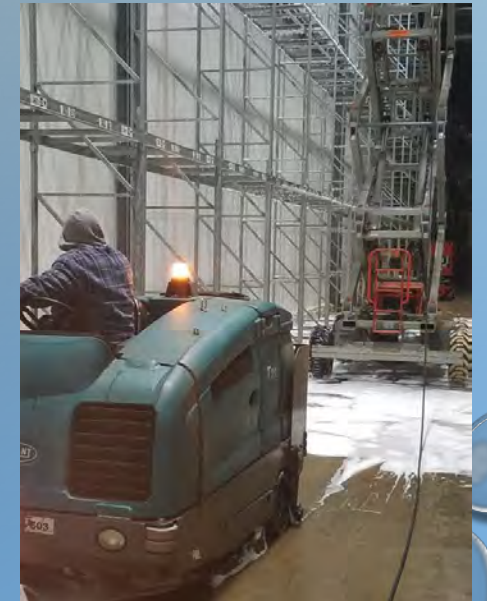
DRY CLEANING - Physical action/removal of residues and particulate. Common tools used: vacuum, broom (sweep and/or brush), scrapers. NO water is used.

CONTROLLED CLEANING - Used during dry cleaning, but uses a controlled amount of water that is typically minimized in order to maximize cleaning effectiveness.

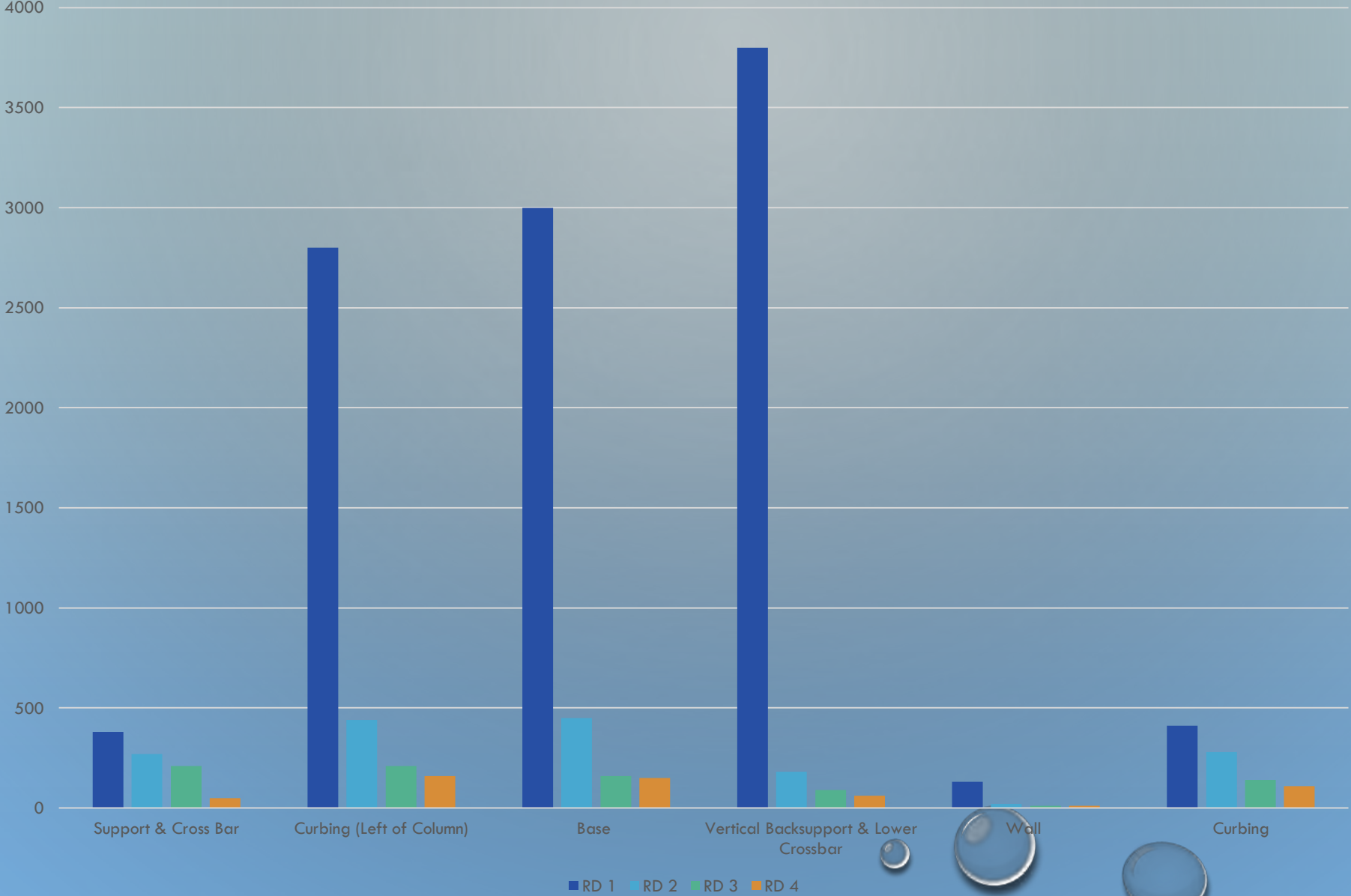
CASE FILE - FSMA PREPARATION

HIGH INCIDENT RATES OF LISTERIA

- >750,000 sq. ft warehouse
- Various temperature controlled areas with many different types of products (i.e. meat, poultry, seafood, produce, dry ingredients)
- Environmental baseline program was implemented
- Over 80 swabs taken
 - > 60% of the areas swabbed in “high risk” areas tested positive for *Listeria* spp.



Enzyme Detergent and PAA Sanitizer



KEY REQUIREMENTS FOR SANITARY TRANSPORTATION RULE



Vehicles and transportation equipment: The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe. For example, they must be suitable and adequately cleanable for their intended use and capable of maintaining temperatures necessary for the safe transport of food.

Transportation operations: The measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready to eat food from touching raw food, protection of food from contamination by non-food items in the same load or previous load, and protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.

Training: Training of carrier personnel in sanitary transportation practices and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.

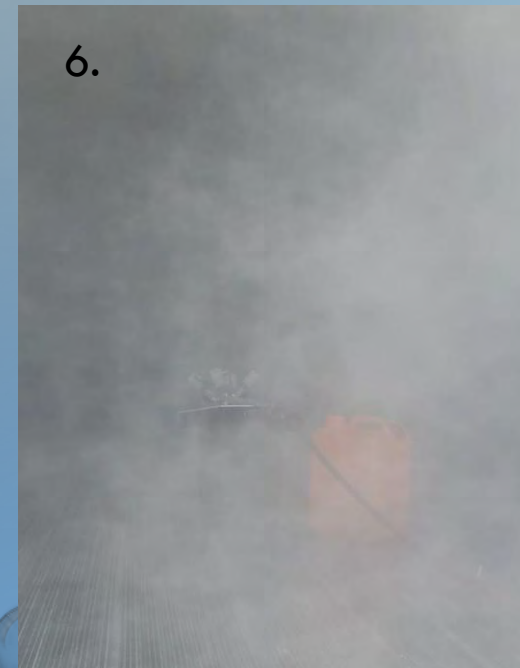
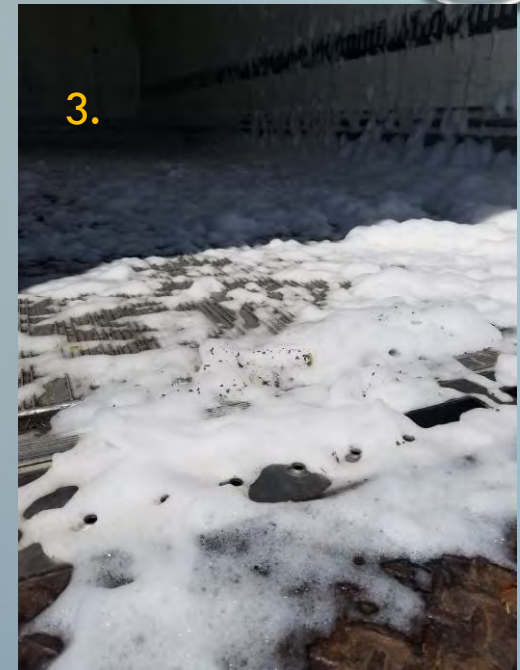
Records: Maintenance of records of written procedures, agreements and training (required of carriers). The required retention time for these records depends upon the type of record and when the covered activity occurred, but does not exceed 12 months.

Preventive Controls ?

- **You** determine which hazards require a sanitation control. Remember ...it is risk based and should be determined based on your hazard analysis.
- For your sanitation controls to be effective, evaluate the sanitation procedures, practices, and processes that you will have in place to comply to make sure they are effective and compliant with the cGMP requirements.



TRAILER CLEANING AND SANITATION



SUMMARY

SANITATION CONTROLS IN WAREHOUSING FACILITIES/DC'S AND TRANSPORTATION EQUIPMENT

- DOCUMENTED SANITATION/HOUSEKEEPING PROGRAM IN PLACE. THE PROGRAM SHALL ASSURE THE SUSTAINABLE CLEANLINESS OF STORAGE FACILITIES, PRODUCT HANDLING AREAS AND ALL TRANSPORTATION EQUIPMENT AND VEHICLES, AS THE NATURE OF THE PRODUCT REQUIRES.
- DETAILED CLEANING PROCEDURES SHOULD BE ON FILE AND UP TO DATE. CLEANING PROCEDURES SHOULD INCLUDE PROPER PPE, NAME(S) OF THE CHEMICALS AND SANITIZERS USED, TOOLS USED FOR CLEANING, PPM OR PH TARGETS &/OR RANGE. MEASURES TO PROTECT EQUIPMENT AND PRODUCT SHOULD BE WRITTEN INTO THE PROCEDURE. IT IS ALSO A BEST PRACTICE TO VERIFY SANITATION EFFECTIVENESS THROUGH DIRECT OBSERVATION OR INSPECTION BY QA OR MANAGEMENT.
- MASTER SANITATION SCHEDULE FOR OTHER THAN DAILY CLEANING SHOULD BE PART OF THE OF THE PROGRAM. THIS SHOULD INCLUDE AREAS SUCH AS: DOCK PLATES, OVERHEADS , CEILINGS, WALLS, AND FLOORS.
- TRAILERS SHOULD BE FREE OF FROM DIRT, INSECTS AND INSECT WEBBING, RODENTS, DUST, DEBRIS, MOLDS AND RUST. A CLEANING PROGRAM IS ALSO RECOMMENDED FOR THE COOLING UNITS INSIDE THE TRAILER.
- SAFETY DATA SHEETS (SDS) NEED TO BE ON FILE AND ALL CLEANING CHEMICALS, SANITIZERS, ENZYMES, ETC. SHOULD HAVE THE PRODUCT INFORMATION SHEETS READILY AVAILABLE AND SHALL BE SUITABLE FOR USE.
- DRAIN CLEANING AND OTHER SENSITIVE AREAS SUCH AS ALLERGEN STORAGE AREAS SHOULD HAVE DEDICATED COLOR-CODED TOOLS (BRUSHES, SQUEEGEES) . THESE COLOR-CODED TOOLS SHOULD BE USED TO PREVENT COROSS-CONTAMINATION (DRAINS) AND CROSS-CONTACT (ALLERGENS) TO DIFFERERNT AREAS OF THE WAREHOUSE OR CONTAINER (SPILLS).

REVIEW YOUR HISTORY, PROGRAM EFFECTIVENESS AND RISK TO DETERMINE IF SANITATION PREVENTIVE CONTROLS ARE NEEDED.

Making Sense of the Sanitary Transport Act

Food Safety Summit
May 9, 2017

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Roles in the Sanitary Transport Act

- ▶ Warehouse
- ▶ Shipper
- ▶ Receiver
- ▶ Loader
- ▶ Carrier

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What will be Expected of Warehouses?

- ▶ Warehouse with open product or temperature controlled product
- ▶ Warehouse with completely enclosed product
- ▶ Protection of the product
- ▶ Sanitation
- ▶ Training
- ▶ Documentation

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Food
SOLUTIONS

What will be Expected of Loader?

- ▶ Training
- ▶ Documentation

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What will be Expected of Carriers?

- ▶ Training
- ▶ Temperature monitoring
- ▶ Cleaning & sanitation
- ▶ Documentation

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What will be Expected of Receiver?

- ▶ Ensure the product was adequately protected
- ▶ Training
- ▶ Documentation

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What will be Expected of Shipper?

- ▶ Ensure the product is adequately protected
- ▶ Training
- ▶ Documentation
- ▶ Grand Poobah of the shipping process

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Usual/Unusual Situations

- ▶ Trucking company contracts drivers
- ▶ Receiving company is subcontracted by the shipper or vice versa
- ▶ LTL shipments & Transfer warehouses & LCL shipments & transfer warehouses

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Solutions to Shipping Challenges

- Supplier Verification
- Contracts

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Regulation Reference

<u>Type of business</u>	<u>Corresponding rule</u>	<u>Regulation reference</u>
Warehouse/Distribution Center (no open food and at room temperature only)	Current Good Manufacturing Practices	21 CFR 117 Subpart B
Warehouse/Distribution Center (fresh produce and/or temperature controlled foods)	Preventive Control Rule Sanitary Transport Rule	21 CFR 117 21 CFR 117 Subpart O
Shipper (does not manufacture food)	Sanitary Transport Rule	21 CFR 117 Subpart O
Shipper (manufacturer)	Preventive Control Rule Sanitary Transport Rule	21 CFR 117 21 CFR 117 Subpart O
Motor carriers (>27.5 million)	Sanitary Transport Rule	21 CFR 117 Subpart O

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Contact information

- ▶ Gina (Nicholson) Kramer
Savour Food Safety International
+1-614-507-5105
gina@savourfoodsafety.com
- ▶ Elise Forward
Forward Food Solutions, LLC
+1-414-915-1070
elise@forwardfoodsolutions.com

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Food Defense and Facility Protection for Warehouses and Distribution Facilities

Food Safety Summit Pre-Conference

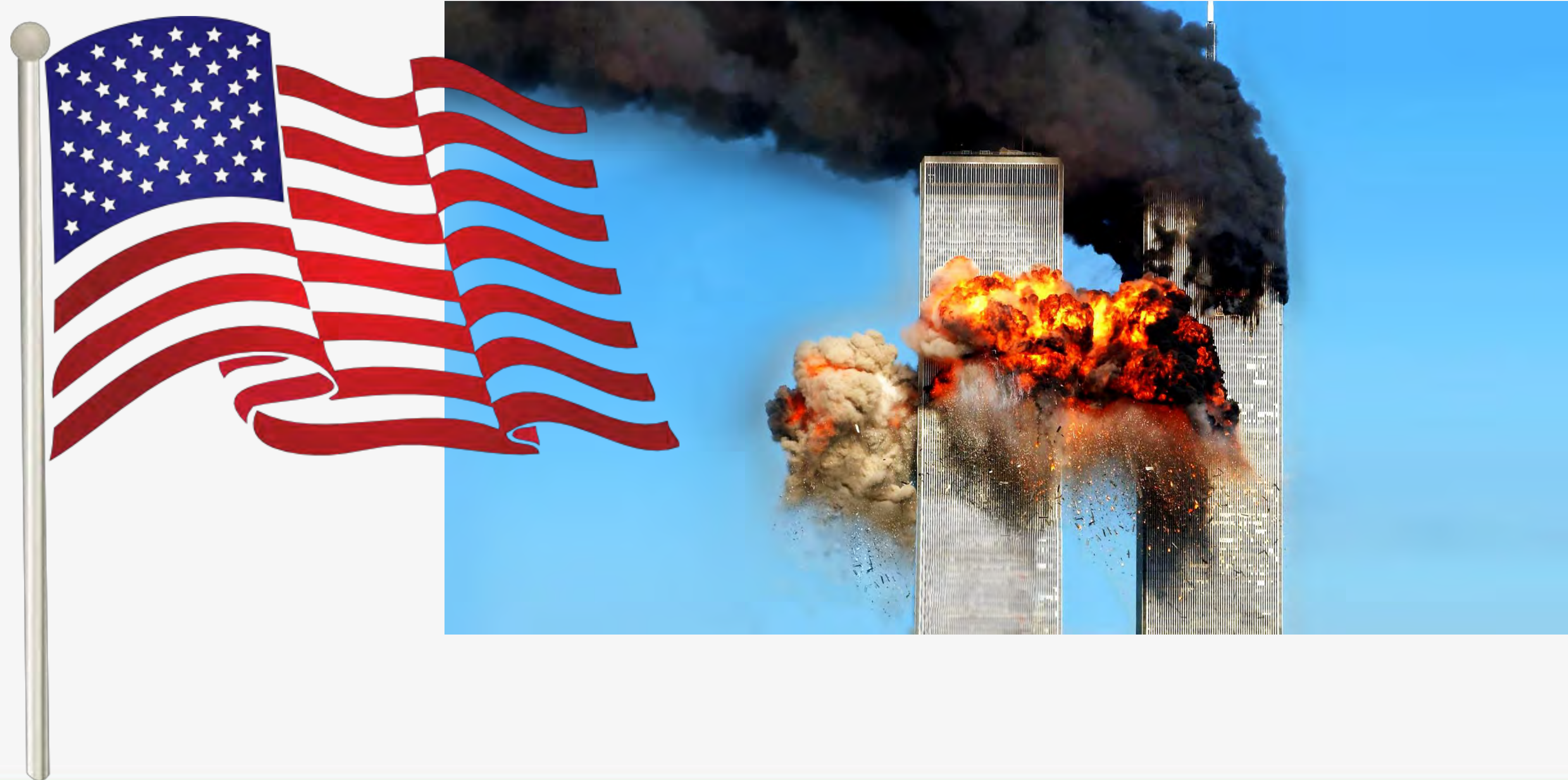
Rod Wheeler

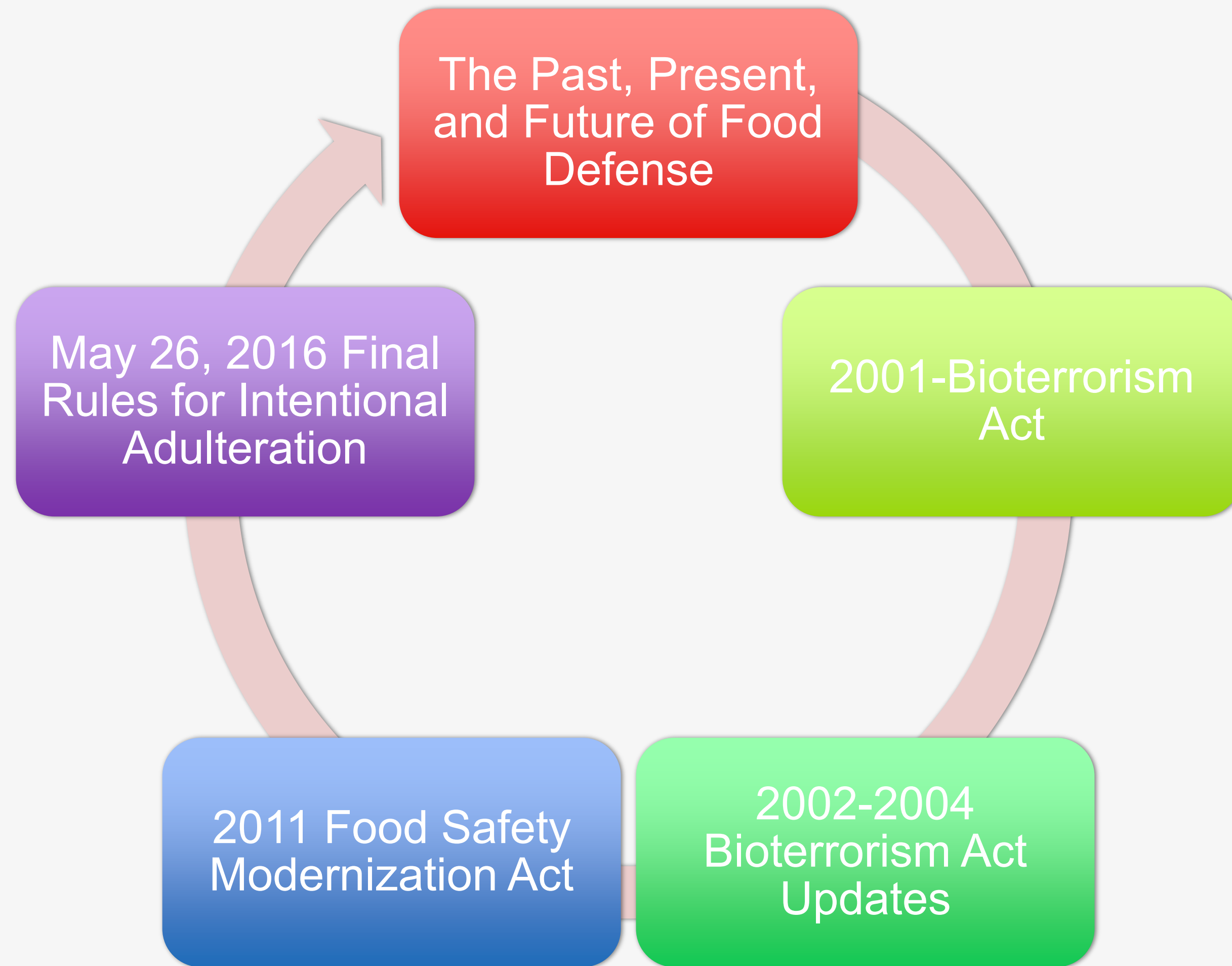
Founder & CEO
Global Food Defense Institute

Homeland Security and Global Food Defense and Law Enforcement Expert, Rod Wheeler is the founder and CEO of the **Global Food Defense Institute** which provides educational, training and certification programs for the food, agricultural and chemical industries to ensure confidence and protection and to guard against intentional contamination or sabotage. He is a former “all-star” Homicide Detective with the Metropolitan Police Department in Washington DC as well as an investigator for the State of Ohio Attorney General. Rod has made over 1000 television appearances as a law enforcement and security expert and is a Crime Analyst for the Fox News Channel, and is seen regularly on ABC’s-Good Morning America, 48 Hours (CBS), as well as several other national news shows.

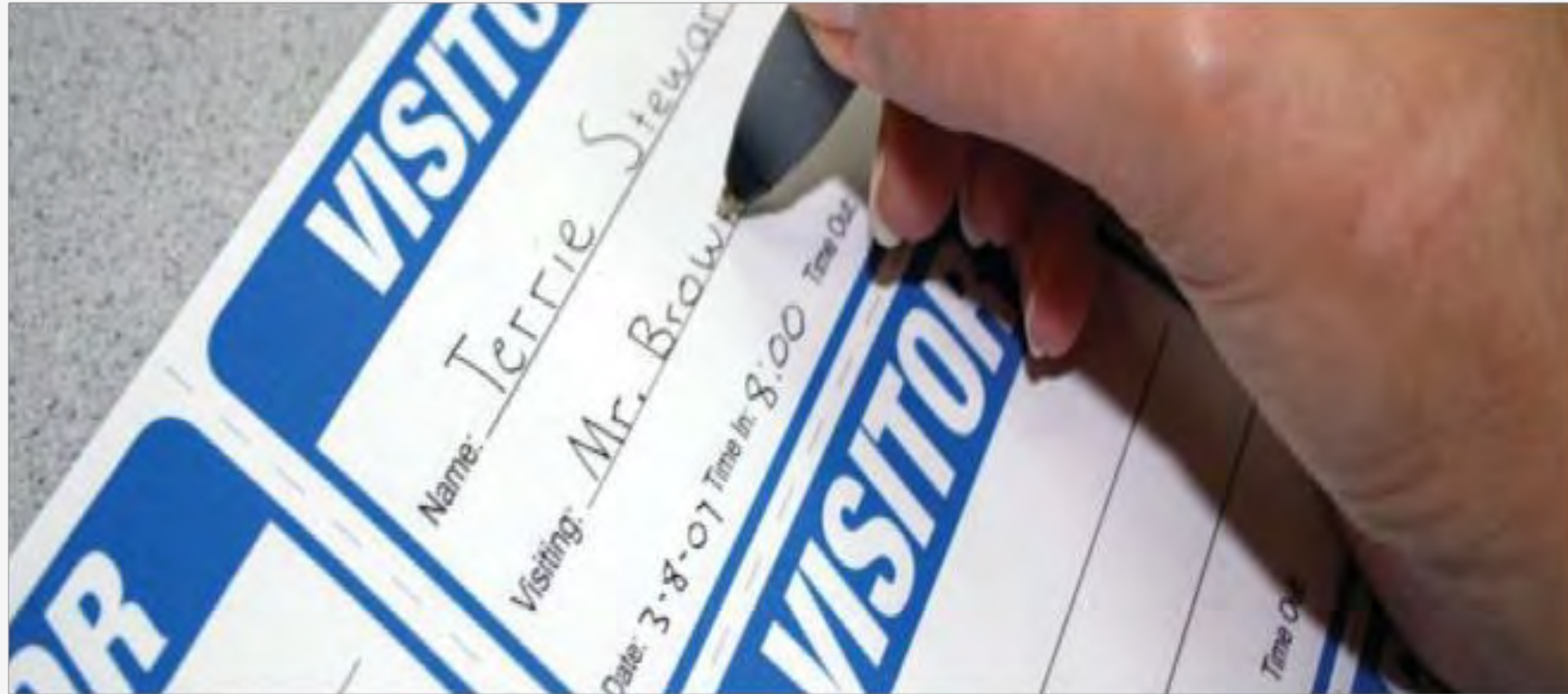


We Will Never Forget...





Does your Facility have a Visitor's log?
What types of ID are required upon entry?



Who Are The Terrorist?

International Extremists

(Al Qaeda, ISIS)

Sympathizers and Lone Wolves

(Homegrown, Unassimilated Individuals)

Liberation Movements and Domestic

Terrorists

(Militia, Racial Supremacists, Religious

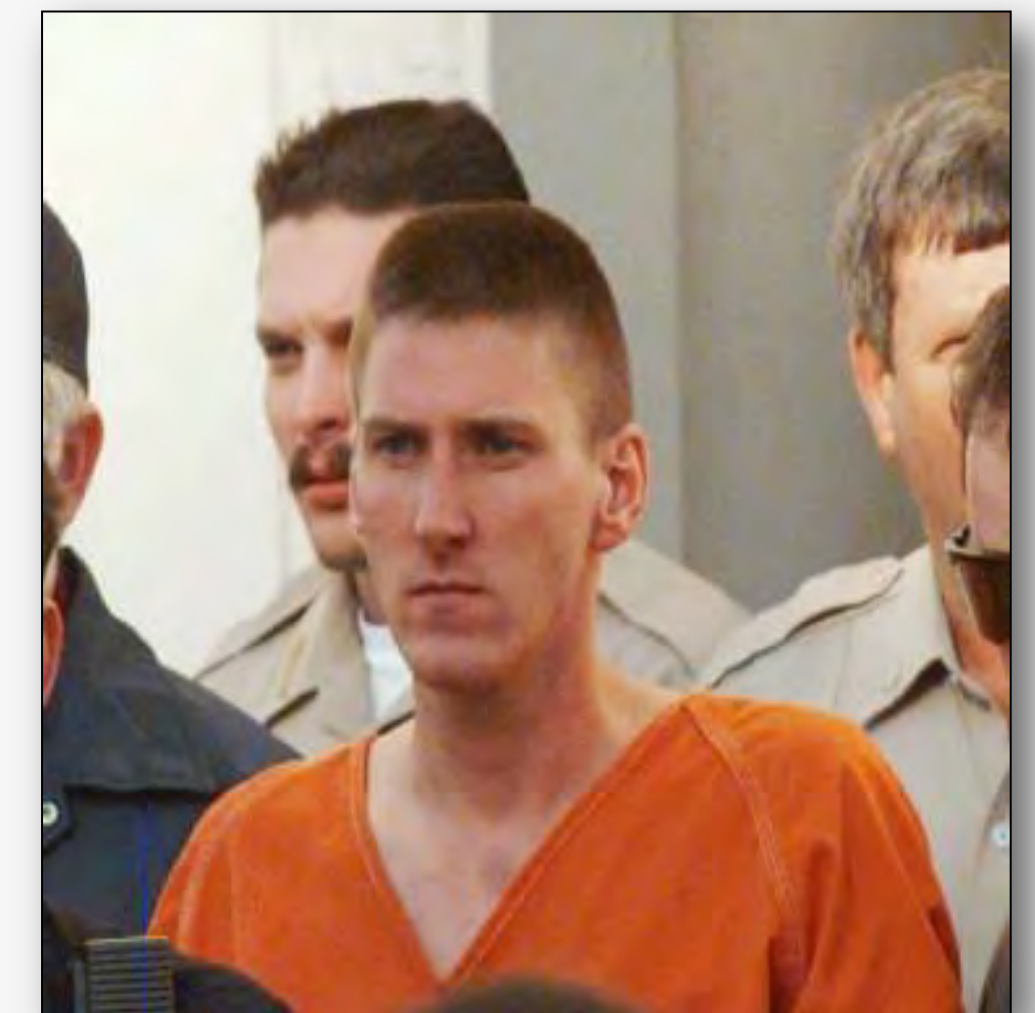
Extremists, Political Fanatics)

Environmental Extremists

(Earth Liberation Front)

Narco-Terrorists

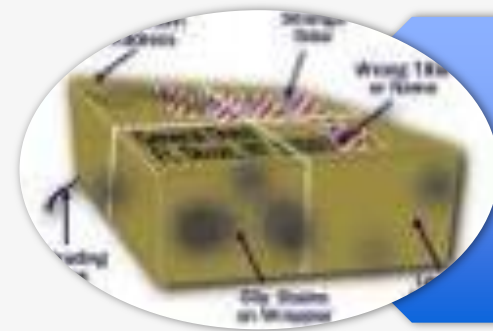
(Colombian and Mexican Cartels)



The Fatal Five-Weapons of Choice Used By Terrorist



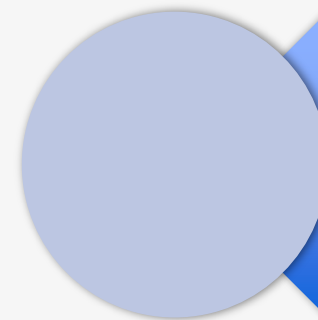
Handheld Weapons



Package Bombs



Vehicle Bombs



Chemical/Biological



Radiological/Nuclear



Take a Close Look...

- Who is the person sitting next to you?
- Do you REALLY know that person?
- What group affiliations does that person have?
- Any telephone calls to Yemen or Pakistan?



Supply Chain Security Farm to Fork Where are we most vulnerable?



Farm

truck
railroad
boat



Processor

truck
railroad
boat



Distributing
Center

truck
railroad



Retail

Home





Food Processing
Supplies
Employees
Bulk Mixing
Bulk Storage
Water supply



Farm to table Supply Chain-Retail

- Retail Food Sales
 - Supplies
 - Employees
- Buffet Service Areas
 - **Farmer's Market**
 - Fresh Produce



Is Food Defense Different than Food Safety?



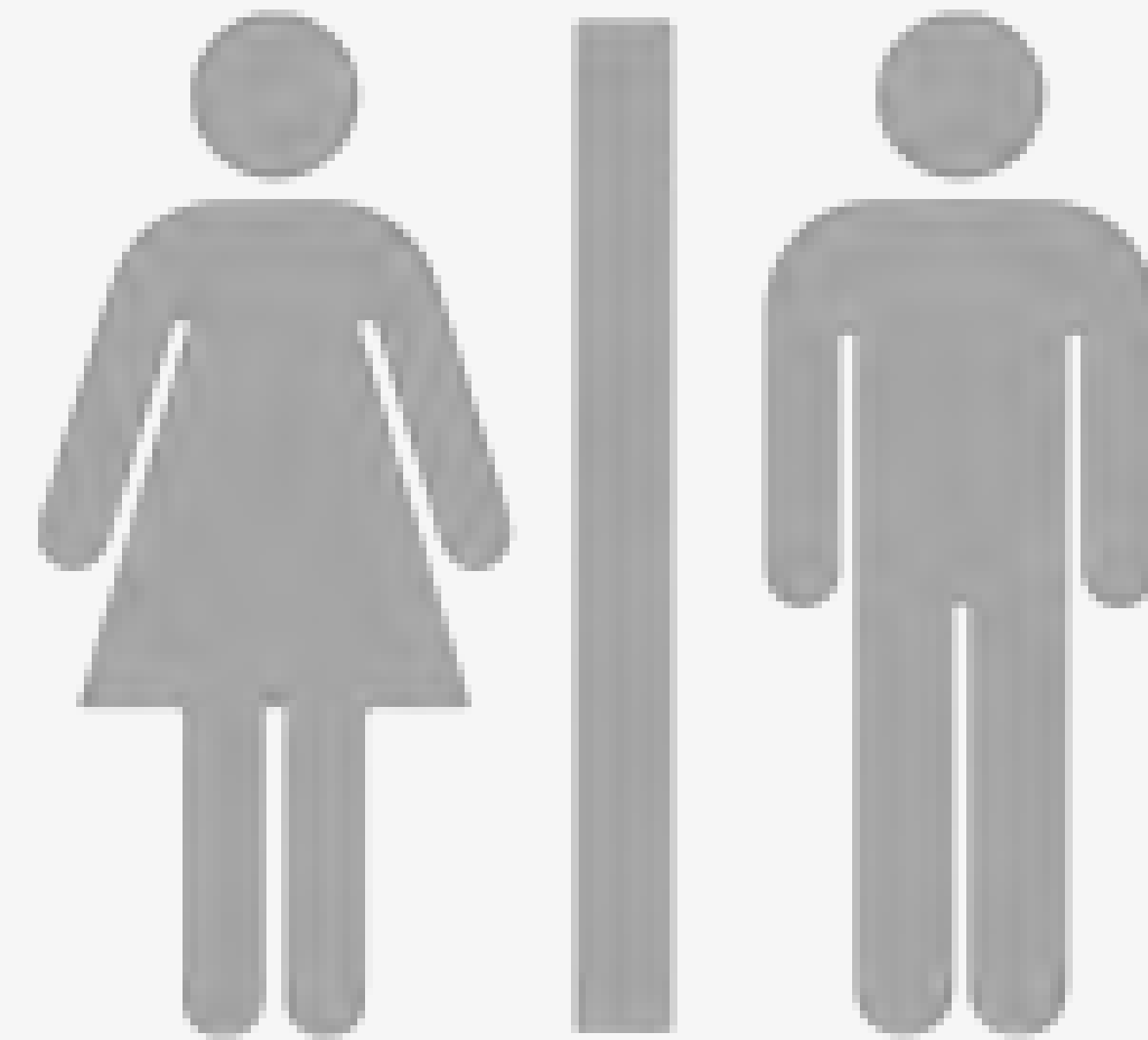
Food Defense focuses on protecting the food supply from **intentional** contamination.



Food Safety (HACCP) and Biosecurity focus on protecting the food supply from **unintentional** contamination. They help with, but are not a substitute for food defense.

Truck Drivers

- Designated restrooms and break area
 - Restroom located at driver entry point
 - Eliminate use of employee restrooms
 - Break area provided with vending machines, telephone, tables, etc.



Truck Drivers

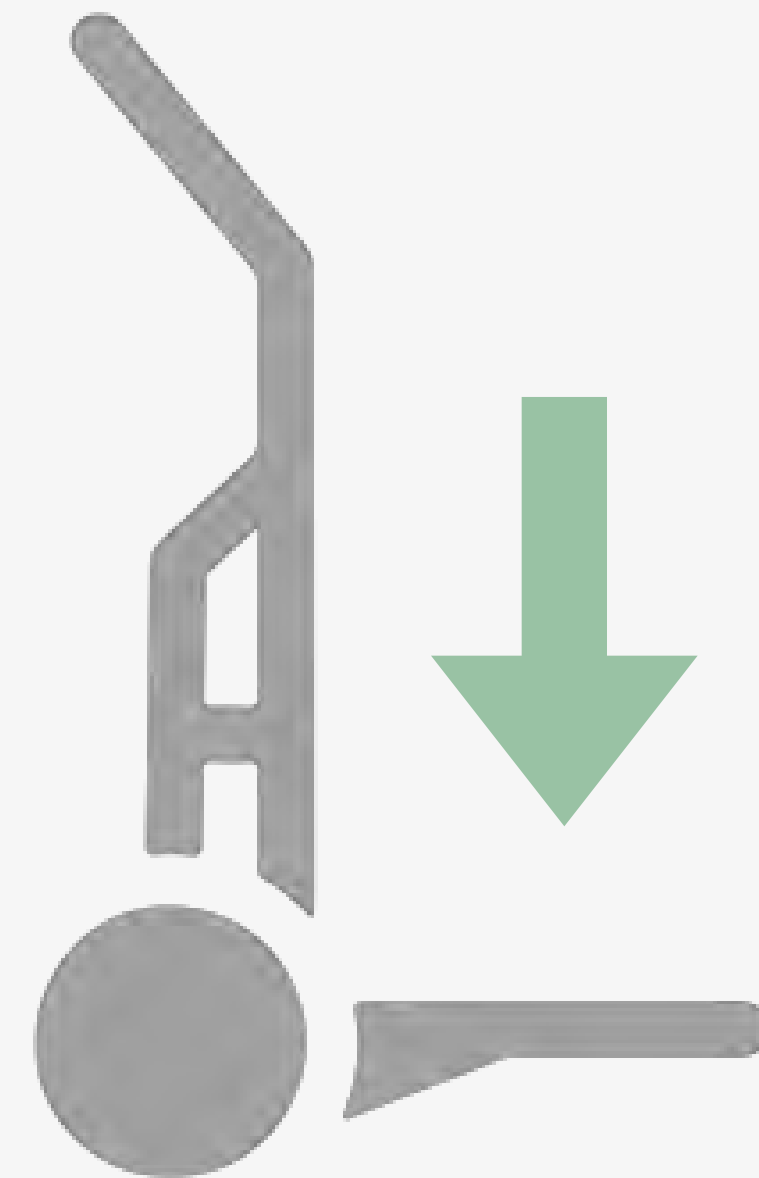
- Do they have access to the dock?
 - Increased security and safety concerns
- Solutions or options
 - Window to view loading of trucks
 - Provide colored hairnets or bump caps
 - Paint lines around the dock area which drivers must stay within
 - CCTV provided in dock area
 - Presence of supervisors to monitor drivers

Transportation Security

- Incoming and outgoing vehicles (both private and commercial) should be inspected for unusual cargo or activity.
- Truck deliveries should be verified against a roster of scheduled deliveries.
- Unscheduled deliveries should be held outside the plant premises, if possible, pending verification of shipper and cargo.
- Driver identification should be checked and documented.

Incoming Shipments

- Seals provided for all inbound loads
 - Must coordinate with purchasing and all suppliers
 - LTLs (less-than-loads)
 - Locks may be a suitable alternative
 - UPS, FedEx, Postal Service, etc.
 - Where are these received and who inspects
 - Inspection of trailer prior to backing up to dock



Incoming Shipments

- Detailed inspection of goods
 - Verification of product quantities
 - Signs of product tampering
 - Damaged boxes or bags, repaired packaging materials, mixed lots
 - Temperature abuse of sensitive items
 - Verification of trailer and product temperatures
 - Lot numbers
 - Verification of lot numbers with bill of lading



Assessments are conducted in order to determine vulnerable areas.

Access to storage areas is restricted.

Security cameras are used to monitor storage areas for suspicious activity.

Product is segregated to prevent intentional mixing of raw and processed products.

Finished products are sealed to limit tampering.

Labels are stored in a secured area.

Labels that are not correct or are no longer needed are destroyed and properly disposed of

Container labels are verified.

Labels and packaging materials are properly stored to prevent theft and misuse.

Periodic examinations for tampering of materials in storage are performed.

Containers are examined before product is loaded.

Good Business Practices and Important Preparedness Measures

- Build a culture of risk management across suppliers
- Improved alert and warning systems
- Identification and elimination of supply chain bottlenecks
- Improved information sharing between government and business (First Responders)

Immediate Steps?

FSMA Compliance



Insure that a valid Site-Specific Facility Security and Vulnerability Assessment is completed by the Global Food Defense Institute.



Write and implement a documented security plan.



Train and educate all employee's on their role in keeping the food supply safe and secure, and the important role they play in Food Defense.



See Something, Say Something



THANK YOU!

Global Food Defense Institute

www.myfooddefense.com

