



Food Defense Implications of the Food Safety Modernization Act

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Overview

- General Goals and Objectives for defending the Nation's food supply chain are extensively articulated
- The pathway to achieve these goals and objectives are not provided in the Law
- Implementation will require new regulatory actions and the development of advisory guidance in numerous areas
- Includes explicit food defense impacts and implicit or secondary impacts on industry and agencies

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Effective Dates for Key Sections

“Immediate”

- 101. Inspection of Records
- 102. Registration of Facilities
- 107. Fees
- 115. Port Shopping
- 116. Alcohol-Related Facilities
- 201. Inspection frequency & Identification of High Risk Facilities
- 206. Mandatory Recall Authority
- 303. Authority to Require Import Certification for Food.
- 402. Whistleblower Protection

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Improving Capacity To Prevent Food Safety Problems

- Sec 101. Inspection of Records
 - “Reasonable belief” that use or exposure to an article of food will cause serious adverse health consequences or death
 - have access to and to copy all records relating to such article and to any other article of food that FDA reasonably believes is likely to be affected in a similar manner.. (paper and/or electronic formats)

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- Sec 102. Registration of Food Facilities
 - Registration with FDA Biennially
 - Even-numbered years – Oct to Dec
 - Domestic and Foreign
 - Suspension of Registration
 - If FDA has a reasonable probability of causing serious adverse health consequences or death to humans or animals FDA may suspend registration
 - cannot introduce food into Interstate or Intrastate Commerce
 - Hearing Provisions
 - Amend definition of “Food Establishment”

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Improving Capacity To Prevent Food Safety Problems

- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Shall evaluate the hazards that could affect and implement preventive controls to significantly minimize or prevent this occurrence of such hazards and provide assurances that such food is not adulterated

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Hazard Analysis
 - Known and reasonably foreseeable hazards
 - Biological, Chemical, Physical, Radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, unapproved food and color additives, naturally occurring hazards
 - Unintentionally introduced hazards
 - Intentionally introduced hazards
 - Develop a written analysis of hazards

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Preventive Controls
 - Shall identify critical control points and
 - Implement preventive controls to
 - Significantly minimize or prevent hazard identified

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Improving Capacity To Prevent Food Safety Problems

- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Monitoring of Effectiveness of preventive controls
 - To provide assurances controls are effective

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Corrective Actions
 - If the preventive controls fails
 - All affected food is prevented from entering commerce
 - All affected food is evaluated
 - Take action to reduce recurrence

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Verification
 - Shall verify preventive controls for the hazard are adequate
 - Conduct monitoring
 - Use environmental and product testing
 - Periodic analysis of the plan

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Recordkeeping
 - Shall maintain for not less than 2 years of monitoring and verification measures
 - Results of testing
 - Instances of nonconformance
 - Corrective actions
 - Efficacy of preventive controls

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Written Plan and Documentation
 - Shall prepare a written plan that documents and describes the procedures
 - Shall provide promptly upon a written or oral request from FDA

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Requirement to Reanalyze
 - Shall conduct a reanalysis
 - Whenever significant changes are made
 - Potential of a new hazard or
 - Not less than once every 3 years
 - Response to new hazards or new scientific understanding
 - Any adjustments needed must be implemented before a change in activity
 - Shall revise the written plan

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Preventive Controls may include:
 - Sanitation
 - Training
 - Environmental Monitoring
 - Food Allergen Control Program
 - A Recall Plan
 - Good Manufacturing Practices
 - Supplier Verification

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- Sec 103. Hazard Analysis and Risk-Based Preventive Controls
 - Promulgate Regulations (18 Months)
 - Science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls and documenting the implementation of the preventive controls.

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- Sec 104 Performance Standards
 - Every 2 years FDA shall review and evaluate health data
 - Shall issue Contaminate-specific and science based guidance documents
 - Proposed rule making to establish science based minimum standards for the safe production and harvest of fruits and vegetables (1 year)

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- Proposed rule making to establish science based minimum standards for the safe production and harvest of fruits and vegetables (1 year)
 - Consider hazards that occur naturally and also those that occur unintentionally
 - And may be intentionally introduced
 - Provide for coordination of education and enforcement activities by state and local

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- Sec 106. Protection Against Intentional Adulteration
 - Conduct a vulnerability assessment of the food system
 - Biological, Chemical, Radiological or other terrorism risk assessments
 - Consider the best available understanding of uncertainties of risks against intentional adulteration of food at vulnerable points
 - Determine the types of science-based mitigation strategies or measures

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Improving Capacity To Prevent Food Safety Problems

- Sec 106. Protection Against Intentional Adulteration
 - Shall promulgate regulations to protect against the intentional adulteration of food.
 - Specify how a person shall assess is required to implement mitigation strategies
 - Specify appropriate science-based mitigation strategies or measures
 - Shall apply only to high risk of intentional contamination
 - Shall include foods of short shelf life, bulk or batch form prior to packaging for the final consumer
 - Does not apply to farms except those that produce milk.

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- Sec 108. National Agriculture and Food Defense
 - Preparedness Goal
 - Vulnerability Assessments
 - Mitigation
 - Detection Goal
 - Detection capabilities
 - Emergency Response Goal
 - Efficient response to emergencies
 - Recovery Goal
 - Business recovery plans

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- Sec 109. Food & Agriculture Coordinating Council
 - Facilitating partnership between public & private entities
 - Regular and timely interchange of information
 - Identification of best practices for improving the coordination among Federal, State & local
 - Recommending methods to protect the economy and public health

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Improving Capacity To Prevent Food Safety Problems

- Sec 110. Building Domestic Capacity
 - Report to Congress in 2 years that identifies programs and practices that are intended to promote the safety of the supply chain security of food and to prevent outbreaks.
 - Review previous food safety programs and practices
 - Outlines the success of those programs
 - Identifies future programs and practices

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Improving Capacity To Prevent Food Safety Problems

- Sec 110. Building Domestic Capacity
 - FDA shall submit to Congress a joint food safety and food defense research plan

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- Sec 115. Port Shopping
 - FDA Shall notify DHS of all instances in which the FDA refuses to admit a food into the United States so Customs and Border Control may prevent food refused admittance into the United States

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 201. Targeting of Inspection Resources for Domestic and Foreign Facilities and Port of Entry
 - Shall identify high-risk facilities and shall allocate resources to inspect facilities according to the known safety risks
 - Based upon – known safety risks, compliance history, effectiveness of facility's hazard analysis and preventive controls, meets the criteria for priority, whether the facility has been certified or any other criteria

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- Sec 201. Targeting of Inspection Resources for Domestic and Foreign Facilities and Port of Entry
 - Inspections
 - Increase frequency of all facilities
 - Domestic High Risk facilities – once every 5 years
 - Domestic Non High Risk facilities – once every 7 yr
 - Foreign Facilities – not less than 600 facilities per year
 - Future years increase by 2x per year

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- Sec 201. Targeting of Inspection Resources for Domestic and Foreign Facilities and Port of Entry
 - Port
 - Known safety risks of the food imported
 - Known safety risks by countries and regions of origin
 - Compliance history of importer
 - Effectiveness of activities conducted by importer
 - Voluntary qualified importer
 - Food or facility has been certified
 - Interagency agreements with respect to seafood

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 202. Laboratory Accreditation For Analyses of Foods
 - Shall establish a program for the testing of food by an accredited laboratories (2 years)
 - Establish a publicly available registry of accredited laboratories
 - Provide for recognition of laboratory accreditation bodies
 - Including independent private and government laboratories
 - Foreign laboratories

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 202. Laboratory Accreditation
 - Shall develop Model Laboratory Standards for accredited laboratories
 - Sampling
 - Analytical procedures
 - Internal quality systems
 - Procedures to handle complaints
 - Training and qualifications of employees

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- Sec 202. Laboratory Accreditation
 - Shall periodically (once every 5 years) reevaluate accreditation
 - Shall promptly revoke the recognition of any accreditation body found not to be in compliance
 - Food testing shall be conducted by accredited laboratories for the appropriate sampling or analytical testing methodology

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- Sec 202. Laboratory Accreditation
 - Results of testing shall be sent directly to FDA
 - May exempt test results of non public health nature
 - Exception
 - New methodology not yet accredited
 - Nothing in Act to limit FDA the ability to review and act upon information from food testing to determine sufficiency of such information and testing

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- Sec 202. Laboratory Accreditation
 - Food Emergency Response Network
 - Report on implementing a National Food Emergency Response Network

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- Sec 203. Integrated Consortium of Laboratory Networks
 - Shall maintain an agreement through which relevant laboratory network members as determined by DHS

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 204. Enhanced Tracking and Tracing of Food and Recordkeeping
 - Shall establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals. (not later than 270 days)

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 204. Enhanced Tracking and Tracing of Food and Recordkeeping
 - Pilots shall include
 - Include at least 3 different types of food that have been subject of significant outbreak during the last 5 years preceding 2011
 - Not later than 18 months report to Congress on the results

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 204. Enhanced Tracking and Tracing of Food and Recordkeeping
 - Evaluate domestic and International Product tracing practice in commercial use
 - FDA shall establish a product tracing system to receive information to track and trace food

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- Sec 204. Enhanced Tracking and Tracing of Food and Recordkeeping
 - Shall publish a notice of proposed rulemaking to establish recordkeeping requirements (2 years)
 - Use information readily available, be science based, not prescribe specific technologies, ensure public health benefits, scale appropriate and practicable for facilities, minimize number of different requirements, not require facilities to change business systems, allow centralized records, provide within 24 hours, International trade
 - Maintain records not more than 2 years depending on perishability
 - Maintain records of immediate previous source and immediate subsequent recipient of such.

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- Sec 204. Enhanced Tracking and Tracing of Food and Recordkeeping
 - Shall designate High Risk Foods (1 year)
 - Known safety risk - history, food outbreaks
 - High potential for microbiological or chemical contamination
 - Likelihood of contamination in manufacturing

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 205. Surveillance
 - Shall enhance foodborne illness surveillance systems to include:
 - Collection
 - Analysis
 - Reporting
 - Usefulness of data in coordinating Federal, States and local into a national network

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- Sec 208. Decontaminated and Disposal Standards and Plans
 - EPA shall provide support for, and technical assistance in preparing for assessing, decontaminating, and recovering from an agricultural or food emergency

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- Sec 209. Improving the Training of State, Local, Territorial and Tribal Food Safety Officials

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 210. Enhancing Food Safety
 - Training
 - Grants
 - Shall establish 5 Centers of Excellence within state health agencies

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Improving Capacity To Detect and Respond to Food Safety Problems

- Sec 211. Improving the Reportable Food Registry
 - May require consumer-oriented information
 - Description of article of food
 - Product identification – UPC, SKU, Lot codes
 - Contact information for responsible party
 - Grocery Store Notification
 - Consumer Notification
 - Post recalls within 24 hours
 - FDA shall publish list of conspicuous locations

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Improving The Safety of Imported Food

- Sec 301. Foreign Supplier Verification Program
 - Verification requirements
 - Importer shall perform risk-based foreign supplier verification
 - Produced in compliance with...
 - Not adulterated or misbranded
 - Exempt food imported in small quantities for research, evaluation or personal consumption

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Improving The Safety of Imported Food

- Sec 302. Voluntary Qualified Importer Program
 - Voluntary Participation in an expedited review of importation of foods
 - This is in cooperation with DHS

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Improving The Safety of Imported Food

- Sec 303. Authority to Require Import Certification for Foods
 - May require certification as a condition in granting admission of an article of food imported or offered for import into the United States

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Improving The Safety of Imported Food

- Sec 305. Building Capacity of Foreign Governments with Respect to Food Safety
 - Shall not later than 2 years of the date of enactment of this Act, develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.

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Improving The Safety of Imported Food

- Sec 306. Inspection of Foreign Food Facilities
 - Shall direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present a high risk.

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Improving The Safety of Imported Food

- Sec 307. Accreditation of Third-Party Auditors
 - Shall establish a system for the recognition of accreditation bodies that accredit third party auditors to certify that eligible entities meet the applicable requirements.
 - Shall develop model standards, including requirements for regulatory audit reports
 - If any time during an audit a certified auditor finds a serious risk ... must report to FDA

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Improving The Safety of Imported Food

- Sec 309. Smuggled Food
 - Shall develop and implement a strategy to better identify smuggled food and prevent entry of such food into the United States

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Miscellaneous Provisions

- Sec 401. Funding for Food Safety
 - Funding ???
 - Shall increase staff
 - 4,000 in fiscal 2011
 - 4,200 in fiscal 2012
 - 4,600 in fiscal 2013
 - 5,000 in fiscal 2014
- Staff for Food Defense by 150 employees 2011

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FSMA Food Defense Tasks for the Private Sector

- **Sec 101 Inspection of Records:**

Stated task:

- Must document and make available “all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location ”

Implied Task :

- The entirety of the firm’s supply chain, from suppliers to buyers must be documented & establish a capability to provide timely access to those records

- **Sec 102 Registration**

Stated Task:

- The registrant must be prepared to be held accountable for what it should have known or should have reasonable probability to know.

Implied task:

- Must create a capability to acquire timely knowledge of hazard and threats, unintentional and intentional and a capability to respond with protective and corrective actions.

FSMA Food Defense Tasks for the Private Sector continued

- **SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.**

Stated Tasks:

- Expands requirement for firms to identify, analyze and document unintentional and intentional hazards and risks across the entire supply chain.
- Must develop, document and deploy protective and control measures to reduce the risk from identified and "reasonably foreseeable hazards" to include WMD risks to the firms products.
- Must implement a monitoring system across the production and supply chain to verify controls and protective measures and to detect protective and control failures

Implied Tasks:

- Must develop and deploy food product/process and supply chain defense plan that include defense against WMD agents targeting food systems
- Must establish a capability to identify reported, reasonably known and foreseeable hazards, risks and WMD threats to their products.
- Must create a supply chain wide surveillance and testing system to monitor effectiveness of protective programs and to detect hazards and potential presence of WMD agents.
- The concept of reasonable knowledge is expanded to "FORESEEABLE" which implies a broadly expanded documentable task of hazard, threat (including WMD threats) and across their supply chain as well as external threats that might be "FORSEEABLE".

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FSMA Food Defense Tasks for the Private Sector Continued

- **SEC. 104. PERFORMANCE STANDARDS**

Stated Task:

- Must comply with the yet to be developed performance guidance for the food supply infrastructure safety & Protection

Implied Task:

- Must assess current performance standards and prepare to adapt to Federally directed changes and additions

- **SEC. 106. PROTECTION AGAINST INTENTIONAL ADULTERATION**

Stated Task:

- Must develop and deploy plans, processes and protocols to protect products against intentional acts & monitor supply chain for such acts and comply with the standards, protocols and provisions of the yet to be developed Federal guidelines for this requirement

Implied Task:

- Must assess risk of intentional adulteration & establish capability to anticipate and defend against this threat & monitor the supply chain and the food sector for indications of such imminent risks

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FSMA Food Defense Tasks for the Private Sector continued

- **SEC. 108. NATIONAL AGRICULTURE AND FOOD DEFENSE STRATEGY.**

Stated Task:

- Must comply with and prepare food defense plans in accordance with the to be developed National Agriculture and food Defense Strategy

Implied Task:

- Must prepare capability to assess current food system defense posture and create capability to implement industry specific provisions in the national food defense strategy to be developed by the Federal Government

- **SEC. 110. BUILDING DOMESTIC CAPACITY**

State Task:

- Must have a product traceback capability that spans the firm's supply chain for inputs

Implied Tasks:

- Must be prepared to respond to and comply with new sector specific health, safety, defense and WMD protection federal regulatory actions that result from the requirements of this Act.
- Prepare for the federal implementation of a new automated risk assessment system for food and agriculture safety surveillance and allocation of response and detection resources
- Must develop the capability of a near real time inputs supply chain monitoring system that enables timely product or inputs documentation and traceback to source.

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FSMA Food Defense Tasks for the Private Sector Continued

- **SEC. 201. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT**

Stated Task:

- Must comply with targeted inspections requirements

Implied Tasks:

- Must be able to provide supply chain documentation of imports to assist in targeting products for inspection at all points along the supply chain.
- Must be prepared to assist the US Government in identifying foreign supplier facilities for inspection and assist with host nation coordination to facilitate such inspections.

- **SEC. 202. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS**

Stated Task:

- Must comply with newly developed laboratory accreditation requirements

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FSMA Food Defense Tasks for the Private Sector Continued

- **204. ENHANCING TRACKING AND TRACING OF FOOD AND RECORDKEEPING**

State Task:

- Must cooperate with the Federal Government to develop new methods to rapidly trace food products
- Must establish record keep capabilities to document the food supply chain and facilitate food product tracing.

Implied Task:

- Develop a capability to provide rapid access to government inspectors for all records associated with supply chain documentation, product traceback and trace forward

- **SEC. 206. MANDATORY RECALL AUTHORITY**

Stated task:

- Must comply with recall guidance and directives and records/documentation requirements

Implied task:

- Prepare to support the WEB based public information sharing tasks of the FDA under a recall with records and documentation on the food(s) involved and traceback and trace forward information.

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Examples of Reports Required

- Detailed analysis of the food system
- Need for further regulation and resource requirements
- Emerging threats
- Communication systems on emerging threats
- Surveillance and laboratory systems and their integrations
- Outreach and training programs for state/local
- Prior outbreak and traceback performance
- Unique facility identifiers
- Costs of compliance for small firms

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Moving Forward

- All submitted questions will be answered by email
- Translation from the Act into guidance, regulation and policy will benefit from significant industry engagement
- NCFPD will hold additional webinars to go into more detail about selected food defense aspects of the Act
- Pending stakeholder input, a symposium on the food defense implications of the Act may also be convened

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NCFPD Vision

Defending the **safety** of the **food system** through **research** and **education**

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