Foreign Supplier Verification Program (FDCA § 805)

- Importers must implement risk-based programs to verify that foreign suppliers are complying with US law

The focus is on foreseeable (but not all) hazards

Foreign Supplier Verification Program

- Risk-based supplier verification program
- Requires use of approved suppliers
- FSVP does not apply if –
  - There are no significant hazards, or
  - All significant hazards are controlled by
    - the importer, or
    - a customer (and written assurance is provided)

Foreign Supplier Verification Program

- Hazard Analysis
  - Analyze hazards associated with each food imported
  - Identify those reasonably likely to occur
  - Evaluate severity of illness or injury if the hazard were to occur
  - Requirement may be met by reviewing foreign supplier’s hazard analysis

Foreign Supplier Verification Program

- Hazard Analysis – changes as of Sept 2014
  - Broader evaluation of hazards in food
  - Broader evaluation of who will apply hazard controls (e.g., foreign supplier, or supplier's supplier) and their procedures

Foreign Supplier Verification Program

- Risk evaluation – to determine verification activities needed:
  - Consider hazard analysis together with –
    - The foreign suppliers' practices and compliance history
    - The source of supply relied on by the foreign supplier

Foreign Supplier Verification Program

- Verification Activities
  - Conduct activities to provide assurance that identified hazards are adequately controlled, which may include –
    - Onsite auditing
    - Periodic or lot-by-lot sampling and testing of food
    - Periodic review of food safety records
    - Other activities

Foreign Supplier Verification Program

- Verification Activities – changes as of Sept 2014
  - When the hazard = reasonably probability of serious adverse health consequences or death
  - And is controlled by the foreign supplier
  - Then onsite audit is required before import and at least annually thereafter
    - Different approach allowed where there is adequate assurance that the hazard is controlled
    - Inspection by FDA or other authority may substitute

Foreign Supplier Verification Program

- Corrective Actions:
  - Importers must review complaints, investigate problems, take appropriate corrective actions, and revise their FSVP when necessary
- Periodic Reassessment:
  - Importers must reassess FSVPs at least every three years, or sooner if they become aware of new potential hazards with the food or the supplier

Foreign Supplier Verification Program

- Importer Identification
  - Importers require a Dun and Bradstreet Data Universal Numbering System (DUNS) number, which must be filed with CBP for each food entry
- Recordkeeping
  - Document all steps

FSVP Exemptions

- Products under existing HACCP regulations (juice, seafood)
- Food research or evaluation
- Food for personal consumption
- Alcoholic beverages
- Food transshipped or imported for further processing and export

Supplier Verification Program under proposed § 117.136

- Changes as of Sept 2014: FDA is proposing a risk-based supplier verification program for all facilities covered by part 117
- This appears in § 117.136
- An importer is deemed to be in compliance with FSVP if it (or its customer) complies with § 117.136

Equivalent Foreign Country Exemption

Some exemptions for imports from foreign suppliers in countries recognized by FDA has having comparable food safety systems

- Need to document compliance status of foreign supplier

“Very Small” Exemption

Some exemptions for very small foreign suppliers and importers:

- average annual monetary value of sales of food during the previous 3-year period is no more than $1 million (new in Sept. 2014)

FSVP Compliance Dates

- Effective date: 60 days after publication
- Compliance date: 18 months after publication, or 6 months after the foreign supplier is required to comply with new FSMA preventive controls regulations

Third-Party Accreditation

Third-Party Accreditation

- Accredited Laboratories
  - FDCA § 422
  - For purposes of
    - Required testing to address a food safety problem
    - Testing of imports
- Accredited Auditors
  - FDA § 808
  - For purposes of
    - Import certification under FDCA § 801(q)
    - Voluntary qualified importer program under FDCA § 806

Accredited Laboratories

- FDA must establish --
  - A program for testing by accredited labs
  - A registry of accreditation bodies and accredited labs
- Eligible labs:
  - Government labs
  - Private labs
  - US or foreign

Accredited Laboratories

- Model accreditation standards must include:
  - Methods to ensure that appropriate sampling and analytical procedures are followed
  - Certification of reports of analyses
  - Internal quality systems
  - Complaint handling procedures
  - Training/experience requirements

Accredited Laboratories

- Accredited labs must be used for –
  - Any specific testing requirement under law or regulation, when addressing an identified or suspected food safety problem
  - Any testing required by FDA to address an identified or suspected food safety problem
  - Any testing to support of admission of an importation of food
  - Any testing under an Import Alert that requires successful consecutive tests

Accredited Laboratories

- The results of tests must be sent directly to FDA
  - Except as exempted by FDA
- If a state lab does testing that results in a recall, then FDA must determine the need for a national recall (or other enforcement)

Accredited Auditors

- FDA may require certification of imports under FDCA § 801(q)
  - Certification must be provided by:
    - The government in the originating country, or
    - An accredited third-party auditor
- FDA must establish a voluntary qualified importer program under FDCA § 806
  - Requires a facility certification provided by:
    - FDA, or
    - An accredited third-party auditor

Accredited Auditors

- FDA must publish model accreditation standards
- FDA must establish a system for recognition of accreditation bodies …
  - That accredit third-party auditors …
    - To certify that foreign entities meet requirements under § § 801(q) and 806
- Each accreditation body must submit a list of accredited auditors to FDA

Accredited Auditors

- Eligible auditors:
  - Foreign governments:
    - Accredited based on review of food safety programs to ensure that the government is capable of determining that US requirements are met
  - Foreign cooperatives and other third parties:
    - Accredited based on review of internal systems and training of auditors to ensure that US requirements are met

Accredited Auditors

- Types of audits:
  - Regulatory audit:
    - To determine whether an entity is in compliance with US law
    - The results of which determine whether –
      - an article of food may be certified under § 801(q), or
      - a facility may be certified under § 806
  - Consultative audit:
    - To determine whether an entity is in compliance with US law
    - The results of which are for internal purposes only

Accredited Auditors

- Reports of audits:
  - Regulatory audit:
    - Report must be prepared by auditor
    - FDA may require submission of the report and other audit documents to FDA
  - Consultative audit:
    - Report must be prepared by auditor
    - FDA may not require submission (but may review under FDCA § 414)
  - Any condition that could cause or contribute to a serious risk to the public health must be immediately notified to FDA

Accredited Auditors

- Requirements for auditors:
  - A regulatory audit may not be performed if the same auditor performed any audit within the past 13 months
  - An auditor must not be under common control with the audited firm
  - By June 2012 FDA must publish regulations to prevent conflicts of interest among auditors, including requirements that
    - Audits must be unannounced
    - Fees must be subject to disclosure requirements
    - Limitations must be met for financial affiliations

Accredited Auditors

Enforcement

- FDA must reevaluate accreditation bodies and accredited auditors once every 4 years
- Accredited auditors must recertify foreign firms annually
- Accreditation must be withdrawn if certified food/facility is linked to an outbreak of illness that has a reasonable probability of causing serious adverse health consequences or death in humans or animals
- Any statement or representation made to an accredited third-party auditor is subject to 18 USC § 1001

Accredited Auditors

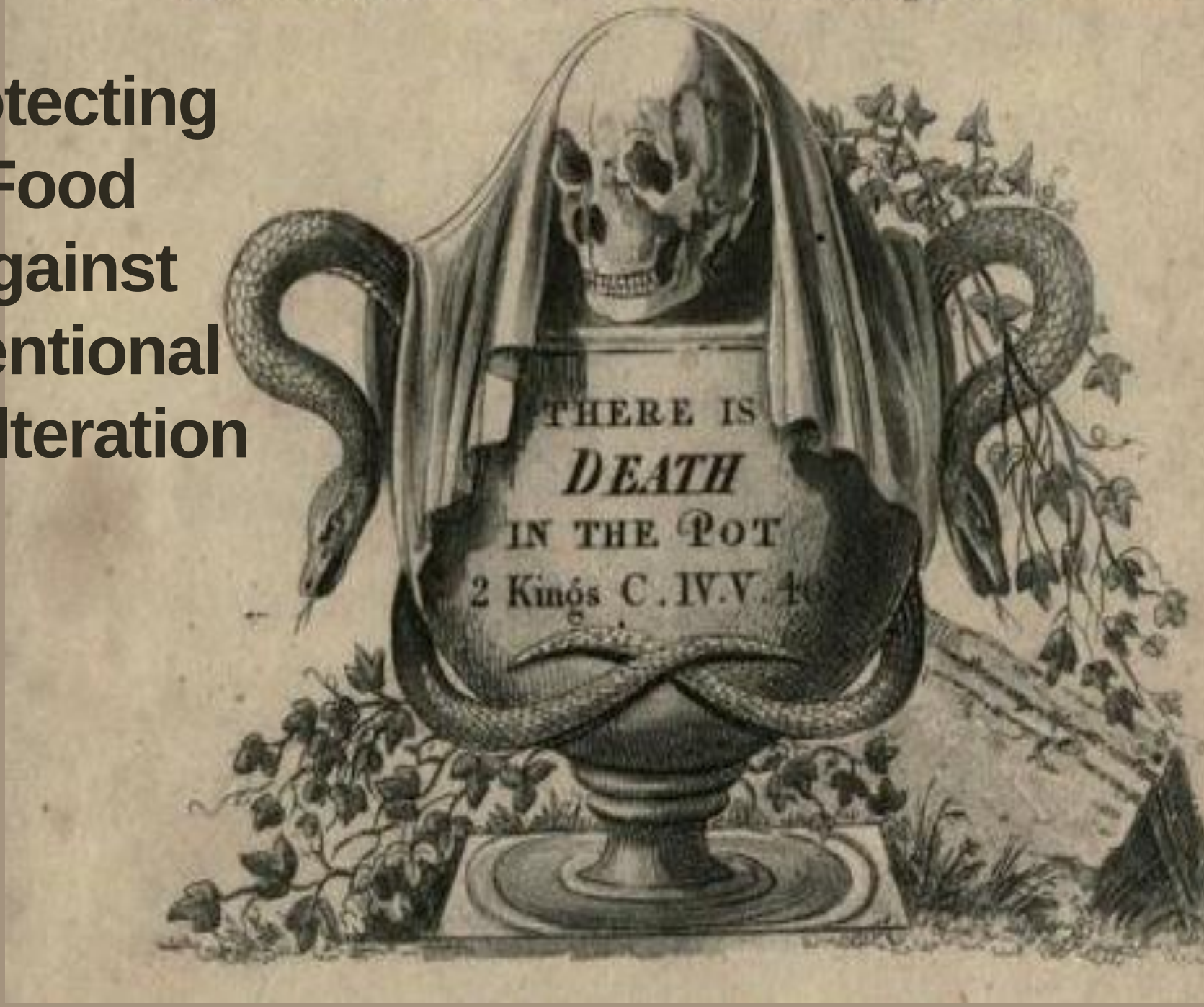
Foreign Supplier Verification Program

- FDA anticipates that importers may rely on audits by accredited third parties to meet their supplier verification requirements under FSVP

Implementation

- FDA intends to implement this program as soon as possible after publication of the final rule and final Model Accreditation Standards, which will be published separately

Protecting Food Against Intentional Adulteration



Protecting Food Against Intentional Adulteration

- Goal: Prevent intentional adulteration of food supply with intent to cause public health harm
- Proposed approach: Target processes most likely to be vulnerable
- Applies to: Domestic and foreign firms required to register

Intentional Adulteration

- 4 most vulnerable activities:
  - bulk liquid receiving and loading
  - liquid storage and handling
  - secondary ingredient handling (the step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient)
  - mixing and similar activities

Intentional Adulteration

- Proposed requirement:
  - Determine if a facility performs these activities – or complete a facility-specific vulnerability assessment
  - Identify “actionable process steps” – points in the process where focused mitigation strategies can reduce risk
  - Complete a food defense plan

Intentional Adulteration

- Food Defense Plan:
  - Vulnerability assessment
  - Actionable process steps
  - Focused mitigation strategies
  - Monitoring
  - Corrective actions (when focused mitigation strategies are not properly implemented)

Intentional Adulteration

- Food Defense Plan (continued):
  - Verification
    - Confirm effectiveness of focused mitigation strategies, monitoring and corrective actions
  - Training
  - Recordkeeping

Intentional Adulteration

- FDA is considering exempting or modifying requirements for on-farm manufacturing, processing, packing, or holding …
- When these practices are low-risk based on FDA risk assessment and conducted by a small or very small business

Intentional Adulteration

- Effective date: 60 days after publication
- Compliance date:
  - Very small (less than $10 M annual sales): 3 years
  - Small (less than 500 employees): 2 years
  - Otherwise: 1 year

Intentional Adulteration

- Exemptions: various activities are wholly or partially exempt, e.g. –
  - Very small businesses
  - Packing, repacking, holding, where container remains intact
  - Farms, animal food, certain alcoholic beverages

Thank you!

Supplemental Slides

Inspection Requirements (FDCA § 421)

Ports of Entry:
Risk-based allocation of inspection resources

Facilities:

- High-risk domestic: once between 2011 & 2016, then every 3 years
- Lower-risk domestic: once between 2011 & 2018, then every 5 years
- Foreign: at least 600 by January 2012, double number annually for 5 years

Records Inspection Authority

Pre-FSMA Authorities

- Records enumerated in regulation or statute for special category (e.g., shell eggs, infant formula, HACCP)
- Conditional records access under 2002 Bioterrorism Act
- Interstate shipment records

FSMA Authorities

- Hazard analysis & preventive control records (FDCA § 418)
- Foreign Supplier Verification Program records (FDCA § 805)
- Third-party auditor reports (non-consultative) (FDCA § 808(c)(3))
- Expanded Bioterrorism Act authority access (FDCA § 414)
- Designated “high-risk” food records (FSMA § 204(d))

New Enforcement Tools

- Mandatory recall authority (FDCA § 423)
- Biennial registration requirement and suspension authority (FDCA § 415)
- Expanded administrative detention authority (FDCA § 304(h))

Registration & Suspension

- 2012 outbreak of *Salmonella* Bredeny traced to contaminated peanut butter produced at New Mexico plant – 42 people, 20 states

- Nov. 2012: FDA issues first registration suspension letter to Sunland Inc.

- Firm entered into consent decree, FDA revoked suspension, and ultimately authorized resumption of manufacturing activities

Administrative Detention

- FDCA § 304(h)
- Authorized by 2002 Bioterrorism Act
- Temporary adjunct to FDA's seizure authority