

Agenda: Foreign Supplier Verification Program (FSVP)

- **Chapter 1: Context**
 - The rise of the Food Safety Modernization Act (FSMA)
 - New rules and regulations
 - The FDA's and the importer's role (your role) in ensuring the safety of imported food

- **Chapter 2: Setting the Stage**
 - Definitions for importer, foreign supplier, and qualified individual
 - Differences between Importer of Record (IOR) and "FSVP Importer," and
 - Scope of FDA's definition of food

- **Chapter 3: Overview of the Requirements**
 - General requirements
 - Make sure all FSVP steps are carried out by a qualified individual
 - Standard requirements (hazard analysis, evaluation and approval of foreign supplier, verification activities and corrective actions, reevaluation, identification of importer at entry, recordkeeping)
 - Exemptions from FSVP and modified requirements

- **Preview of the Preventive Controls (PC) and Produce Safety Session**
 - The PC and Produce Safety Session is intended as a timeout from FSVP instruction to briefly focus on the PC rules for human and animal food and the Produce Safety rules that your foreign suppliers may be subject to.

- **Preview of Chapters 4-9: FSVP Core Elements**
 - All of these requirements are FSVP core elements and will be presented in detail as we proceed through the course.
 - A preview of the core elements are covered in the next few slides.

- **Chapter 4: Hazard Analysis:**
 - Define hazards,
 - Identify known or reasonably foreseeable hazards in the food being imported,
 - Evaluate the food risk (probability and severity), and

- Determine if any hazards require controls.
- **Chapter 5: Evaluate and Approve Foreign Supplier(s)**
 - Evaluate foreign supplier performance—procedures, processes, compliance history.
 - Approve foreign suppliers before importing from them.
- **Chapter 6: Foreign Supplier Verification**
 - Choose appropriate verification activities and frequency, if needed.
 - Apply verification activities.
 - Evaluate results of verification.
 - Take corrective actions, if needed.
- **Chapter 7: Reevaluation of Food Risk and Foreign Supplier**
 - Reevaluate FSVP, at any time if changes or for cause, but at least every 3 years.
- **Chapter 8: Importer Identification at Entry**
 - The importance of identifying the importer at entry
 - Determining which entity will be the FSVP importer
 - Ensuring entry data identifies the designated FSVP importer
- **Chapter 9: Importance of Records:**
 - Recognizing the importance of records
 - Creating records to document your FSVP
 - Describing the requirements for record maintenance
- **Chapter 10: FDA Oversight:**
 - FDA inspection process, enforcement tools, consequences, and compliance dates

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