

FSMA Animal Food Final Rule – November 2016



Mr. Gary Smith
Director, Food Safety Systems

November 2016

Food Safety Modernization Act (FSMA) 2010



- Congress passed FSMA on December 20th 2010
- President Obama signed it into law on January 4th, 2011
- Final rule initially scheduled to be implemented July of 2013
- Human Food and Animal Food final rule issued September 10th, 2015 (930 and 666 pages, respectively)
- Other sections of the rule will be issued over the next 6 months

- Title 1** Designed to improve capacity to **prevent** food safety problems

- Title 2** Designed to improve capacity to **detect and respond** to food safety problems

- Title 3** Designed to improve the safety of **imported food**

- Title 4** Includes miscellaneous provisions

Foundational Rules for Implementation of FSMA



1. Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventative Controls for Human Food
2. Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventative Controls for Animal Food
3. Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption
4. Foreign Supplier Verification Program (FSVP) for Importers of Food for Humans and Animals
5. Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certificates
6. Focused Mitigation Strategies to Protect Food Against Intentional Adulteration
7. Sanitation Transportation of Human and Animal Food

Preventive Control Food Rule – Who's Covered?

- All facilities who are required to register with the FDA under section 415 who are not exempted
- Human and animal food manufacturing/processing/packing/holding facilities, both domestic and importers
- Storage and distribution centers
 - Exposed product
 - Unexposed product



- **Retail food establishment – covered under the “food code” by local public health authorities**
- **Protein (meat, pork, poultry) production facilities – covered by USDA jurisdiction**
- **Farms – covered by the Produce Safety Rule**
 - **Primary production farm – growing and harvesting of plants and animals**
 - **Secondary activities farm – harvesting, packing and holding raw agricultural commodities**
 - **Feed Mill – if the feed mill is vertically integrated for the growing of live animals within the company site**

- **Subpart A – General Provisions**
- **Subpart B – Current Good Manufacturing Practices**
- **Subpart C – Hazard Analysis and Risk Based Preventive Controls**
- **Subpart D – Withdrawal of Exemption to a Qualified Facility**
- **Subpart E - Reserved**
- **Subpart F – Requirements of Records which must be established and maintained**

Current Good Manufacturing Practices (507 Subpart B)



- **Personnel (507.14)**
 - **Cleanliness (handwashing, jewelry, hairnets, clothing)**
- **Plant and grounds (507.17)**
 - **Grounds**
 - **Plant construction and design**
- **Sanitary operations (507.19)**
 - **Facility clean and in good repair**
 - **Equipment and utensils clean and maintained**
 - **Cleaning chemicals**
 - **Storage of toxic chemicals**
 - **Pest control**
 - **Trash controlled**

cGMPs for Animal Food

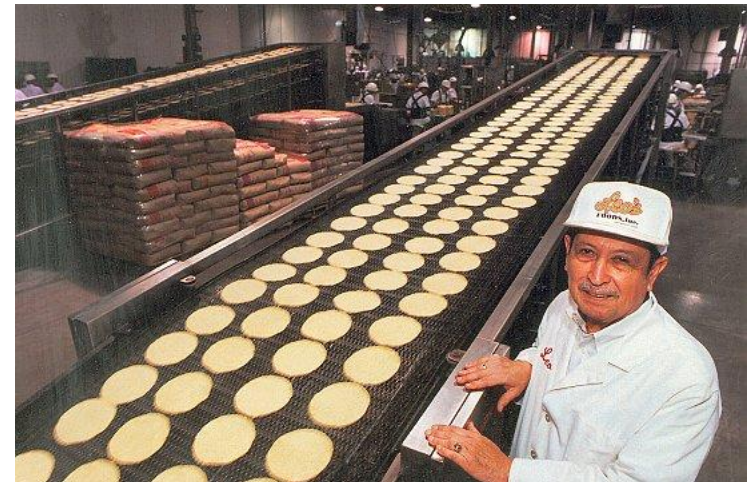
Current Good Manufacturing Practices (507 Subpart B) (cont.)



- **Water supply and plumbing (507.20)**
 - **Water supply**
 - **Plumbing**
 - **Sewage disposal**
 - **Toilet facilities**
 - **Handwashing facilities**
 - **Equipment and utensils (507.22)**
 - **Design**
 - **Cooler and freezers**
 - **Instruments**
 - **Compressed air**
 - **Plant Operations (507.25)**
 - **General operations**
 - **Raw materials**
 - **Manufacturing operations**
 - **Holding and distribution (507.27)**
 - **Protection in storage**
 - **Labeling for distribution**
 - **Shipping containers**
 - **Product returns**
 - **Bulk storage**
 - **Human food by-products (507.28)**
- cGMPs for Animal Food**

Preventive Control Rule Requirements

- **A written food safety plan**
- **Hazard analysis**
- **Preventative controls**
- **Monitoring**
- **Corrective actions and corrections**
- **Verification / Validation**
- **Supply chain program**
- **Recall plan**
- **Records**

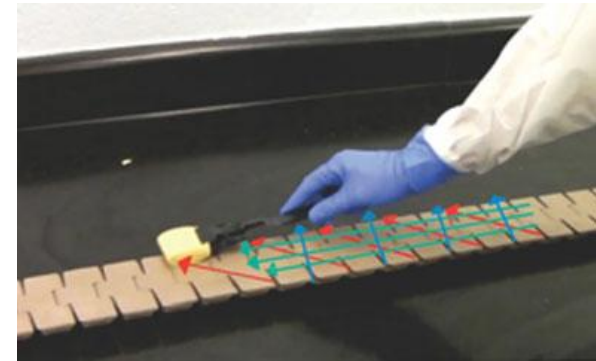


- **Written procedures for all preventative controls**
- **Documented monitoring procedures, with frequency for monitoring**
- **Documented corrective actions and correction procedures**
- **Verification**
 - **Validation – by preventive control qualified individual**
 - **Record review – by preventive control qualified individual, within 7 days**
 - **Calibration of equipment**
 - **Testing**
 - **Product**
 - **Environmental (RTE food risk of environmental contamination)**
- **Records of all activities**

Is testing required? FDA preamble – If the facility produces RTE food, the RTE food is exposed to the environment and there is a risk of environmental contamination

117.165 (3) Environmental Monitoring

- Be scientifically valid
- Identify the test microorganism
- Specify the locations for the samples to be collected with number of sites
- Identify the timing and frequency for collecting samples
- Identify the test to be conducted
- Identify the laboratory conducting the testing
- Include the corrective action



- **117.4 – management must ensure that all individuals are qualified to perform their assigned duties**
 - **Qualified individual – have education, training or experience necessary**
 - **Receive training in the principles of food hygiene and food safety – Records maintained**
- **117.180 – Preventative controls qualified individual**
 - **Attend preventive control training course (FDA recognized) OR**
 - **Qualified through job experience**

A preventive controls qualified individual* must do or oversee the following activities:

- 1. Preparation of the food safety plan**
- 2. Validation of the preventive controls**
- 3. Determine if validation is not required**
- 4. Review of records within 7 days**
- 5. Reanalysis of food safety plan (at least every 3 years)**

***Individual does not need to be an employee of the facility**

Records Required (117.190)

- **Monitoring of preventive controls**
- **Corrective actions taken**
- **Verification activities**
 - **Validation**
 - **Verification of monitoring**
 - **Verification of corrective action**
 - **Calibration**
 - **Product testing**
 - **Environmental monitoring**
 - **Record review**
 - **Reanalysis**
- **Records that document the supply chain program**
- **Records that document training**
- **Records that document training of the preventive controls qualified individual and qualified auditor**
- **Records justifying any deviation from this rule**

FSMA Foreign Supplier Verification Program (FSVP) - Overview



Importers are now required to verify that food imported into the U.S. has been produced using the same level of risk-based food safety precautions as food produced within the U.S.

Definitions:

- **Importer** – the U.S. owner or consignee of food offered for import into U.S.
- **FSVP** – a program that importers must have in place to verify their foreign suppliers are producing food in a safe manner equivalent to the Preventive Controls rule and is not adulterated
- **Hazard** – any known or reasonably foreseeable biological, chemical or physical element(s) that could cause illness or injury if the food is consumed. They could occur naturally, be unintentionally introduced or intentionally introduced for economic gain.

FSVP needed for each food imported by each supplier

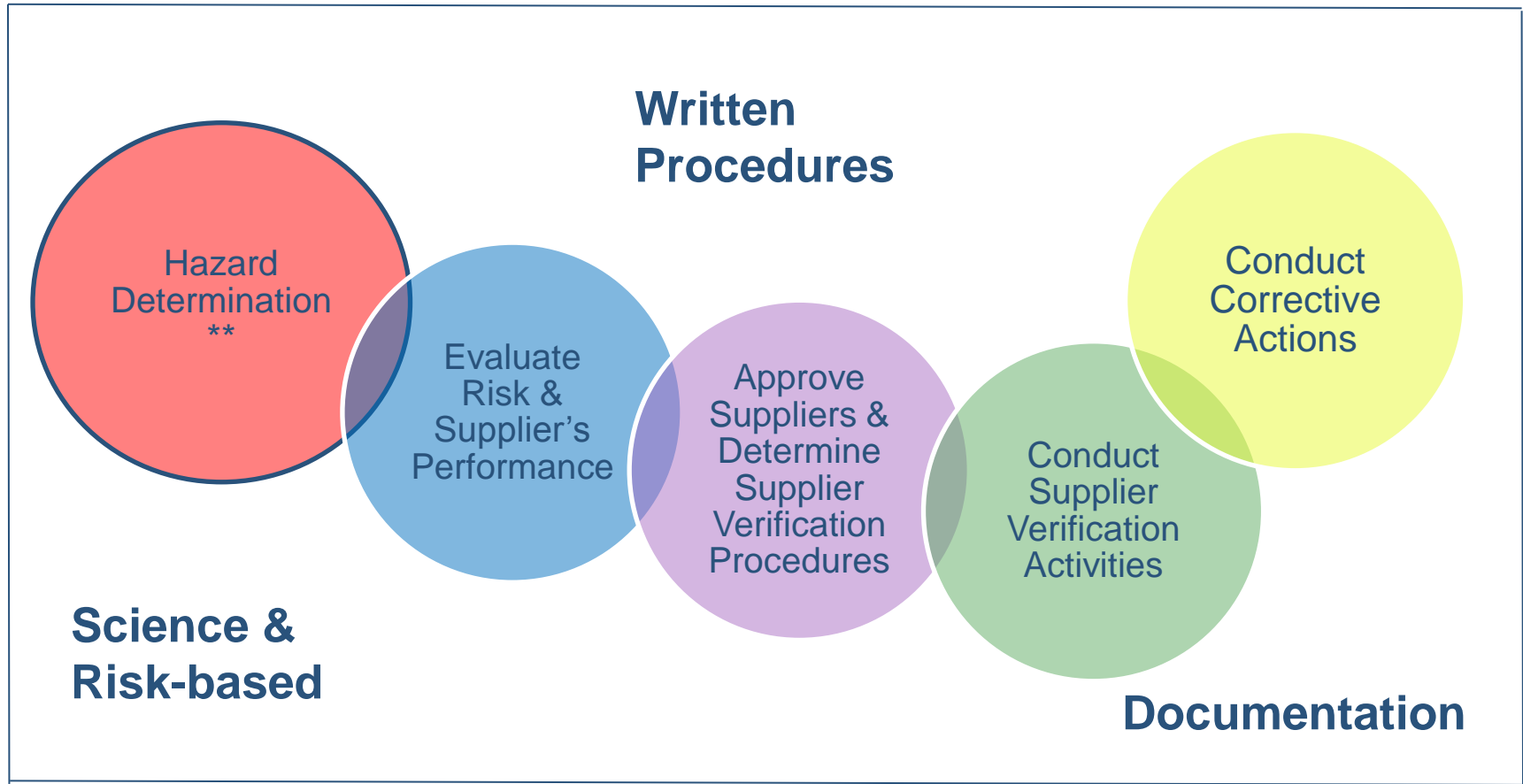
- **If multiple suppliers for same food, separate FSVP needed for each supplier**
- **Must be written**

Reanalysis of risk & supplier's performance at least every 3 years OR more often if:

- **Supplier's performance warrants it**
- **A new potential hazard is identified**

Manufacturing/Processing Importers can be compliant via:

- **Have Supply Chain Program in place per Preventive Controls rules**
- **They implement Preventive Controls for the hazard at their manufacturing facility**
- **The Customer will be minimizing or preventing hazards (with your disclosure and their written assurance of the hazard control process)**



Compliance Dates (From Sept 2015)



- **Very small businesses – 3 years**
 - Human food - <\$1M in sales, Animal food - <\$2.5M
- **Business subject to PMO - 3 years**
- **Small businesses – 2 years**
 - <500 full time equivalent employees
- **All other businesses – 1 year**
- **Animal food facilities will get an additional year to implement preventative controls**
- **Foreign supplier verification program – May 2019**



Contact Details:

Gary M. Smith

Director of Food Safety Systems

515-299-6979

GarySmith@eurofinsus.com

Questions submitted will be answered by email

