

**National Grain
and Feed Association**

FSMA – An Overview

Food Safety Modernization Act Informational Seminar

March 10, 2016

The logo for the California Grain & Feed Association, featuring a stylized orange and green graphic of a grain stalk and a feed trough, with the text "CALIFORNIA" above, "GRAIN & FEED" in large green letters, and "ASSOCIATION" below.

**CALIFORNIA
GRAIN
& FEED
ASSOCIATION**

Food Safety Modernization Act of 2011

- Signed into law on Jan. 4, 2011
- Greatly expands FDA's authority to regulate the U.S. food supply
 - Mandates that FDA create a new prevention-based regulatory system to ensure the safety of food/feed products
 - Requires FDA to develop and issue more than 50 regulations and/or guidance documents



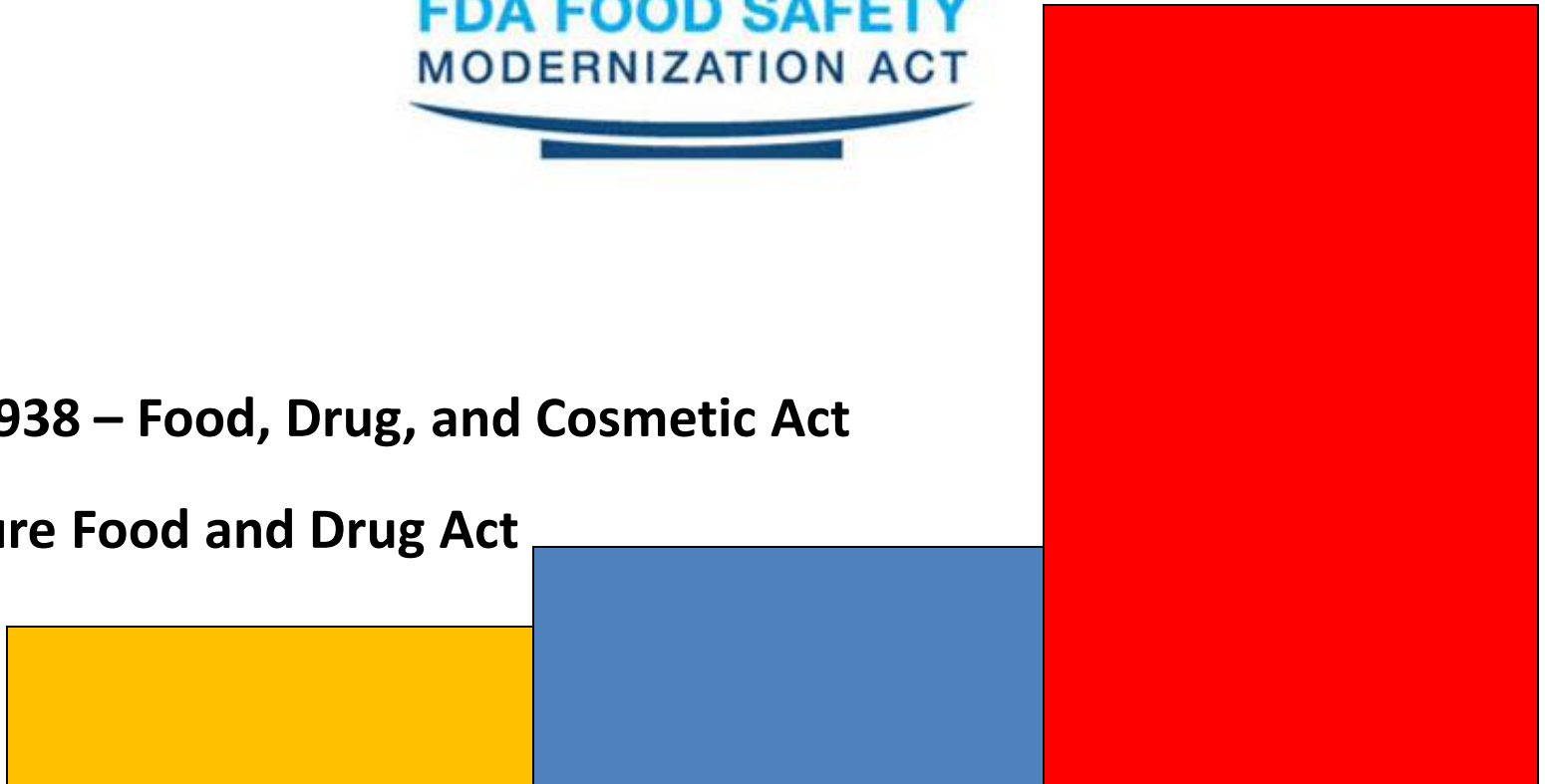
FSMA: Historic Legislation – Authority to Regulate the Food Supply

2011



1938 – Food, Drug, and Cosmetic Act

1906 – Pure Food and Drug Act



FSMA – New Authority to FDA

- **Facility registration** is required with FDA every two years on even numbered years
- FDA granted expanded authority to **access food- and feed-related records** during food safety incidents
- FDA granted authority to **issue mandatory recall** notices to facilities
- FDA to **inspect all food/feed facilities**
 - Initial inspections within 5 to 7 years
 - Subsequent inspections every 3 to 5 years
- FDA to **collect fees** for cost of
 - Reinspecting facilities that fail an original inspection
 - Conducting mandatory recalls
 - Hourly rate: \$217 for domestic work



Subject of FSMA Rule	Date Regs Issued
Current Good Manufacturing Practice (CGMPs) and Preventive Controls – Human Food	Aug. 30, 2015
Current Good Manufacturing Practice (CGMPs) and Preventive Controls – Animal Food	<i>(Sept. 17, 2015)</i>
Produce Safety Standards	Oct. 31, 2015
Foreign Supplier Verification Programs	<i>(Nov. 27, 2015)</i>
Accreditation of Third-Party Auditors	Oct. 31, 2015
Sanitary Transportation of Food **	March 31, 2016
Food Defense/Intentional Adulteration **	May 31, 2016

Applicability of FSMA Rules

- **Who's In, Who's Out ...**
 - FSMA rules apply to facilities required to register as a “food facility” with FDA under Bioterrorism Act requirements
 - Farms (operations meeting FDA’s definition of a “*farm*”) are exempt
 - Individual rules also specify certain exemptions and modified requirements

Updated Farm Definition

Farm means:

- 1) Primary production farm.** A primary production farm is an operation **under one management** in one general **(but not necessarily contiguous)** physical location devoted to the growing of crops, **the harvesting of crops**, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:
 - i) Pack or hold raw agricultural commodities;**
 - ii) Pack or hold **processed** food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and
 - iii) Manufacture/process food, provided that:
 - A) All food used in such activities is consumed on that farm or another farm under the same **management**; or
 - B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:**
 - (1)Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);**
 - (2)Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and**
 - (3)Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); OR**



Updated Farm Definition

Farm means:

- 2) *Secondary activities farm.* A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.**



The Farm Definition and Feed

- The farm definition includes operations under one management devoted to the raising of animals that manufacture feed so long as the feed is consumed on that farm or another farm under the same management; e.g., feedlots, laying operations where hens are feed on farms under the same management
 - Current definition is size-neutral; FDA says this is a “gap” they intend to address

The Farm Definition and Feed

- The farm definition does not include operations under one management where feed is manufactured and animals are fed on a farm or farms not under the same management; e.g., contract grower arrangements where animals are fed on farms not under the same management that produces the feed

Applicability of FSMA Rules

1-2. Human Food and Animal Food CGMP and Preventive Controls

- Facilities “solely engaged” in storing grain and oilseeds exempt from requirements to implement CGMPs and preventive controls
 - **Different treatment for elevators handling “fruits”** [i.e., lentils, kidney beans, pinto beans, lima beans, coffee beans, cocoa beans, peanuts, tree nuts and seeds for direct consumption (e.g., sunflower seeds)]
 - Elevators solely engaged in storing, handling such “fruits” exempt from CGMP requirements, but not exempt from the preventive controls and supply chain program requirements
- Grain millers, processors potentially covered by human, animal food rules
- Feed and pet food facilities covered by animal food rule



Applicability of FSMA Rules

3. Foreign Supplier Verification Programs

- Applies to *importers* of grains and oilseeds, feed ingredients - *could include a grain elevator*

4. Accreditation of Third-Party Auditors

- Applies to foreign food in certain circumstances; i.e., high-risk designation by FDA or participation in Voluntary Qualified Importer Program (VQIP)

5. Sanitary Transportation of Food

- Will apply to grain elevators and feed facilities

6. Food Defense/Intentional Adulteration

- FDA proposed that animal food be exempt, human food covered



FSMA – An Overview

David Fairfield

Senior Vice President, Feed Services
National Grain and Feed Association

Email: dfairfield@ngfa.org

Phone: (712) 243-4035

Matt Frederking

Vice President, Regulatory Affairs and Quality
Ralco Animal Nutrition

Email: Matt.Frederking@ralconutrition.com

Phone: (507) 532-5748

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