

**National Grain
and Feed Association**

FSMA: Past, Present, Future



Presentation Outline

- **FSMA Overview**
 - Rules
 - Compliance Dates
 - Applicability
- **FSMA and Regulatory Reform**
- **Summary of Major Rules Impacting Grain/Feed**
 - Areas of NGFA Focus for Improvement



Food Safety Modernization Act of 2011

- Signed into law on Jan. 4, 2011
- Amended Federal Food Drug and Cosmetic Act and greatly expanded FDA's authority to regulate the U.S. food supply
 - Mandated that FDA create a **new prevention-based regulatory system** to ensure the safety of food products

FDA FOOD SAFETY
MODERNIZATION ACT

FSMA Compliance Dates

Final Rule	Compliance Date - Large Business	Compliance Date - Small Business	Compliance Date - Very Small Business
CGMP Preventive Controls – Human Food	Sept. 19, 2016	Sept. 18, 2017	Sept. 17, 2018
<i>CGMP Preventive Controls – Animal Food</i>	<i>Sept. 19, 2016 (CGMP) Sept. 18, 2017 (PCs)</i>	<i>Sept. 18, 2017 (CGMP) Sept. 17, 2018 (PCs)</i>	<i>Sept. 17, 2018 (CGMP) Sept. 17, 2019 (PCs)</i>
<i>Foreign Supplier Verification Program</i>	<i>May 30, 2017</i>	<i>Not applicable</i>	<i>Not applicable</i>
<i>Third Party Accreditation</i>	<i>Requirements go into effect after FDA publishes Model Accreditation Standards – Issued Dec. 6, 2016</i>		
<i>Sanitary Transportation - Human and Animal Food</i>	<i>April 6, 2017</i>	<i>April 6, 2018</i>	<i>Not applicable</i>
Food Defense/ Intentional Adulteration	July 26, 2019	July 26, 2020	July 26, 2021

Applicability of FSMA Rules

- **Who's In, Who's Out ...**
 - **Generally**, FSMA rules apply to food-related operations required to register as a “food facility” with FDA under Bioterrorism Act requirements
 - Exception: Foreign Supplier Verification Programs; Carriers under sanitary transportation of food rule
 - **Farms** (operations meeting FDA's definition of a “*farm*”) are exempt
 - Individual rules also specify certain exemptions and modified requirements

Applicability of FSMA Rules

1-2. Human Food and Animal Food Current Good Manufacturing Practice (CGMP) and Preventive Controls (PC)

- Facilities **“solely engaged”** in storing grain and oilseeds [e.g., a **“facility”** consisting only of a grain elevator] **exempt** from both rules
 - **Different treatment for elevators handling commodities that FDA characterizes as “produce”** [e.g., dried beans, pulses]
 - Elevators solely engaged in storing, handling “produce” not subject to PCs, but are subject CGMPs
 - Grain elevator exemptions apply only when no other food-related activity that is subject to the rule(s) occurs at the facility
- Grain millers, processors potentially covered by both human, animal food rules
- Animal 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, human food – *could include a grain elevator*

4. Accreditation of Third-Party Auditors

- Applies only 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 Human and Animal Food

- Applies to grain and feed facilities; truck and rail transportation

6. Food Defense/Intentional Adulteration

- Applies to human food, *animal food exempt; grain elevators exempt*



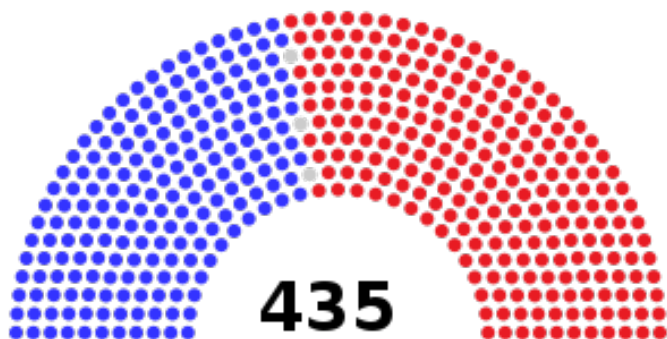
The TRUMP Administration, Congress and FSMA



Republican Majorities in Senate and House for 115th Congress

House

239 Republicans; 193 Democrats; 3 Vacant



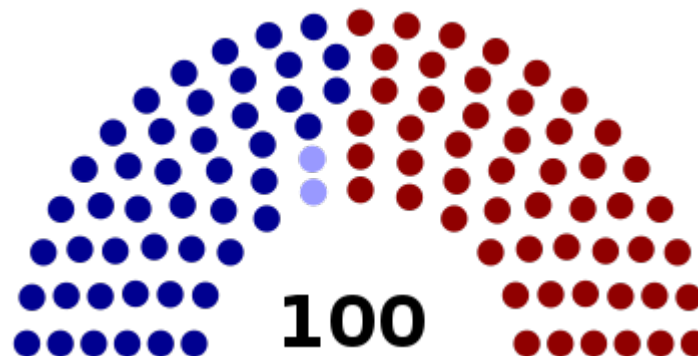
Before: **247 Republicans, 188 Democrats**
Turnover: **Republicans -8, Democrats +5**

Republicans +46

2018: All seats up; Party of newly elected President suffers average loss of 23 seats during mid-term election

Senate

51 Republicans; 47 Democrats; 2 Ind.*



Before: **54 Republicans, 46 Democrats**
Turnover: **Republicans -3, Democrats +1**
** two Independents caucusing with Democrats*

Republicans +4

2018: Democrats defend 23 seats (+2 Ind.), Republicans defend 8 seats

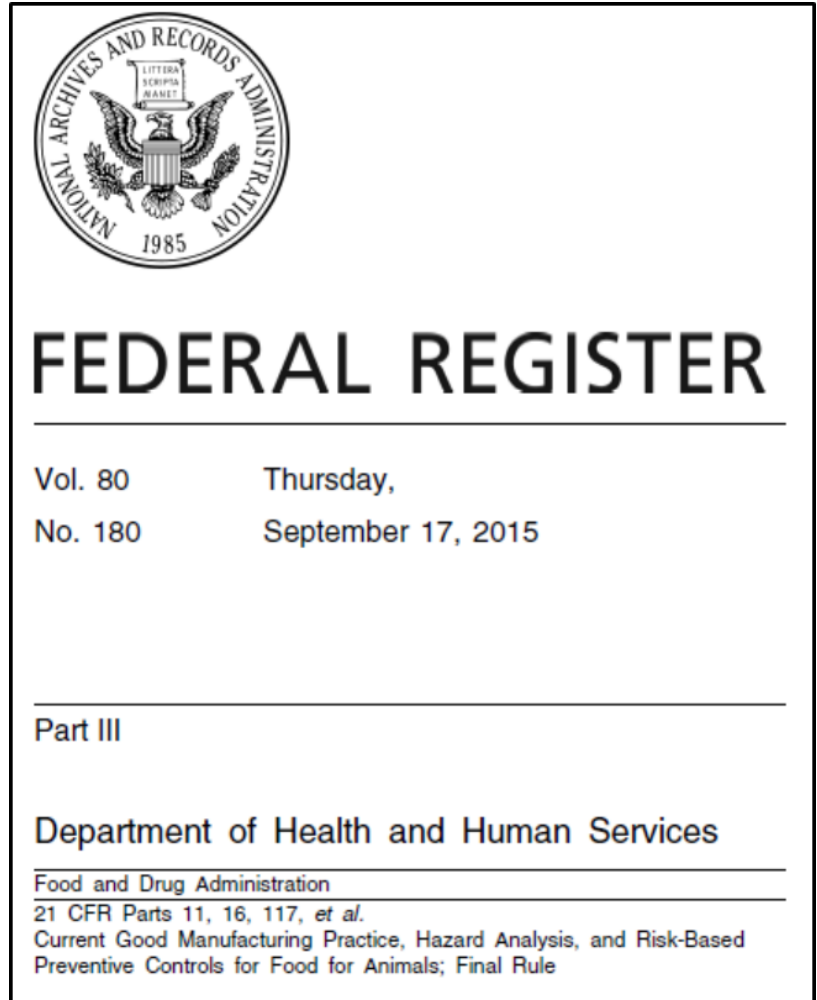
Regulatory Reform

- **Jan 30, 2017:** EO 13771 – *Reducing Regulation and Controlling Regulatory Costs*
- **Feb. 24, 2017:** EO 13771 – *Enforcing the Regulatory Reform Agenda*
- **Oct. 1, 2017:** “*Cut The Red Tape*” Initiative



21 CFR PART 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk–Based Preventive Controls

- Subpart A: General Provisions
- **Subpart B: Current Good Manufacturing Practice**
- **Subpart C: Hazard Analysis and Risk-Based Preventive Controls**
- Subpart D: Withdrawal of a Qualified Facility Exemption
- Subpart E: Supply-Chain Program
- Subpart F: Requirements Applying to Records That Must Be Established and Maintained



21 CFR PART 507 – Current Good Manufacturing Practice

- **FSMA CGMPs**
 - About 85 provisions, many have qualifiers – e.g., “as necessary and appropriate” – to accommodate the scope of animal food facilities covered under requirements
 - Livestock feed versus pet food
- **Qualified Individual Training**
 - Required, documented training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual’s assigned duties

21 CFR PART 507 – Preventive Controls

- A written food safety plan is required
- Hazard evaluation is the cornerstone of the PC requirements
 - Assess the severity of the illness or injury to man and/or animals if the hazard were to occur
 - Assess the probability that the hazard will occur in the absence of preventive controls

RISK = Severity x Probability

Inspections – Inspections – Inspections

- FDA initial enforcement and compliance approach: ***“Educate Before and While We Regulate”***
- Small “cadre” of federal and state investigators trained to perform initial inspections
 - Inspectional focus still may vary depending on investigator’s own interests
- FDA “Program Alignment Initiative” intended to improve investigator expertise related to specific inspection assignments

Inspections – Inspections – Inspections

- Issuance of FDA Form 483's – “Notice of Observations” – if any, are made in consultation with FDA headquarters
- FDA typically does not impose monetary penalties, instead -
 - Detain product
 - Mandate recalls
 - Impose consent decrees
 - Suspend facility registration

PART 507 Animal Food CGMP Inspections

- CGMP inspections began first quarter 2017 for “large businesses” – about 250 inspections conducted through Sept. 2017 (federal fiscal year: Oct 1 – Sept. 30)
- Sept. 18, 2017 – CGMP compliance date for “small businesses”
- Inspections are “conversation- and systems-based”

PART 507 Animal Food CGMP Inspections

- **NO** recordkeeping requirements for CGMPs, but records will be useful
- Sanitation conditions will be a focal point – FDA generally believes conditions across the animal food industry should improve
- October 2017: FDA issued [Final Animal Food CGMP Guidance for Industry](#)

PART 507 Animal Food PC Inspections

- Sept. 18, 2017 – PC compliance date for “large businesses”
- Sept. 17, 2018 – PC compliance date for “small businesses”
- **Routine** PC inspections slated to begin fall 2018
- FDA will inspect for PC compliance at “large companies” **before** fall 2018 when investigating an animal food safety incident
- Records to be established and maintained for all activities required under PC regulation
- First section of FDA Draft PC Animal Food Guidance likely to be issued later this year

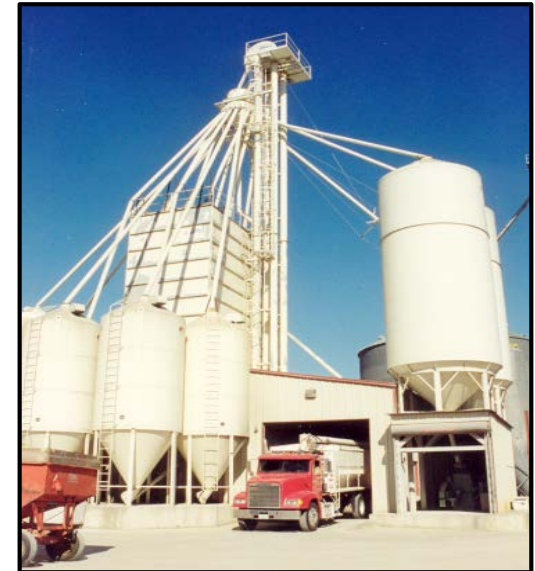
NGFA PART 507 Focus

- CGMP and Preventive Controls Rules
 - Guidance/Clarifications
 - CGMPs versus Preventive Controls
 - Exemptions
 - Grain Elevators – “Solely Engaged”
 - “Grain” Versus “Produce”
 - FDA: “Educate Before and while We Regulate”



NGFA PART 507 Focus

- **NGFA Foundation Research Project**
 - Conducted with University of Minnesota; provides valuable tool for hazard evaluation in risk analysis
- **NGFA Animal Food Rule Compliance Efforts**
 - 2016: 16 regional outreach seminars
 - 2017: Shift to intensive PCQI training
 - Delivered ten courses in 2017
 - More in 2018
 - Comprehensive NGFA FSMA Guidance Document – www.ngfa.org





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



Menu ▾

FSPCA Preventive Controls for Animal Food

Training

[FSPCA Preventive Controls for Animal Food Course](#)

[FSPCA Preventive Controls for Animal Food Lead Instructor Training](#)

[FSPCA Preventive Controls for Animal Food Course AND Lead Instructor Training](#)

[Selection Criteria for Lead Instructor](#)

[Animal Food Lead Instructor Course Schedule](#)

FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD

COURSE DESCRIPTION

The *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Animal Food* regulation (referred to as *the Preventive Controls for Animal Food* regulation) is intended to ensure safe manufacturing/processing, packing and holding of food products for human consumption in the United States. The regulation requires that certain activities must be completed by a “preventive controls qualified individual” who has “successfully completed training in the development and application of risk-based preventive controls, or is otherwise qualified through job experience to develop and apply a food safety system”. This course

« FSPCA HOME

- + THE ALLIANCE
- COURSES
 - + FOREIGN SUPPLIER VERIFICATION PROGRAMS (FSVP)
 - INTENTIONAL ADULTERATION
 - **FSPCA PREVENTIVE CONTROLS FOR ANIMAL FOOD**
 - FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD
- LEAD INSTRUCTOR
- TECHNICAL ASSISTANCE NETWORK (TAN) DATABASE
- + RESOURCES
- + FAQ
 - INTERNATIONAL
 - INTENTIONAL ADULTERATION
- + COMMITTEES
- + NEWS
- RETURN TO IFSH

21 CFR PART 1 – Sanitary Transportation of Human and Animal Food

- **Subpart O**

- **General Provisions** – 1.900 Who is subject?
- **Vehicles and Transportation Equipment** – 1.906 What requirements apply to vehicles and transportation equipment?
- **Transportation Operations – 1.908 What requirements apply to transportation operations?**
- **Training** – 1.910 What training requirements apply to carriers engaged in transportation operations?
- **Records** – 1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?
- **Waivers**



FEDERAL REGISTER

Vol. 81

Wednesday,

No. 66

April 6, 2016

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11

Sanitary Transportation of Human and Animal Food; Final Rule

21 CFR PART 1 – Sanitary Transportation of Human and Animal Food

- **Generally**, applies to:
 - Intrastate and interstate food transportation, including grain and feed
 - Truck and rail transportation operations, not waterborne or air
- Compliance dates
 - “Large Businesses” – April 6, 2017
 - “Small Businesses” – April 6, 2018
- Exempt transportation activities include:
 - Activities performed by a “farm”
 - Activities performed by “non-covered businesses.” A “non-covered business” is defined as “a shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000 in average annual revenues

Requirements for Shippers

- Shippers must specify in writing to the carrier and, when necessary, to the loader, all sanitary specifications necessary for the carrier's vehicle and transportation equipment pursuant to the product to be transported
 - One time notification is sufficient, unless specifications change
- Shippers must develop and implement written procedures to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition
- Shippers of food transported in bulk must develop and implement written procedures to ensure that a previous cargo does not make the food unsafe



21 CFR PART 1 – Sanitary Transportation of Human and Animal Food

- **NO** requirement for “Shipper” or “Loader” to know last load hauled, cleanout information, but “Shipper” needs to establish adequate written procedures to ensure a prior load does not cause food to become unsafe during transportation
- **NO** training requirements, except for carriers when the carrier agrees to take on responsibility under rule
- “Loaders” are to determine that conveyances are suitable for bulk cargoes prior to loading

PART 1 – Sanitary Transportation Inspections

- Inspections likely to begin fall 2018
- For grain and feed facilities, inspections likely will be combined with evaluation of other topics, e.g., CGMPs/PCs, BSE, general sanitation, etc.
- FDA has issued “[Small Entity Compliance Guide](#)”

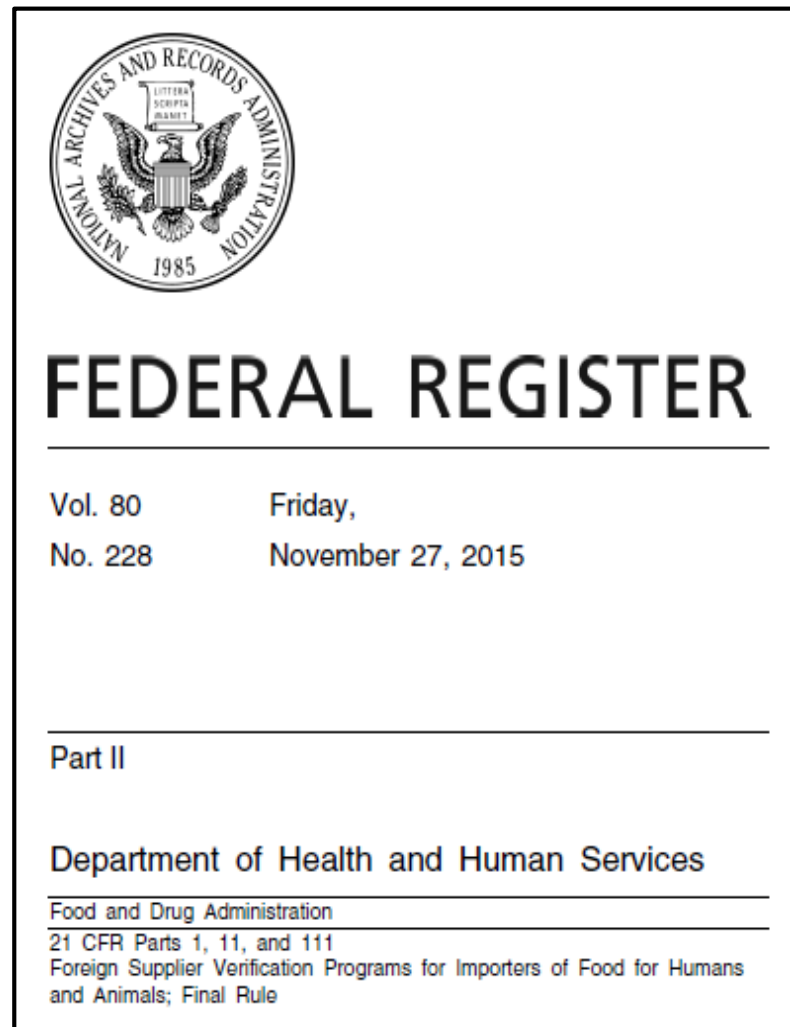
NGFA Sanitary Transportation Focus

- Efficient exchange of relevant information between affected parties
 - Last load hauled, cleanout info
 - Conveyance appropriate for product hauled
- Best Practices – NGFA leading a coalition of stakeholders to discuss/develop best transportation practices



21 CFR PART 1 – Foreign Supplier Verification Program for Food Importers

- **Subpart L**
 - **1.501 To what foods do the regulations in this subpart apply?**
 - **1.502 What foreign supplier verification program (FSVP) must I have?**
 - 1.503 Who must develop my FSVP and perform FSVP activities?
 - **1.504 What hazard analysis must I conduct?**
 - **1.505 What evaluation for foreign supplier approval and verification must I conduct?**
 - 1.506 What foreign supplier verification and related activities must I conduct?



21 CFR PART 1 – Foreign Supplier Verification Program for Food Importers

- Currently applies to:
 - Foreign foods, including raw agricultural commodities – grain, oilseeds
 - Importers of the foreign food, including brokers with no facility. Users of foreign food are not covered if they are not the importer
- Importer is required to perform a hazard evaluation of foreign food to identify if any hazards exist that require control
- Hazard evaluation and controls, if needed, are subject to FDA review
 - Under this rule, FDA has authority to request that importer send FSVP to FDA upon request

21 CFR PART 1 – Foreign Supplier Verification Program for Food Importers

- Compliance dates are complicated....
 - Depends on applicable compliance dates for importer and foreign supplier under other FSMA rules
 - Earliest date – May 30, 2017

The following compliance dates are grouped according to the category of FSVP importer. **This list does not include importers that are themselves a manufacturer or processor subject to the supply-chain program provisions in the PC rules.** If importers are subject to the supply-chain program requirements in those rules, the compliance date for FSVP is the later of the applicable date in the below list or the date by which the importer is required to comply with the PC supply-chain program provisions.

1. **FSVP importer whose foreign supplier is not subject to the PC or produce safety rules: May 30, 2017**
2. **FSVP importer whose foreign supplier is required to comply with the PC rule for human food.** Compliance dates when foreign suppliers are in these categories:
 - Small businesses as defined in 21 CFR 117.3: **March 19, 2018**
 - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 117.3: **March 18, 2019**
 - Suppliers subject to the Pasteurized Milk Ordinance: **March 18, 2019**
 - "All Other" Businesses Suppliers: **May 30, 2017**
3. **FSVP importer of animal food whose foreign supplier is subject to the current good manufacturing practices ("CGMP") requirements in subpart B of 21 CFR part 507 in the PC rule for animal food.** Compliance dates when foreign suppliers are in these categories:
 - Small Businesses as defined in 21 CFR 507.3: **March 19, 2018**
 - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: **March 18, 2019**
 - "All Other" Businesses: **May 30, 2017**
4. **FSVP importer whose foreign supplier is required to comply with the animal food preventive controls requirements in subpart C of part 507 of the PC rule for animal food, but that is not required to comply with the CGMP requirements in subpart B of 21 CFR part 507.** Compliance dates when foreign suppliers are in these categories:
 - Small Businesses as defined in 21 CFR 507: **March 18, 2019**
 - Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3: **March 17, 2020**
 - "All Other" Businesses: **March 19, 2018**
5. **FSVP importer whose foreign supplier is required to comply with the produce safety rule, except for the requirements applicable to sprouts in subpart M of 21 CFR part 112.** Compliance dates when foreign suppliers are in these categories:
 - Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**
 - Very Small Businesses as defined in as defined in 21 CFR 112.3: **July 27, 2020**
 - "All Other" Businesses: **July 26, 2018**
6. **FSVP importer whose foreign supplier is required to comply with the requirements in the produce safety rule applicable to sprouts in subpart M of 21 CFR part 112.** Compliance dates when foreign suppliers are in these categories:
 - Small Businesses as defined in 21 CFR 112.3: **July 26, 2018**
 - Very Small Businesses as defined in 21 CFR 112.3: **July 29, 2019**

NGFA FSVP Focus

- Requirements potentially create WTO concerns for grains and oilseeds
- Gain regulatory discretion or exemption for grains and oilseeds from rule
 - Regulatory “equivalence” determinations with other countries do not provide relief for grain and oilseeds from requirements



Questions/Comments

- Further Contact Information:

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