


Dissecting the FSMA Animal Food Rule

American Agricultural Law Association Annual Symposium
Oklahoma City, Oklahoma
October 8, 2016


John Dillard
Olsson Frank Weeda Terman Matz PC
www.ofwlaw.com
(202) 789-1212
jdillard@ofwlaw.com
@DCAgLawyer



OFW
LAW
OLSSON FRANK WEEDA TERMAN MATZ PC

Overview


- Background
- Applicability & Exemptions
- Current Good Manufacturing Practice
- Hazard Analysis & Risk-Based Preventive Controls



John G. Dillard – jdillard@ofwlaw.com

Background


- Food Safety Modernization Act signed into law on January 4, 2011
- *CFS v. Hamburg*, 4:12-cv-04529 (N.D. Cal.) – Judge ordered FDA to issue major final rules by June 30, 2015
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
 - Proposed on October 29, 2013
 - Supplemental Proposal released on September 29, 2014
 - Final rule published in *Federal Register* on Sept. 10, 2015



John G. Dillard – jdillard@ofwlaw.com

Major Components

- CGMPs (Subpart B)
 - Manufacturing, processing, packing, and holding animal feed
- Preventive Controls (Subpart C)
 - If applicable:
 - Written food safety plan
 - Implement controls to mitigate identified hazards
- Supply-Chain Controls (Subpart E)
 - Risk-based supply chain program to control for hazards identified by facility




John G. Dillard – jdillard@ofwlaw.com

4

Applicability

- All animal food facilities registered under the Bioterrorism Act of 2002
 - Includes feed mills owned by integrators that service contract growers
- “Farms” are exempt
 - Must have common management/ownership of mill, birds, and farm in one general location
 - Mills serving contract growers are not deemed part of a farm

FDA has indicated that it will seek to place integrator mills that qualify as “farms” placed under the Animal Food Rule in the future




John G. Dillard – jdillard@ofwlaw.com

5

Compliance Timelines

| Business Size | CGMPs | Preventive Controls |
|---|----------------|--|
| Not “small” or “very small” | Sept. 19, 2016 | Sept. 18, 2017 |
| Small Business (Fewer than 500 full-time employees company-wide – including subsidiaries) | Sept. 18, 2017 | Sept. 17, 2018 |
| Very Small Business (Averages less than \$2.5 M in animal food sales + market value of animal food manufactured) | Sept. 17, 2018 | Sept. 17, 2019 (except records to demonstrate VSB status due by Jan. 1, 2017) |




John G. Dillard – jdillard@ofwlaw.com

6

Current Good Manufacturing Practices

- The Animal Food Rule CGMPs establish protocols for various aspect's of a plant's operation to ensure that the risk of a foodborne illness outbreak is minimized or eliminated
- Apply to all facilities, regardless of whether Preventive Controls are required


 John G. Dillard – jdillard@ofwlaw.com 7

CURRENT GOOD MANUFACTURING PRACTICES

 John G. Dillard – jdillard@ofwlaw.com 8



Personnel


- Establishment must take reasonable precautions and to ensure individuals working in direct contact with animal food, contact surfaces and packaging materials conform to hygienic practices to protect against contamination
- Includes:
 - Maintaining adequate personal cleanliness
 - Washing hands thoroughly as necessary and appropriate
 - Removing or securing jewelry and other objects that could fall into feed
 - Storing clothing and personal belonging in areas separate from exposed feed or cleaning stations (e.g., cell phones, tools)
 - Taking any other necessary precautions to prevent contamination

 John G. Dillard – jdillard@ofwlaw.com 9

Plant & Grounds


- Grounds surrounding plant must be maintained to protect against contamination
 - Storing equipment;
 - Removing litter;
 - Trimming grass and weeds to prevent pest attraction;
 - Maintaining roads, yards, and parking lots to prevent contamination of exposed animal feed;
 - Draining areas of standing water; and
 - Treating and disposing of waste to prevent pest attraction




John G. Dillard – jdillard@ofwlaw.com10

Plant & Grounds


- Plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control
 - Providing sufficient space for equipment and storage of materials;
 - Allowing for proper precautions to reduce contamination of animal food, contact surfaces, packaging materials;
 - Protecting bulk containers stored outside a facility;
 - Allowing for adequate cleaning of floors, walls & ceilings; and
 - Provide adequate lighting, ventilation & screening to protect against pets
- Plant must also protect any feed stored outdoors from contamination



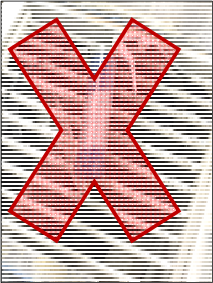
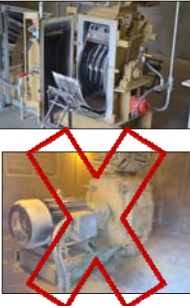
John G. Dillard – jdillard@ofwlaw.com11

Sanitation

- Plant buildings, equipment, & utensils to be maintained such that contamination with animal food, contact surfaces, & packaging is prevented
 - contact surfaces must be cleaned & appropriately sanitized & non-contact surfaces must be cleaned at appropriate intervals to prevent contamination
 - proper storage & usage of cleaning compounds & sanitizing agents, especially toxic materials
 - prevention of pest contact with animal food, contact surfaces, & packaging materials

John G. Dillard – jdillard@ofwlaw.com12

Sanitation



OFW John G. Dillard – jdillard@ofwlaw.com 13

Water Supply & Plumbing

- Water must be adequate for the operations and derived from an adequate source
- Running water must be available at suitable temperature and suitable temperature in all areas required for plant
- Water must be safe for its intended use
- Drainage and sewage systems must be adequate to prevent contamination of feed
- Employees must have adequate toilet facilities and handwashing stations

OFW John G. Dillard – jdillard@ofwlaw.com 14


Equipment and “Utensils”

- Equipment & utensils must be designed so can be regularly cleaned
 - Design must prevent contamination with lubricants, fuels, metal fragments, & contaminated water
 - Surfaces must resist corrosion & be made of materials that can withstand working environment & necessary cleaning compounds & sanitizing materials
 - Cold storage units must be fitted with thermometers & temperature recording devices
 - Instruments & controls used to measure, regulate, or record temperatures, pH, aw, & other devices must be accurate, precise & adequately maintained

OFW John G. Dillard – jdillard@ofwlaw.com 15




Plant Operations


- Oversight to ensure:
 - All operations conducted in accordance with adequate sanitation principles;
 - Containers labeled accurately as to contents;
 - Finished product labels contain proper animal-specific instructions;
 - Quality control operations are employed;
 - Competent supervisors are assigned responsibility of ensuring plant sanitation;
 - All reasonable precautions against contamination taken;
 - Chemical, microbial, or extraneous-material testing procedures used (where necessary) to identify sanitation failures or contaminations; &
 - Contaminated animal food rejected or reworked (if allowed) to eliminate contamination

 John G. Dillard – jdillard@ofwlaw.com 16

Plant Operations


- Controls to ensure raw products are safe
 - Before processing raw product inspected to ensure clean & suitable for processing
 - Cannot contain microorganisms at a level harmful to human or animal health
 - If possible, heat treatment can be used to reduce microorganism populations
 - Particular care must be given to materials susceptible to aflatoxin and other natural toxins




 John G. Dillard – jdillard@ofwlaw.com 17

Holding and Distribution

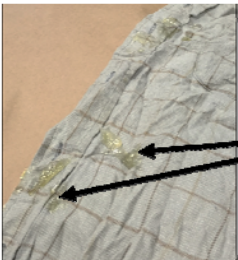
- Storage & distribution of animal food must be conducted under conditions that protect against:
 - Biological;
 - Chemical;
 - Physical;
 - Radiological contamination; and
 - Deterioration of animal food & containers

 John G. Dillard – jdillard@ofwlaw.com 18


CGMP QUIZ!

 John G. Dillard – jdillard@ofwlaw.com 19

Which CGMP does this Concern?

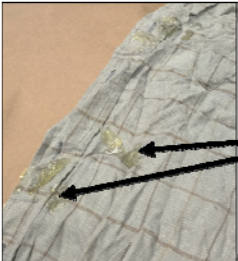
 **Petroleum-based grease on employee's shirt**

Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual


 John G. Dillard – jdillard@ofwlaw.com 20

Which CGMP does this Concern?

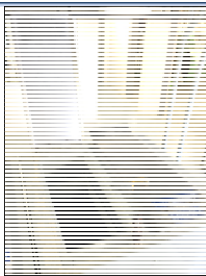
§ 507.14(b)(1) Personnel – Maintaining adequate personal cleanliness

 **Petroleum-based grease on employee's shirt**

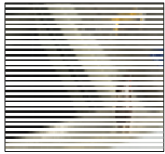
Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

 John G. Dillard – jdillard@ofwlaw.com 21

Which CGMP does this Concern?



Sunglasses and utility knife at open microingredient bin



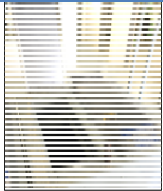
Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

OFW
John G. Dillard – jdillard@ofwlaw.com

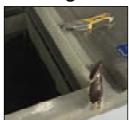
22

Which CGMP does this Concern?

§ 507.14(b)(3) Personnel – Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers
§ 507.14(b)(4) Personnel – Storing clothing or personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned



Sunglasses and utility knife at open microingredient bin




Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

OFW
John G. Dillard – jdillard@ofwlaw.com

23

Which CGMP does this Concern?




Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

OFW
John G. Dillard – jdillard@ofwlaw.com


24

Which CGMP does this Concern?

§ 507.17(a)(1) Plant and grounds– Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests




Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual


 John G. Dillard – jdillard@ofwlaw.com

25

Which CGMP does this Concern?




Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

 John G. Dillard – jdillard@ofwlaw.com


26

Which CGMP does this Concern?

§ 507.17(a)(4) Plant and grounds– Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed

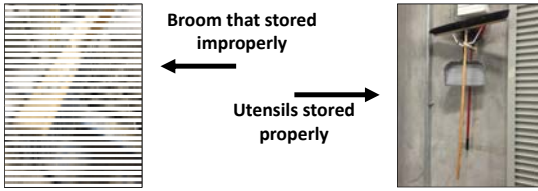


Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

 John G. Dillard – jdillard@ofwlaw.com

27

Which CGMP does this Concern?



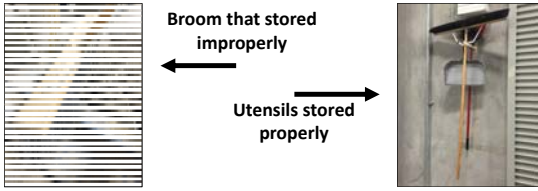
Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

OFW
John G. Dillard – jdillard@ofwlaw.com

28

Which CGMP does this Concern?

§ 507.19(b) Sanitation – Animal food-contact and noncontact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food packaging materials. When necessary, equipment must be disassembled for thorough cleaning.



Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

OFW
John G. Dillard – jdillard@ofwlaw.com

29

PREVENTIVE CONTROLS


OFW
John G. Dillard – jdillard@ofwlaw.com

30

Applicability and Exemptions – Qualified Facility


- Small businesses & very small businesses are subject to modified requirements
- A “qualified” facility must notify FDA about its qualified status and either:
 - Notify FDA that it is addressing hazards (that require controls) through preventive controls and monitoring; OR
 - Notify FDA every 2 years (concurrent with registration renewal) that:
 - It complies with non-federal food safety regulations; and
 - Notify consumers of the name and complete business address of the facility where the feed was manufactured or processed

FDA can withdraw a facility’s “qualified” status: (1) in the event of an active investigation of an outbreak linked to the facility; or (2) if FDA determines that it is necessary to protect public health (human or animal) and prevent or mitigate outbreak

John G. Dillard – jdillard@ofwlaw.com31


Applicability and Exemptions

- Total Exemptions
 - Low-risk, on-farm activities performed by small businesses and very small businesses
 - E.g., re-packaging feed or cracking grains
 - Facilities solely engaged in the storage of raw agricultural commodities
 - Facilities solely engaged in the storage of unexposed, packaged feed that does not require time/temperature controls to minimize or prevent the growth of toxin production by pathogens

John G. Dillard – jdillard@ofwlaw.com32

Applicability and Exemptions – Preventive Controls

- If no exemption applies, then a facility must conduct a hazard analysis
- If the hazard analysis identifies a “hazard requiring a preventive control,” then the facility must implement preventive controls

John G. Dillard – jdillard@ofwlaw.com33

What is a hazard requiring a preventive control?

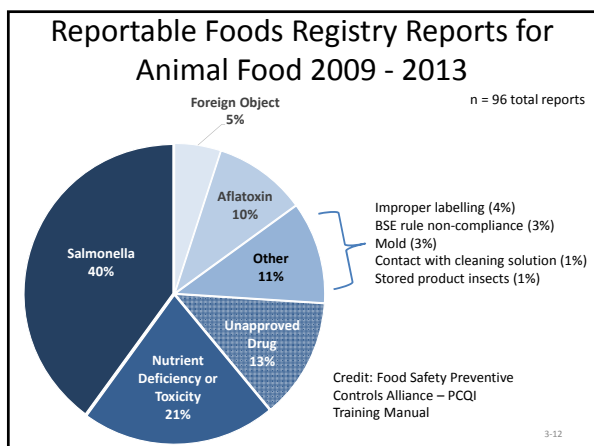
Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

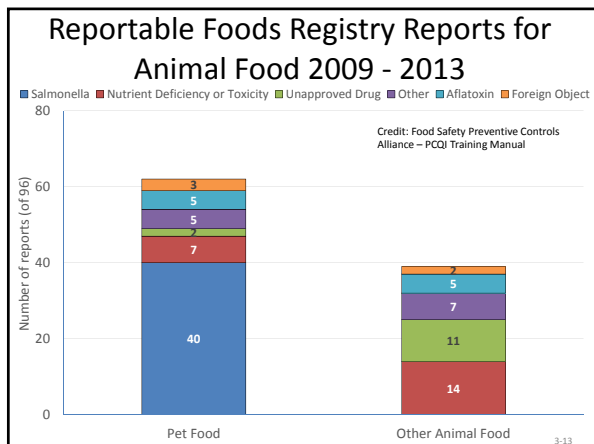
John G. Dillard – jdillard@ofwlaw.com 34

What is a hazard requiring a preventive control?

- Hazard is not:
 - Violation of regulatory standards not directly related to food safety or other regulations, such as misbranding
 - Labeling requirements
 - Economic fraud
 - Product quality

John G. Dillard – jdillard@ofwlaw.com 35





What is a hazard requiring a preventive control?

- Biological hazards:
 - *Salmonella* spp.
 - *Listeria monocytogenes*
- Chemical hazards:
 - Mycotoxins
 - Pesticides residues, industrial chemicals
 - Drug carryover
 - Nutrient deficiencies or toxicities
- Physical Hazards
 - Stones
 - Glass
 - Debris

Credit: Food Safety Preventive Controls Alliance – PCQI Training Manual

John G. Dillard – jdillard@ofwlaw.com

38

Food Safety Plan


- Must be prepared and implemented by a “preventive controls qualified” individual
- Includes:
 - Written hazard analysis
 - Written preventive controls
 - Written supply-chain program
 - Written recall plan
 - Written preventive controls monitoring procedures
 - Written corrective action procedures
 - Written verification procedures

John G. Dillard – jdillard@ofwlaw.com

39

Hazard Analysis

- Identify and evaluate known or reasonably foreseeable hazards for each feed to determine whether any hazards require preventive controls
 - Biological (including microorganisms)
 - Chemical
 - Physical
- Known or reasonably foreseeable hazards include:
 - Naturally-occurring hazards
 - Unintentionally-introduced hazards
 - Hazards intentionally introduced for economic gain




John G. Dillard – jdillard@ofwlaw.com

40

Hazard Analysis

- Consideration must be given to:
 - formulation of animal food;
 - condition, function, & design of plant & equipment;
 - raw materials & ingredients;
 - transportation practices;
 - manufacturing/processing procedures;
 - packaging activities & labeling activities;
 - storage & distribution;
 - intended or reasonably foreseeable use;
 - sanitation, including employee hygiene; &
 - any other relevant factors




John G. Dillard – jdillard@ofwlaw.com

41

Preventive Controls

- Process Controls
 - Procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiation, and refrigeration, including:
 - Parameters associated with the control of the hazard; and
 - The maximum or minimum value, or combination of values to which any hazard must be controlled
- Sanitation Controls
 - Procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to significantly minimize or prevent hazards, such as environmental pathogens and biological hazards
- Supply Chain Controls
 - Must comply with Subpart E (discussed later)
- Recall Plan
 - There must be a recall plan for each feed requiring a preventive control




John G. Dillard – jdillard@ofwlaw.com

42


Preventive Controls Qualified Individual

- PCQI is a qualified individual who has either:
 - Successfully completed certain 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
- Each facilities preventive controls and food safety plan must be overseen by a PCQI

 John G. Dillard – jdillard@ofwlaw.com 43


Preventive Controls Management – Required Procedures

- **Monitoring**
 - Monitor the preventive controls with adequate frequency to provide assurance that they are adequately performed
- **Corrective actions and corrections**
 - Corrective action procedures must describe steps to ensure:
 - Appropriate action taken to ID and correct problem with implementation of a preventive control;
 - Appropriate action to reduce reoccurrence;
 - All affected animal food is evaluated for safety; and
 - All affected food is prevented from entering commerce

 John G. Dillard – jdillard@ofwlaw.com 44

Preventive Controls Management – Required Procedures

- **Verification activities**
 - Document verification and validation activities to ensure that preventive controls are consistently implemented and mitigate risk to health to humans and animal


 John G. Dillard – jdillard@ofwlaw.com 45

SUPPLY-CHAIN CONTROLS

 John G. Dillard – jdillard@ofwlaw.com **46**


Supply-Chain Controls

- Risk-based supply chain program required for raw materials and ingredients if they require a supply-chain-applied control program
 - E.g., aflatoxin in corn
- Facilities are required to ensure raw materials requiring controls are received from
 - Approved supplier, or
 - On a temporary basis only, from suppliers subject to verification activities
- Receiving facility will not have to implement a preventive control, but must disclose that feed is “not processed to control (identified hazard)”

 John G. Dillard – jdillard@ofwlaw.com **47**

Supply-Chain Controls – Program Requirements

- Using approved suppliers;
- Determining appropriate supplier verification activities;
- Conducting supplier verification activities;
- Documenting supplier verification activities; and
- When applicable, verifying a supply-chain applied control applied by an entity other than the receiving facility’s supplier and documenting that verification

 John G. Dillard – jdillard@ofwlaw.com **48**


**Supply-Chain Controls –
Verification Activities**

- Annual on-site audits
- Sampling and testing
- Review of the suppliers food safety records
- Other activities based on the risk


 John G. Dillard – jdillard@ofwlaw.com 49

**Supply-Chain Controls –
Recordkeeping Requirements**

- Documentation that a receiving facility is an importer is in compliance with the FSVP rule
- Supplier approval
- Procedures for receiving raw materials and other ingredients
- Demonstration of the use of the written procedures for receiving raw materials and other ingredients
- Determination of the appropriate supplier verification activities for raw materials and other ingredients
- Onsite audits
- Sampling and testing records
- Review of the supplier's food safety records
- Documentation of other verification activities


 John G. Dillard – jdillard@ofwlaw.com 50

RECORDKEEPING REQUIREMENTS

 John G. Dillard – jdillard@ofwlaw.com 51

Recordkeeping Requirements

- Two-year retention requirement
 - All records required under the Animal Food Rule relating to preventive controls must be maintained for two years
 - Records demonstrating “qualified” status must be kept 3 years
- Remote record storage
 - All records except the written food safety plan may be stored electronically or remotely
 - Must be retrieved and onsite within 24 hours of request
- Food safety plan
 - Physical copy must be maintained onsite
- Use of existing records
 - Records that are kept to comply with other federal, state, or local regulations do not need to be duplicated
 - Records for the Animal Food Rule does not need to be kept in one set
- Records Availability
 - Records required under the rule must be made available to an authorized representative of HHS for official review and copying upon oral or written request




John G. Dillard – jdillard@ofwlaw.com

52

Dissecting the FSMA Animal Food Rule

American Agricultural Law Association Annual Symposium
Oklahoma City, Oklahoma
October 8, 2016

John Dillard
Olsson Frank Weeda Terman Matz PC
www.ofwlaw.com
(202) 789-1212
jdillard@ofwlaw.com
@DCAgLawyer



OFW
LAW
OLSSON FRANK WEEDA TERMAN MATZ PC

