FSMA is Here … Let's Roll

December 10, 2015

growing ADVANTAGE
The Almond Conference

Speakers

Brian Dunning, Blue Diamond Growers
(Moderator)

Maile Hermida, Hogan Lovells

Brian Dunning,
Blue Diamond Growers

growing ADVANTAGE
The Almond Conference

Maile Hermida, Hogan Lovells

growing ADVANTAGE
The Almond Conference

Hogan Lovells

FSMA is Here…Let's Roll!

Presentation to the Almond Board of California

Maile Gradison Hermida, Senior Associate

December 10, 2015

Agenda

- Overview of major FSMA rules
- Key definitions
- Almond industry activities that trigger certain FSMA requirements
- Summary of applicable FSMA requirements
- Compliance dates
- Enforcement

FSMA Overview

- Law enacted January 4, 2011
- U.S. Food and Drug Administration (FDA) responsible for implementation
- 3 major FSMA rules now final and coming into effect
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Food
    - Including human food by-products sent to animal food use
  - Produce Safety Standards


FEDERAL REGISTER

Vol. 80 Thursday,
No. 180 September 17, 2015

Part II

Department of Health and Human Services

Preventive Controls Regulation

- Updated GMPs
- Established new requirements for preventive controls
- Updated definitions of key terms relating to facility registration and affecting legal responsibilities (e.g., “farm”)

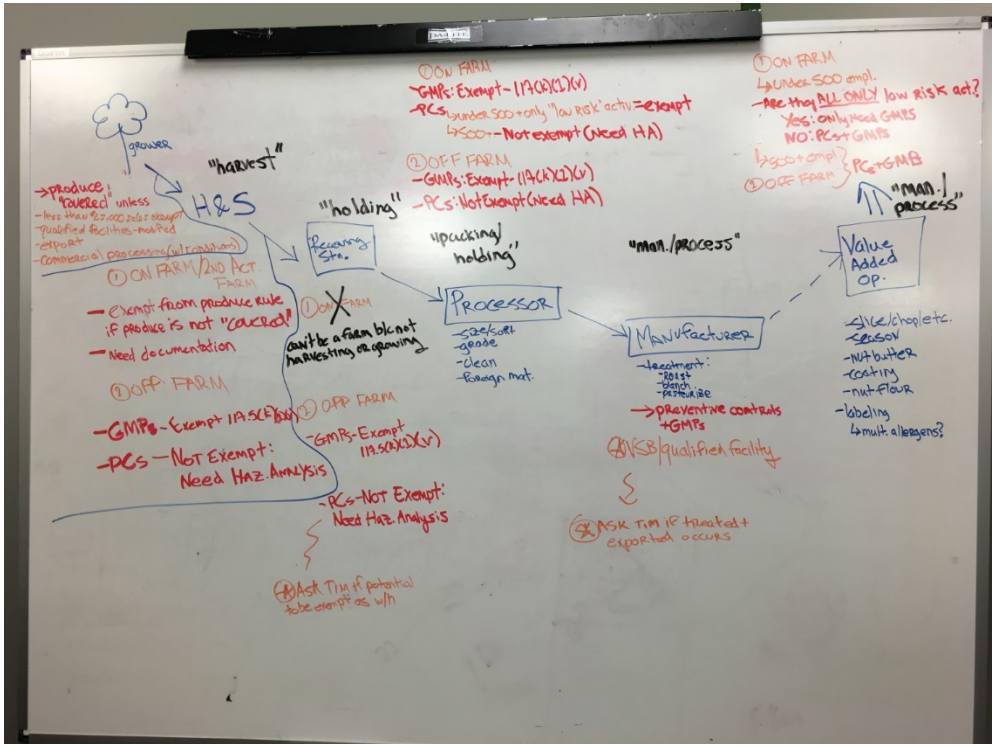
Produce Safety Regulation

- Documentation of commercial processing is needed to “opt out”
- Requirements for:
  - Worker training
  - Health and hygiene
  - Agricultural water
  - Biological soil amendments
  - Domesticated and wild animals
  - Growing, harvesting, packing, and holding
  - Equipment, tools, and buildings

What FSMA Means for You

- Determining the regulations that apply to your business and what you need to do to comply, is very case-specific
  - Consider applicability of both
    (1) GMPs, and
    (2) Preventive Controls
- Key issues include:
  - Location of the operation
  - Ownership structure
  - Company size
  - Activities performed
    - Growing
    - Hulling and Shelling
    - Handling
    - Manufacturing
- **Note: Conducting multiple activities can change your compliance obligations!**

It’s Complicated!



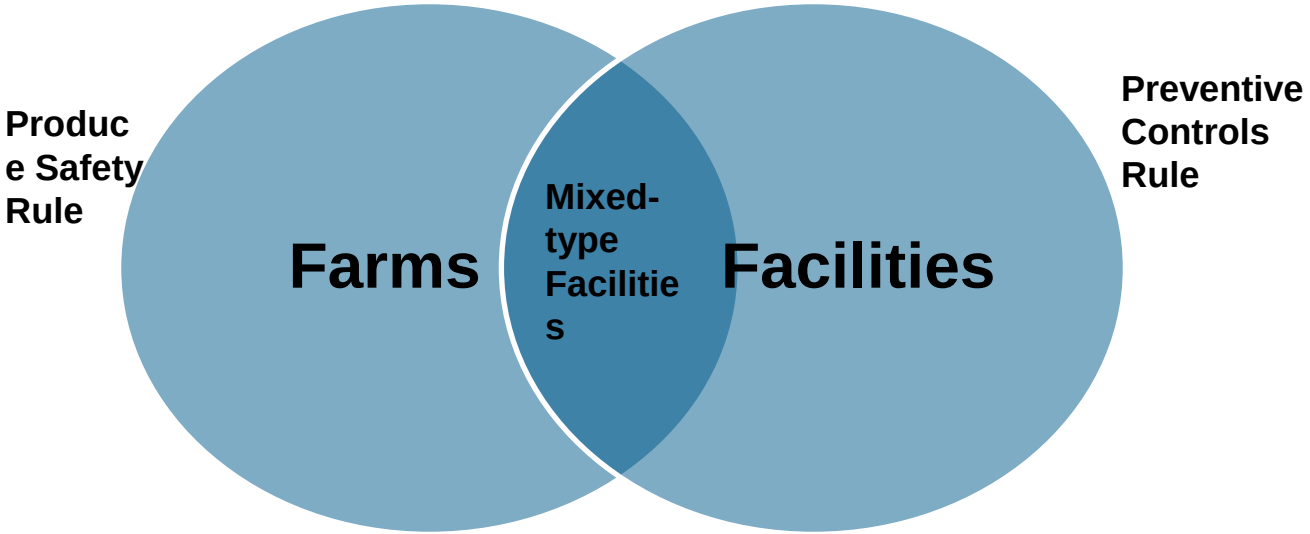
** Don’t rely on this brainstorming as legal advice!

Key Definitions

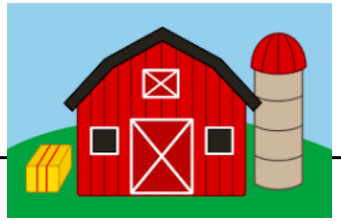
Introduction

- Through the FSMA rulemaking, FDA has updated key definitions for terms describing certain operations/activities
- Many of these are the same terms used in the almond industry, but they have a different meaning
- The meaning matters, because whether you engage in these operations/activities (and where you do so) affects which rules you must comply with

Introduction



“Farm” Definition



- Primary Production Farm:
  - Operation under one management in one general (but not necessarily contiguous) location devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
  - In addition to these activities, may also pack or hold raw agricultural commodities (RACs)

Farm Definition Continued..

- Secondary Activities Farm:
  - Operation, not located on a primary production farm, devoted to harvesting, packing, and/or holding of RACs
  - Provided the majority of the product harvested or packed by the secondary activities farm must have been grown by the majority owner (or joint ownership) of the secondary activities farm

Harvesting

- Activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food
- Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Packing

- Placing food into a container other than packaging the food
- Includes re-packing and activities performed incidental to packing or re-packing a food
  - *e.g.,* activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)
- Does not include activities that transform a raw agricultural commodity into a processed food

Holding

- Storage of food and also includes activities performed incidental to storage of a food
  - *e.g.,* activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)
- Includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food
- Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Facility

- Domestic and foreign entities engaged in:
  - Manufacturing/Processing
  - Packing
  - Holding

  Food for consumption in the United States

Manufacturing/Processing

- Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients
  - Examples include: Baking, boiling, cooking, cooling, cutting, formulating, grinding, homogenizing, labeling, milling, mixing, packaging, pasteurizing, peeling, washing
- For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding

Almond Industry Activities

Types of Almond Operations

- Growers
- Hullers and Shellers
- Handlers
  - Sizing, sorting, grading
  - Cleaning (separating out foreign material)
  - Bulk packing
- Manufacturers
  - Treat almonds through pasteurization, roasting, and/or blanching
- Value Added Operations
  - Slicing, chopping
  - Seasoning, coating
  - Making nut butters, nut flour
  - Labeling
  - Packaging

Growers

- Are “raising” crops and therefore are “farms”
- Subject to the Produce Safety Rule unless:
  - Annual sales of food are less than $25,000
  - Qualified farms (subject to modified requirements)
    - To be explained later in presentation
  - The almonds will receive commercial processing that adequately reduces the microorganisms of public health significance (e.g., pasteurization), provided the grower and its customer(s) have and provide written attestations to that effect
    - To be explained in more detail later in presentation

Hullers and Shellers

- *Activity Performed: "Harvesting"*
- Located on Primary Production Farms and on Secondary Activities Farms
  - Exempt from Produce Safety Rule if the produce is not "covered"
    - Need written assurances
- Located Off-Farm
  - Exempt from GMPs (if solely engaged in hulling, shelling, drying, packing and/or holding nuts)
  - Covered by the Preventive Controls Rules
    - Will need a written hazard analysis, at a minimum

Handlers

- *Activities Performed: "Packing" and "Holding"*
- Located on Primary Production Farms and on Secondary Activities Farms
  - Exempt from GMPs
  - If (1) under 500 FTE employees *and* (2) only perform the following designated "low risk" activities, then exempt from preventive controls
    - Packing (or repacking) (including weighing or conveying incidental to packing or repacking);
    - Sorting, culling, or grading incidental to packing or storing; and
    - Storing (ambient, cold and controlled atmosphere)
- Located Off-Farm
  - Exempt from GMPs (if no manufacturing/processing)
  - Covered by the Preventive Controls Rules
    - Will need a written hazard analysis, at a minimum

Manufacturers

- *Activities Performed: “Manufacturing/Processing”*
- Located on Primary Production Farms, Secondary Activities Farms, or Off-Farm
  - Covered by GMPs
  - Covered by the Preventive Controls Rule

- Note: If “on-farm” then considered a “mixed type facility” and only manufacturing/processing activities covered by the PC rule, “farm” activities are not covered by PC

Value Added Operations

- *Activities Performed: "Manufacturing/Processing"*
- Located on Primary Production Farms, Secondary Activities Farms, or Off-Farm
  - If (1) under 500 FTE employees and (2) only perform designated "low risk" activities (on the next slide), then:
    - Covered by GMPs
    - Exempt from Preventive Controls
  - Otherwise, covered by GMPs and preventive controls
- Located Off-Farm
  - Covered by GMPs
  - Covered by the Preventive Controls Rule

On-Farm Low-Risk Exemption

- **Chopping, coring, cutting, peeling, pitting, shredding, and slicing** almonds
- **Coating** dried/dehydrated almonds (*e.g.,* adding seasonings provided that the seasonings have been treated to significantly minimize pathogens)
- **Grinding/cracking/crushing/milling** almonds
- **Labeling** almond products (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (*e.g.,* roasted or seasoned whole nuts, single-ingredient almond flours))
- **Making candy** from almonds (*e.g.,* nut brittles)
- **Making trail mix and granola** from almond products, provided that almonds are treated to significantly minimize pathogens
- **Mixing** almond products
- **Packaging** almond products
- **Salting** almond products for direct consumption
- **Sifting** almond products (*e.g.,* almond flour)
- **Packing or holding** almond products

<u>This is an exhaustive list!</u>

Preventive Controls Requirements

Overview of Preventive Controls Requirements

- Conduct hazard analysis
- Identify and implement preventive controls
- Apply the management components, as appropriate and necessary based on the nature of the preventive control and its role
  - Monitoring
  - Verification
  - Validation
  - Corrective Actions
- Document everything

What is a Food Safety Plan?

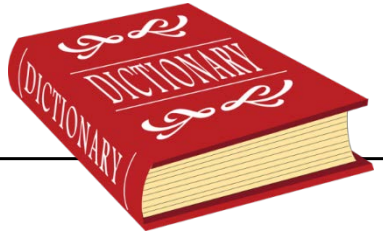
The written food safety plan must include:

- (1) The written hazard analysis as required by § 117.130(a)(2);
- (2) The written preventive controls as required by § 117.135(b);
- (3) The written supply-chain program as required by subpart G;
- (4) The written recall plan as required by § 117.137(a);
- (5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);
- (6) The written corrective action procedures as required by § 117.150(a)(1); and
- (7) The written verification procedures as required by § 117.165(b).

Hazard Analysis – Basic Requirement

- Identify and evaluate, based on experience, illness data, scientific reports, and other information “known or reasonably foreseeable hazards” for each type of food manufactured, processed, packed, or held at your facility to determine whether there are “any hazards requiring a preventive control”
- Must be written regardless of outcome (i.e., even if you conclude there are no hazards requiring a preventive control)

Definitions



- "Hazard":
  - Any biological, chemical (including radiological), or physical agent that **has the potential to cause illness or injury**
- "Known or Reasonably Foreseeable Hazard":
  - A biological, chemical (including radiological), or physical hazard that is known to be or has the potential to be associated with the facility or the food
- "Hazard Requiring a Preventive Control":
  - A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (including an assessment of the severity of illness or injury if the hazard were to occur and the probability that it will occur in the absence of preventive controls), establish one or more preventive controls to SMOP the hazard and components to mange those controls

Hazard Identification

- Biological, including microbiological hazards (e.g., parasites, environmental pathogens, and other pathogens)
- Chemical, including radiological hazards, pesticide residues, drug residues, natural toxins, decomposition, unapproved food and color additives, and food allergens
- Physical, such as stones, glass, metal fragments
- Hazards may be naturally occurring or unintentionally introduced
- Hazards that may be intentionally introduced for economic gain (EMA)

Hazard Evaluation

- The hazards identified must be evaluated to assess:
  - (1) the severity of the illness or injury if the hazard would occur, and
  - (2) the probability that the hazard will occur in the absence of preventive controls
- Environmental pathogens must be evaluated whenever a ready-to-eat food is exposed to the environment before packaging, when a lethality treatment is not applied to the packaged food

Hazard Evaluation

- The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:
  - The formulation of the food
  - The condition, function, and design of the facility and equipment
  - Raw materials and ingredients
  - Transportation practices
  - Manufacturing/processing procedures
  - Packaging activities and labeling activities
  - Storage and distribution
  - Intended or reasonably foreseeable use
  - Sanitation, including employee hygiene
  - “Any other relevant factors” (such as temporal nature of some hazards)

Preventive Controls

- Identify and implement preventive controls to significantly minimize or prevent (SMOP) those hazards requiring a preventive control (i.e., make sure the food is not adulterated and does not contain any undeclared allergens)
- PC = “Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about [food safety] would employ to [SMOP] the hazards identified under the hazard analysis….”
    - Includes controls at CCPs, if any
    - Includes controls other than those at CCPs

Types of Preventive Controls

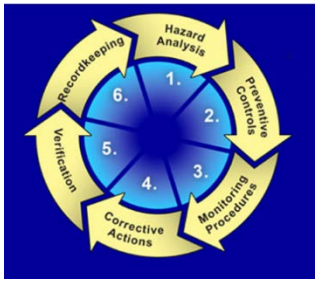
- Process controls
  - Including, as appropriate to the nature of the control and its role in the facility's food safety system, parameters and the min/max value to which the parameter must be controlled
- Food allergen controls
  - Protect food from allergen cross contact handling and use
  - Ensure proper labeling
- Sanitation controls
  - Cleanliness of food contact surfaces
  - Prevention of allergen cross contact tamination
- Supply-chain controls
- Recall plan
- Other controls

Exclusions from Preventive Controls

- Preventive controls are not required:
  - When the type of food could not be consumed without application of an appropriate control (e.g., coffee beans, cocoa beans, grains)
  - When a hazard is controlled by another entity later in the distribution chain (e.g., your customer)
    - Disclose that food is for further processing (e.g., “not processed to control *Salmonella*”)
    - Obtain assurances the hazard will be controlled, including an identification of the procedures
      - “Customer” = commercial customer, not a consumer
      - Customer must document compliance with its own procedures

Management Components

- Preventive controls are subject to the following management components, "*as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system*"
  - Monitoring
  - Corrective actions and corrections
  - Verification
  - Validation

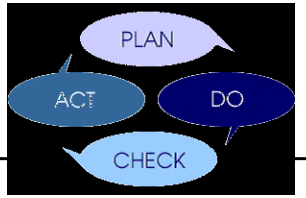


- Each management component is applied "*as appropriate to [the nature of] the preventive control and its role in the facility's food safety system*"

Monitoring Requirements

- Establish and implement written procedures for monitoring preventive controls, including frequency
  - Does not need to be continuous
- Monitoring activities must be:
  - Documented
    - Exception records permitted
  - Monitoring records are subject to verification, including records review

Corrective Actions



- Establish and implement written corrective action procedures to be used if the preventive controls are not properly implemented
  - Identify and correct the problem
  - Take action to reduce the likelihood of reoccurrence
  - Evaluate affected food for safety
  - Prevent food from entering commerce if its safety cannot be assured
- Procedures must address product testing and environmental monitoring results
- Can take “corrections” for isolated problems that do not impact product safety
  - Do not need to be documented

Verification Activities

- Must include “as appropriate to the preventive control and its role in the facility’s food safety system”
  - Validation
  - Verification that monitoring is being conducted
  - Verify that appropriate decisions about corrective actions are being made
  - Verification of implementation and effectiveness
  - Reanalysis
- All verification activities must be documented in records

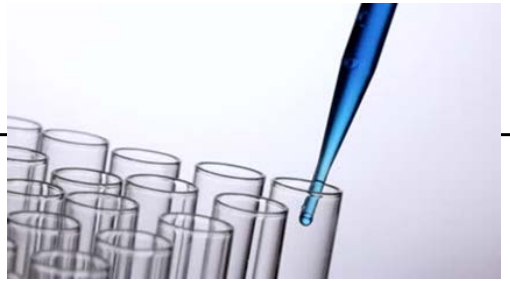
Verification of Implementation and Effectiveness

- As appropriate to the facility, the food, the nature of the control and its role in the facility's food safety system, verify the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards via:
  - Calibration of process monitoring instruments and verification instruments (or checking them for accuracy)
  - Product testing
  - Environmental monitoring
  - Records reviews
- Note: There is no requirement to review consumer complaints

Record Review Timing

- Records of monitoring and corrective actions
  - within 7 working days or
  - within reasonable timeframe, if written justification prepared
- Records of calibration, product testing, environmental monitoring, and supplier verification and other verification activities
  - within a reasonable time

Testing



- Product testing and environmental monitoring only are required “as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility’s food safety system”
  - Thus, the use of testing and program design is discretionary
- Based on their hazard analysis, some facilities may conclude that product testing and environmental monitoring are not required

Validation

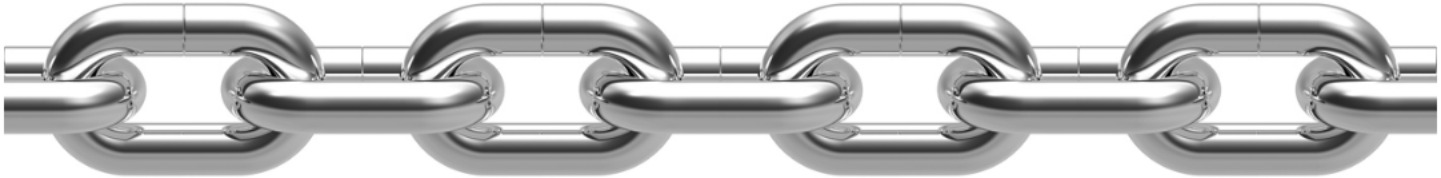
Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

- You generally need to validate process controls
- You do not need to validate:
  - Food allergen controls
  - Sanitation controls
  - The recall plan
  - The supply chain program
  - Other preventive controls, if you have a written justification

Reanalysis

- Required for the whole plan, or the applicable portion:
  - At least every 3 years (must be whole plan)
  - Whenever a significant change is made in the activities at the facility affecting the hazard analysis
  - Whenever the facility becomes aware of new information about potential hazards
  - Whenever appropriate after an “unanticipated food safety problem”
  - Whenever a preventive control, combination of PCs, or the plan as a whole is found ineffective
  - As mandated by FDA in response to new hazards and developments in scientific understanding

Supplier Verification



- Supply-chain controls are a type of preventive control
- Supplier verification is required whenever your supplier controls a hazard requiring a preventive control
- Linear approach, detailed requirements, and very record intensive

General Supplier Verification Requirements

1. Identify hazards controlled earlier in the supply chain (i.e., before receipt) and the suppliers that control those hazards
2. Determine appropriate verification activities and frequency of activities for each supplier
   - You “must” consider specified factors, including the supplier’s performance, food safety history, and compliance with FDA food safety regulations
3. Conduct verification activities
   - Annual audits required for SAHCODHA suppliers, unless you can support another approach
4. Take prompt corrective actions, as needed
5. Verify records
6. Document all decisions and activities

Supplier Verification Recordkeeping Requirements

56166 Federal Register / Vol. 80, No. 180 / Thursday, September 17, 2015 / Rules and Regulations

[redacted]

(3) Documentation of the approval of a supplier;
(4) Written procedures for receiving raw materials and other ingredients;
(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;
(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;
(7) Documentation of the conduct of an onsite audit. This documentation must include:
(i) The name of the supplier subject to the onsite audit;
(ii) Documentation of audit procedures;
(iii) The dates the audit was conducted;
(iv) The conclusions of the audit;
(v) Corrective actions taken in response to significant deficiencies identified during the audit; and
(vi) Documentation that the audit was conducted by a qualified auditor;
(8) Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include:
(i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested;
(ii) Identification of the test(s) conducted, including the analytical method(s) used;
(iii) The date(s) on which the test(s) were conducted and the date of the report;
(iv) The results of the testing;
(v) Corrective actions taken in response to detection of hazards; and
(vi) Information identifying the laboratory conducting the testing;
(9) Documentation of the review of the supplier's relevant food safety records. This documentation must include:
(i) The name of the supplier whose records were reviewed;
(ii) The date(s) of review;
(iii) The general nature of the records reviewed;
(iv) The conclusions of the review; and
(v) Corrective actions taken in response to significant deficiencies identified during the review;
(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;
(11) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans;
(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility:
(i) The written assurance that the supplier is a qualified facility as defined by § 117.3, before approving the supplier and on an annual basis thereafter; and
(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);
(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:
(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and
(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);
(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:
(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and
(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations

§ 117.475 Records documenting the supply-chain program.

(a) The records documenting the supply-chain program are subject to the requirements of subpart F of this part.
(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 117.165(a)(4).
(c) The receiving facility must document the following in records as applicable to its supply-chain program:
(1) The written supply-chain program;
(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification activities conducted under § 1.506(e) of this chapter;

Federal Register / Vol. 80, No. 180 / Thursday, September 17, 2015 / Rules and Regulations 56167

of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);
(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;
(16) Documentation of actions taken with respect to supplier non-conformance;
(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and
(18) When applicable, documentation of the receiving facility's review and assessment of:
(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;
(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;
(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;
(iv) Applicable documentation, from its supplier, of:
(A) The results of sampling and testing conducted by the supplier; or
(B) The results of an audit conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435; and
(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

There are <u>many</u> records required to comply with the supply-chain program

General Recordkeeping Requirements (Subpart F)

- Records must:
  - Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities
  - Be accurate, indelible, and legible
  - Be created concurrently with performance of the activity documented
  - Be as detailed as necessary to provide the history of the work performed
  - Include:
    - Information adequate to identify the plant/facility
    - The date and**, when appropriate,** the time of the activity documented
    - The signature or initials of the person performing the activity
    - Identity of the product and lot code (if any), where appropriate

Records Requirements

- Required records must be retained for at least 2 years after the date they were prepared
  - Records relating to general adequacy of equipment/processes being used by the facility (e.g., results of scientific studies used for validation) must be retained for 2 years after their use is discontinued
- All records, except for the food safety plan, can be stored offsite so long as they can be retrieved and provided onsite within 24 hours

Copying Records

- All required records must be made “promptly available” for official review and copying upon oral or written request
  - FDA intends to copy records on a case-by-case basis—and primarily when conducting an inspection for cause (e.g., outbreak investigation)

FOIA

- Records are subject to disclosure under the Freedom of Information Act (FOIA)
  - Food safety plans are expected to be exempt from public release as a “trade secret”
  - Disclosure of verification records, such as the results of product testing and environmental monitoring, would be evaluated on a case-by-case basis

Qualified Individuals and Employee Training

- All employees must be “qualified individuals”
  - The definition of “qualified individual” has changed -- “Qualified individual” now is defined more broadly, essentially to means that employees must be qualified to do their jobs
- All employees must receive training
  - Each individual engaged in manufacturing, processing, packing, or holding food, or in the supervision thereof, must receive training in principles of food hygiene and food safety, including employee health and personal hygiene
    - **Applies to GMPs and PCs**
  - Facilities must keep records of this required training

Preventive Controls Qualified Individual

- "Preventive controls qualified individual" must prepare or oversee certain preventive controls functions
  - A PCQI is a qualified individual who has successfully completed training in the development of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience…

Preventive Controls Qualified Individual Responsibilities (Must Do or Oversee)

- Preparation of the food safety plan
- Validation of preventive controls
  - Justification for validation timeframe
  - Justification for determining validation not required
- Review of records
  - Justification for timeframe for reviewing monitoring and corrective action records
- Reanalysis of the food safety plan
  - Determination of timeframe for reanalysis and validation of additional preventive controls

Updated cGMPs

- Now housed in 21 CFR Part 117, Subpart B
- Focus on protection against allergen cross-contact
- Food contact surfaces for low moisture foods must be in a clean, dry, and sanitary condition “prior to use” instead of “at the time of use”

Qualified Facility

- Exception from general PC and supply-chain requirements for (1) VSBs and (2) facilities with <$500,000 annual sales, primarily to qualified end-users
- Subject to modified requirements:
  - Determine and document status by July 1 of each year
  - Submit an attestation to FDA every 2 years that the facility is either (1) implementing & monitoring preventive controls to address potential hazards; or (2) in compliance with other non-federal food safety law (e.g., state or local law)
  - Maintain records supporting attestation (these do not need to be submitted with the attestation)
- Compliance date of January 1, 2016 for records to support the facility's status as a qualified facility

Warehouses

- Exemption from general preventive controls and supply-chain program requirements for facilities “solely engaged in storage of unexposed packaged foods”
  - Solely means solely
  - At a minimum, food must be in a form that prevents any direct human contact with the food

Animal Food Diversion by Manufacturers

- Specific GMPs apply to human food by-products held for distribution as animal food without further manufacturing or processing by the human food processor:
  - Held under conditions to protect against contamination
  - Labeled by the common or usual name during distribution
  - Shipping containers and bulk vehicles generally must be examined prior to use

Animal Food Diversion for Hullers & Shellers

If no manufacturing/processing (e.g., grinding):

- Located on Primary Production Farms and on Secondary Activities Farms
  - Exempt from GMPs and preventive controls
- Located Off-Farm
  - Exempt from GMPs
  - Subject to special GMP regulations requiring:
    - Food to be held under conditions to protect against contamination
    - Labeling with the common or usual name during distribution
    - Shipping containers and bulk vehicles generally must be examined prior to use

Animal Food Diversion for Hullers & Shellers

If manufacturing/processing (e.g., grinding):

- Located on Primary Production Farms and on Secondary Activities Farms
  - Covered by (full) animal food GMPs
  - Covered by PCs unless: (1) under 500 FTE employees *and* (2) only grind, label, package or hold almond hulls and shells
- Located Off-Farm
  - Covered by (full) animal food GMPs
  - Covered by animal food PCs

Produce Safety Rule

Produce that Receives Commercial Processing

- Produce that receives commercial processing that adequately reduces microorganisms of public health significance is exempt, provided certain conditions are met
  - Examples of commercial processing include processes that comply with LACF requirements, acidified food processes, juice HACCP, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer

Commercial Processing Exemption Continued…

- Farm must disclose in documents accompanying the produce that it is “not processed to adequately reduce the presence of microorganisms of public health significance”
- Farm must obtain annual written assurance from the customer that performs the commercial processing that it has established and is following procedures identified in the written assurance that adequately reduce the presence of microorganisms of public health significance

Commercial Processing Exemption Continued…

- If the farm's customer is not the processor, then it must obtain documentation from the customer that some other party in the distribution chain will process the produce and
  - It will make the requisite disclosure in documentation accompanying the produce
  - It will only sell to an entity that agrees in writing either
    - To follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance OR
    - obtain a similar written assurance from its customer
- Farm must keep documentation of its disclosures and annual written assurances

Requirements for Processors

- Commercial processors must:
  - Provide annual written assurances identifying the procedures they have established and will implement to adequately reduce microorganisms of public health significance
  - Document compliance with those procedures
- This applies to any entity that agrees to provide the written assurance

Applicability for Exports

- Almonds grown solely for export purposes are covered by the product rule in the same way as almonds grown for domestic consumption
- You still need documentation of commercial processing to be exempt!

Modified Requirements for Qualified Farms

- Qualified farms:
  - Must have food sales averaging less than $500,000 per year during the previous three years; and
  - The farm's food sales to consumers and/or local retailers and restaurants must exceed sales to all others combined during the previous three years
- Modified requirements:
  - Disclose the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase.
  - Establish and keep certain documentation

Requirements for “Covered” Produce

- Worker training
- Health and hygiene
- Agricultural water
- Biological soil amendments
- Domesticated and wild animals
- Growing, harvesting, packing and holding
- Equipment, tools, and buildings

Worker Training Provisions

- Establish qualification and annual training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors
  - Importance of health and hygiene
  - Produce safety standards
- Special training requirements for workers engaged in harvesting
  - Recognizing produce that cannot be harvested
  - Inspecting harvesting containers and equipment
- Require documentation of required training and corrective actions

Health and Hygiene Provisions

- Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance
  - No communicable diseases
  - Personal cleanliness
  - Avoiding contact with animals
  - Hand washing
  - Maintaining gloves in an intact and sanitary condition
  - No eating, chewing gum, using tobacco products

Agricultural Water Provisions

- Safe and adequate sanitary quality of water
- Inspection of water system under farm's control
- Water treatment, if a farm chooses to treat water
- Tiered approach to water testing based on source
  - Lower frequency for untreated ground water
  - High frequency for untreated surface water
- Specific microbial criteria for water used for certain purposes
  - Direct contact vs. growing
- Corrective measures
- Records requirements

Biological Soil Amendment Provisions

- Standards for “treated” (stabilized compost) and “untreated” (raw manure)
- Restrictions on application method depending on treatment status
  - Application-to-harvest interval for certain “untreated” BSAs of animal origin is [reserved]
    - FDA currently working on risk assessment
  - Use of human waste for growing covered produce is prohibited except in compliance with EPA regulations for such uses
  - Untreated BSA of animal origin cannot contact covered produce during application
- Requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, biological, physical and/or chemical processes that satisfy certain specific microbial standards
- Require certain records, including documentation from suppliers

Domesticated and Wild Animals

- If there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce, then the farm must take measures to assess as needed relevant areas during growing
- If significant evidence of potential contamination is found
  - Evaluate whether covered produce can be harvested
  - Take measures reasonably necessary throughout the growing season to ensure covered produce that is reasonably likely to be contaminated will not be harvested (e.g., identify contaminated areas with flags)

Growing, Harvesting, Packing and Holding

- Establishes requirements to keep covered produce separate from excluded produce and to adequately clean and sanitize food contact surfaces that contact excluded produce before using them for covered produce
- Prohibits harvesting produce that is likely to be contaminated, including that visibly contaminated with animal excreta
  - Visual assessment of the growing area required
- Prohibits distribution of dropped produce
- Food packaging materials must be appropriate for use

Equipment, Tools, and Buildings

- Requirements include:
  - Equipment/tools: designed and constructed to allow adequate cleaning and maintenance.
  - Food contact surfaces of equipment and tools must be inspected, maintained, cleaned, and sanitized as necessary.
  - Buildings: size, design and construction must facilitate maintenance and sanitary operations.
  - Toilet and hand-washing facilities must be adequate, and readily accessible during covered activities.
- Require certain records related to the date and method of cleaning or sanitizing equipment and corrective actions

Compliance Dates

Preventive Controls – Compliance Dates

Business Type	Time Until Compliance Date	Compliance Date
Businesses with 500+ FTE Employees	1 year	September 19, 2016
Small Businesses (<500 FTE Employees)	2 years	September 18, 2017
Qualified Facilities (including very small businesses)	3 years	September 17, 2018

Supplier Verification Compliance Dates

Business Type	Compliance Date
Businesses with 500+ FTE Employees	The later of: • March 17, 2017, or • 6 months after a supplier is required to comply with PC/produce rule (if applicable)
Small Businesses (<500 FTE Employees)	The later of: • September 18, 2017 • 6 months after a supplier is required to comply with the PC/produce rule (if applicable)

Produce Rule – General Compliance Dates

- Most produce safety requirements:
  - Large business: 2 years
  - Small business: 3 years
    - Average annual monetary value of produce sold during the previou  od is more than $250,000, but no more than $500,000
  - Very small business: 4 years
    - Average annual monetary value of produce sold during the previous 3-year period is no more than $250,000
- Add an extra two years for compliance with certain agricultural water requirements

Produce Rule – All Compliance Dates

Size of covered farm	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)		
		Compliance date for certain specified agricultural water requirements	Compliance date for all other requirements	Compliance date for retention of records supporting eligibility in § 112.7(b)	Compliance date for modified requirement in § 112.6(b)(1)	Compliance date for all other requirements in §§ 112.6 and 112.7
	Time periods starting from the effective date of this rule					
Very small business	3 years	6 years	4 years	Effective date of rule	January 1, 2020	4 years
Small business	2 years	5 years	3 years			3 years
All other businesses	1 year	4 years	2 years			N/A

Enforcement

Inspections

- FDA has the authority to inspect farms and facilities
- Inspections will be based on risk
- FDA intends to rely significantly on the states to conduct inspections
- FDA hopes that other audits will foster compliance:
  - USDA audits
  - Marketing agreements
  - Private audits required by commercial purchasers
    - FDA very much wants to leverage
- Inspectors will be experts in produce safety and PC

Inspections Continued . . .

- FDA is training inspectors through:
  - Having them attend either the Produce Safety Alliance training or the Food Safety Preventive Controls Alliance training
  - Special regulator training
- Inspector training is a tiered process; using a train-the-trainer model
- FDA is struggling to identify small and very small businesses who have different compliance dates and education needs

Consequences of Noncompliance

- FFDCA is a strict liability statute (intent doesn't matter)
- FDA has the authority to impose civil and criminal penalties
  - And there is "responsible corporate officer" or "Park doctrine" liability for officers and directors
- FDA enforcement tools include:
  - Warning Letters
  - Deficiency letters
  - Administrative detention of food
  - Mandatory recall authority
  - Suspension of registration
  - Reinspection fees
  - Civil injunction

Consequences continued . . .

- Business impacts
  - Supplier verification audits by customers
    - Customer liability
  - Publicity
- Enforcement will look different in year 1 vs. year 10

Conclusion

- FSMA implementation is in full swing, but we have some time before the rules take effect
- Everyone is responsible for understanding their legal obligations and coming into compliance
- We’re working with the Almond Board to be sure everyone understands the requirements
- The Almond Board is developing tools to help you understand what you need to do to comply and will assist with compliance
- **You’re not alone!**

Questions?

Maile Gradison Hermida, Senior Associate
(202) 637-5428
Maile.Hermida@hoganlovells.com

Elizabeth Fawell, Counsel
(202) 637-6810
Elizabeth.Fawell@hoganlovells.com

www.hoganlovells.com

Hogan Lovells has offices in:

Alicante	Dusseldorf	London	New York	Silicon Valley
Amsterdam	Frankfurt	Los Angeles	Northern Virginia	Singapore
Baltimore	Hamburg	Luxembourg	Paris	Tokyo
Beijing	Hanoi	Madrid	Philadelphia	Ulaanbaatar
Brussels	Ho Chi Minh City	Mexico City	Rio de Janeiro	Warsaw
Budapest*	Hong Kong	Miami	Riyadh*	Washington DC
Caracas	Houston	Milan	Rome	Zagreb*
Colorado Springs	Jakarta*	Monterrey	San Francisco	
Denver	Jeddah*	Moscow	São Paulo	
Dubai	Johannesburg	Munich	Shanghai	

*Associated offices