

# FSMA: Overview of Produce Safety and Preventative Controls Rules

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**FMI**



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# Overview

- Both rules are proposals and do not require compliance.
- Comments will be received and reviewed on both proposals and rules finalized.
- Comments due for both rules on May 16, 2013. Deadline could be extended.
- FMI will be filing comments on both.

# Produce Safety Rule

# Produce Safety Overview

- Establishes minimum standards for safe growing, harvesting, packing and holding of produce on farms.
- Applies to both domestic and imported produce.
- Contains several exemptions.

# New Standards In Key Areas

- Worker training and health and hygiene
- Agricultural water
- Biological soil amendments
- Domesticated and wild animals
- Equipment, tools and buildings
- Sprouts

# Compliance Dates

- Very small businesses—average annual monetary value of food sold during previous three-year period is no more than \$250k.
  - 4 years from effective date
- Small businesses—average annual monetary value of food sold during previous three-year period is no more than \$500k.
  - 3 years from effective date
- All other farms—2 years.
- Water quality requirements—additional two years from above dates.

# Various

- Food defense not part of Produce Safety Rule—will be addressed in separate rulemaking.
- FDA states it is not proposing to require farms to hire third party to assist in compliance, standards intended to be capable of implementation by those who engage in routine activities on farm.
- Applies to activities that are intrastate in nature.
- Only commodity-specific requirements proposed in the rule are designated for sprouts.

# Activities

- Produce Safety Rule does not apply to activities of a facility that are subject to section 418 (Food Facility Registration).
  - Activities to be regulated under the Produce Safety Rule will not trigger the requirement to register under section 415 of the FD&C Act
  - Activities within the definition of a farm consistent with the definition utilized to implement the section 415 registration requirement are not subject to section 418 of the FD&C Act, but activities outside such a definition of “farm” are subject to section 418 when they cause a facility to be required to register with FDA under section 415



# What Food is Covered?

- Produce for use as human food that is a raw agricultural commodity (RAC) both grown domestically and that will be imported or offered for import in any state or territory of US, DC or PR.
  - RAC includes any food in raw or natural state, including all fruits that are washed, colored or otherwise treated in unpeeled natural form prior to marketing

# What Food is Covered?

- Mixes of intact fruits and vegetables (e.g. fruit baskets).
- Mushrooms, sprouts, tree nuts and herbs.

# What Food is Not Covered?

- Produce that is rarely consumed raw.
  - FDA includes exhaustive list in regulation (on next slide)
- Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership.
- Produce that is not a raw agricultural commodity (e.g. fresh-cut produce).

# List of Produce Rarely Consumed Raw

Arrowhead	Brussels sprouts	Kale	Pinto beans	Sweet corn
Arrowroot	Chick-peas	Kidney beans	Plantains	Sweet Potatoes
Artichokes	Collard greens	Lentils	Potatoes	Taro
Asparagus	Crabapples	Lima beans	Pumpkin	Turnips
Beets	Cranberries	Okra	Rhubarb	Water chestnuts
Black-eyed peas	Figs	Parsnips	Rutabaga	Winter squash (acorn and butternut)
Bok choy	Ginger root	Peanuts	Sugarbeet	Yams

# What Food is Not Covered?

- Grains grown and processed for use as meal, flour, baked goods, cereals and oils (rather than for fresh consumption).
- Produce that receives commercial processing that adequately reduces presence of microorganisms (e.g. thermally processed low acid foods in sealed containers, acidified foods, HACCP).
  - Records must be kept of the identity of the recipient of the covered produce that performs the commercial processing

# Who is Subject to the Requirements?

- Farms and Farm mixed-type facilities (engages in both activities that are exempt from registration under section 415 and activities that require registration.

# Qualified Exemptions (Tester Amendment)

- Eligible if during previous 3-year period the monetary value of food sold to consumers, restaurants or retailers located in same state or less than 275 miles from farm exceeded the average annual monetary value of food sold to all other buyers; and
- The average annual monetary value of all food sold during 3 year period was less than \$500k.
- Must have name and address of farm on label (if required for product), sign/placard or electronically for internet sales.

# Qualifications and Training for Personnel

- All personnel who handle produce or food-contact surfaces (or supervise those who do) must receive adequate training upon hiring, at the beginning of each growing season, and periodically thereafter.
- All personnel must have training, in combination with education or experience to perform assigned duties in compliance with rule.



# Training

- Training must include:
  - Principals of food hygiene and food safety
  - Importance of health and personal hygiene
  - Applicable parts of Produce Safety Rule
- For employees conducting harvest activities, training must include:
  - Recognizing produce that should not be harvested
  - Inspecting harvest containers and equipment
  - Correcting problems with harvest containers and equipment
- At least one supervisor or responsible party for firm must have successfully completed adequate food safety training.
- Records of training must be kept including date of training, topics covered and person(s) trained.

# Preventing Contamination from Humans

- Measures must be taken to prevent contamination of produce and food-contact surfaces from any person with applicable health condition (AHP) (e.g. infection, vomiting, diarrhea):
  - Must include excluding ill (AHP) persons from working in operations that could contaminate food.
  - Must include instructing personnel to notify supervisors if they have or there is reasonable possibility they have AHP.

# Required Hygienic Practices of Personnel

- Adequate personal cleanliness
- Avoiding contact with animals other than working animals; minimize contamination when in direct contact with working animals.
- Washing hands thoroughly with soap and water:
  - Before starting work
  - Before putting on gloves
  - After using the toilet
  - Upon return to the work station after any break or absence
  - As soon as practical after touching animals, or animal waste; and
  - Any other time when hands may have been contaminated in manner that could lead to contamination of produce
- Gloves must be maintained in an intact and sanitary condition.

# Farm Visitors

- Must be made aware of policies and procedures to protect produce and food-contact surfaces against contamination by people.
- Must take steps to ensure visitors comply with policies and procedures.
- Must make toilet and handwashing facilities available to visitors.

# Water Quality

- Entire agricultural water system must be inspected at beginning of each growing season.
- Agricultural water sources and distribution systems under control of farm must be adequately maintained.
- If water is determined or suspected to be unsafe its use must be immediately discontinued until water system is reinspected, changes are made to address problem and water is tested to ensure safety or water is treated in accordance with rule.
- Must take steps to reduce potential for contamination by pooled water.

# Water Treatment

- Agricultural water that is known or suspected to be unsafe must be treated (e.g. EPA-registered antimicrobial pesticide).
- Treatment of agricultural water must be monitored at an adequate frequency.

# Water Standards

- Ag water must be tested using a quantitative, or presence-absence method of analysis to ensure there is no detectable E. coli in 100 ml when it is:
  - Used as sprout irrigation water
  - Applied in any manner that directly contacts produce during or after harvest
  - Used to make agricultural tea
  - Used to contact food-contact surfaces
  - Used for washing hands during and after harvest activities

# Water Standards

- When agricultural water is used during growing activities using a direct water application method, cannot have more than 235 CFU (or MPN) of E. Coli per 100 mL for any single sample or a rolling geometric mean of more than 126 CFU per 100 mL of water.



# Water Testing

- Ag water must be tested at the beginning of each growing season and every three months thereafter unless:
  - Water is received from a public water system
  - Water is treated by farm consistent with regulations (§112.43)
- Untreated surface water must be tested:
  - Every seven days during growing season if from source with significant runoff (e.g. river or lake)
  - Every month during growing season if from aquifer source and in containment where runoff drainage is minimized

# Water Used in Harvesting, Packing and Holding

- Water used during harvesting, packing and holding must be managed to maintain adequate sanitary quality.
- Must be visually monitored for build-up of organic material.
- Appropriate temperature of the water must be monitored and maintained.

# Water Recordkeeping

- Findings of inspections of agricultural water system.
- Results of analytical tests to determine safety and sanitary quality.
- Scientific data or information relied on to support the adequacy of testing method.
- Documentation of the results of water treatment monitoring and testing.
- Scientific data relied on to justify alternatives to regulatory requirements.
- Annual documentation of results or certificates of compliance from public water system.

# Biological Soil Amendments

- Biological soil amendments (BSA) of animal origin must be handled, conveyed and stored so as not to become a potential source of contamination to produce, food-contact surfaces, covered activities (growing, harvesting, packing, holding) and water sources and distribution systems.

# Biological Soil Amendments

- Must store and handle treated BSA in a manner and location which minimizes risk of contamination with untreated BSA.
- Human waste—sewage sludge biosolids may be used in accordance with EPA rules, other forms prohibited.

# Biological Soil Amendments

- Acceptable treatment processes for animal BSAs are:
  - Physical, chemical or combination of the two demonstrated to satisfy microbial standard in § 112.55(a) for *Listeria*, *Salmonella* and EC O157:H7
  - Physical, chemical or combination of the two demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms
  - Composting process demonstrated to satisfy the microbial standard in § 112.55(b) for *Salmonella* and fecal coliforms

# Microbial Standards § 112.55(a)

- Listeria—not detected using a method that can detect on CFU per 5 gram analytical portion.
- Salmonella—less than three MPN per 4 grams of total solids.
- E. coli O157:H7—less than 0.3 MPN per 1 gram analytical portion.

# Microbial Standards § 112.55(b)

- Less than three MPN Salmonella species per four grams of total solids and less than 1,000 MPN fecal coliforms per gram of total solids.



# Application Requirements/Intervals

## BSA of Animal Origin

If the biological soil amendment of animal origin is:	Then the biological soil amendment of animal origin must be applied:	And then the minimum application interval is:
(1)(i) Untreated ...	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application ...	9 months
(ii) Untreated ...	In a manner that does not contact covered produce during or after application ...	0 days
(2) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a) ...	In any manner (i.e., no restrictions) ...	0 days
(3) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b) ...	In a manner that minimizes the potential for contact with covered produce during and after application ...	0 days
(4)(i) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) ...	In a manner that minimizes the potential for contact with covered produce during and after application ...	45 days
(ii) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) ...	In a manner that does not contact covered produce during or after application ...	0 days

# Animal BSA Recordkeeping

- Document date of application and date of harvest of covered produce, except when produce does not contact soil after application of BSA.
- For treated BSA received from third-party a certificate of conformance.

# Domesticated and Wild Animals

- Rules apply when there is a reasonable probability that animals will contaminate produce.
- Requirements do not apply when covered activity takes place in a fully-enclosed building.

# Domesticated and Wild Animals

- Adequate waiting period between grazing and harvesting for produce in grazed area.
- Measures to prevent introduction of hazards from working animals.
- Must monitor areas for evidence of animal intrusion if reasonable probability of it.
- Observation of significant quantities of animals, excreta or crop destruction must evaluate whether produce can be harvested.

# Harvest

- Must take all measures reasonably necessary to identify and not harvest contaminated produce including steps to identify and not harvest produce visibly covered with animal excreta.
- Harvested produce must be handled in a manner that protects against contamination (for example, by avoiding contact of cut surfaces with soil).
- Produce that drops to the ground before harvest must not be distributed unless exempt. This does not include root crops that grow underground or crops that grow on the ground.

# Packing

- Must package produce to prevent formation of *Clostridium botulinum*.
- Must use food-packing material adequate for its intended use.
- If reuse food-packing material, you must take steps to ensure that food-contact surfaces are clean.

# Equipment and Tools

- Must be of adequate workmanship to enable adequate cleaning and maintenance.
- Must be installed and maintained to protect from contamination and attracting and harboring pests.
- Seams on food-contact surfaces must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, etc.
- Must maintain and clean as frequently as necessary to protect against contamination.
- Food contact surfaces must be sanitized when necessary and appropriate as frequently as necessary.

# Buildings

- Must be suitable in size, construction and design to facilitate maintenance and sanitary operations.
- Provide sufficient space for placement of equipment and storage of materials.
- Permit proper precautions to reduce contamination including separations of operations.
- Be constructed in a manner that floors, walls, ceilings, fixtures, ducts and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate produce, food-contact surfaces or packing materials.
- Adequate drainage must be provided.
- Adequate pest control required.



# Toilet Facilities

- Must provide personnel with adequate, readily accessible toilet facilities including those accessible to growing areas during harvest.
- Must be designed, located and maintained to prevent contamination of produce, food-contact surfaces, areas used for covered activity, and water sources and systems with human waste.
- Be serviced and cleaned on a sufficient schedule and kept supplied with toilet paper.
- Provide for the sanitary disposal of waste and toilet paper.
- Provide hand-washing station in close proximity to toilets.

# Hand Washing

- Personnel must be provided with adequate, readily accessible hand-washing facilities.
- Must have soap or other effective surfactant, running water and adequate drying devices (single service towels, clean cloth towels or sanitary towel service).
- Must provide for appropriate disposal of waste associated with hand washing.
- Can't use antiseptic sanitizer or wipes as a substitute.

# Various

- Sewage system must be adequate and maintained to prevent contamination of produce.
- Trash, litter and waste must be managed to minimize potential to attract pests and protect against contamination of produce.
- Plumbing must be adequate.
- Excreta and litter of domestic animals must be adequately controlled and a system maintained for such.

# General Recordkeeping

- All records must include:
  - Name and location of farm
  - Actual values and observations obtained during monitoring
  - An adequate description of produce applicable to record
  - Location of growing area applicable to record
  - Date and time of activity documented
- Be created at the time an activity is performed or observed.
- Be accurate, legible and indelible.
- Be dated, and signed or initialed by the person who performed the activity documented.

# General Recordkeeping

- Offsite storage of records permitted after 6 months following the date the record was made if can be retrieved and provided onsite within 24 hours of official request.
- Electronic records are considered to be onsite at your farm if the are accessible from a location at farm.
- Existing records may satisfy requirements of rule.
- Records must be kept for 2 years.
- Records relating to adequacy of equipment or processed being used by a farm, including scientific studies and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes is discontinued.

# Variations

- A state or foreign country from which food is imported into the U.S. may request a variance from one or more requirements of the regulation where it determines the variance is necessary in light of local growing conditions and the practices followed under the variance reasonably likely to ensure that the produce is not adulterated.

# Hazard Analysis and Risk-Based Preventative Controls

# Who is covered?

- Facilities that are currently required to register with FDA as food facilities.
- Includes facilities that manufacture, process, pack and hold food.
- Includes distribution centers.
- Does not include retail stores.



# Overview

- Each owner, operator or agent in charge of a facility is required to comply with the hazard analysis and risk-based preventative controls (HARBP-C) rule.
- The proposed requirements are similar to HACCP systems.

# Overview

- Each covered facility is required to prepare and implement a written food safety plan which includes:
  - A hazard analysis
  - Preventative controls
  - Monitoring
  - Corrective actions
  - Verification activities
  - Recordkeeping

# Exemptions

- Very small businesses (FDA considering threshold between \$1 million and \$250k in food sales).
- A facility where during 3-year period preceding applicable calendar year, avg sales to consumers, or sales to restaurants or retail establishments within state or 275 miles from facility exceeded sales to all other purchasers and average sales for previous 3 years less than \$500k.

# Exemptions

- Activities in compliance with Seafood HACCP rule.
- Activities subject to Juice HACCP.
- Activities subject to low acid canned foods (CGMP) part 113 (applicable only with respect to micro hazards regulated under part 113).
- Dietary supplements in compliance with CGMP.
- Activities subject to Produce Safety Rule.
- Certain on-farm activities by small or very small businesses.
- Certain alcoholic beverages at certain facilities.

# Exemptions

- Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits or vegetables) intended for further distribution or processing.
- Farms.
- Facilities solely engaged in storage of packaged food not exposed to the environment.

# Compliance Date

- 1 year after publication of final rule in the Federal Register.
- 2 years for small businesses (<500 employees).
- 3 years for very small businesses (<\$250k in annual sales of food).

# CGMP Revisions

- CGMP regulations modified to clarify that certain existing CGMP provisions requiring protection against contamination of food also require protection against cross-contact of food by allergens.
- Deletes provisions containing recommendations, including specific temperatures for maintaining foods.
- Expands provisions directed to preventing contamination of food and food-contact substances to preventing contamination of food-packaging materials as well.

# Food Safety Plan

- The owner, operator, or agent in charge of a food facility must prepare, or have prepared, and implement a written food safety plan.
- FDA recommends following HACCP guidelines in developing plan.



# Supplier Verification Not Required

- FDA acknowledges benefits of supplier approval and verification.
- Cites SQF 2000 Code.
- Does not require supplier verification and approval in proposed rule but is requesting comment on whether it should be required in final version.

# Food Safety Plan Must Include

- Written hazard analysis.
- Written preventative controls.
- Written procedures and frequency which they are to be performed, for monitoring the implementation of the preventative controls.
- Written corrective action procedures.
- Written verification procedures.
- Written recall plan.

# FS Plan Must Be Prepared By a “Qualified Individual”

- Plan must be prepared by a person who has successfully completed training in development and application of risk-based preventative controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

# Qualified Individuals

- In addition to preparing FS plan, must do or oversee:
  - Validation of preventative controls
  - Review of records for implementation and effectiveness of preventative controls and corrective actions
  - Reanalysis of food safety plan

# Hazard Analysis

- Must identify and evaluate known or reasonably known or reasonably foreseeable hazards for each type of food.

# Hazard Identification

- Must consider hazards that may occur naturally or may be unintentionally introduced including:
  - Biological hazards
  - Chemical hazards
  - Physical hazards
  - Radiological hazards

# Hazard Evaluation

- Hazard analysis must include an evaluation of the hazards in previous slide to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if hazard were to occur.
- Must include evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging.

# Hazard Evaluation

- Must consider effect of the following on the safety of the finished food for the consumer:
  - Formulation
  - Condition, function, and design of 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



# Preventative Controls

- Must identify and implement preventative controls, including at CCPs, to provide assurances that hazards identified in hazard analysis as reasonably likely to occur will be significantly minimized or prevented and the food will not be adulterated or misbranded.

# Preventative Controls Must Include

- Parameters associated with control of the hazard (e.g. heat processing, refrigerating).
- Max or min value, or combination of values to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

# Preventative Controls Must Include

- Process controls.
- Food allergen controls—cross-contact and proper labeling.
- Sanitation controls—cleanliness of food contact surfaces and prevention of cross-contact and cross-contamination from insanitary objects, personnel and raw product.
- Recall plan.
- Any other controls necessary to satisfy rule.

# Recall Plan

- Written recall plan for food is required.
- Must include the procedures that describe the steps (and assign responsibility) to be taken to:
  - Notify direct consignees of how to return or dispose of affected food
  - Notify the public about hazard presented by the food
  - Conduct effectiveness checks
  - Appropriately dispose of the recalled food

# Monitoring

- Must establish and implement written procedures, including frequency with which they are to be performed, for monitoring preventative controls.
- Must monitor preventative controls with sufficient frequency to assure they are consistently performed.

# Corrective Actions

- Must establish and implement written corrective action (CA) procedures that must be taken if preventative controls are not properly implemented.
- Must describe the steps to be taken to ensure that:
  - Action is taken to identify and correct a problem with implementation of a preventative control to reduce the likelihood that the problem will reoccur
  - Affected food is evaluated for safety
  - Affected food is prevented from entering commerce if cannot ensure it is not adulterated or misbranded

# Corrective Actions

- If a preventative control is not properly implemented and CA not established, or preventative control found to be ineffective, must:
  - Take CA to identify and correct the problem to reduce the likelihood the problem will reoccur
  - Evaluate affected food for safety
  - Prevent affected food from entering commerce
  - Reanalyze food safety plan to determine whether modification is needed

# Verification

- Must validate that preventative controls are adequate.
- Validation must:
  - Be performed by a qualified individual prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and
  - Whenever a reanalysis of the food safety plan reveals the need to do so
- Must include collecting and evaluating scientific and technical information (or studies) to determine whether the preventative controls will effectively control hazards.



# Verification

- Validation does not need to address:
  - Allergen controls
  - Sanitation controls
  - Recall plan
- Must verify that monitoring is being conducted and corrective actions are being taken.

# Verification

- Must verify that preventative controls are consistently implemented and minimizing or preventing hazards. Must include:
  - Calibration of process monitoring and verification instruments
  - Review of records by qualified individual to ensure that records are complete, reflect consistency with food safety plan, preventative controls are effective and appropriate decisions made about corrective actions:
    - Records of monitoring and corrective action must be reviewed within a week after they are made
    - Records of calibration must be reviewed within a reasonable time.
  - Written procedures required for frequency of calibrating instruments.

# Reanalysis of Food Safety Plan

- Required at least every 3 years; also whenever:
  - Change is made in the activities creating potential new hazard or significant increase in previously identified hazard
  - Aware of new information about potential hazards
  - A preventative control is not properly implemented and specific corrective action procedure has not been established
  - Preventative control is found to be ineffective

# Reanalysis of Food Safety Plan

- Must complete reanalysis and implement any additional preventative controls needed before change in activities in facility is operative or when necessary during first 6 weeks of production.
- Must revise written plan if a significant change is made or document basis for conclusion that no changes to PCs are needed.
- Reanalysis must be performed or overseen by a qualified individual.
- FDA reserves right to require reanalysis to respond to new hazards and developments in science.

# Recordkeeping

- Must establish and maintain records on:
  - Written food safety plan, including hazard analysis , preventative controls, monitoring procedures, corrective action procedures, verification procedures and the recall plan.
  - Monitoring of preventative controls
  - Corrective actions
  - Verification—including validation, monitoring, corrective actions, instrument calibration, record review, reanalysis
  - Training for qualified individual

# Recordkeeping-General Requirements

- Original records, true copies, electronic records acceptable.
- Contain actual values and observations obtained during monitoring.
- Created concurrently with performance of activity documented.
- Be detailed as necessary.
- Include: name and location of facility; date and time of activity documented; signature or initials of person performing activity; identity of product or product code (where appropriate).

# Recordkeeping—General Requirements

- Food safety plan must be signed and dated by owner/operator/agent in charge of facility upon initial completion or any modification.
- All records must be retained at plant or facility for at least 2 years.
- Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of studies and evaluations, must be retained at facility for at least 2 years after their use is discontinued.
- Except for food safety plan, offsite storage of records is permitted after 6 months if such records can be retrieved and provided onsite within 24 hours of official request. Electronic records are considered to be onsite if they are accessible from an onsite location.
- Records may be transferred from closed plant but must be returned with 24 hours upon request.
- Records are subject to public disclosure.

# Questions?

## Thank You!

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