

Japan External Trade Organization

U.S. Food and Drug Administration's

Produce Safety Regulation

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# Overview

- Review of Produce Safety regulation
  - Key definitions
  - Exemptions
  - Variances
  - Minimum standards
- Risk-based Preventive Controls regulation versus Produce Safety

# Produce Safety

- Intended to establish science-based minimum standards for safe production and harvesting of fruits and vegetables considered raw agricultural commodities (RACs) where FDA has determined such standards would minimize the risk of serious adverse health consequences or death
- Focuses on **biological hazards** related to produce growing, harvesting, packing and holding
  - FDA reserved authority to take enforcement action “directly from the statute” for chemical, physical, or radiological hazards
- Applies to domestic and imported produce unless an exemption applies

# Key Definitions

- *Raw Agricultural Commodity* – any food in its raw or natural state
- *Farm* – not required to register under Bioterrorism Act
  - *Primary production farm* – one management and one general location (although not necessarily contiguous) that is devoted to growing and harvesting of crops/raising animals and may pack or hold RACs

# Key Definitions (con't)

## – *Secondary Activities Farm* -

- Not located on a primary production farm
- Devoted to the key farming operations of harvesting, packing, and/or holding of raw agricultural commodities . . .
- *PROVIDED* that the primary production farm(s) that grow, harvest, and/or raise the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm
- In a November 2016 Guidance document, FDA announced its intent to engage in further rulemaking on the “farm” definition and exercise enforcement discretion on facilities that would be registration-exempt secondary activities farms but for the requirement that the primary production farm own a majority interest in the secondary activities farm.

# Key Definitions (con't)

- *Food hub* –
  - **Not** an FDA-defined term
  - Operations determine whether it can be a “facility” required to be registered or a registration-exempt “farm”
- *Facility* –
  - Under one ownership at one general physical location that manufactures, processes, packs, or holds food for consumption in the U.S.
  - Registered under Bioterrorism Act
  - Preventive Controls
  - Preventive Controls Qualified Individual

# Exemptions

- Produce commodities rarely consumed raw:
  - Asparagus, black beans, great Northern beans, kidney beans, lima beans, navy beans, pinto beans, beets, cashews, sour cherries, cocoa and coffee beans, collards, sweet corn, peppermint, potatoes, pumpkins, water chestnuts, food grains, etc.
- Produce that is *not* a RAC (i.e., fresh cut fruits or vegetables, bagged salads)
- Produce for personal or on-farm consumption
- Farms with  $\leq$ \$25000 average annual value of produce sold during previous three-year period
- Produce to receive commercial processing to adequately address presence of microorganisms of public health concern
- Farms with with a qualified exemption

# Variations

- States, tribes or foreign countries may submit petition with supporting information requesting variations from one or more requirements
  - Those that may be problematic based on local growing conditions
  - Must demonstrate requested variance reasonably likely to ensure produce not adulterated and same level of public health protection provided
  - Systems recognition arrangement or equivalence agreement with FDA not needed
  - Must include scientifically valid information



# Standards

- Worker Training and Health and Hygiene
  - Prevent contamination of produce and food contact surfaces by ill persons
  - Use hygienic handling practices
  - Prevent visitors from contaminating produce/food contact surfaces
  - Training required

# Standards

- Agricultural Water
  - Water intended to, or likely to, come in contact with harvestable portion of covered produce or food-contact surfaces and in harvesting, packing, and holding activities
  - Includes water used for washing or cooling harvested produce and water used for preventing dehydration
  - Must be of safe and sanitary quality for its intended use
  - Standards for inspection, maintenance, and follow-up actions;
  - Requires monitoring of treatment;
  - Includes agricultural water standards used for certain specified purposes, periodic analytical testing and mandates certain actions be taken when water does not meet quality standards
  - Requires maintenance of records, including inspectional findings, scientific data or information relied on to support adequacy of treatment methods, treatment monitoring results, water testing results, and scientific data or information relied on to support actions

# Standards (con't)

- Biological Soil Amendments
  - FDA is conducting risk assessment on use of raw manure and number of days needed between application and harvesting
    - Must apply in manner not permitting contact with product during application and minimizes potential for contact after application
  - Establishes standards for detectable amounts of bacteria after treatment of biological soil amendments including stabilized compost

# Standards (con't)

- Domesticated and Wild Animals
  - Establishes same intrusion standards for both
  - Farmers required to take all measures reasonably necessary to identify and not harvest contaminated produce
    - Requires visual examination of growing area and all covered produce to be harvested
    - May require additional assessment during growing season if evidence of potential contamination observed
    - Encourages waiting periods between grazing and harvest
    - Rule does not require or encourage removal of animals or habitat from around growing areas

# Standards (con't)

- Equipment, Tools, and Buildings
  - Establishes standards to prevent these from contaminating produce
    - Includes need for toilet and handwashing
    - Use of appropriate storage and maintenance and sanitation of equipment and tools
- Sprouts
  - Requires measures to prevent introduction of pathogenic organisms into or onto seeds or beans and treating
  - Testing spent sprout irrigation water from each production batch
  - Testing of the growing, harvesting, packing, and holding environment for *Listeria* species or *monocytogenes*
  - Corrective actions
  - Less time to comply – one to three years

# Compliance with Preventive Controls Regulation

- If a farm manufactures or processes a food **not** consumed on that farm or another under the same management
  - Includes a step such as slicing or irradiation
  - Includes making a food from one or more ingredients such as baking, canning, grinding, etc.
  - Activities that transform a RAC

# FDA Reservation of Authority

- Despite the fact that the rule may not be “in effect,” FDA can still take action in the event adulterated food is found
- Enforcement action would ***not*** be based on violation of this final rule, but rather the ***underlying prohibited act of producing or distributing adulterated food***
- Even exempt farms and farms with modified requirements may still be regulated directly from the statute

# Modified Compliance Date

## Facilities Solely Engaged in Packing or Holding Raw Agricultural Commodities

- **Was** September 2016
- **Now** beginning January 2018
- FDA announced its intent to engage in further rulemaking on the “farm” definition (Nov. 2016)



# Questions?