



Implications of FSMA for Wholesale Market Managers and Managing Entities

Jenny Scott

Senior Advisor, Office of Food Safety

FDA CFSAN

Presented to NAPMM/UFPA Meeting
January 25, 2018

FSMA Regulations

- **Preventive Controls for Human Food**
- Preventive Controls for Food for Animals
- Produce Safety
- Sanitary Transportation of Human and Animal Food
- Mitigation Strategies to Protect Food Against Intentional Adulteration
- Foreign Supplier Verification Programs (FSVP)
- Accredited Third-Party Certification



Do You Have to Register?

- You must register your facility if you are the owner, operator, or agent in charge of a facility and your facility is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, unless your facility qualifies for an exemption, e.g., as a
 - Farm
 - Retail food establishment
 - Restaurant

Do You Have to Register?

- We intend to provide additional information on who must register when space is shared by multiple entities.
- We are interested in who is responsible for specific activities at wholesale produce markets.
 - What specific activities (holding, packing, manufacturing/processing) are conducted on produce?
 - Who is responsible for stored produce?
 - Who employs the people that handle the produce?
 - Who is responsible for maintaining/cleaning the space in which produce is held/handled?
 - What records are kept by the wholesale produce market?
 - When, if ever, does the wholesale produce market have physical control over the produce.

Preventive Controls Requirements

- 21 CFR part 117
- Conduct a hazard analysis (must be written)
- Implement preventive controls for identified hazards
- Prepare a food safety plan
 - If there are no hazards requiring a preventive control, there would only be the written hazard analysis

CGMPs

- CGMPs apply to establishments that hold food
- The modernized CGMPs in part 117 require that individuals engaged in manufacturing, processing, packing, or holding food
 - have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties;
 - receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties (must be documented).

Preventive Controls Qualified Individual

- Required to do or oversee preparation of the food safety plan (including the hazard analysis)
- To be a PCQI:
 - successfully complete training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA;
 - be otherwise qualified through job experience to develop and apply a food safety system.

Supply-Chain Programs

- Do not apply to wholesale markets (only to “receiving facilities” (manufacturers/processors))
- Receiving facilities must approve suppliers and conduct supplier verification activities when hazards are controlled by suppliers (e.g., farms controlling enteric pathogens through compliance with the produce safety rule)
- An entity other than the receiving facility may conduct certain functions such as conducting supplier verification activities (documentation of the activity, such as farm audits, must be obtained by the receiving facility to review)

FDA's Enforcement Discretion Guidance for Several FSMA Rule Provisions

- Indicates FDA's intent to exercise enforcement discretion with respect to preventive controls requirements for, among other things, certain facilities (entities that must register) that engage in farm-related activities.
- For example, Facilities that would qualify as Secondary Activities Farms except for ownership of the facility, such as
 - Facilities engaged in farm-related activities on produce RACs (e.g., produce packinghouses and warehouses)

Enforcement Discretion and CGMPs

- Enforcement discretion does not extend to CGMPs for farm-related activities on produce RACs
 - Packing of produce RACs has long been subject to CGMP requirements*
 - Produce RACs packed on farm are subject to GMP-like requirements
 - Compliance with CGMPs for off-farm packaging, packing, and holding of produce RACs can be achieved by complying with subpart B of part 117 or with the applicable requirements for packing and holding in part 112 (21 CFR 117.8)

*The “RAC exemption” for CGMPs continues to apply to establishments solely engaged in the holding and/or transportation of one or more RACs.

FDA

U.S. FOOD & DRUG

ADMINISTRATION

CENTER FOR FOOD SAFETY & APPLIED NUTRITION