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Identifying hazards & preventing harm: How to apply FSMA preventive controls in your firm

- Focus: Overview of 21 CFR 117 Subparts A (focus on Exemptions and Training Requirements) and E (focus on Loss of an Exemption).

21 CFR 117 Subpart A—Exemptions and Training

Every commercial food processing facility is subject to 21 CFR 117. The qualified facility and exemptions listed in 21 CFR 117.5 are exempt only from 21 CFR 117 Subpart C (Hazard Analysis and Risk-Based Preventive Controls) and Subpart G (Supply-Chain Program).

Every facility, no matter the size, is required to do a hazard analysis and will be inspected either under 21 CFR 117 Subpart B, or under 21 CFR 117 Subpart C and G.

Not all exempt activities will be listed here. 21 CFR 117.5 describes why some activities may be exempt, such as some high-risk processes, baked goods, on-farm packing and holding of food by a small and very small firm, and alcoholic beverages.

Training Records (21 CFR 117.4)

Applicable records for training procedures and employee training must be established, written and maintained for subparts B, C, and G, as described in subpart F. The training topics must provide qualification of an individual to include: education, training, and experience necessary to manufacture, process, pack or hold clean and safe food as appropriate to the individual's assigned duties.

High-Risk Processes (21 CFR 117.5)

Exemptions are for foods covered by laws that provide microbiological hazards of concern, critical control points, monitoring, corrective actions, verification activities, records, a recall plan, and GMPs that control hazards of concern.

These high-risk processes include:

- Fish and Fishery products subject to 21 CFR 123
- Juice products subject to 21 CFR 120
- Low Acid Canned Foods subject to 21 CFR 113
- Dietary Supplements subject to 21 CFR 111
- Produce subject to 21 CFR 112

➤ Subpart C & G: The above high risk processes are not exempt, if an additional biological, chemical or physical hazard (not addressed in each process) is identified and requires a preventive control and monitoring. These firms must then develop a Food Safety Plan to identify the hazard, control and monitoring. For example, if a firm has a low acid canning operation, 21 CFR 113 requires that allergens be listed on the label. The hazard is allergens, the allergen control is developed to monitor labels, and a food safety plan is implemented under 21 CFR Subpart C. This is an additional supplemental plan that "wraps" around 21 CFR 113.

Farm Mixed-Type Facility (21 CFR 117.5)

This type of exemption applies to the packing or holding of certain processed foods, packaging, and labeling of commodities without additional manufacturing and processing. Activities must be conducted on a farm mixed-type facility that are not subject to Subparts C and G.

- Farm mixed-type facility: A facility that conducts activities outside the definition of a farm as written in 21 CFR 1.227.
- The Farm Mixed-Type Facility exemption **does apply** to the following examples*:
  - Dried/dehydrated fruit and vegetable products
  - Peanut and tree nuts
  - Processed seeds
  - Herbs and spices
  - Grains and milled grain
  - Baked goods, that are made on the farm and do not provide any additional manufacturing, drying/dehydrating, packaging or labeling
  - Alcoholic beverages
  - Raw produce
  - Fishing vessels
  - Small or very small firms that process, store, or distribute their products.

* Please read 21 CFR 117.5(g) for a description of all exempted products.

- The Farm Mixed-Type Facility exemption **does not apply** to commodities to create a distinct product, such as:
  - Raisins
  - Products that are chopped or sliced
  - Products that require time/temperature control for safety such as fresh herbs in oil and cream filled pastries
  - Roasted nuts, seasoned nuts, or nut flours

These firms may still be inspected under Subparts A, B, and F. This includes an off-farm firm that is packing and holding raw agricultural commodities (except as provided in 117.5(k)(1)) and is in compliance for packing and holding of raw produce as defined in the Produce Rule of 21 CFR 112.

Warehouse Storage Facility (21 CFR 117.7)

Firms are that are solely engaged in the storage of unexposed packaged food **are not** subject to Subparts C and G. A facility solely engaged in holding unexposed packaged food that requires time/temperature control to significantly minimize or prevent growth of vegetative pathogens or toxins produced by pathogens **are** subject to 21 CFR 117.206 in Subpart D.

This requires the facility to:

- Establish and implement temperature controls, calibrate temperature monitoring and recording devices, monitor the temperature, and verify the temperature controls are consistently implemented.
- Take appropriate corrective actions if a loss in temperature occurs, evaluate affected products for food safety, correct the problem, and reduce the likelihood the problem will reoccur. Review all records within seven working days.

21 CFR 117 Subpart E—Withdrawal of a Qualified Facility Exemption

In the event of an active investigation of a foodborne illness outbreak that is likely linked to the qualified (exempt) facility, a firm may have an exemption withdrawn under 117.5(a).

This may occur should the FDA determine:

1) The active investigation of a foodborne illness outbreak is directly linked to the qualified facility; or
2) That it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility.

If a food establishment loses its exemption, there are time frames for complying with Subparts C and G for an appeal of exemption loss, and requirements for reinstatement of an exemption.

Implementation and Inspection of the New Rules

A cGMP inspection will be conducted using 21 CFR 117 Subpart B. The inspector will be looking at training records for food safety and employee hygiene, hazards, sanitation, building and equipment construction, sanitary operations, controls, food contact surfaces and equipment, and adequate processes and controls for microbial growth in the food.

A preventive controls inspection using 21 CFR 117 Subpart C will, as with an cGMP inspection, look at training records for food safety and employee hygiene, reporting of employee illnesses, and proper hand washing. The food safety plan component will review the hazard analysis, implemented preventive controls, monitoring of the controls, corrective actions developed and taken, verification and validation of processes, the recall plan, and the supply-chain program.

These inspections will be a systems approach following the flow of incoming ingredients, through the processing of the product, to the storage of the finished product. ODA will look for routes of potential contamination of a product, insanitary processing conditions, and allergen cross-contact.