Dr Brian A Nummer, PhD.
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Food Commissaries under FSMA and the US FDA model Food Code

Introduction

A food commissary is a facility or operation that procures and/or produces foods intended for distribution. A retail or foodservice commissary generally delivers foods to its own or allied satellites. Some commissaries may sell foods to outside entities. Satellites can be retail grocery stores or individual restaurants. When the commissary purchases foods for distribution it acts as a distribution center (DC). When it prepares foods, it acts as a central kitchen and distributor. When a commissary sells all foods to outside entities, it is simply a food manufacturer or wholesaler.

Some commissaries grow sprouts or microgreens as part of their operation. A Commissary might also have an internal restaurant where foods are sold direct to consumers. Or the opposite, a large restaurant could also manufacture foods for distribution to other businesses. And, of course, there might be internet or mail-order sales. All of these complexities lead to the potential for a regulatory minefield for operators of commissaries connected with the retail and foodservice industry.

Regardless of the nature and business structure, all food facilities MUST have some form of food safety program. The question then, is what should that food safety system look like? Most retail-foodservice commissaries are regulated under a state or local code based on the US FDA model Food Code (Food Code). State or local Health Inspectors generally perform a standardized Food Code inspection twice yearly. Commissary kitchens that perform special processes as described in the Food Code §3-502.11 or §3-502.12 are required to operate under an approved HACCP Plan. Examples of special processes include vacuum packaging, cook-chill and sous vide. Sprouts, microgreens, and fermented foods are also examples of special processes.

Generally, the Food Code considers a commissary kitchen as a food operation that produces food with the intent to distribute to its own or allied satellites. When a commissary kitchen starts to sell foods to external business entities it is considered, at least partially, a food manufacturer. A commissary that distributes foods is considered a distribution center. A commissary that manufacturers, processes, packs, holds, or distributes foods for sale to other food businesses may be regulated by the US FDA, USDA, or both.

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Note that the FDA has defined restaurants specifically excluding central kitchens: “Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers” (21 CFR 1.227). If a commissary or central kitchen was inside a retail grocery store, then there is a question of primary function. The FDA says the following:

“Retail food establishment means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term consumers does not include businesses. A retail food establishment includes grocery stores, convenience stores, and vending machine locations” (21 CFR 1.227).

The FDA confirms: “The commissary does not meet the definition of a retail food establishment, as defined in 21 CFR § 1.227, because it does not sell the food that it manufactures directly to consumers” (FDA TAN case number 00077077). Thus, a commissary would be considered by the FDA as a food manufacturer or at best a mixed-type facility. “Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered” (21 CFR 117.3).

FOOD FACILITY REGISTRATION?

Since 2002, domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. must register with FDA as part of the Bioterrorism Preparedness Response Act of 2002. That Act was amended in 2011 as part of the Food Safety Modernization Act. Quite simply, it means that a food manufacturer (including food commissaries) must “register” with the FDA as a food facility.

There are three exemptions to FDA food facility registration related to commissaries: (1) Restaurants – see definition above, (2) Retail – see definition above; and lastly, (3) Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture, that is, facilities handling only meat, poultry, or egg products. If a facility must “register” with the FDA, they must do so immediately, and they are subject to FDA inspection.

So, now what happens that your commissary must be registered as a food facility (manufacturer)? Basically, as an FDA registered facility you must now comply with the Food

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Safety Modernization Act (FSMA 21 CFR 117). FDA food facilities are classified into large, small, and very small. The deadline for compliance with FSMA for large and small operations has already passed. New facilities must be compliant before they open. The deadline for "very small" operations is September 2018.

What are the elements of FSMA compliance? Five main FSMA elements are listed in the table below. Note that many may apply to food commissaries based on the commissaries' activities.

FSMA Compliance Matrix for Commissaries

		Growing Produce	Central Kitchen	Distribution Center	Imports	Manufacturer
-	*FSMA exempt*	FDA Food Code				
1	Produce Safety	Sprouts Microgreens	Packing or holding a raw agricultural commodity			
2	GMPs and Preventive Controls		Processing a food or raw agricultural commodity			
3	Food Defense Plan		?			?
4	Sanitary Transportation	Shipper, carrier, or receiver				
5	Foreign Supplier Verification				Imports?	
-	*Mixed Facility*		USDA?			USDA?

RAC = Raw agricultural commodity = Ready to Eat produce
6. USDA FSIS meat products (non-FSMA)

1. PRODUCE SAFETY RULE

The Produce Safety rule may apply to any commissary growing sprouts or microgreens or solely packing or holding raw agricultural commodities. The new food safety requirements roughly resemble the voluntary Good Agricultural Practices (GAPs) and fall into six categories: (1) worker training and hygiene; (2) agricultural water; (3) biological soil amendments; (4) domesticated and wild animals on the farm; (5) equipment, tools, and buildings; and (6) sprouts.

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2. GMPS AND PREVENTIVE CONTROLS

21 CFR 117 Good Manufacturing Practices and Preventive Controls
Subpart A - Education and Training
Subpart B – Good Manufacturing Practices
Subpart C - Preventive Controls
Subpart D – Modified Requirements
Subpart F – Recordkeeping Requirements
Subpart G - Supply-Chain Program

Any domestic or foreign facility engaged in manufacturing, processing, packing, or holding of food for human consumption that is required to register as a food facility with the FDA and makes gross sales of > 1 million dollars annually must comply with subparts C and G below. A mixed-type commissary facility that has gross sales of ≤ $1,000,000/annually and sells more than 50% of that food ***directly*** to consumers is exempt from meeting subparts C and G. Additional exemptions from subparts C and G are provided for facilities completely under food safety systems for Seafood, Juice, or Low Acid Canning.

Subpart A.

The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food are knowledgeable in food safety. They should 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 and the facility. Supervisors must have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food. And, most importantly, records that document training are required.

Subpart B. GMPs

All food facilities regardless of size must adhere to the Good Manufacturing Practices outlined in 21 CFR 117 Part B. Food facility management must ensure that reasonable measures and precautions are taken regarding: personnel, plant-grounds, sanitary operations, sanitary facilities, sanitary equipment-utensils, safe processing, and safe warehousing-distribution. Do GMPs have to be written?

Subpart C. Preventive Controls Food Safety System

A written and implemented Preventive Controls food safety plan is required. The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals (special workshop certification). The written food safety plan must include: a hazard analysis, preventive controls (allergen, sanitation, and process), supply-chain program,

and recall plan. Written procedures for monitoring, corrective action and verification procedures of the preventive controls are required. Records of preventive control programs demonstrate implementation.

Subpart D. Modifications

This subpart covers some of the exemptions provided for various facilities under 21 CFR §117.206. Examples are some modified requirements that apply to a facility solely engaged in the storage of unexposed packaged food.

Subpart F. Recordkeeping

This subpart re-iterates records requirements. It also specifies that records must be kept for 2 years and may be kept in a location where records can be retrieved within 24 hours.

Subpart G. Supplier-applied Controls

This subpart covers a Preventive Control program where expectations are placed upon suppliers of foods and ingredients to control a hazard. In most cases the hazard is something that cannot be controlled by the operator. Almost all ready-to-eat (RTE) foods fall into this category.

3. FOOD DEFENSE PLAN

The Mitigation Strategies to Protect Food Against Intentional Adulteration rule (21 CFR Part 121) requires the creation of a food defense plan. All large and small food businesses must comply by July 2019 and 2020, respectively. Very small businesses (< 1 million gross annual sales) do not have to comply.

4. SANITARY TRANSPORTATION OF FOODS

Sanitary transportation of foods covers all foods (including USDA regulated foods) that are not packaged in a manner that protects it from the environment. For exposed foods, shipping controls, carrier controls, and receiving controls are required. Controls would include simple hygiene and protection from cross contamination (microbial), cross contact (allergens), and protection from pests. Both exposed and packaged foods that require temperature control must be monitored as part of this rule. Therefore, at the very least commissaries shipping refrigerated or frozen foods must provide verification of their safety.

5. FOREIGN SUPPLIER VERIFICATION

If a commissary functions directly as an importer, then there will be additional requirements for those foods specifically imported from foreign suppliers.

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6. USDA FSIS

The last complexity that may need to be navigated is the commissary production or processing of meats. Meats produced for commissary distribution to same entity satellites is likely regulated under the FDA model Food Code (as a restaurant commissary). However, meat products sold externally from a commissary kitchen may require oversight by the USDA FSIS. The rules for USDA are different than FDA under FSMA. In some states the USDA FSIS may permit state level inspection under a "meat processing or custom exempt" status. The only way to know for sure which regulatory authority will have oversight is to contact your state Department of Agriculture. If that office is not sure, then contact the USDA FSIS directly.