

New Regulations For Food Storage and Manufacturing Facilities

21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

The Virginia Department of Agriculture and Consumer Services' (VDACS) Food Safety Program has adopted and is now enforcing 21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. This regulation replaces 21 CFR 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, more commonly referred to as the GMPs. The full regulation can be found here: <https://tinyurl.com/ybz4sfbo>.

It is your responsibility to familiarize yourself with the regulation as it applies to your business.

Below we have summarized what you need to know as a food manufacturer or warehouse in Virginia.

ALL FACILITIES, no matter the commodity or size, must comply with Subpart A and Subpart B.

Training: all employees must be trained in food safety and food hygiene as they relate to their job duties. This would include employees whose job duties involve receiving packaged goods, to those involved directly in food preparation. Each employee must understand food safety principles as they apply to their assigned task. Additionally, this training must be documented as described in Subpart F. Hard copy, written training records, as opposed to electronic, are strongly preferred and they must document items such as who was trained, when, where, what the training covered and signature of the supervisor.

Prevention of allergen cross-contact: the regulation explicitly describes actions facilities must take to prevent allergen cross-contact. Allergen cross-contact happens when food containing one of the 8 major food allergens contaminates a food that does not contain any allergens. Effective cleaning and sanitizing of surfaces that are used with both allergen and non-allergen products is one way to prevent cross-contact. Physical separation in storage can also be employed, and using separate equipment when possible can help too.

Human food by-products used for animal foods: food waste that is sold for use as animal food must now be stored, handled and labeled properly. It should be stored so that it doesn't become contaminated and it should be labeled to identify the contents. In other words, handle it no differently than you would food that will be sold for human consumption.

Subpart F

Records are required to document actions that occur during daily business activities. Records must be available for onsite review by an inspector. In general, records must be kept for at least 2 years. You must keep records of the following activities: employee and management training, and that the Food Safety Plan has been prepared and is being implemented. Records should be completed at the time of the activity and should show the who, what, when, where, and how of the activity. Providing more information is better.

THE REMAINDER OF THIS DOCUMENT DOES NOT APPLY IF YOU ARE LISTED BELOW:

Who is not subject to the requirements in Subparts C and G?

- Home-based food business
- Facilities who *exclusively* handle or manufacture seafood, juice, dietary supplements, or alcoholic beverages. To clarify, if your facility handles any of the above products, plus other commodities, then you are subject to Subparts C and G.
- Retail food stores regulated under the *Retail Food Establishment Regulations for the Enforcement of the Virginia Food Laws*

KEY POINTS

- 1.) 117 IS NEW AND APPLIES TO EVERYONE
 - 2.) WAREHOUSES AND SEAFOOD, JUICE, DIETARY SUPPLEMENT OR ALCOHOLIC BEVERAGE MANUFACTURERS ONLY NEED TO COMPLY WITH SUBPARTS A, B AND F
 - 3.) EVERYONE ELSE NEEDS TO COMPLY WITH THE ENTIRE REGULATION
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- Very small businesses that have attested to FDA. You may attest here using the Qualified Facility Attestation module: <https://www.access.fda.gov/>
- Warehouses that store only pre-packaged food (*more information directly below*)

Subpart D: Warehouses That Store Only Pre-Packaged Food

If the warehouse holds refrigerated or frozen food then they must implement temperature controls, such as storage below 41°F, monitor the storage temperature often, calibrate or check accuracy of thermometers and maintain temperature records. When temperature control is lost, corrective action should be taken to prevent negatively affected food from entering the food supply.

WHAT DOES EVERYONE ELSE NEED TO COMPLY WITH?

Subpart C

This subpart applies to all businesses not in the list on page one above, which is the vast majority of food manufacturers. Facilities that are subject to this subpart must have a written and implemented Food Safety Plan (FSP). If you are familiar with Hazard Analysis Critical Control Point (HACCP), then this will sound familiar. The FSP must be overseen by a Preventive Controls Qualified Individual (PCQI). One becomes a PCQI by successfully completing a training course online, or in person. The FSP must include the following:

- Hazard analysis
- Preventive controls*
- Supply chain program
- Recall plan
- Monitoring procedures
- Corrective action procedures
- Verification procedures

*Preventive controls are not required when the food cannot be reasonably consumed without another control being applied (coffee beans or grains) or when the manufacturer is relying on a subsequent manufacturer to control the hazard

Subpart G

Subpart G outlines the requirements for a supply chain program. The safety of the product you manufacture not only depends on the controls you put in place, but the controls applied by your suppliers or your customers. If a known hazard exists in your product or ingredients, it needs to be controlled, whether that be at your supplier's facility, at your facility, or by the next facility in the supply chain. If you decide that the hazard will not be controlled at your facility, then you should identify a supply chain control in your hazard analysis. If you do so, you will need to implement supply-chain control which may include using approved suppliers and conducting verification of these suppliers.

RESOURCES FOR CREATING YOUR FOOD SAFETY PLAN

FDA: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>

Virginia Tech Food Innovations Program: Joell Eifert, Director foodbiz@vt.edu or (540) 231-5770

Food Safety Preventive Controls Alliance: <https://www.ifsh.iit.edu/fspca>
