

WASHINGTON STATE VERY SMALL FOOD PROCESSORS: AN OVERVIEW OF WHAT YOU NEED TO KNOW ABOUT FSMA



Introduction

The Food Safety Modernization Act (FSMA) is the most significant update to food production laws in decades. As a part of the FSMA, the Preventive Controls for Human Food (PCHF) rule regulates all companies that process, pack, and hold food for human consumption. The FSMA-PCHF regulation is included in the [Code of Federal Regulations, CFR Title 21 Part 117](#) (e-CFR 2020).

Food processors that qualify as “very small businesses” are eligible for “modified requirements,” meaning they are exempt from some parts of the PCHF rule, such as the requirement to develop and maintain a food safety plan (Figure 1). Food processors that meet the definition below should file an attestation with the Food and Drug Administration (FDA) to obtain this exemption. Qualified very small businesses also have the option of complying with all parts of the PCHF rule if they choose to do so. This publication will help you to determine whether you qualify for modified requirements, how to report this to the FDA, and what requirements still apply to you.

How does the FDA define a “very small business”?

Very small businesses—“A business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee)” (21 CFR 117.3).

My business fits that definition. Now what?

To be eligible for modified requirements as a very small business, a qualified facility is required to notify the FDA and attest that it is either:

1. Addressing food safety hazards by identifying and applying appropriate controls; or
2. Complying with applicable federal, state, and local food safety regulations. These businesses must also notify consumers of the name and complete business address of the facility where the food was manufactured or processed. States or other non-federal entities can impose requirements for compliance. For example, in Washington, a firm that *scored below 90 or received a critical violation on their last WSDA inspection* would *not* be considered to be in substantial compliance and would not be eligible for the very small business exemption.

If a business fails to file for the exemption, they would then be required to comply fully with the PCHF rule, including having a documented food safety plan and required records in place.

How do I notify the FDA?

It is the responsibility of the business to submit the information to the FDA needed to qualify. First, you must register with the FDA as a [Food Facility](#) (U.S. FDA 2020b). Only after you register with the FDA can you then complete the exemption called a “Qualified Facility Attestation” by submitting the form [FDA 3942a](#) either online or by mail (U.S. FDA n.d.).

The FDA recommends you submit the information through the [online system](#) and use the physical mail only if you do not have reliable internet access (U.S. FDA 2020a).

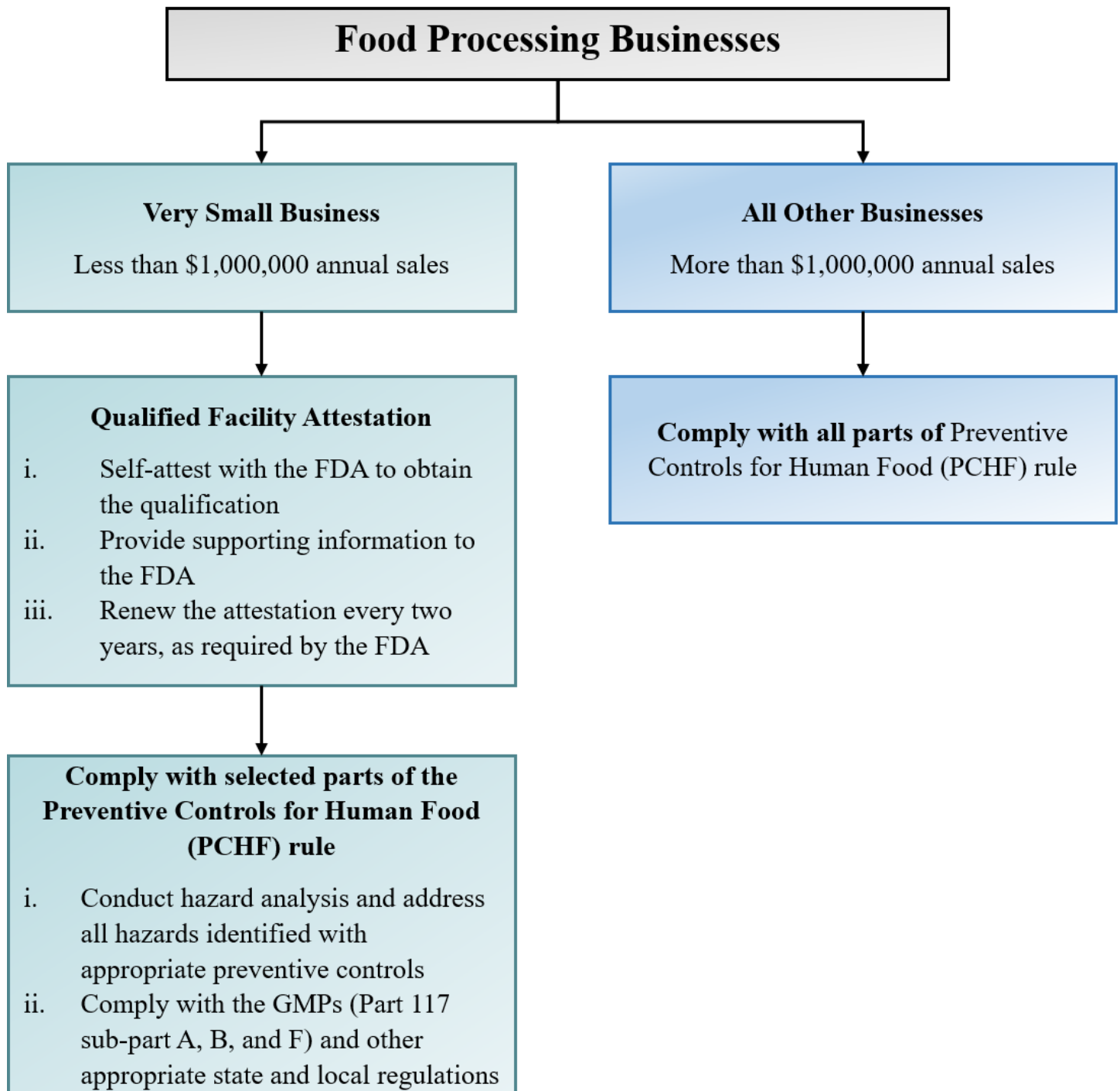


Figure 1. Compliance requirements under the Preventive Controls for Human Food (PCHF) rule, depending on the business size.

What parts of the PCHF rule still apply to me?

All businesses need to identify and control food safety hazards and use industry best practices. Providing safe food to the consumer is critical, no matter the size of the business.

A processor eligible for modified requirements is still required by the PCHF rule to do the following:

- Conduct a thorough analysis of product- and process-related food safety hazards and identify the hazards associated with their food and the processing facility;
- Take appropriate steps to address the hazards using industry best practices;
- Comply with the current good manufacturing practices (GMPs) (21 CFR Part 117 Subpart B);
- Ensure that all employees are trained in food safety principles appropriate for their job duties and the products produced (21 CFR Part 117 Subpart A);

- Maintain appropriate food safety records for employee training (as required in 21 CFR Part 117 Subpart F).

Note: the current GMPs replace the previous version of the GMPs included in 21 CFR Part 110. The current GMPs provide food processors with more guidance to address the food safety hazards commonly found in processing facilities. Adhering to GMPs, including employee and sanitation practices, can effectively minimize or eliminate many food safety risks.

Acknowledgments

This work was supported by the Washington State Department of Agriculture (WSDA).

References

e-CFR (Electronic Code of Federal Regulations). 2020. Title 21 Part 117 Subpart B. [Part 117—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food](#).

U.S. FDA (United States Food and Drug Administration). 2020a. [FDA Industry Systems](#).

U.S. FDA (United States Food and Drug Administration). 2020b. [Registration of Food Facilities and Other Submissions](#).

U.S. FDA (United States Food and Drug Administration). n.d. [Qualified Facility Attestation](#).

By

Girish M. Ganjyal, Associate Professor & Extension Food Processing Specialist, Interim Director, School of Food Science, Washington State University;

David Smith, Food Safety Program Manager, Washington State Department of Agriculture;

Ewa Pietrysiak, Postdoctoral Research Associate, School of Food Science, Washington State University



FS343E



Copyright © Washington State University

WSU Extension publications contain material written and produced for public distribution. Alternate formats of our educational materials are available upon request for persons with disabilities. Please contact Washington State University Extension for more information.

Issued by Washington State University Extension and the US Department of Agriculture in furtherance of the Acts of May 8 and June 30, 1914. Extension programs and policies are consistent with federal and state laws and regulations on nondiscrimination regarding race, sex, religion, age, color, creed, and national or ethnic origin; physical, mental, or sensory disability; marital status or sexual orientation; and status as a Vietnam-era or disabled veteran. Evidence of noncompliance may be reported through your local WSU Extension office. Trade names have been used to simplify information; no endorsement is intended. Published May 2020.