SOUTH CAROLINA DEPARTMENT OF AGRICULTURE

QUALIFIED FACILITY QUICK GUIDE

Disclaimer: Please note this is intended as a guidance document only. For official regulatory guidelines, please see the Preventive Controls for Human Food (PCHF) Rule, also known as 21 CFR 117, and any regulations promulgated thereunder.

WHAT IS FSMA?

The FDA **Food Safety Modernization Act (FSMA)** was signed into law in 2011 and establishes requirements for hazard analysis and risk-based preventive controls for facilities that produce food for humans and animals.

The purpose of this guidance document is to help you determine if you are a Qualified Facility, which are exempt from certain parts of the rules and are subject to modified, less stringent, requirements. This guide provides guidance on how to attest as a Qualified Facility under the **Preventive Controls for Human Food (PCHF) Rule also known as 21 CFR 117.** Attestation is not applicable to firms who sell mostly retail.

BACKGROUND INFORMATION

Under FSMA, a "Qualified Facility" is a facility that is considered exempt from parts of the PCHF Rule, *specifically* Subpart C (Requirements for Hazard Analysis and Risk-Based Preventive Controls) and Subpart G (Requirements for a Supply-Chain Program).

However, a qualified facility is still subject to **modified requirements (Subpart D)**. These modified requirements include the requirement that the facility submit a form to FDA, attesting to its status as a "qualified facility."

A firm that believes they are a Qualified Facility must submit two attestations to the FDA:

1. FDA Form 3942a: the attestation form for a qualified facility

AND

2. Either an attestation that it has identified potential hazards, is implementing preventive controls to address the hazards, and is monitoring performance of the preventive controls **or** an attestation that the facility is in compliance with non-federal food safety laws and regulations based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as the State Department of Agriculture) or other evidence of oversight.

AM I A QUALIFIED FACILITY?*

**It is your responsibly to determine your status. You are attesting to the FDA, not SCDA. SCDA cannot determine your qualified status.*

Part 117 defines a "qualified facility" as (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate):

- **A facility that is a very small business**
  - » Part 117 defines "very small business" as 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).

OR

- **A facility to which both of the following apply:**

» During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers;

AND

» The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

WHAT RECORDS DO I NEED?

- Part 117 requires that you keep records that you rely upon to support the attestations you make on Form FDA 3942a but does not otherwise specify the types of records that you must keep.
- You should keep the records that you use for your calculations of annual sales and records of the actual calculations that you make.

The records you are required to keep to support your attestation as to food safety practices/compliance may vary depending on how you comply with 21 CFR 117.201(a)(2). The two options are as follows:

- **Option 1:** You have identified potential hazards associated with the food being produced, are implementing preventive controls to address the hazards associated with the food being produced and are monitoring the performance of the preventive controls to ensure that such controls are effective.
  - » When selecting Option 1, you must keep records documenting your identification of potential hazards, the preventive controls you are implementing to address those hazards, your implementation of your preventive controls, and your monitoring of your preventive controls. (21 CFR 117.201(f)(1)). For example, you could have a document identifying the hazards and the preventive controls you will implement to address those hazards, and batch records demonstrating your implementation and monitoring of the preventive controls.

OR

- **Option 2:** Your facility is in compliance with State, local, country, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.
  - » When selecting Option 2, you must maintain records that document your compliance with the applicable non-Federal food safety law that you are following. (21 CFR 117.201(f)(1)). For example, you could keep a record of licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency or other evidence of oversight. If the applicable food safety law does not result in a license, inspection report, certificate, or permit, you could have a printed or electronic copy of the applicable food safety law.

HOW DO I ATTEST?

When:

- You are subject to the full requirements of the PCHF rule until you submit attestation to FDA. Attestation paperwork should be submitted as soon as possible if you believe you are not subject to the full PCHF rule.
- Beginning in 2020, you must re-submit Form FDA 3942a to FDA every 2 years during the food facility biennial registration renewal period beginning on October 1 and ending on December 31 (21 CFR 117.205(c)(2)(ii)). Note that you must also renew your facility registration at this time (21 CFR 1.230).

Where:

- Submit the qualified facility attestation form (FDA Form3942a) electronically at ***access.fda.gov*** via the Qualified Facility Attestation Module. Please note that facilities must have a valid food facility registration to submit their attestation.

IMPORTANT REMINDERS

Although Qualified Facilities are exempt from the preventive control requirements in Subparts C & G of 21 CFR 117—the following requirements still apply to qualified facilities:

- **Subpart A – General Provisions:** Consists of definitions, exemptions, applicability, and requirements for qualified individuals.
- **Subpart B – Current Good Manufacturing Practices:** Similar to the requirements in 21 CFR 110 and now includes controlling allergen cross-contact.
- **Subpart D – Modified Requirements:** Includes the modified requirements that apply to a Qualified Facility and a facility solely engaged in the storage of unexposed packaged food.
- **Subpart F – Records Requirements:** Includes requirements for employee training records and record retention.

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