SOUTH CAROLINA DEPARTMENT OF AGRICULTURE

QUALIFIED FEED FACILITY QUICK GUIDE

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 Animal Food (PCAF) Rule also known as 21 CFR 507.**

BACKGROUND INFORMATION

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

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

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

AND

2. An attestation that, to the best of your knowledge and belief, the information provided in the Qualified Facility Attestation is true, accurate, and complete and that your facility qualifies for the exemption requested; you understand that, as the owner, operator, or agent in charge of the facility, you must maintain those records relied upon to support these attestations (21 CFR 507.7(f)) and make those records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request (21 CFR 507.200(c)); and you understand that under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

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.*

A facility to which both of the following apply:

1. During the 3-year period preceding the applicable calendar year, the business averaged less than $2.5 million, adjusted for inflation, per year, in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale;

OR

2. Your facility meets the definition of "qualified facility" in 21 CFR 507.3 because:

a. During the preceding three calendar years, the average annual monetary value of the food manufactured, processed, packed, or held at your facility that was sold directly to qualified end-users (as defined in 21 CFR 507.3) exceeded the average annual monetary value of the food sold by your facility to all other purchasers; and

b. The average annual monetary value of all food sold during the preceding three calendar years was less than $500,000, adjusted for inflation.

AND

i. You have identified potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and

are monitoring the performance of the preventive controls to ensure that such controls are effective;

OR

ii. Your facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulation of foreign countries, based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

HOW DO I ATTEST?

When:

- You are subject to the full requirements of the PCAF 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 PCAF rule.
- You must re-submit Form FDA 3942b to FDA every 2 years during the food facility biennial registration renewal period beginning on October 1 and ending on December 31 (21 CFR 507.7(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 Form3942b) 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.

WHEN MUST I NOTIFY IF MY FACILITY'S STATUS CHANGES?

If your facility's status changes from "qualified facility" to "not a qualified facility" based on the annual determination, you must submit Form FDA 3942b notifying FDA of that change in status by July 31 of the applicable calendar year (See 21 CFR 507.5(c)(3)).

IMPORTANT REMINDERS

Although Qualified Facilities are exempt from the preventive control requirements in Subparts C & E of 21 CFR 507—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:** General overview of practices including personnel, plant and grounds, sanitation, water supply, equipment and utensils, plant operations, and holding and distributions.
- **Subpart D – Withdrawal of a Qualified Facility Exemption:** FDA may withdraw a qualified Facility Exemption under 507.5(d)
- **Subpart F – Records Requirements:** Includes requirements for employee training records and record retention.

Disclaimer: Please note this is intended as a guidance document only. For official regulatory guidelines, please see Preventive Controls for Animal Food (PCAF) Rule also known as 21 CFR 507 and any regulations promulgated thereunder.

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