IF YOUR FACILITY IS A VERY SMALL BUSINESS OR A SMALL (OR VERY SMALL) FARM MIXED-TYPE FACILITY, WHAT PC ANIMAL FOOD RULE EXEMPTIONS/MODIFIED REQUIREMENTS APPLY TO YOU?

Facilities that are very small businesses or small (or very small) farm mixed-type facilities may be exempt from or subject to modified requirements under the Preventive Controls (PC) for Animal Food Rule, one of the FDA Food Safety Modernization Act (FSMA) foundational rules.

Does that include your facility or farm mixed-type facility? This fact sheet will help answer that question.

What are a "small business" and "very small business"?

A "small business" is a business, including any affiliates and subsidiaries, employing fewer than 500 full-time equivalent employees.

A "very small business" is a business (including any subsidiaries or affiliates) that averages less than $2,500,000 (adjusted for inflation) in sales of animal food plus the market value of animal food that is manufactured, processed, packed, or held without sale (for example, held for a fee or supplied to a farm without sale), per year during the previous three-year period. For current values adjusted for inflation, see "FSMA Inflation Adjusted Cutoffs" at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm.

Who is subject to the PC Animal Food Rule?

Generally, domestic and foreign animal food facilities that are required to register with the FDA under the Federal Food, Drug, & Cosmetic Act are required to comply with the PC Animal Food Rule, entitled Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food rule.

Who is not subject to the entire PC Animal Food Rule?

Certain operations are exempt from the PC Animal Food Rule because they don't have to register with the FDA. These include farms, restaurants (including pet shelters, kennels, and veterinary facilities) that prepare and sell food directly to consumers for immediate consumption, retail food establishments that sell directly to consumers as its primary function (this does not include sales made to commercial customers, such as farms, which would be considered sales to businesses), nonprofit food establishments, and establishments that process only meat, poultry and egg products that are inspected by the U.S. Department of Agriculture. For more information about food facility registration and exemptions, see Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition).

Even if you are required to register as a food facility, there may be other situations in which your facility is eligible for an exemption, subject to modified requirements, or subject to enforcement discretion, regardless of the size of your business. For more information see GFI #241: Small

Entity Compliance Guide; What you Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, and the Enforcement Discretion Policy for Certain FSMA Regulations.

Can a facility be exempt from the preventive controls requirements of the PC Animal Food Rule based on its size?

Yes, a facility may qualify for an exemption from the preventive controls requirements of the PC Animal Food Rule if it meets certain criteria related to the size of the business that would make the facility a "qualified facility," e.g., it is a "very small business." For requirements applicable to qualified facilities, see the question "What modified requirements apply to a qualified facility?" on page 3 of this fact sheet.

You may also qualify for an exemption from the PC requirements based on size if your facility is a farm mixed-type facility that is a small or very small business, and you conduct only certain low-risk activities on specified animal food. A "farm mixed-type facility" is an establishment that is a farm that would otherwise meet an exemption from registration except that it also conducts activities outside the farm definition that require the establishment to be registered. For more information about this exemption, see the section titled "Exemption for On-Farm Low-Risk Activities Conducted by Facilities That Are Small or Very Small Businesses" on page 4 of this fact sheet.

Have compliance dates or enforcement policy changed since FDA published the PC Animal Food Rule?

Yes, for some facilities. In a final rule published in August 2016, FDA extended the compliance dates for the PC Animal Food Rule for certain facilities to address concerns about the practicality of compliance with certain provisions, consider changes to the regulatory test, and better align the dates with other FSMA rules. Then, in January 2018, FDA published guidance indicating its intent to exercise enforcement discretion in certain circumstances, including some related to the "farm" definition (see Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs).

Qualified Facilities

What is a qualified facility?

A qualified facility is either: (1) a "very small business," or (2) a business (including any subsidiaries and affiliates) whose average annual monetary value of the food sold during the previous three-year period was less than $500,000 (adjusted for inflation) and whose average annual monetary value of food manufactured, processed, packed or held and sold directly to consumers, retailers, restaurants, within the same state or the same Indian reservation or within 275 miles of the facility was more than the monetary value of food sold by the facility to all other purchasers.

FDA anticipates that most "qualified facilities" will be ones that meet the definition of "very small business."

What modified requirements apply to a qualified facility?

A qualified facility is required to submit a Form FDA 3942b, attesting to its qualified facility status (meaning the facility meets the financial requirements to be a qualified facility) and attesting that it is either:

1. Addressing identified hazards through preventive controls and monitoring the preventive controls; or
2. Complying with applicable non-federal food safety law (including state food safety laws) and notifying consumers of the name and complete business address of the facility where the animal food was manufactured or processed.

A qualified facility is also required to maintain the records they rely upon to support the attestations they make on Form FDA 3942b. In addition, qualified facilities are required to comply with the Current Good Manufacturing Practice (CGMP) requirements found in 21 CFR part 507, subpart B (and related requirements in subparts A and F).

How do I send my Form FDA 3942b to FDA?

The form can be submitted in two ways:

- **Electronically** – Log into your FDA Industry Systems account at http://www.fda.gov/furls and follow the instructions. FDA encourages electronic submission.
- **Mail** — Send a completed paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.
  - The form can be downloaded from: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM620468.pdf

    Alternatively, you can request a copy of the form by writing to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740, or calling 1-800-216-7331 or 301-575-0156

Additional information on how to submit the Form FDA 3942b can be found in the guidance entitled "Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA Form 3942b (for Animal Food): Instructions for Submitting your Attestation."

What compliance dates apply to my qualified facility? And when do I have to tell FDA that my facility is a qualified facility?

Qualified facilities had to comply with CGMP requirements for animal food by September 17, 2018. Qualified facilities have until September 17, 2019 to comply with the modified requirements for qualified facilities.

In addition, a qualified facility must retain records to support its status as a qualified facility starting January 1, 2017.

In August 2018, FDA stated that it intends to begin routine regulatory inspections to assess compliance with CGMP requirements at qualified facilities starting in the fall of 2018. However,

FDA also stated it would not begin routine regulatory inspections to assess compliance with the modified requirements applicable to qualified facilities until the fall of 2020.

The attestation form (Form FDA 3942b) stating that your facility is a qualified facility must be submitted to FDA initially:

- By December 16, 2019, for a facility that begins manufacturing, processing, packing or holding animal food before September 17, 2019
- Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after September 17, 2019

Beginning in 2020, your attestation must be submitted to FDA every 2 years between October 1 and December 31.

Your determination of whether your facility meets the definition of a qualified facility must be made no later than July 1 of each calendar year.

Exemption for On-Farm Low-Risk Activities Conducted by Facilities That Are Small or Very Small Businesses

What exemption for on-farm low-risk activities might apply to a farm mixed-type facility that is a small or very small business?

If a facility is a farm mixed-type facility that is a small or very small business, and the only activities that the non-farm part of the facility conducts are certain low-risk activities on specified animal food, the facility is entirely exempt from the hazard analysis and preventive controls requirements but is still subject to the CGMP requirements.

If the non-farm part of a farm mixed-type facility is engaged in activities other than the specified low-risk activities, but it meets the definition of a qualified facility, then the facility must follow the modified requirements applicable to qualified facilities, including submitting a Form FDA 3942b.

What are some of those low-risk activities exempt from hazard analysis and preventive controls requirements in some circumstances?

Certain low-risk activities on certain animal foods are not subject to the requirements for hazard analysis or risk-based preventive controls (including supply-chain requirements), or to the modified requirements, if the activities are conducted on farms by farm mixed-type facilities that are small or very small businesses, and if these are the only activities they conduct that would be subject to hazard analysis and preventive controls or the modified requirements. The activities include packing and holding or manufacturing/processing certain animal foods, as described in the following lists.

Packing and holding activities limited to packing (or re-packing), sorting, culling, grading, or storing the following products:

- Roughage products (e.g., alfalfa meal, entire plant meal, stem meal, pomace, and pulp)
- Plant protein meal (e.g., algae, coconut, guar, peanut)

- Grain by-products and processed grain products (e.g., bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middling, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal)
- Oilseed products (e.g., oil and meal of safflower, soybean, or sunflower)
- Molasses (e.g., processed sugar cane, sugar beets, and citrus)
- Animal protein meals (e.g., blood, feather, meat, meat and bone, and marine such as crab, fish, or shrimp)
- Milk products (e.g., casein, cheese rind, and lactalbumin)
- Animal tissue-derived products (e.g., fat)
- Vitamins, minerals, and concentrates
- Processing aids (e.g., enzymes, preservatives, and stabilizers)
- Any other processed animal food that does not require time/temperature control for safety

Performing the following low-risk manufacturing/animal food combinations:

- Chopping or shredding hay
- Cracking, crimping, flaking, pearling, peeling, shelling, or wafering grain or oilseed
- Crushing, dry rolling, grinding, milling, or pulverizing grain, oilseed, grain by-products and processed grain products, oilseed products, hay, ensiled material, culled fruits and vegetables, roughage (such as cobs, hulls, husks, and straws), or roughage products
- Ensiling such as making silage or haylage from forage, grain, culled fruits and vegetables or roughage –
  - In January 2018, FDA announced its intention to exercise enforcement discretion with regard to the animal food CGMP requirements for farm mixed-type facilities making silage until the completion of future rulemaking related to farm activities.
- Extracting (mechanical) or wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products
- Labeling roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety
- Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished and ready-to-eat animal food, and any other processed animal food that does not require time/temperature control for safety.

For More Information

- Determination of Status as a Qualified Facility Under the PC Human Food Rule and PC Animal Food Rule: Guidance for Industry
- Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation
- Qualified Facility Attestation
- Form FDA 3942b: Qualified Facility Attestation for Animal Food Facilities
- FSMA Inflation Adjusted Cut Offs
- Guidance for Industry: Small Entity Compliance Guide: What You Need To Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals
- Draft Guidance for Industry: Determining the Number of Employees for Purposes of the "Small Business" definition in Parts 117 and 507
- Draft Guidance: Guidance for Industry #239: Human Food By-Products for Use As Animal Food
- Final Rule; Extension and Clarification of Compliance Dates for Certain Provisions
- Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry