

Does PCAF apply?

This worksheet was developed by NC State Extension to help you determine what, if any, parts of the Preventive Controls for Animal Food may apply to your facility. As you read each question, select the YES or NO button and follow the decision tree until you reach a STOP.

1

Does your facility manufacture, process, pack or hold animal food for consumption in the U.S.?



Your facility is not subject to the Preventive Controls for Animal Food rule.

2

Is your facility subject to registration under Section 415 of the Federal Food, Drug, and Cosmetic Act (Bioterrorism Act)?



Your facility may be subject to all or parts of the PCAF rule. To determine if your facility is eligible for an exemption, go to question 3.



Your facility is not subject to the Preventive Controls for Animal Food rule.

3

Is your facility a retail food establishment, restaurant, pet shelter, or veterinary facility that provides food to animals?



You are not required to register and are exempt from the PCAF rule.

4

Is your facility **solely** engaged in the holding and/or transportation of raw agricultural commodities, the hulling, shelling, drying, packing, and/or holding of nuts and hulls (without manufacturing/processing), or the ginning of cotton (without manufacturing/processing)?



Subparts B (CGMP), C (Hazard analysis and risk-based preventive controls) and E (supply chain applied controls) do not apply to your facility, but subpart A still applies.

5

Is your facility engaged in activities subject to regulations for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers for the control of microbiological hazards or that are subject to standards for the Produce Safety Rule?



Subparts C and E do not apply to Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers activities, but may still apply to the whole facility. Subparts C and E do not apply for facilities engaging in activities subject to the Produce Safety Rule.

6

Is your facility a **small business** or **very small business** that is a mixed-type facility and the only packing or holding activities that are specified low-risk packing or holding activity/animal food combinations or low-risk manufacturing/processing activity/animal food combinations, even if the activities are intended to distribute animal food into commerce?



Subparts C and E do not apply to your facility.



If your facility meets the PCAF definition of a primary production farm or secondary activities farm **and** does not have outside customers **or** the feed mill is under the same management as the farms that raise the animals, the facility does not have to register as a food facility and is not subject to the PCAF.



8

Does your facility or business (including subsidiaries and affiliates) average less than \$2,500,00, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g. held for fee or supplied to a farm without sale)?



Your facility meets the definition of a very small facility, which is a type of qualified facility, and its status must be determined July 31 each year and resubmit attestations to the FDA every two years to maintain exemption.



9

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



10

Was the average monetary value of all food sold during the 3-years preceding the applicable calendar year less than \$500,000, adjusted for inflation?



Your facility meets the definition of a qualified facility and must determine status by July 31 each year and resubmit attestations to the FDA every two years to maintain exemption.



11

Is your facility **solely** engaged in the storage of **unexposed, packaged** animal food?



Your facility is not a warehouse or a qualified facility and is therefore subject to all parts of the PCAF rule.

12

Does the animal food require time/temperature controls to control pathogens?



Your warehouse is exempt from the full requirements of subparts C and E, but the warehouse would be subject to the modified requirements for this type of facility.



Your warehouse is exempt from the requirements for subparts C and E.

Get help with the Preventive Controls for Animal Food rule



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Appendix

This appendix has further requirements for some of the worksheet questions. Browse this appendix, or use the **See more requirements** buttons in the document to navigate to the appendix sections.

Question 8

Your facility meets the definition of a qualified facility and must determine status by July 31 each year and resubmit attestations to the FDA every two years to maintain exemption. Must also meet one of the following: Option 1: Has 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 such controls are effective or Option 2: Is in compliance with state, local, county, tribal, or other applicable non-federal food safety laws.

You can choose to apply for the exemption OR choose to meet the full requirements of the rule.

Question 10

Your facility meets the definition of a qualified facility and must determine status by July 31 each year and resubmit attestations to the FDA every two years to maintain exemption. Must also meet one of the following: Option 1: Has 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 such controls are effective or Option 2: Is in compliance with state, local, county, tribal, or other applicable non-federal food safety laws.

You can choose to apply for the exemption OR choose to meet the full requirements of the rule.

Question 12

Your warehouse is exempt from the full requirements of subparts C and E, but the warehouse would be subject to the modified requirements for this type of facility: the facility must establish and implement temperature controls that can control the growth (or toxin formation) of a pathogen, monitor the implemented controls at a frequency determined to be adequate by the facility, take corrective actions if there is a loss of temperature, verify that temperature controls are consistently implemented, and establish and maintain records of monitoring, corrective action, and verification.

Farm definitions

This appendix has definitions of farm types. These definitions are from the Food Safety Preventive Controls Alliance Preventive Controls for Animal Food course manual.

Primary Production Farm

A primary production farm is an operation under one management in one general, but not necessarily contiguous, location that is devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities.

If an operation grows crops, harvests crops, or raises animals, the operation can do additional activities as part of its farming operation, such as: pack or hold raw agricultural commodities; pack or hold processed foods, provided that all processed food is consumed on the farm or another farm under the same management; or manufacture/process food, provided that all food that the farm manufactures/processes is consumed on that farm or another farm under the same management; OR any food not consumed on that farm consists only of manufacturing/processing in the following limited categories:

- drying/dehydrating raw agricultural commodities to create a distinct commodity;
- treatment to manipulate ripening of a raw agricultural commodity; or
- packaging and labeling without additional manufacturing/processing.

Secondary Activities Farm

A secondary activities farm must be majority owned by the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, or held by the secondary activities farm.

A secondary activities farm may also conduct the additional activities that are allowed on a Primary Production Farm.

[RETURN TO QUESTION #7](#)

[SEE PREVENTIVE CONTROLS FOR ANIMAL FOOD DEFINITIONS \(§507.3\)](#)