NEBRASKA
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DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH PROTECTION
COMMERCIAL FEED PROGRAM

Farm Mixed Type Facility Guidance

Your answers indicate that your facility is Farm Mixed Type Facility, is small or very small, and is engaged only in low risk processing or handling of animal feed. Facilities of this type are exempt from 21 CFR 507 Subparts C and E. These portions relate to the Food Safety Plan (FSP) and Supply Chain Program Preventive Control. However, your facility should remain aware of Subpart A (General Provisions), Subpart B (Current Good Manufacturing Practices), and Subpart F (Requirements Applying to Records That Must Be Established and Maintained).

A facility that is required to comply with Subpart A should be aware of the General Provisions as outlined in that portion of the PCAF Rule. Important areas of focus include definitions used throughout the rule (Section 507.3), requirements for Qualified Individuals who handle animal food (Section 507.4), and various firm exemptions (Section 507.5).

Of the General Provisions, Section 507.4 is likely to be the most important area of concern for a firm of this type. This section deals with firm management's responsibility to ensure that all employees handling animal food are appropriately trained for their jobs. An appropriately trained employee is defined as a Qualified Individual in Section 507.3 of the rule. The qualifications can be training, education, experience or any combination of the three. The rule also states that supervisory personnel are to be responsible for the training and its documentation.

The most important portion for a facility of your type to be familiar with is 21 CFR 507 Subpart B. This section outlines all the areas that require a firm's attention to remain in compliance with the Current Good Manufacturing Practices (CGMPs) portion of the PCAF Rule. There are sections for Personnel, Plant and Grounds, Sanitation, Water Supply and Plumbing, Equipment and Utensils, Plant Operations, as well as Holding and Distribution.

Each facility will have its own challenges related to compliance with each of these sections. Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals is a good starting point for FDA's guidance to comply with this portion of the rule. The last portion of that document includes a Self Assessment Tool which you can use to compare your facility's practices with FDA's expectations.

Another section which applies to Farm Mixed Type Facilities is documentation records. Rules regarding recordkeeping are outlined in Subpart F. Warehouses that hold packaged animal feed should consider being aware of requirements applying to records (Section 507.202) and requirements for record retention (Section 507.208). General requirements for records include items such as they must be originals or true copies, be accurate, indelible and legible, as detailed as necessary, and include the identity of the facility, date, and identity of person performing the documented activity. Regarding record retention, all records are to be kept at the facility they were prepared for at least two years unless indicated otherwise.

These are some key points to remember to ensure that your facility remains in compliance with these new rules. For further information, you may reference 21 CFR 507 here or you can view Guidance for Industry #235: Current Good Manufacturing Practices for Food for Animals here. FDA has released some additional information and guidance specifically for small businesses which you may find useful. That can be found here. If you have further questions, you may reach out to your local Commercial Feed Inspector or contact the Commercial Feed Program at 402-471-2351 or agr.webmaster@nebraska.gov.

The above is provided for informational purposes only. It is not intended to be legal advice and does not replace the advice of independent legal counsel.