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Commercial Feed Program's Mission

The Nebraska Department of Agriculture Commercial Feed Program is one of many programs under the Animal and Plant Health Protection (APHP) banner that have mandated “statutes to meet the needs of those being regulated and protected by those statutes and accompanying regulations. APHP is vested with the power to, and charged with the duties of, protecting both general livestock and plant health, and thus maintaining commerce opportunities for Nebraska products. Ongoing surveillance, testing, certification, outreach, tracing, inspecting, and eradication efforts are some of the regulatory duties charged to APHP.” - nda.nebraska.gov/aphp

The Commercial Feed Program (CFP) helps safeguard human food and animal health, and ensures that feed is safe, unadulterated, and honestly prepared.

For consumer protection, all feed manufacturers, transporters, and distributors/retailers are subject to random inspections and sampling to assure compliance with state and federal feed safety and labeling regulations.

Federal Inspection Spotlight

Are you a Qualified Facility?

A business that meets the definition of a “qualified facility” is subject to modified requirements of preventive controls rules.

The best source for information is: [“Guidance For Industry: Determination of Status as a Qualified Facility Under Part 117: CGMP, Hazard Analysis, and Risk-Based PCs for Human Food And Part 507: CGMP, Hazard Analysis, and Risk-Based PCs for Food for Animals.”](#)

For help submitting an attestation for a Qualified Facility: [“Instructions for Submitting Qualified Facility Attestation.”](#)

21 CFR 507.3 “Qualified facility”

Qualified facility means (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 as defined in this part, or a facility to which both of the following apply:

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- (1) 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 (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
- (2) 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.

Program Report Feed Firm Risk Assessments

Each state-licensed animal food establishment in Nebraska is assessed for risk based on the types of operations conducted and types of products produced. Minimum inspection intervals are then determined based on the final risk score. 0-25 is Low; 26-74 is Medium; 75 and above is High.

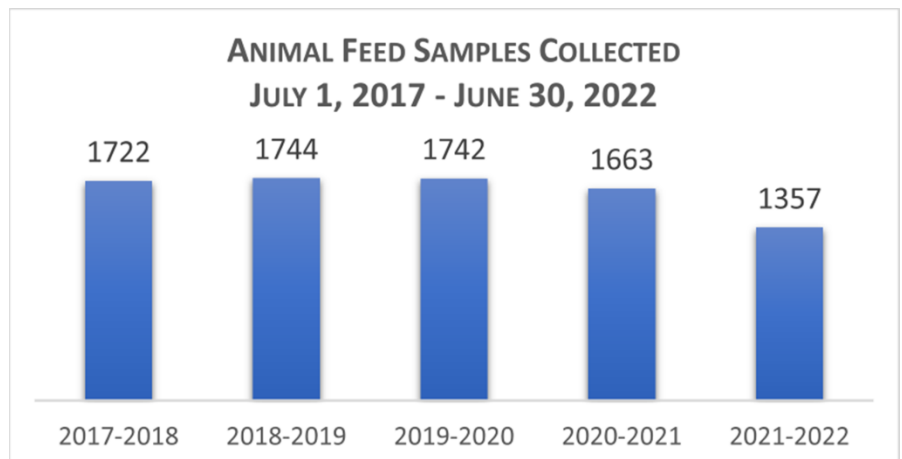
Count of Animal Food Firms by Risk Category	
High	88
Medium	402
Low	641
To Be Assessed	61



Feed Sampling Program

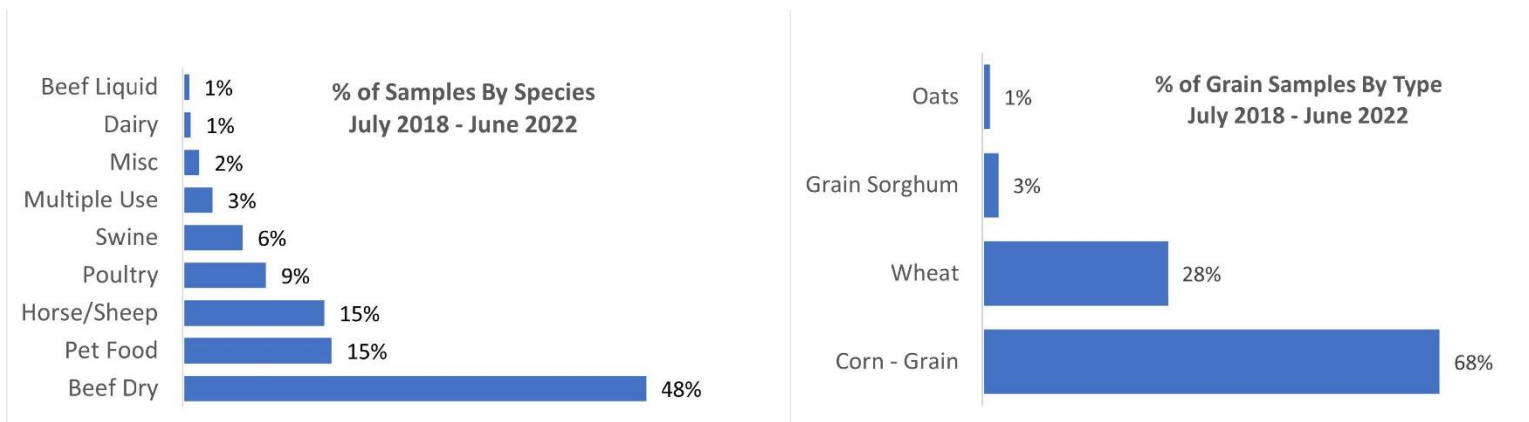
Nebraska Feed Program staff collects animal feed product samples and submits them for laboratory analysis to protect animal and public health and to enforce feed regulations.

The state program works closely with the Nebraska Department of Agriculture Lab to ensure that sampling plans, sampling procedures, and instructions for documenting sample collections are established and managed with laboratory personnel.



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Feed program inspectors also collect samples on behalf of the Agriculture Lab as part of their FDA grant projects. Projects have included testing swine feed and pet food for the mycotoxin Zearalenone; horse or multi-species feeds for monensin, and dried distillers grains for mycotoxins. These projects are intended to be surveys, so results are not released unless there is a violation.



I just got an off sale. What do I do now?

Your rights and responsibilities when you receive a Withdrawal from Sale

The Withdrawal from Sale Order (WFS), also known across the industry as an “Off Sale” is a legal hold on a product that does not meet its label guarantee or is found to be adulterated. Once this document is issued, the feed product addressed cannot be sold or removed from the premise without permission from the Nebraska Commercial Feed Program (CFP).

Our program has a sampling goal of 1,700 feed products or ingredients each year. On average eight percent of products do not meet all their label guarantees or other requirements and result in a WFS.

What this means for your establishment

Our program priorities are to ensure that the product is safe for intended species and class of animals when fed according to label directions; and that the product honestly delivers the nutrients listed on the label.

Addressing different issues

An inspector will contact the establishment where the feed sample was collected to address the WFS, the issue with the product, and the options available to remedy the situation.

If the feed can be safely used with a modification, CFP is generally willing to work with the feed establishment to remanufacture and relabel, or modify the labeling in some way, to not force the destruction of the product and keep it in commerce. In the event that the feed is not salvageable (i.e. improper drug combination) destruction may be the only option. The establishment can also decide it is not worth the time and effort to make corrections and may choose this option on its own.

Enforcement Program

NDA has an enforcement program with documented enforcement strategies. The enforcement program also has a documented process for evaluating enforcement strategies to identify improvements or modifications to the program.

Violation Categories

- Administrative
 - Fees; Tonnage
- Labeling
- Inspection
- Sampling Analysis & Results
- Contamination

Each violation is scored based on the following factors: Compliance History; Responsiveness; Scope; Nature of Violation; Impact of Violation; and Resources.

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The establishment must obtain a Release Order from NDA prior to moving or modifying any product under a WFS. If the product has all been sold prior to receiving the WFS report and the deficiency does not require a recall, we will close this instance. However, all WFS are recorded in the program enforcement record. If feed is salvageable, the feed will be released for sale when the agreed upon modifications are made. A WFS resulting in the voluntary destruction of a feed should obtain a Release Order before disposing of the product on hand. Destruction options can be discussed with CFP at this time.

Very rarely, we do find a sampled feed that may be adulterated to a level that could cause death or illness in the intended species. All analytical results from our lab are run twice before reporting. If we encounter a situation where we believe there is a potential problem on the initial lab run, our lab will contact the regulatory program and our staff will try to reach you as soon as possible to make you aware of the preliminary results. While we do not have legal authority at that point to put a hold on your product, we do ask that you consider placing a hold on that product until results are complete.

We know Nebraska feed businesses strive to meet the needs of their customers and, along with the Commercial Feed Program, have a goal of providing safe, nutritious, healthy, and honestly prepared feeds, foods, and treats for our livestock and pets.



Fiscal Year	WFS	Samples Collected	WFS Rate
2019-2020	133	1742	8%
2020-2021	153	1663	9%
2021-2022	95	1357	7%



Good Manufacturing Practices Reminders

The Nebraska Department of Agriculture (NDA) Commercial Feed Program would like to offer some helpful reminders to ensure feed safety and animal health, but also aid in keeping your operation in good regulatory standing. The Commercial Feed Program is here as a resource for you. If you have questions about regulatory policy, manufacturing and labeling, or feed and feed ingredients, please reach out to your inspector or the NDA Feed Program office. We hope you'll find the list below to be a helpful resource.

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Current Good Manufacturing Practice (CGMP)

There are 8 components of CGMP compliance that establish a baseline for safe animal food and the creation of a food safety plan.

1. Personnel
2. Plant and Grounds
3. Sanitation
4. Water Supply and Plumbing
5. Equipment and Utensils
6. Plant Operations
7. Holding and Distribution
8. Holding and distribution of human food by-products for use as animal food

To read the entire [Subpart B—CGMP law](#), visit [the online Code of Federal Regulations](#).

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This list is not all-inclusive. It is the responsibility of each facility to comply with applicable rules/regulations.

Training Records: (21 CFR 507.14 – Personnel)

- Review the training records and Standard Operating Procedures (SOPs) that you keep for both your new and long-term employees. These training records should be updated at whatever terms, and for any processes that you deem applicable for your operation.
- Maintain easily accessible records of training even if you are the only employee.
- If you handle Medicated Feed or Veterinary Feed Directive (VFD) products, routine training regarding handling and storage is especially important to prevent loading errors or cross contamination that could result in animal health risks or regulatory consequences.

Pest Control: All firms should be monitoring some sort of pest control program year-round.

- This can be hired out or done in house.
- This includes a program for rodents, wildlife, and insects.
- This will help to mitigate infestations and ensure feed integrity and animal and employee health.

Feed Rotation/Expiration Dates:

- It's important to keep track of feed that may have been in storage for a long period.
- Not all feed has an expiration date. Some feed will just have a date of manufacture, and sometimes receiving records of when the product came in will need to be checked, but a rotation plan still applies.
- If you find product has reached or exceeded its expiration date, there are some disposal options. If it is medicated feed, before disposal, please contact your inspector or the NDA office for guidance. It may be worth also contacting your local landfill for local restrictions regarding medicated feed disposal.

General Housekeeping:

Routine cleaning is important when it comes to safeguarding feed integrity.

Interior of facility:

- Do a quick cleaning with a blower or broom.
- Keep doors and access points closed and properly sealed when not in use.
- Fix any leaking equipment right away to prevent product contamination or safety hazards.

Exterior of facility:

- Keep weeds and landscaping well-trimmed and pick up any trash or old equipment that would provide harborage to pests.
- Maintain drainage systems and fix any leaks that arise in the roof or walls promptly.
- Clean up manufacturing areas regularly to prevent buildup of dust and debris. Clean up any spilled feed or broken bags when they occur so that messes don't get out of control.

Reach out to us: Navigating all the regulations and elements of the ever-changing feed industry can be challenging. Don't hesitate to talk to your local feed inspector when you have questions or concerns. Contact info for the NDA Feed Program is listed at the end of this newsletter.

Preventative Controls for Animal Food Rule (PCAF) 21 CFR 507

“The PCAF requirements implement certain provisions of the FDA Food Safety Modernization Act (FSMA) established in section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g).”

“Establishing risk-based preventive controls designed to protect your animal food and the consumer (humans purchasing the animal food and animals consuming the food) from biological, chemical (including radiological), and physical hazards, enables you to apply a proactive and systematic approach to your food safety program. Risk-based preventive controls will not give you a zero-risk system for manufacturing, processing, packing, and holding animal food; rather, risk-based preventive controls are designed to minimize the risk of known or reasonably foreseeable animal food hazards that may cause illness or injury to humans or animals if they are present in the animal food you produce.”

- “Guidance for Industry #245: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals”

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

That is the first question to determine an establishment’s requirement to comply with the PCAF Rule. There are other questions to narrow down if an establishment is subject to all of 507, only some parts of 507, or exempt entirely.

To help determine if you are required to be in compliance, NDA has an online tool to walk you through those questions: [21 CFR Compliance Tool](#)

A requirement of the PCAF Rule is to have a written Food Safety Plan.

Components of a Food Safety Plan are:

- Hazard Analysis: To identify and evaluate known or reasonably foreseeable hazards for each type of animal food at your animal food facility, to determine whether they require a preventive control. (21 CFR 507.33 (a)(1))
- It’s possible you may determine that there are no hazards requiring a preventive control.

If a hazard requires a preventive control, the Food Safety Plan must include the following written documents:

- Preventive Controls as appropriate to your facility and animal food. (21 CFR 507.34)
- Procedures for monitoring the implementation of the preventive controls. (21 CFR 507.40 (a))
- Corrective Action procedures. (21 CFR 507.42 (a)(1))
- Verification procedures. (21 CFR 507.49 (b))
- Recall Plan. (21 CF 507.38 (a)(1))

It’s important to understand that the person preparing or overseeing the preparation of the Food Safety Plan must be a “qualified individual.” (21 CFR 507.3 (b)). The Food Safety Plan must also be signed and dated by the owner, operator, or agent in charge of the facility when the Food Safety Plan is first completed and whenever it is modified. (21 CFR 507.26)

NOTE: There is no standardized or required way to organize a Food Safety Plan. It can be electronic or hardcopy. However, it must be accessible.

Food Safety Plan Resources:

These are just some of the food safety plan resources out there. Find what works for your situation and facility.

Food Safety Preventive Controls Alliance

- [Training & Materials](#)
- [Guide to Creating a Livestock Food Safety Plan Under the Preventive Controls for Animal Food \(PCAF\) Rule](#)

North Carolina State Extension

- [PCAF Food Safety Plan](#)

California Department of Food and Agriculture

- [Food Safety Modernization Act—Templates, Examples, and Checklists](#)

Kansas Department of Agriculture

- [Feed Safety—video series, Food Safety Plan examples, fillable Food Safety Plan](#)

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One final thing that NDA would like to emphasize is that your establishment is likely already doing something similar to a Food Safety Plan. The key is making sure components are documented and employees are trained to understand the Food Safety Plan.

For help on the PCAF Rule, see [“Guidance for Industry #245: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.”](#)

Animal Feed Regulatory Program Standards (AFRPS)

“In 2011, the FDA and the Association of American Feed Control Officials (AAFCO) partnered to develop the Animal Feed Regulatory Program Standards (referred to as the Feed Standards). The 11 Feed Standards establish a uniform foundation for the design and management of states' programs responsible for the regulation of animal food. Through implementing the Feed Standards, a state's program will be better able to achieve and maintain programmatic improvements that help ensure the safety and integrity of the U.S. animal food supply. A state's implementation of the feed standards also helps to ensure a uniform and consistent approach to animal food regulation among jurisdictions. The goal of the standards is to leverage resources and share common successes to build systems within state regulatory feed programs.”

In Nebraska, AFRPS is a cooperative agreement between the state and FDA where the FDA provides funding opportunities to the state to develop and maintain best practices, enhance animal food safety, and direct regulatory activity to reducing foodborne illness attributed to safety hazards in facilities that manufacture, process, pack, or hold animal food. AFRPS has allowed our feed program to purchase equipment, attend trainings and conferences, and update technology.

Nebraska's CFP achieved full implementation in January 2020 and FDA verified continued implementation by audit in August of 2022.

For more information regarding AFRPS visit:

<https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/regulatory-program-standards/animal-feed-regulatory-program-standards-afmps-and-preventive-controls-cooperative-agreement-program>



AFRPS
Animal Feed Regulatory Program Standards

States participating in AFRPS:	
Alabama	Missouri
California	Nebraska
Colorado	New Jersey
Connecticut	New Mexico
Florida	North Carolina
Georgia	Ohio
Iowa	Pennsylvania
Indiana	South Carolina
Kansas	Tennessee
Kentucky	Texas
Louisiana	Washington
Michigan	West Virginia

Resources	Website
NDA's Commercial Feed Program Website	https://nda.nebraska.gov/animal/feed/index.html
Reportable Food Registry for Industry	https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry
Veterinary Feed Directive	https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-vfd
Registration of Food Facilities and Other Submissions	https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions
AAFCO: For Startups – Starting a Pet Food Business	https://www.aafco.org/resources/startups
Code of Federal Regulations: 21 CFR 500-589	https://www.ecfr.gov/current/title-21/chapter-1/subchapter-E

Commercial Feed Inspection Fees FAQs

When are inspection fees due?

- Commercial Feed Tonnage fees are due twice each year.
- For sales Jan-June, due by the following Aug. 15.
- For sales July-Dec, due by the following Feb. 15.
- Inspection fees for small package products (10 lbs. and less) are due one time per year by Jan. 31. Fees are \$25 per product.

Are there late fees?

- A 25% late fee will be assessed for fees submitted within 30 days of the due date.
- A 50% late fee will be assessed for fees submitted after 30 days from the due date.

Who must pay the inspection fee?

Commercial feed inspection fees are the responsibility of the manufacturer. These can be paid by a broker or distributor if the Department of Agriculture is aware of the arrangement and the manufacturer maintains documentation of the arrangement.

For a complete FAQs list, see [“FAQs for Commercial Feed, Fertilizers and Soil Conditioners, and Agricultural Liming Materials Inspections Fees.”](#)

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