NEBRASKA
Good Life. Great Roots.
DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH PROTECTION
COMMERCIAL FEED NEWSLETTER

AUTUMN 2024 VOLUME 2

Inside This Issue:

Commercial Feed Program's Mission

To safeguard human food and animal health, and ensure 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.

nda.nebraska.gov/aphp

Food Facility Registration Renewal Period

Domestic and foreign facilities that manufacture, process, pack, or hold food as defined by 21 CFR 1.227 for human or animal consumption in the U.S. must register as a food facility with FDA under the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002," and then renew that registration biannually on even-numbered years.

The next renewal period is open until December 2024. There is no fee for registration, updates, or renewals. For more up-to-date information or to renew your food facility registration, go to: https://www.fda.gov/food/registration-food-facilities-and-other-submissions/online-registration-food-facilities.

If you require additional assistance, please contact the FDA Industry Systems Help Desk at furls@fda.gov, toll-free in the USA 1-800-216-7331 or 240-247-8804.

In accordance with 21 CFR 1.232(a)(2), since Oct. 1, 2020, all facilities must include a unique facility identifier (UFI) recognized by the FDA with their registration information. The FDA recognizes the Data Universal Numbering System (DUNS) number as an acceptable UFI. DUNS numbers are assigned and managed by Dun & Bradstreet (D&B).

To obtain a DUNS number, please contact D&B directly by phone at 866-705-5711 or at https://www.dnb.com/duns/get-a-duns.html.

Obtaining a DUNS number is available free of charge for the first four numbers. It may take up to 45 days to get your DUNS number. You will be required to provide your UFI in "Section 2- Facility Name/Address Information" of your food facility registration.

Animal Feed Labeling

NDA's Feed Program has been conducting outreach to aid animal feed manufacturers with labeling. There have been several instances of incorrect labels found in commerce, so we would like to remind animal feed establishments of the requirements, and provide resources for animal food labeling, specifically for livestock and for bulk feed deliveries with/without medication.

Livestock Feed Labeling Overview

- Product name and its brand name, if any
- Purpose statement for the feed (identifying species and animal class(es))
- Guaranteed analysis statement
- Ingredient statement
- Directions for safe and effective use ("feeding directions" or "mixing directions," etc.)
    - Any required precautionary statements to enable the safe use of the product by users with no special knowledge of the purpose and use of the product.
- Manufacturer's or distributor's name and address
- Quantity or net weight statement, in both standard and metric units.

Nutrient / Guaranteed Units When Listed on a Label

Nutrient	Guaranteed Units
Crude protein (minimum)	Percentage by weight (%)
Equivalent crude protein from non-protein nitrogen (NPN) (minimum)	Percentage by weight (%)
Amino acids (minimum)	Percentage by weight (%)
Crude fat (minimum)	Percentage by weight (%)
Crude fiber (maximum)	Percentage by weight (%)
Acid detergent fiber (maximum)	Percentage by weight (%)
Neutral detergent fiber (maximum)	Percentage by weight (%)
Dietary starch (maximum)	Percentage by weight (%)
Sugars (maximum)	Percentage by weight (%)
Fructans (maximum)	Percentage by weight (%)
Calcium (minimum & maximum)	Percentage by weight (%)
Phosphorus (minimum)	Percentage by weight (%)
Salt (minimum & maximum)	Percentage by weight (%)
Sodium (minimum & maximum)	Percentage by weight (%)
Other required minerals (minimum) (grouped by units of measure)	Percentage by weight (%) (See exceptions)
Vitamins (minimum)	A, D, and E: International Units (IU) per pound D_3: International Chick Units (ICU) per pound B_{12}: milligrams or micrograms per pound
Other Vitamins (minimum)	Menadione, Riboflavin, D-pantothenic acid, Thiamine, Niacin, Vitamin B_6, Folic acid, Choline, Biotin, Inositol, p-Amino benzoic acid, Ascorbic acid, and Carotene: milligrams per pound (mg/lb)
Total sugars as invert (minimum)	Percentage by weight (%)
Viable microorganisms (minimum)	Colony-Forming Units (CFU) per unit of weight consistent with use directions (CFU/lb or CFU/gram)
Enzymes (minimum)	Units of enzymatic activity per unit of weight or volume consistent with use directions

Figure 1 - Listing Units on Label - from AAFCO Feed Labeling Guide, p. 10

For Labeling Medicated Animal Feeds

An issue we've seen is distributing the appropriate label with bulk delivered medicated feed. According to the Code of Federal Regulations, all deliveries of medicated feeds shall be adequately labeled.

It's a good practice to distribute the appropriate labels with the delivery of the feed itself. Sometimes that may be difficult when there is no one on site to receive the feed. Care should be taken to notify the customer in a timely manner of the delivery and where they can obtain the appropriate labels for their feed, whether placed somewhere onsite or distributed through email. If mailing the labels through postal service, ideally, they would be sent the same day and not, for example, at the end of the month with their bill.

CFR - Code of Federal Regulations Title 21 (fda.gov)

Animal Food Labeling Resources

- 21 CFR Part 501 -- Animal Food Labeling
- Animal Drugs @ FDA - Blue Bird Labels
- Guides and Manuals – AAFCO
- AAFCO Animal Feed Labeling Guide.pdf (aafco.org)

"Part 225 Current Good Manufacturing Practice for Medicated Feeds"

Subpart H.
Sec. 225.180 Labeling.
Labels shall be received, handled, and stored in a manner that prevents label mix-ups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used.

Labels with Bulk Orders ("Customer-formula" or "Custom formula")

Commercial Feed Act 54-852 (2)(a-g). Commercial feed; label requirements; customer-formula feed; requirements.

(2) In the case of a customer-formula feed, it shall be accompanied by a label, invoice, delivery slip, or other shipping document bearing the following information:

(a) Name and address of the manufacturer;
(b) Name and address of the purchaser;
(c) Date of manufacture;
(d) The product name and net weight of each commercial feed and each other feed ingredient used in the mixture;
(e) Adequate directions for use for all customer-formula feeds;
(f) The directions for use and precautionary statements as required by rules and regulations adopted and promulgated by the director; and
(g) If a drug-containing product is used:
(i) The purpose of the medication or a claim statement;
(ii) The established name and level of each active drug ingredient and the level of each drug used in the final mixture expressed in accordance with rules and regulations adopted and promulgated by the director; and
(iii) All appropriate precautions, warnings, and withdrawal statements as required by the director.
A duplicate copy of all the information required in subdivision (2) of this section shall be kept by the manufacturer for use by the department for sampling and inspection purposes.

Food Safety Plan and the PCQI

Do you have a food safety plan?

§ 21 CFR 507.31 Food Safety Plan

(a) You must prepare, or have prepared, and implement a written food safety plan.
(b) One or more preventive controls qualified individuals (PCQI) must prepare, or oversee the preparation of, the food safety plan.
(c) The written food safety plan must include:
(1) The written hazard analysis as required by § 507.33(a)(2);
(2) The written preventive controls as required by § 507.34(b);
(3) The written supply-chain program as required by subpart E of this part;
(4) The written recall plan as required by § 507.38(a)(1);
(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a);
(6) The written corrective action procedures as required by § 507.42(a)(1); and
(7) The written verification procedures as required by § 507.49(b).
(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

Do you use your food safety plan?

Do you have a PCQI?

§ 21 CFR 507.3 Definitions

- Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

507.53 Requirements applicable to a preventive controls qualified individual and a qualified auditor.

continued next page

(a) One or more preventive controls qualified individuals must do or oversee the following:
(1) Preparation of the food safety plan (§ 507.31(b));
(2) Validation of the preventive controls (§ 507.47(b)(1));
(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food;
(4) Determination that validation is not required (§ 507.47(c)(4));
(5) Review of records (§ 507.49(a)(4));
(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;
(7) Reanalysis of the food safety plan (§ 507.50(d)); and
(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable animal food.

(b) A qualified auditor must conduct an onsite audit (§ 507.135(a)).

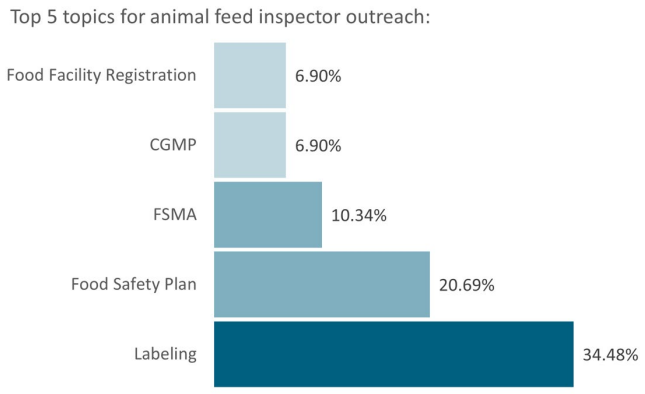
(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility; and

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

Food Safety Plan Resources

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



The Food Safety Preventive Controls
- PC Animal Food PCQI Participant Course
- FSPCA Guide for Creating a Livestock Food Safety Plan

North Carolina State Extension
- PCAF Food Safety Plan
- CGMP Self-Audit Summary Checklist (ncsu.edu)
- How Animal Food Facilities Can Prepare for Regulatory Inspections | NC State Extension Publications (ncsu.edu)

California Department of Food and Agriculture
Food Safety Plan Resources; Animal Food Hazards Resources; Supplier Verification; Self-Assessment Checklists
- Food Safety Modernization Act—Templates, Examples, and Checklists

Kansas Department of Agriculture
- Feed Safety—video series, food safety plan examples, fillable food safety plan

American Feed Industry Association (AFIA)
- Educational Resources & Events - AFIA

National Grain and Feed Association (NGFA)
- Training – National Grain and Feed Association (ngfa.org)

Program Report

Report of Retail Commercial Feed Sales in Nebraska for the period Jan. 1, 2023, to Dec. 31, 2023
(All units are in tons).

Feed Ingredients	Period Jan23-Dec23	% of Total
Distillers Products	6,788,425.9	65.80%
Corn Products	1,440,056.5	13.96%
Soybean Products	646,094.4	6.26%
Beet Products	495,826.3	4.81%
Wheat Products	248,476.2	2.41%
Minerals	164,891.9	1.60%
Animal Products	146,678.5	1.42%
Fats & Oils	134,280.1	1.30%
Brewers Products	106,597.1	1.03%
Miscellaneous	64,621.7	0.63%
Molasses	13,155.1	0.13%
Marine Products	12,738.6	0.12%
Alfalfa Products	12,663.3	0.12%
Sunflower,Linseed & oth meal	9,784.9	0.09%
Urea/NPN	9,341.9	0.09%
Barley Products	7,803.5	0.08%
Vitamins	3,883.5	0.04%
Cottonseed Products	3,789.6	0.04%
Yeast Products	3,338.3	0.03%
Oat Products	2,043.1	0.02%
Milk Products	2,027.7	0.02%
Poultry Products	368.5	0.00%
Peanut Products	218.3	0.00%
Rice Products	190.2	0.00%
Grain Sorghum Products	1.2	0.00%
Rye Products	-	0.00%
Total	**10,317,296.2**	

Feed Types	Beef Dry	Beef Liquid	Dairy	Horse/Sheep	Misc.	Multiple Use	Pet Food	Poultry	Swine
Complete	181,854.3	20,445.4	7,306.6	25,978.4	27,418.8	10,305.8	161,414.1	84,580.7	112,185.4
Mineral	28,247.5	-	532.2	941.7	23,679.2	343,222.9	173.3	202.3	1,511.5
Premix	21,860.2	-	3,052.5	135.9	8,401.4	268,088.2	3,820.5	677.2	7,988.5
Supplement	249,069.7	665,115.1	42,494.4	4,372.9	7,007.1	2,452.7	530.8	2,029.2	24,852.2
Vitamin	-	-	-	-	-	6,765.8	-	-	-

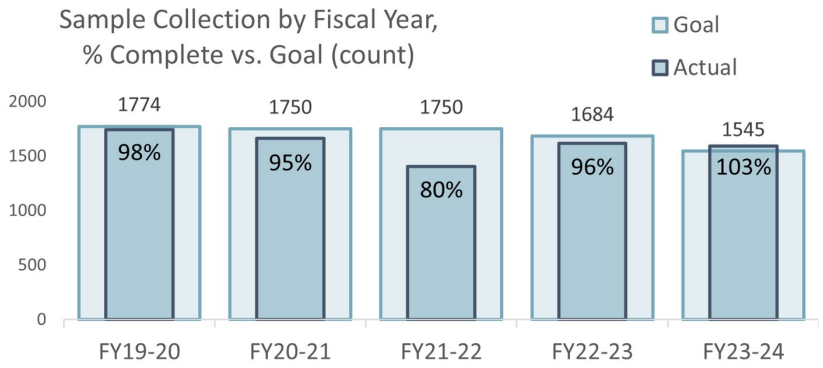
Description	Total Tons
Feed Ingredient Tonnage	10,317,296.2
Feed Tonnage	2,348,714.4
Total	**12,666,010.6**

Feed Sampling Program

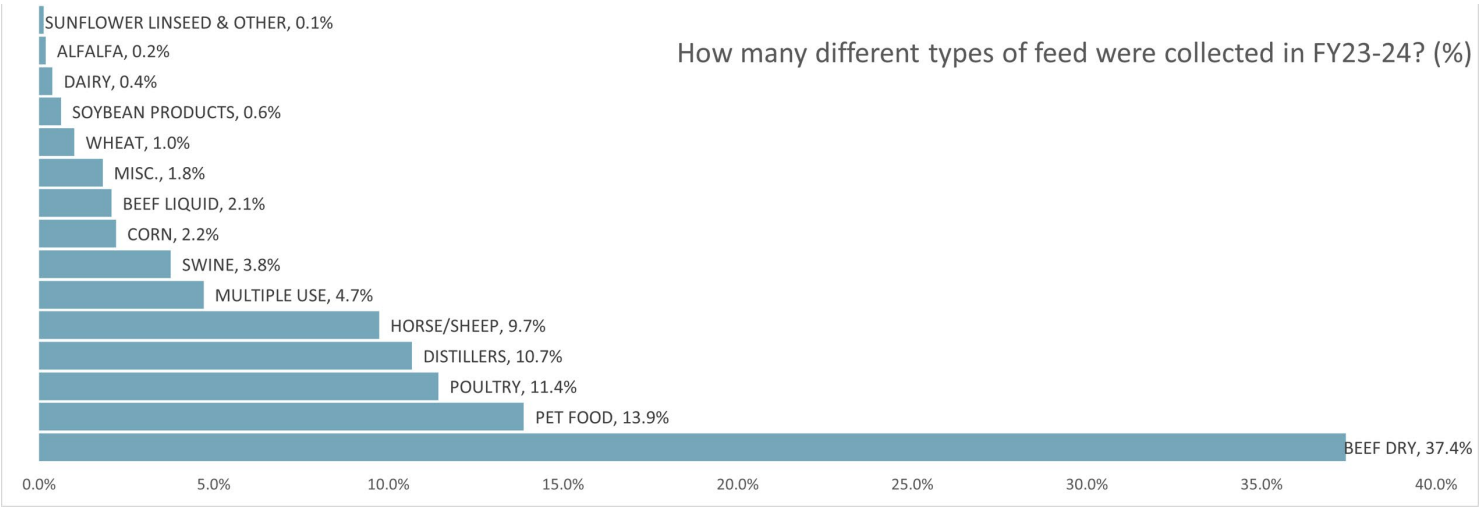
Nebraska Feed Program staff collects animal feed product samples and submits them for laboratory analysis to protect animal and public health and to enforce feed regulations.

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.

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.



Grain Survey FY23-24					
Corn				Wheat	
Samples Collected	Protein (Low;%)	Protein (Avg;%)	Protein (High;%)	Samples Collected	Mycotoxin Testing
35	6.62	7.61	9.03	15	All samples below FDA action levels for aflatoxin, fumonisin, vomitoxin (DON), zearalenone.

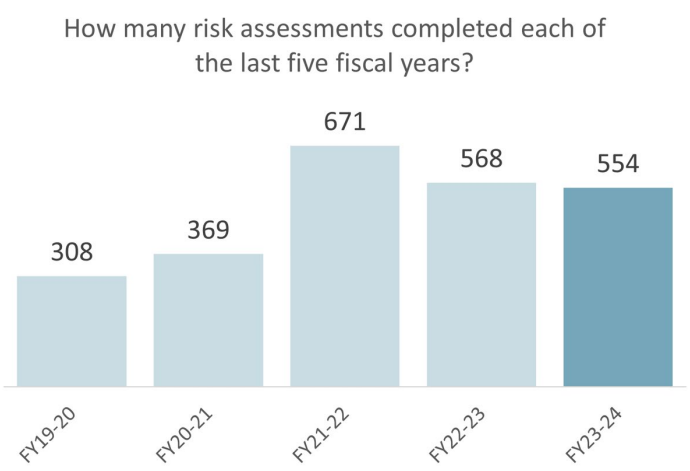


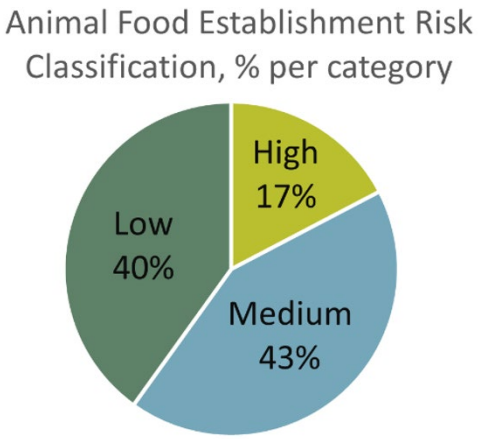
Feed Firm Risk Assessments

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. New firms are designated high risk until an assessment is completed within 1 year.

Minimum Inspection Timelines:
Low Risk: at least every 5 years.
Medium Risk: at least every 2 years.
High Risk: at least every year.

Risk Assessment Scoring:
Low Risk: 0-25 points;
Medium Risk: 26-74 points;
High Risk: 75+ points





The below charts represent the risk assessments completed during the period July 1, 2023, to June 30, 2024. These are the firms that received a risk assessment and the types of operations and feed they have. Each firm can have multiple types of each.

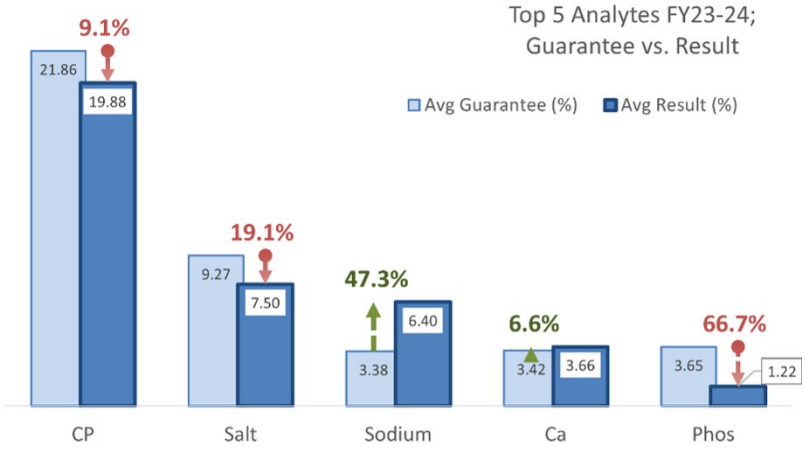
Types of Operations	Exstrusion	Steam Flaking	Human Food Processor	RePackage-ReLabel	Transporter
	7	1	1	3	104
Feed Mill	**Pelleting**	**Liquid Feed**	**Pet Food Manufacturer**	**Retail Only**	**Warehouse**
137	17	23	12	201	283
Ethanol Plant	**Mixing**	**Grinding**	**Tub Block**	**Renderer**	**Toll Milling**
9	115	107	4	1	7

Types of Feed				
Bulk	**Free Choice**	**Mixed Species**	**Pet Food**	**Single Species**
139	211	219	428	439
Canned	**Liquid**	**Non-Feed Product Hazards**	**Prohibited Material**	**Small Package**
176	31	33	1	214
Custom Formula	**Medicated Feed**	**Non-Medicated**	**Raw Pet Food**	**VFD**
120	277	413	36	200

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.

Each violation is scored based on the following factors: compliance history; responsiveness; scope; nature of violation; impact of violation; and resources.



The top 5 analytes that have been found to be violative are:

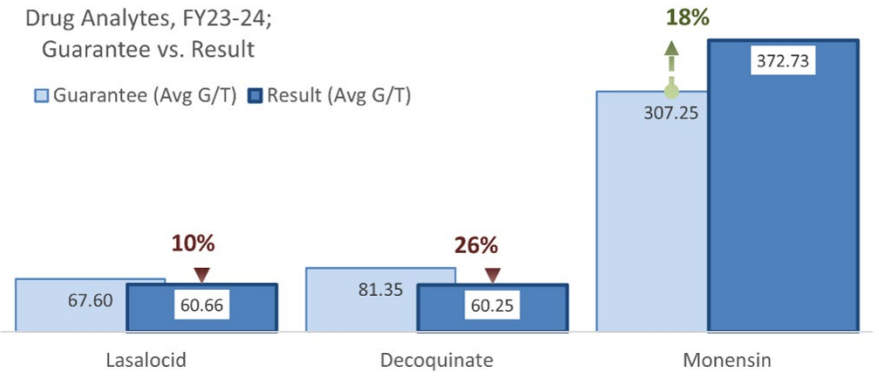
- Crude Protein (CP)
- Salt
- Sodium
- Calcium (Ca)
- Phosphorus (Phos)

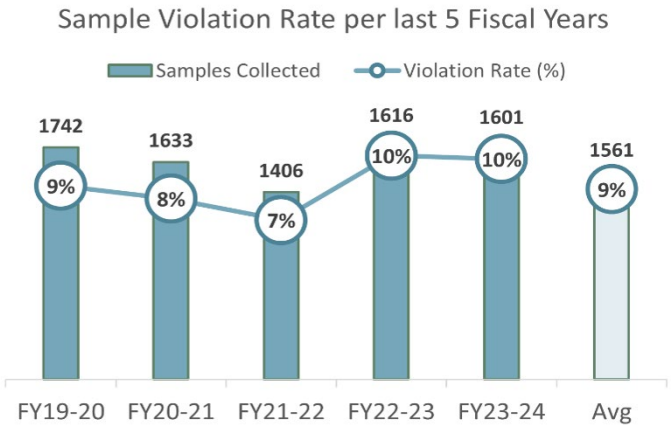
The ratios for some may appear quite large, but with the amount that is included in feed and the analytical variances, the tolerance between passing and violation can be quite small.

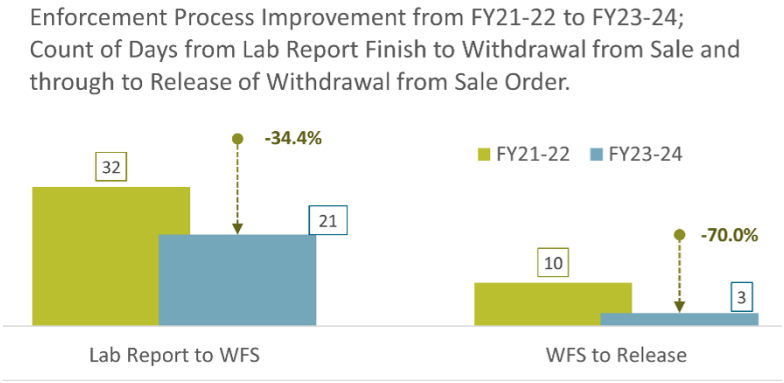
The animal drugs that have been found to be violative are:

- Monensin
- Decoquinate
- Lasalocid

When deciding enforcement actions, the lab result in comparison to the guarantee and impact of violation (minor economic, animal safety, human health and safety) , and target species are considered before a decision is finalized.







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 NDA's 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 2022, and June 2024.

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-afrps-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

Resource	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- I/subchapter-E
FSPCA Preventive Controls for Qualified Individuals	https://www.fspca.net/pc-animal-food-preventive-controls-qualified-individual

Commercial Feed Inspection Fees FAQs

When are inspection fees due?

- Commercial Feed Tonnage fees are due twice each year.
- For sales Jan-June, fees are due by the following Aug. 15.
- For sales July-Dec, fees are 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 after the due date.
- A 50% late fee will be assessed for fees submitted after March 1/ September 1.

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 Inspection Fees"

Department of Agriculture
Commercial Feed Program
402-471-2351

Steve Gramlich
Feed Program Manager

Charles Hubenka
Feed Program Specialist/ AFRPS Coordinator

Chelsea Mills
Feed Program Specialist/ AFRPS Auditor

Thomas Minary
Office Specialist

Kaylie Fritts, DVM
Deputy State Veterinarian

Inspectors:
Liam Dunn - West (Panhandle)
Kent Exstrom - Southwest
Doug Koester - Northeast
Sarah Marx - East Central
Kellen Novak - Southeast