

DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION NOTICE OF PROPOSED GUIDANCE DOCUMENTS

Pursuant to section 227.112 of the Wisconsin Statutes, the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) is hereby accepting comments on the proposed guidance document:

CY2020 Webinar Series: Non-Medicated Feed Tonnage, Sampling, and Inspections

LOCATION OF PROPOSED GUIDANCE

Proposed guidance document may be reviewed by accessing:

https://datcp.wi.gov/Pages/About_Us/GuidanceDocuments.aspx

SUBMITTING PUBLIC COMMENTS

Public comments on proposed or adopted guidance document may be submitted by accessing:

https://datcp.wi.gov/Pages/About_Us/GuidanceDocuments.aspx

DEADLINE FOR SUBMISSION

The comment period will run no fewer than 21 days after the publication of this document in the Administrative Register.

AGENCY PUBLICATION

The attached guidance document contains statements or interpretations of law under the following applicable provisions of federal law or the applicable state statutory or administrative code provisions: Wis. Stat. ch. 94.72, Wis. Admin. Code, ch. ATCP 42.

CERTIFICATION

Pursuant to the authority delegated to me by the Secretary, I have reviewed the attached guidance document or proposed guidance document and I certify that it complies with sections 227.10 and 227.11 of the Wisconsin Statutes. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is not explicitly required or explicitly permitted by a statute or a rule that has been lawfully promulgated. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is more restrictive than a standard, requirement, or threshold contained in the Wisconsin Statutes.



Sara Walling

Administrator

Division of Agricultural Resource Management



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GUIDANCE DOCUMENT

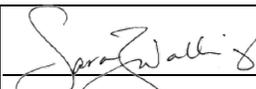
CY2020 Webinar Series: Non-Medicated Feed Tonnage, Sampling, and Inspections

This guidance document is based on Wis. Stat. ch. 94.72 and chapter(s) ATCP 42 Wis. Admin. Code. This document is intended solely as guidance, and does not contain any mandatory requirements except where requirements found in statute or administrative rule are referenced. This guidance does not establish or affect legal rights or obligations, and is not finally determinative of any of the issues addressed.

25 (ARM)

The feed program is planning a webinar series for the spring of CY2020 related to the different types of feed manufacturers in the state of Wisconsin, according to the inspection type. This is one of three unique webinars that will be presented as an outreach effort. The non-medicated feed manufacturer webinar will cover content related to human food manufacturers distributing byproduct as animal feed, organic feed mills, ingredient manufacturers that do not use animal drugs, and the like. The non-medicated feed webinar is tentatively planned to be a 90 minute presentation held in the late morning of February 25, 2020. Topics covered include feed tonnage, feed surveillance sampling, and “what to expect from an inspection.”

A previous feed specialist conducted regional meetings similar to these webinars in format, and the meetings were well-received by industry. In order to limit travel expenses for DATCP staff and the attendees, webinars seemed one of the most suitable ways to bring the outreach idea back into the feed program.

	11-12-19 Click or tap to enter a date.
Sara Walling - Administrator, Division of Agricultural Resource Management	DATE
Contributors: Heather Bartley, Carla Doelle, Kevin Brey, Andrew Dal Santo, Robby Personette	

Commercial Feed Program - Non-Medicated Feed Manufacturers

Housekeeping and Agenda

- Speakers on mute
- Questions at end (30 min)
- Tonnage
- Sampling
- Inspections
- Labels

Feed Tonnage Statute Changes



To help you delineate

- **Inspection fee (money)**

- Fees collected based upon distribution of commercial feed by the first to sell or distribute in or into the state of WI
- The money assessed on the quantity of commercial feed sold or distributed
- Commonly known as “tonnage tax”



- **Tonnage (commodity)**

- A quantity of commercial feed and is based upon distribution by the first to sell or distribute in or into the state
- Quantity or count



Licensing

Licenses required for:

- Manufacturers of commercial feed
- Labelers of commercial feed
- Distributors of commercial feed (see below)

Activities currently not required to have a commercial feed license:

- Distribution of packaged commercial feed as packaged and labeled by the entity whose name appears on the label
- Distribution of bulk commercial feed in the form received from and labeled by a licensee, except for net weight statement
- Distribution of custom-mixes, if ingredients in the mixture were already assessed the inspection fee by a previous licensee.

Change to Responsibility Requirement

If more than one manufacturer or distributor is involved in the chain of distribution, the one who first sells or distributes commercial feed in this state or to a person in this state for further sale is responsible for the payment of the inspection fees for the feed.

***Note – Brokers and distribution businesses may now be responsible to report and pay inspection fees under the revisions*

Summary of changes to Statute

Minimum inspection fee of \$50.00 for 0 – 200 tons

- Removed exempt buyer license status
- Removed credit reporting requirements
 - prepaid purchases
 - distributions/purchases to exempt buyers
 - exempt buyers' out of state distributions



New Guidances Available

Check them out at datcp.wi.gov

- Frequently Asked Questions & Flowchart
- Tonnage Form Instructions

[DATCP Home](#) > Commercial Feed Licensing Forms and Tonnage Reporting

Commercial Feed Licensing Forms and Tonnage Reporting

Feed Tonnage Changes

Changes to commercial feed tonnage and inspection fees have changed, effective January 1, 2018. For reporting purposes, these changes are effective with reporting for calendar year 2018 distributions, with paperwork to be completed in early 2019. Changes that took effect January 1:

- Minimum inspection fee increases to \$50.00 for 0-200 tons, or \$0.25/ton for 201 or more tons, whichever is greater. Fee was previously \$0.25 per ton.
- Exempt buyer status licenses go away
- All credits go away (prepaid purchases, exempt buyer sales/purchases, out-of-state distributions)
- Invoices no longer required to display that inspection fees are not paid
- Report only tons of feed and feed ingredients if you are the first to distribute into Wisconsin

[Tonnage reporting guidance](#)

[Summary of changes -- marked-up legislation](#)

Commercial Feed Surveillance Sampling

Sampling - Background

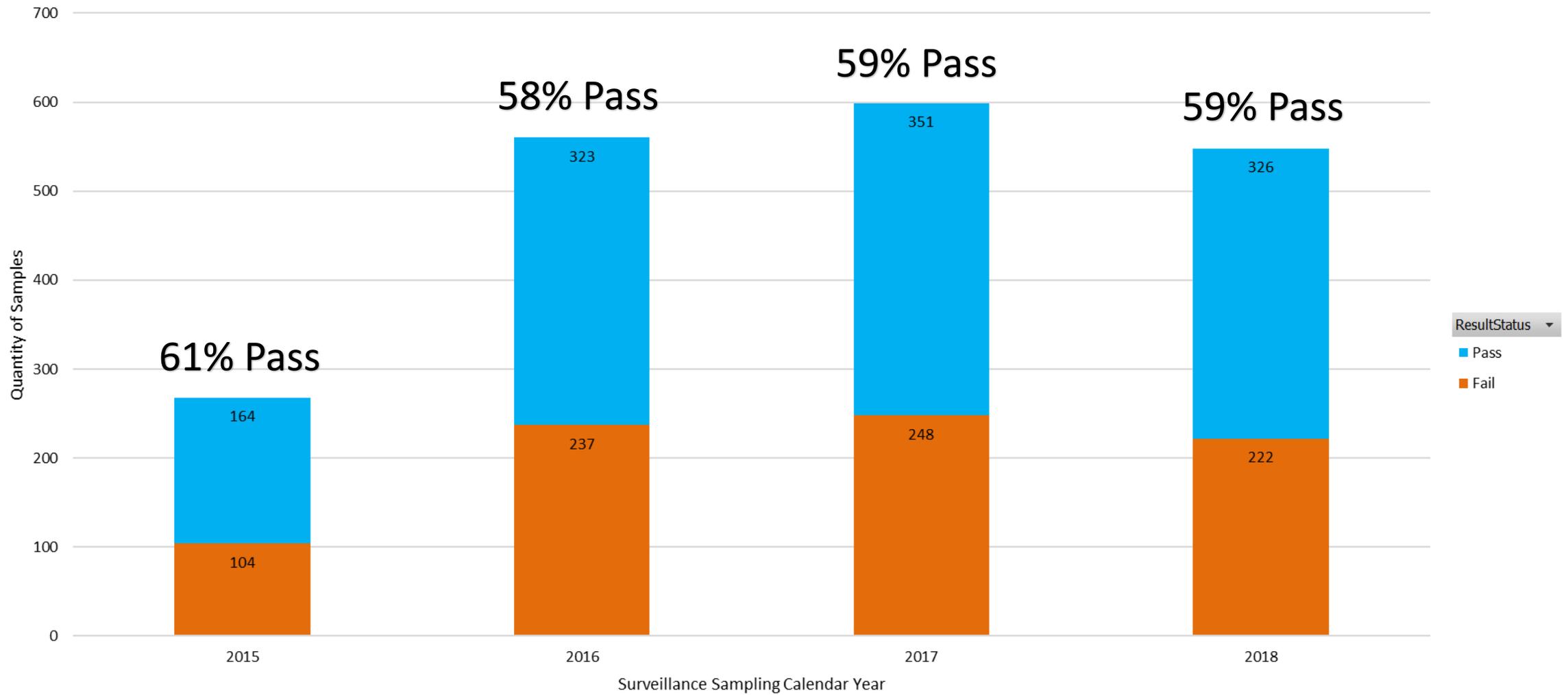
- Sample quantities were not representative in the past
- Conducted Six Sigma project to review quantities and goals to determine “knobs to turn” for representative samples
- 2015 - Now:
 - 2015 – approx. 370 samples
 - 2016 – approx. 600 samples
 - 2017 – approx. 600 samples
 - 2018 – approx. 600 samples
 - 2019 – tentatively 600 samples

Pet Food Sampling

- No pet (dog/cat) food samples are included within the data in this presentation.
- Pet Food sampling project conducted in 2017
 - Number of samples collected: 100
 - Pass/Fail: 85/15
 - Pass percentage: 85%
- Number of analytes for each sample: 25-27

Count of ResultStatus

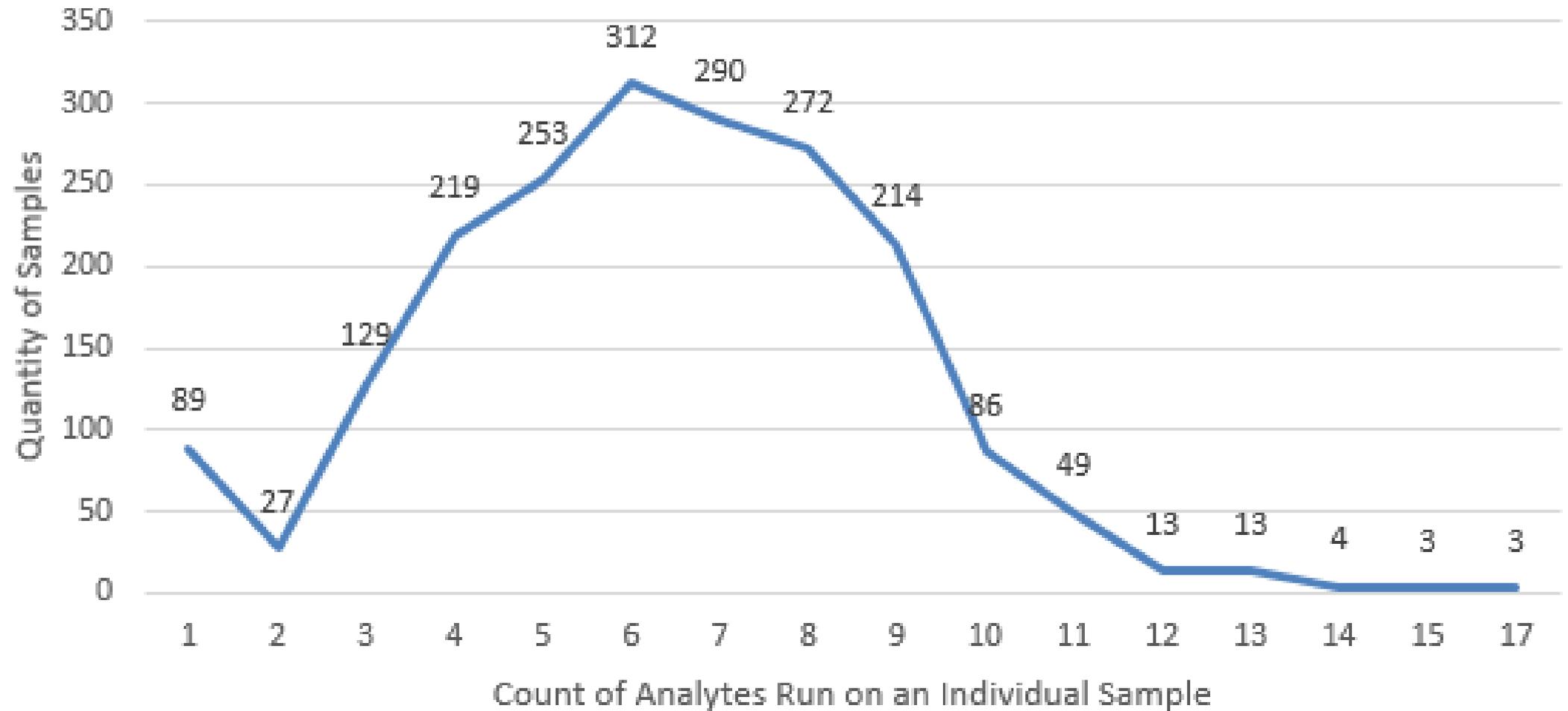
Feed Surveillance Samples 2015-2018



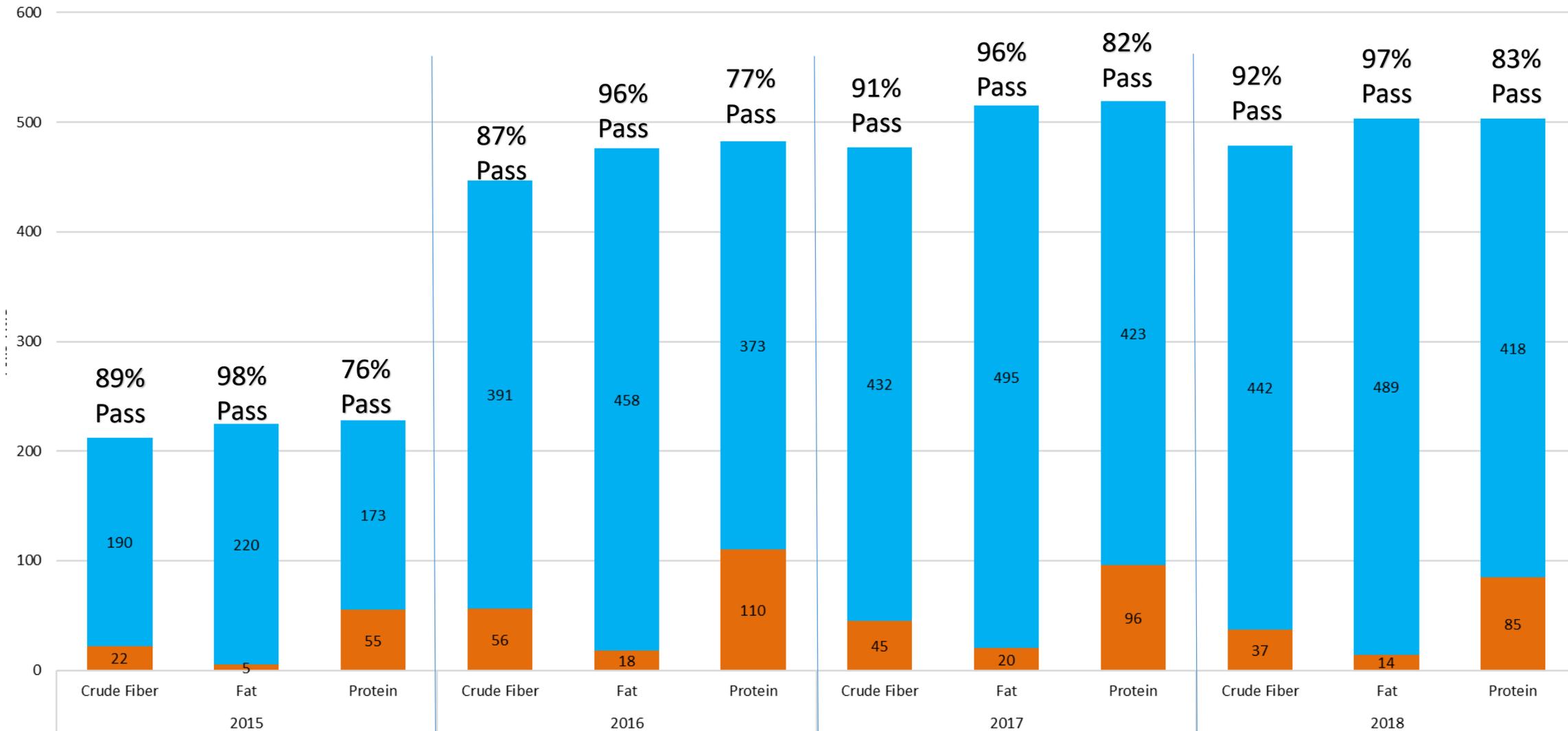
Years ▾ Quarters ▾ Sampling_Date ▾

+ -

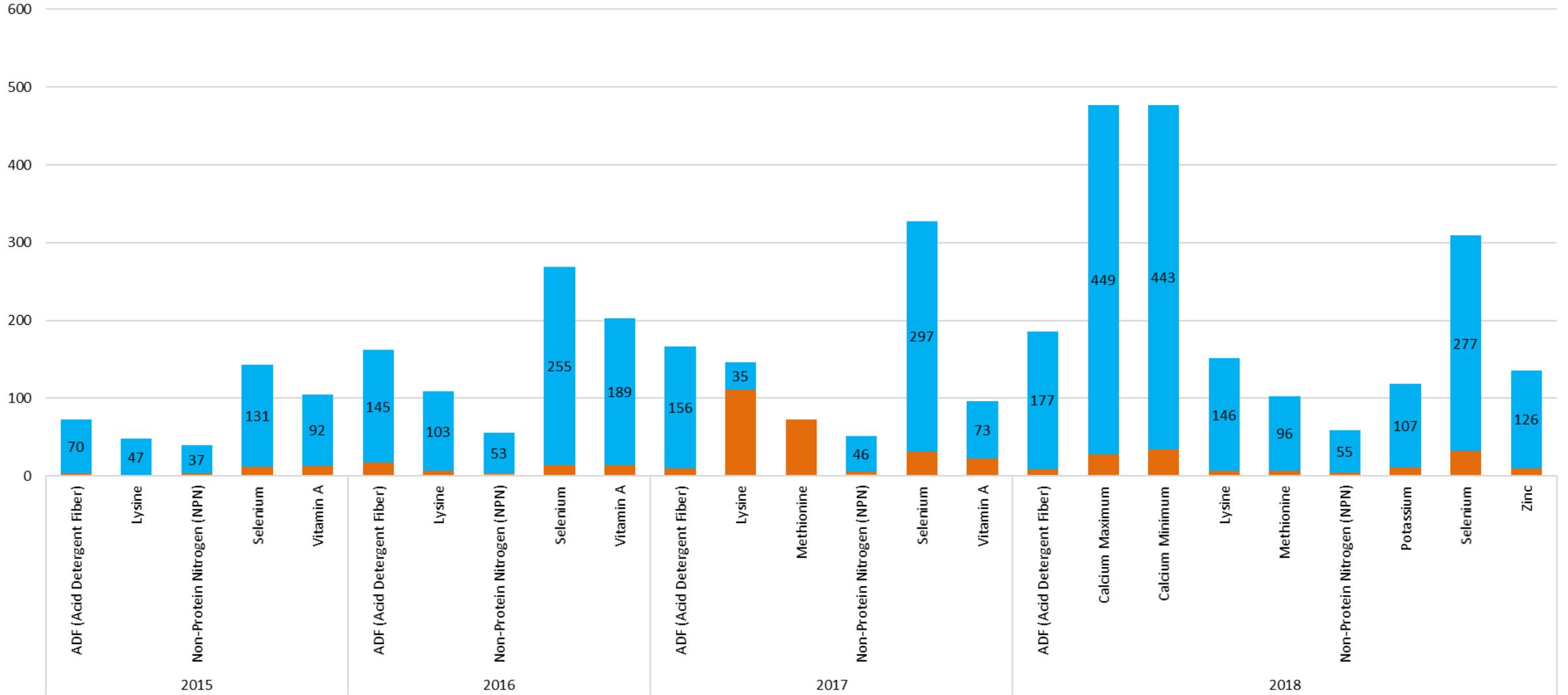
Quantity of Analytes Run Per Sample 2015-2018



Results by Analyte for Feed 2015-2018



Results by Analyte for Feed 2015-2018

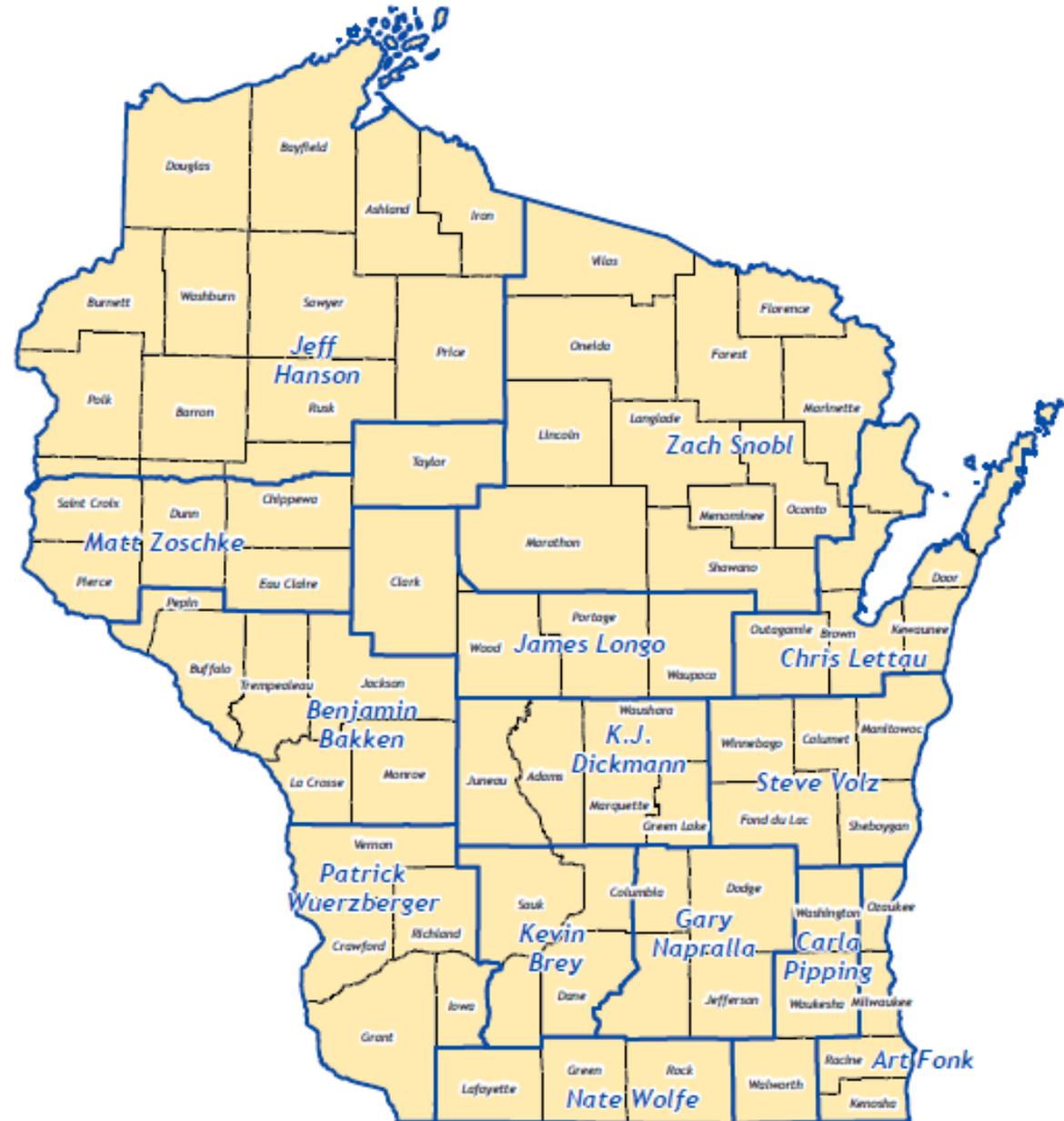


Ideas to Positively Impact Results

- Regularly check nutrient values against label guarantees of mill-formulated feeds
- Remember to update labels when updating formulas
- Review mixing SOPs
 - Are the times adequate for a homogenous mixture?
 - Is the mixer in good working order?
 - Is it outdated for today's ingredient types, premixes and formulations?
- Regularly update nutrient values in ration software
- Check expiration dates – especially on feed-through medications and direct-fed microorganisms
 - Destroy expired products
- Check inclusion rates to factor in degradation by time, temperature and processing

*See
Handout*

Inspections



Stepped Enforcement Activity

- For critical violations involving labeling and cGMP, DATCP has a stepped enforcement plan to address continuing violations that will initiate an investigation result in civil forfeitures.
 - Civil penalties available as of 2017
 - Criminal penalties always available

Four Key Aspects

- Licensing
- Cleanliness (buildings, equipment)
- Records
- Labeling



Cleanliness

- Buildings and facilities shall be clean, in good repair, and free of unhealthful or unsanitary conditions.
- Rodents, raccoons, birds, cats, insects, etc. can
 - carry disease,
 - contaminate feed with feces, and
 - damage bags which results in a direct economic loss to you.
- Cleanliness inside and outside the mill will minimize or prevent pest infestation.

A long, red metal warehouse building with a grassy area in front of it. The building is on the left side of the frame, extending into the distance. The grassy area is overgrown with various weeds and shrubs, particularly near the base of the building. In the background, there are utility poles, a fence, and some trees under an overcast sky.

Vegetation control along
warehouse and mill needed to
prevent pest infestations



Pallets stored
along wall can
harbor pests

Unrepaired damage to wall
can allow pest access



Unrepaired roof leaks may lead to mold growth

Extensive sparrow activity in mill led to significant bird poop on floor and bags



Consider establishing a written housekeeping schedule to make sure spills are routinely cleaned up



11/04/2015 12:03



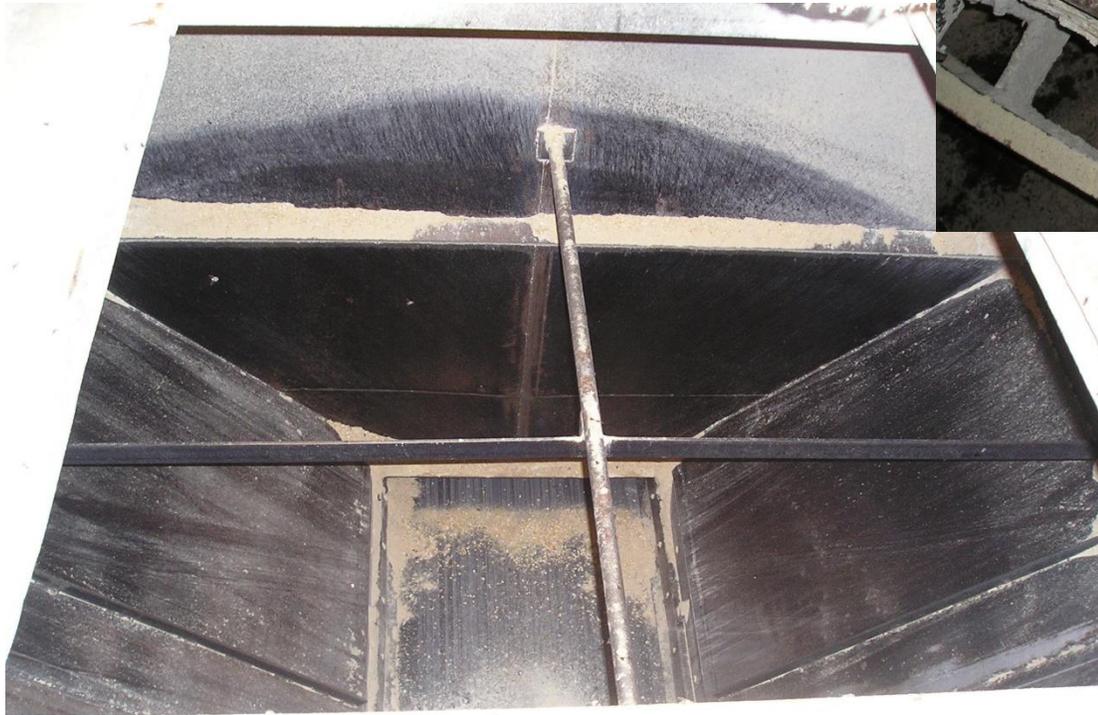
Establish a written housekeeping schedule to make sure spills and feed dusts are routinely cleaned up



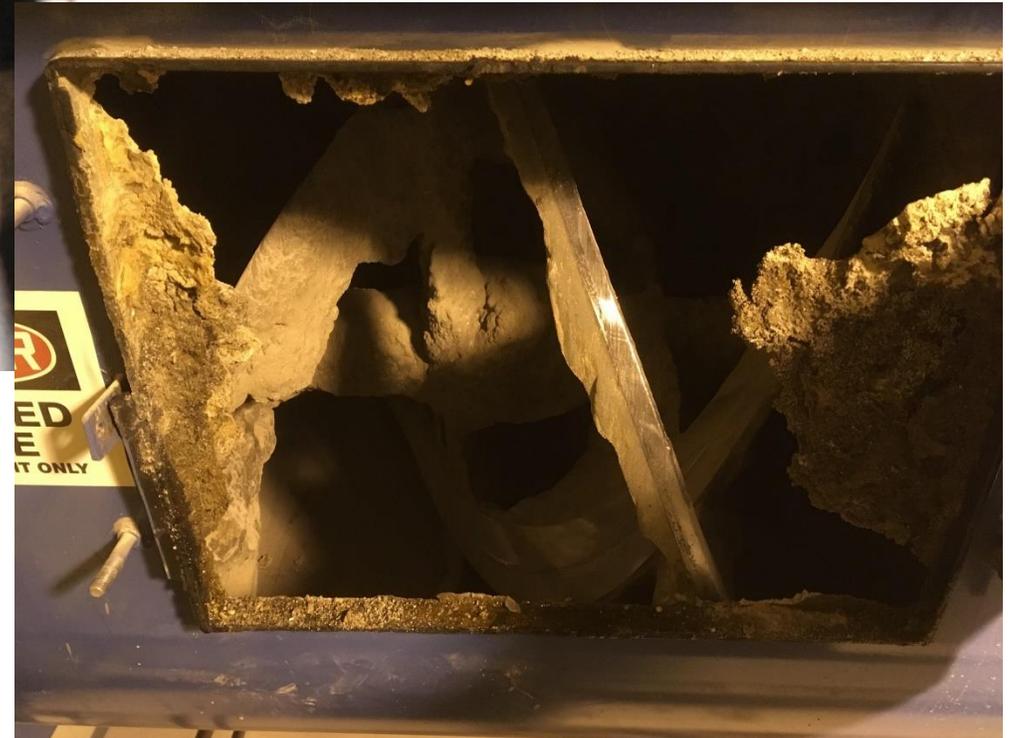
Cleanout Procedures

- Adequate cleanout procedures to prevent unsafe contamination of feeds – such as vitamin or mineral carryover
 - Sequencing
 - Flushing
 - Physical

Trucks



Mixers



Inadequate Cleanout

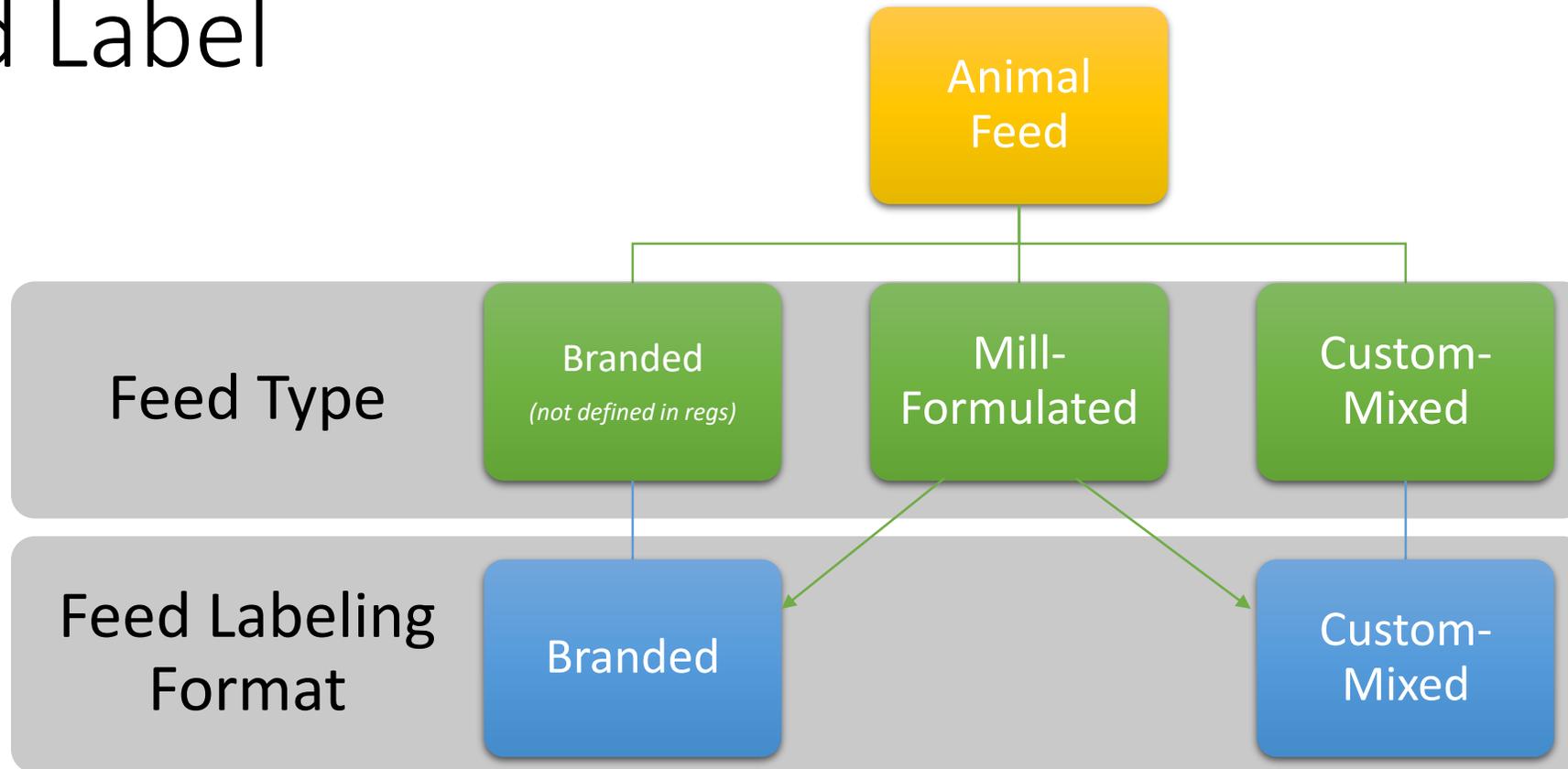




Labels

(5 min break)

Feed Type v. Feed Label



Non-medicated “branded” format

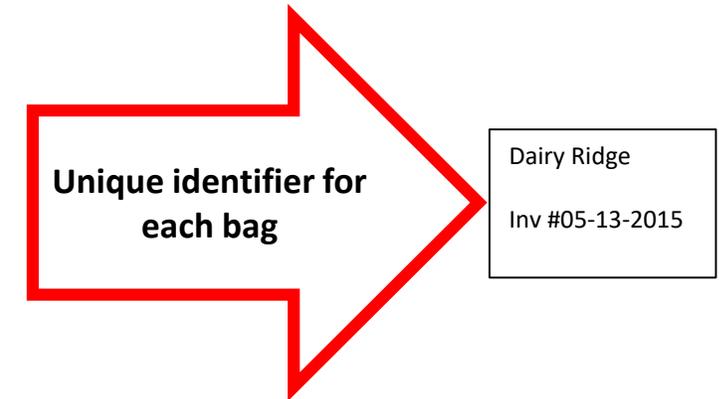
Brand Name	YOUR NAME FEEDS
Product Name	401's Special SHEEP FEED
Purpose Statement (and medicated claim if required)	 For breeding ewes.
Drug Guarantee (if applicable)	
Guaranteed Analysis	<p>Guaranteed Analysis</p> <p>Crude Protein, minimum15.0% (This includes not more than 1.0% equivalent crude protein from non-protein nitrogen)</p> <p>Crude Fat, minimum2.0%</p> <p>Crude Fiber, maximum20.0%</p> <p>Calcium, minimum0.8%</p> <p>Calcium, maximum1.3%</p> <p>Phosphorus, minimum0.35%</p> <p>Salt, minimum0.35%</p> <p>Salt, maximum0.85%</p> <p>Copper, minimum5.0 ppm</p> <p>Copper, maximum10.0 ppm</p> <p>Selenium, minimum0.3 ppm</p> <p>Vitamin A, minimum.....7000 IU/lb</p>
Ingredient Statement	<p>Ingredient Statement</p> <p>Grain Products, Plant Protein Products, Processed Grain By-Products, Roughage Products, Ammonium Chloride, Vitamin A Supplement, D-Activated Animal Sterol (source of Vitamin D₃), Choline Chloride, Biotin, Thiamine Mononitrate, Pyridoxine Hydrochloride, Vitamin E Supplement, Copper Sulfate, Folic Acid, Ethoxyquin (a preservative), Calcium Carbonate, Dicalcium Phosphate, Monocalcium Phosphate, Manganous Oxide, Zinc Oxide, Ferrous Sulfate, Cobalt Carbonate, Potassium Chloride, Sodium Selenite.</p>
Use Directions	<p>FEEDING DIRECTIONS</p> <p>Feed as the sole source of grain to breeding ewes at the rate of 2 to 3 pounds per head per day.</p>
Precautionary Statement (if required)	Caution: Use as Directed. For Sheep Only.
Responsible Party's Name & Address	<p>Guaranteed by: YOUR NAME FEEDS City, State Zip</p>
Quantity Statement	NET WT 50 lb (22.67 kg)

Single ingredient

Brand Name	BLUE BIRD
Product Name	Solvent Extracted Soybean Meal
Purpose Statement (and medicated claim if required)	For further manufacture of feed
Drug Guarantee (if applicable)	
Guaranteed Analysis	<p>Guaranteed Analysis</p> <p>Crude Protein, minimum.....44.0%</p> <p>Crude Fat, minimum3.0%</p> <p>Crude Fiber, maximum6.0%</p>
Ingredient Statement	
Use Directions	
Precautionary Statement (if required)	
Responsible Party's Name & Address	<p>Distributed by</p> <p>Bob's Feed Mill</p> <p>345 Main St., Nowhere, TX 96456</p> <p>713-555-5555</p>
Quantity Statement	Lot #030411 Net wt on Bulk invoice

Non-medicated “custom-mix” format

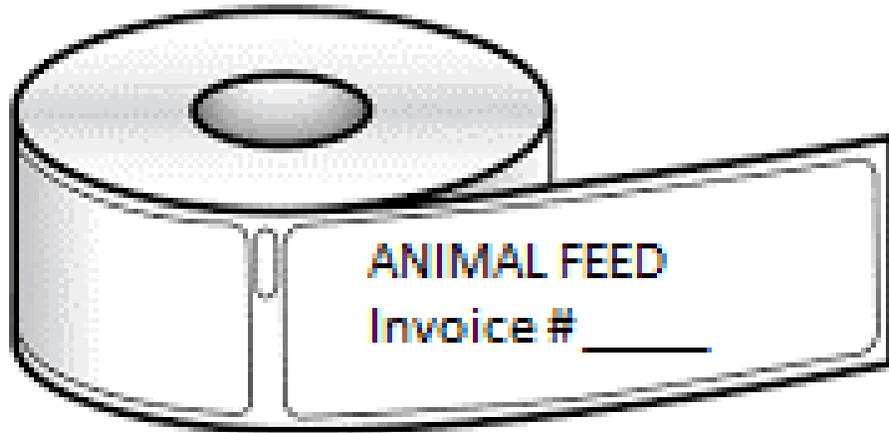
Sugar Magnolia Feeds® 100 W. Mill St. City, State Zip	
Name of customer: Dairy Ridge Farm W234S3159 Ridge Rd City State Zip	Sold: May 13, 2015
4-20-15 Dairy Ridge Dairy Complete	
Feed Products: 44% Soybean Meal Brewers Dried Grain Corn Distillers Grain Whole Cotton Seed Ground Limestone Sugar Cane Molasses ABC White Salt University Dairy Premix	Net weight: 2 ton 1700 lb 800 lb 700 lb 300 lb 200 lb 150 lb 100 lb 50 lb
Directions for use: Feed at a rate of 0.5% of bodyweight per head per day.	



Non-medicated custom-mix feed

- Label each bag of custom mixed feed with an identifier that will associate each of those bags as a part of that batch
- Options:
 - Invoice number
 - Formula number
 - Customer's name, date, and feed name
 - Other? Just has to be unique to the feed

Actual examples of unique identifiers



Custom-mix feed labeling

Record the actual product name of the ingredients used on invoice style labels of custom mixed feed.

For example:

- 44% ADM Soybean Meal v. soybean meal
- Redmond Salt v. salt
- Keep the records (formula and labeling) for at least 1 year

Questions?

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CY2020 Commercial Feed Inspection, Sampling and Labeling Webinar Script – Non-medicated Feed

Slide 1. Hello everyone and thank you all for joining us today! *[next slide]*

Slide 2. Before we get started, I would like to run through a couple housekeeping items. First, please ensure your speakers are on mute. In order to be sure we get through all of the presentation content, we have 30 minutes reserved for questions at the end. You are welcome to submit your questions into the chat box as we go, and we will answer those at the end. In the next hour, we will discuss commercial feed requirements pertaining to manufacturers that do not mix medicated feeds in Wisconsin. We're going to talk about tonnage and the changes that took effect in 2018, the sampling program – what data shows right now, and how to make tweaks toward a positive improvement, what to expect from an inspection, and last we'll go through the label requirements for non-medicated feed tags. *[next slide]*

Slide 3. With that, we will start by going over the feed tonnage statute changes that took effect on January 1, 2018. *[next slide]*

Slide 4. It is important to remember inspection fees and tonnage are two different things. The inspection fees are monies collected by the department and are assessed based on the quantity of feed sold or distributed. The fee is paid by the business that is **first** to distribute or sell the feed in or into the state of Wisconsin. Tonnage is the quantity of feed itself. *[next slide]*

Slide 5. Any person who is manufacturing in the state or distributing commercial feed in or into the state of Wisconsin is required to hold a valid commercial feed license, issued by the department. This also applies to persons whose name and address appears on the label of a commercial feed as the guarantor of that feed. However, there are three exceptions to the licensing requirements: If you distribute commercial feed as it was packaged and labeled by a licensed manufacturer or distributor, you do not need a license. If you distribute bulk commercial feed as it was manufactured and labeled by a licensed manufacturer or distributor, and repackage the bulk commercial feed into small containers, you do not need a license. The exception to not needing a license for repackaging bulk feed into smaller containers is when multiple bulk feeds are commingled and repackaged – then a license is required. Lastly, if you distribute only custom-mixed feed using ingredients that you purchased from other licensed manufacturers or distributors, you do not need a license. ****Please remember that a custom-mixed feed is one that is formulated by the animal producer, and you as the manufacturer are not representing any nutritive guarantees for the finished feed. Remember that retailers are still exempt from licensing. When we talk about retailers, we are referring to entities that merely purchase and resell feed manufactured and labeled by a third party feed company. We also want to clarify that with the statute changes, brokerages and distribution businesses that are **first** to distribute in or into this state would require a commercial feed license. There is a chance that those entities may have been able to conduct business in the past without being licensed. We look forward to working cooperatively to notify anyone who may not have needed a license in the past, that they may need a license going forward. [next slide]**

Slide 6. In the past, the very first person to manufacture and distribute a feed, no matter how many times it changed hands, was responsible for reporting tonnage and remitting the inspection fees to the Department. In today's world, that's no longer realistic. In layman's terms, the changes that took effect January 1, 2018, bump the responsibility to the person or entity that is the first to distribute a commercial feed in or into Wisconsin. In other words, if a feed moves from the original manufacturer in California to an animal producer in Wisconsin and changes hands five times along the way, the fifth person – the one that sold the feed to the animal producer in Wisconsin - is responsible for reporting the tonnage and remitting the inspection fees. If the feed was sold out of California, to Wyoming, then to Iowa, then to Minnesota and finally to Wisconsin, the Minnesota firm is responsible for reporting the tonnage and remitting the fees. Again, the fifth transaction is the only one to report the tonnage and remit fees. *[next slide]*

Slide 7. Along with the change to the responsibility requirement, several other changes were made to the statute. One change was the implementation of a minimum inspection fee of \$50.00 for 200 tons or less, including distributions of zero tons. Another change made was removal of the exempt buyer license status

option. This means that no licensee may apply for or receive exempt buyer status regardless of the amount of feed being exported, or distributed out of state. In other words, all licensees will be held to the very same requirements. Finally, all credit reporting requirements were removed. While prepaid purchases are no longer required to be reported to the Department, please know you still can reduce your total tonnage by the cumulative total of commercial feeds and feed ingredients that another licensee first distributed in or into Wisconsin to you. All four changes, the responsibility of the tonnage reporting, the minimum inspection fee, the removal of the exempt buyer license status, and the reduced reporting requirements for credits, took effect on January 1, 2018 and are applicable to reports filed in January 2019. *[next slide]*

Slide 8. One last thing before we switch topics... In 2019, the feed program staff worked with a group of industry members to revise and create some documents to help make reporting tonnage easier. The documents are available on our website, and ready for you to print and use. *[next slide]*

Slide 9. Now we'll transition to the manufacturing side of things, and start by going through feed surveillance sampling conducted by the Department. *[next slide]*

Slide 10. In the years before I started with the Department, sample quantities and types were not representative of the quantity of feed out in commerce. Staff worked together on a six sigma project, and ultimately learned the program needed a higher quantity of samples, from a diverse portfolio of feeds, to put together a more representative data set. Using that justification, we assembled a feed sampling program that meets those stipulations, and is feasible with the resources available. *[next slide]*

Slide 11. Before we start going through the data, I'd like to point out that pet food – which refers explicitly to dog or cat food – does also get sampled. Specialty pet foods – critters like fish, hermit crabs, gerbils, and other caged type pets that are not livestock – get sampled with the livestock feeds as a part of the regular surveillance sampling program. Most recently, we conducted a sampling project in 2017 that tested 100 samples of wet and dry dog and cat foods. The summary of the project is on our website. Ultimately, pet food is a sole source diet and it gets run for a full nutrient profile of protein, fat, vitamins, minerals, and amino acids – up to 27 different analytes. When it was all said and done, the pet foods had an 85% passing rate. I'll ask you to keep that number in your mind, because we're going to come back to it in a few minutes. *[next slide]*

Slide 12. Feed surveillance samples consist of livestock feeds, like cattle, swine, chicken, and horse feeds, and specialty pet foods like gerbil, hamster, aquarium fish, and aquarium reptile foods, as well as some single ingredients and drug and mineral premixes. The other thing to keep in mind is that no matter how many different analytes, or nutrients, we run on a feed, if it fails in one, the entire sample is considered a fail. With that, as you can see, the overall sample results are trending at a 58%-plus pass rate. I have some additional breakdowns for you, but remember, regulatorily we have to look at sample results like you see them here. As such, I'm presenting this data to you as a heads up, and as an effort to educate and cooperate with you in bringing the passing rate to a better number. Ideally, we would love to see 100% passing, but that's not realistic. We want samples to pass at a rate that is as high as possible, but if we saw the pass rate hit 85% or better, I think everyone would feel a lot better about looking at it up on a screen like this. *[next slide]*

Slide 13. Remember back on slide 11 when we looked at the pet food samples, and how all 100 of those samples were run for anywhere between 25 to 27 analytes? This line graph shows you how many analytes we ran on surveillance livestock feed and specialty pet food samples. The bulk of our samples were run for 4 to 9 different analytes. We had some outliers where 3 samples were run for 15 or 17 analytes, and 89 samples were run for 1 analyte. Those 1 analyte feeds are predominantly custom-mixes that we only ran for a drug level. Looking at this chart, I personally think that if pet food can pass 85% of the time when run for 25-27 analytes, the rest of our feeds in distribution can pass 85% of the time when we run for 4-9 analytes. It's just going to take some tweaks. Think of it as an enormous control panel, with hundreds of knobs. No one knob is the magic key to an 85% passing rate. It will take some trial and error, and some turning of multiple knobs to get our passing rate up there. But it IS achievable. *[next slide]*

Slide 14. If a person looks at the analytes run on an individual basis, the results are pretty darn good. That just emphasizes the ability to improve to me, since every analyte has a fairly respectable passing rate for the most

part – we just need to tweak a little bit to get all of the analytes to pass. If we look at the three primary analytes – protein, fat, fiber as pictured here – we started out in 2015 and 2016 with only protein struggling to meet or exceed 85%. By 2017, protein was up to 82%, a big improvement in just three years. The fat and fiber, as you can see, were well within an acceptable passing rate. Most recently, protein ran at an 83% passing rate, which is almost to the 85% goal. [next slide]

Slide 15. This slide looks at a few miscellaneous analytes, acid detergent fiber, amino acids, non-protein nitrogen, and a couple minerals. Overall, everything on a per-analyte basis looks good again. Note that in 2017, our methods for lysine and methionine went down, so those results are displaying as a failure, when really they should be neither a pass or a fail. Some of the other analytes we run that won't fit on the display in front of you include minerals like cobalt, copper, iron, magnesium, manganese, and phosphorus. The results for those look like the ones on display – really good passing rates per analyte. If you have an interest in seeing the detailed data beyond what we've seen today, please contact someone from the Department to put in an open records request. [next slide]

Slide 16. In summary, because the Department has to use the overall sample result, we are asking firms to ensure they are utilizing the tips on this slide to help boost the passing rate from the current average of 56% to 85% or better. Rather than run through these, I'll just let you know that they are also available on a handout that is available as a download for this webinar. If you have anything that you'd like to discuss with regard to sampling that you don't want to go through in a public setting, please feel free to contact me. [next slide] Next, we're going to go through feed inspections and what you should expect when your state feed inspector visits. [next slide]

Slide 17. Next, we're going to go through feed inspections and what you should expect when your state feed inspector visits. [next slide]

Slide 18. First, let's cover the enforcement activity related to inspections. Field staff generally try to educate before they regulate, and will strive to inform facility staff how to comply before going to the verbal or written warnings, or the civil or criminal fines. It is worth pointing out that the feed program has only recently acquired civil penalty authority, in 2017. Prior to that, enforcement actions could only go the criminal penalty route. The Department strives for uniformity in all aspects of the feed program. That is related to what the field staff inspect for, what they are looking to see or what they expect to see, and how they utilize enforcement action when there is a violation. All that said, multiple factors have an impact on enforcement decisions, such as employee turnover, compliance history, type of violation, severity of the violation, and most importantly, the health and safety risk to animals and people. In some cases, companies have multiple facilities, and that can play a role in the enforcement action decision as well. Let's move on to what to expect from an inspection, so that enforcement actions don't have to be a decision with an inspection at your facility. [next slide]

Slide 19. Every non-medicated feed manufacturer inspection has four key aspects. The main things an inspector will look for are a current feed license, cleanliness of your buildings and equipment, proper recordkeeping and retention of records, and adequate labels for all commercial feeds and feed ingredients. [next slide]

Slide 20. When the inspector first arrives at your facility, he or she will request to meet with the most responsible person on-site. The most responsible person, and possibly other employees, will be interviewed for the duration of the inspection, and will be expected to answer, or acquire an answer, related to the good manufacturing practice standard operating procedures in use at your facility. Initially, the inspector will do a walk through of the facility, to look at the cleanliness and maintenance of the buildings and equipment, inside and out. The inspector will look to ensure that there is minimal or no evidence of rodents, vermin, birds, or insects. Part of that, will include an overview of pest control. If your facility uses its own pest control, our inspectors are educated in the use of pesticides and can answer any compliance questions you may have related to the use of pesticides in an animal-food producing facility. Your inspector will be firm on requesting clean-up when necessary; especially with today's heightened awareness of biosecurity related to avian influenza, African swine fever, and other infectious diseases. This is where we will strongly discourage the reuse of feed bags as biological contaminants are not visible to the naked eye. Inspectors are looking to ensure physical contaminants

or potential adulterants – like stored pesticides, fertilizers, non-food grade grease, or cleaning compounds – are stored in a separate, segregated area. During the outside walk-about, the inspector will be looking for areas that may harbor pests, or grant access to your facility, such as significant holes or openings in the wall or floor, or overgrown foliage. [next slide]

- Slide 21. This photograph demonstrates what we're talking about on the outside of a facility – overgrowth of plants. Not only does the foliage provide a place for pests to reside, it could also hide access points for rodents and other vermin. [next slide]
- Slide 22. Similarly, in the top left of this photo, we see a stack of pallets leaning against the wall. Rodents love to live in those types of materials, especially when there is an access point down the wall like the holes in the tin of this building in the center of the picture. [next slide]
- Slide 23. A wet floor is a strong hint to an inspector that they should look at the ceiling for holes in the roof. Sometimes facilities do wet cleaning, and the water on the floor is not because of a leaky roof. Obviously, leaks can damage the integrity of packaging and cause bags to tear and spill, or mold the feed. [next slide]
- Slide 24. Feed mills commonly experience bird activity. Inspectors will look to see that the bird population and activity is controlled as much as possible. Bird droppings carry diseases like histoplasmosis which can cause high fever, blood abnormalities, pneumonia, and even death in humans. Facilities have instituted a variety of methods to control birds – nets, plastic flaps over doors, visual repellants (like plastic predators or reflective bird diverters). [next slide]
- Slide 25. The outside walk-about will include a look at spillage from outside feed transfers via legs, bins, loading areas, and unloading areas. Spills such as the ones in this photo must be cleaned up. The spilled feed attracts the pests we are striving so hard to keep away, and it can be a source of mold. [next slide]
- Slide 26. Dust from regular manufacturing activities is expected and acceptable. However, inspectors are taught to see the difference between fresh dust accumulations, and build-up from a long period of time. Remember, the best way to demonstrate an SOP, is to have the documentation to support it. It isn't required, and is still acceptable if your facility is apparently undergoing regular cleaning without a document to substantiate the routine housekeeping. Remind employees to keep an eye open for ripped and torn bags. Sometimes they come that way from suppliers, sometimes someone is texting and driving the forklift. Your inspector is going to work with you; however, they want to see effort at ensuring spills get cleaned up promptly. [next slide]
- Slide 27. After reviewing the housekeeping, your inspector will look for adequate procedures related to equipment cleanout. The procedures shall be established and used for all equipment used in the production and distribution of non-medicated feeds to avoid unsafe contamination of non-medicated feeds.

In other words, your inspector is looking to hear about, and see, production and control procedures that prevent unsafe contamination of feeds by residual feed material in mixers, legs, bins, trucks, baggers and other equipment.

Sequencing, flushing, and physical cleanout are all acceptable ways to mitigate the potential risks. [next slide]

- Slide 28. Your inspector is going to request visual inspection access, whenever possible. Here are photos that document the inside of bulk delivery trucks. The top right photo could be a little cleaner – there is some lingering feed down by the auger.

In preparing for FSMA, I've heard of certain ingredients, like urea, that carry a static charge so that it clings to equipment. Firms that deliver feed should consider sequencing, flushing, or physical cleanout of the trucks in addition to the main mixers, as well use of a sufficient quantity of material that will adequately mitigate the risk of unwanted carryover. [next slide]

- Slide 29. Mixers are the obvious piece of equipment when it comes to flushing, sequencing, and physical clean out. Manufacturing with molasses and/or fats can create build-up a lot quicker than a mill that doesn't mix with

molasses or fat. Please take that into consideration when establishing equipment clean-out procedures. It may mean that your facility has to tweak the clean-out frequency based on the seasons. [next slide]

Slide 30. Ultimately, we are encouraging these practices because we want you to avoid this. The photo on this slide is of a hunk of ribbon build-up material that fell off into a bag of feed. Not only would this raise consumers' eyebrows, but it could contain elevated levels of nutrients such as copper or selenium.

The Department is often requested to conduct an investigation into situations like the one I just described. Subsequent to the investigation, the complainant can request a copy of the investigation file, and they can pursue their own case as a civil matter. Proactive measures such as adequate cleanout, sequencing and flushing can prevent such scenarios. [next slide]

Slide 31. That wraps up the good manufacturing practices, or GMPs, portion of our webinar. Let's take a 5 minute break, so that you can grab a coffee before we start on the labeling section of today's presentation.

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Alright, we are ready to start again. As I mentioned earlier, this segment is going to go through the requirements for feed labels – medicated and non-medicated. [next slide]

Slide 32. This slide displays the differences between label types and feed types. As you can see from this chart, in regulation, we have three kinds of feed types: branded which is also referred to as floor-stock, mill-formulated, and custom-mixed. Let me talk about the three feed types for a minute.

Branded feeds, or floor-stock feeds, are those feeds that your feed mill formulates and stocks to sell to any customer that walks in the door. There is no special formulation, it is just a standardized feed for a single species, or sometimes multiple species, that anyone can buy. A lot of times, this will include those feeds that your facility retails for another, larger manufacturer. Branded feeds are, as I mentioned a minute ago, mill-formulated feeds. Because your mill formulated the feed to meet a specific purpose, it has a nutritional backing to it. In other words, your mill guarantees the feed to provide a certain level of a number of nutrients. It is important to point out that the phrasing "branded" feeds isn't something you'll find in regulation. Regulation basically points to what we call "branded feeds" as "commercial feed." Well, since everything we look at is technically commercial feed, in order to provide a level of distinction to everyone involved, we call the "commercial feed" bearing the standardized label that we'll discuss in a few slides "branded feed".

That brings us to the mill-formulated feeds. Remember, we just said branded feeds are also considered mill-formulated feeds. What else is a mill-formulated feed? The other mill-formulated feeds that are not branded feeds are the customer-specific mill-formulated feeds. If your mill has one or more nutritionist(s) on staff, and those nutritionists develop formulas for livestock feeds for certain customers, those are mill-formulated feeds. They are customer-specific mill-formulated feeds, where an employee of the mill developed the formula for just that one, individual customer.

Our last feed type is custom-mixed feed. In regulatory-speak, the definition of custom-mixed feeds differs a bit from the way the phrase is used in industry. In industry, a custom-mixed feed could refer to a feed formula that was developed by the mill, a third-party nutritionist, or the customer himself. The regulatory definition of a custom-mixed feed is limited to feeds mixed at the customers request, using quantities specifically directed by the customer. Custom-mixed feeds do not have a nutritional guarantee for any nutrients.

That leads us to how the feed types are labeled. Branded feeds (remember, regulatorily that's just a "commercial feed") are labeled in the branded format. That's the standard tag we're used to seeing with a feed name, guaranteed analysis, etc. There is no option on that – branded feeds are all required to bear that standardized format style tag. Similarly, custom-mixed feeds –remember, those are the ones that the customer requested, with specific ingredient inclusion rates per the customer – are to be labeled in the custom-mix

format. A custom-mix format tag is the invoice style tag that pretty much is a line-by-line itemized invoice.

Finally, the mill-formulated feeds. Remember, a mill-formulated feed can either be for ANY customer as a floor-stock feed, or a mill-formulated feed might be for ONE customer. A mill-formulated feed, when developed as a floor-stock feed, must be labeled in the branded format. A mill-formulated feed developed for a specific individual customer, can be labeled at the customer's option – either in a branded format, or a custom-mix format. Its up to the customer.

Just a quick reminder, as you think of questions – please write them down. We've reserved about 30 minutes at the end to take your questions. Now that all of that is clear as mud, lets walk through a few examples. [next slide]

Slide 33. You should see a branded label for a non-medicated feed on your screen. It has a specific format and order to the label components.

At the very top, regulations outline placement for the product name and brand name, where applicable. There isn't a lot of detail regarding the product and brand names, other than they must be truthful, and not false, deceptive or misleading.

Second from the top of the label a person will find the purpose statement. A purpose can be drafted in one of two ways. It can identify the species and classes of animals for which the feed is intended, and the specific use of the feed. Alternatively, the purpose could outline the species and weight ranges, or species and age ranges of animals for which the feed is intended, as well as the intended use of the feed. The only reason the intended use of the feed would not be included in the purpose is if the feed is intended as a complete feed.

Third from the top of the label will be the guaranteed analysis. Guarantees depend heavily on the purpose statement. If the feed is intended for specific species of animals, the guarantees will be derived from the requirements for the one or more species of animals in the purpose statement. If the feed is not species specific, but rather a specialty supplement, such as an amino acid premix, then the guarantees would need to be developed to substantiate the presence of the promised amino acids in the feed.

Fourth down from the top is the ingredient statement. The ingredient statement follows a format most are familiar with on any type of human or animal food label, where every single ingredient in the feed is listed in order of most to least by the common or defined name. For example, a person would list salt instead of sodium chloride in the ingredient statement. In addition, ingredients cannot be listed by brand names. For example, if a mill uses a vitamin premix called VitaBlend, the individual vitamins comprising the premix must be listed in the finished feed label's ingredient statement. The label would not be compliant by listing "VitaBlend" in the ingredient statement.

The fifth label component down from the top is the use directions. The section could also be called "feeding directions" or "mixing directions". Immediately following the use directions would be the precautionary statements. The label on your screen is for a feed containing a non-protein nitrogen source, so there are cautions related to the presence of the NPN.

The sixth or second to last label component is the manufacturer's information. It must include the company name, city, state and zip code. The option piece is to include a street address and phone number. Some firms also choose to include an email address. At a minimum though, the manufacturer information will need the company name, city, state, and zip code.

Finally, the last or seventh label component from the top is the net quantity. Bulk feeds can just list bulk. Packaged feeds should identify how much feed is in the container, using suitable units of liquid or dry measure, in both metric and imperial units. Most commonly, we see packages of 50 lbs of feed, which equates to 22.67 kg.

When it comes to single ingredient feeds and custom-mixes, the requirements change a little, but the premise is still the same. [next slide]

Slide 34. Here is an example of a single ingredient feed label. These labels are usually simpler than complete feed labels.

At the very top, regulations outline placement for the product name and brand name, where applicable. In place of a product name, a firm can just use the defined ingredient name. In the example in front of you, the firm opted to do just that and call it “solvent extracted soybean meal.” By using the defined ingredient name, often times, the firm is exempt from including an ingredient statement further down on the label, since it would be redundant information.

Second from the top of the label a person will find the purpose statement. For single ingredients, especially those that are defined by AAFCO, the purpose is generally going to be “For further manufacture of animal feed.” Using such a general statement keeps the facility from having to include use directions on the label – with a few exceptions. Some defined ingredients, depending on what they are, may require use directions to ensure that limitations and cautions are clearly portrayed to the user. For example, urea, as a non-protein nitrogen ingredient, would not be exempt from use directions.

Third from the top of the label will be the guaranteed analysis. Guarantees depend heavily on the purpose statement. If the feed is intended for specific species of animals, the guarantees will be derived from the requirements for the one or more species of animals in the purpose statement. If the feed is not species specific, but rather a specialty supplement, such as an amino acid premix, then the guarantees would need to be developed to substantiate the presence of the promised amino acids in the feed.

Fourth down from the top is the ingredient statement, if it is required. When a single ingredient is labeled with a product name that ***IS*** the name of the defined ingredient, such as the one on your screen, an ingredient statement is not required because it would be redundant. However, if the feed is given a product name different from the defined ingredient name, an ingredient statement is required. Just like a complete feed, the ingredient statement lists every single ingredient in the feed in order of most to least by the common or defined name. In instances where the product name on the label is the defined ingredient name, but a technical or processing additive is included in the feed – such as a flow aid or anticaking agent, or a preservative – an ingredient statement is required, so that business customers are aware of the presence of that processing aid or technical additive. Again, looking at the label on your screen, if Bob’s Feed Mill had included calcium carbonate as an anticaking agent, an ingredient statement would be required for disclosure of the calcium carbonate.

The fifth label component down from the top is the use directions, if required. Most of the time, ingredients are used for further manufacture, so the section would best be titled as “mixing instructions”. Immediately following the use directions would be the precautionary statements, when applicable.

The last two label components, required to be in the same order as a finished feed label are the manufacturer’s information, and at the bottom of the label, the net quantity. The standard for both label components is the same as for a complete feed label. The manufacturer’s information must include the company name, city, state and zip code. The net quantity can be the word “bulk” for bulk feeds, or it can be listed in both the imperial and metric units for the contents of a packaged ingredient.

The last label we're going to go through is for a customer-specific feed. [next slide]

Slide 35. Similar to branded labels, non-medicated custom feeds require label content to provide information about the feed. As you can see from the example on your screen, the custom-mixed feed label is literally a line-item invoice displaying 7 specific label components. The required elements include the name and address of the manufacturer, the name and address of the customer, the date the feed was sold or delivered to the customer, the name of the custom-mixed feed, the net quantity of the entire batch, the name and net quantity or inclusion rate of each of the individual ingredients in the feed, and any corresponding use directions or precautionary statements for the feed.

A couple things to point out –

When naming the feed, it doesn't need to be anything special. It just needs to be a way to discern one feed from another feed for that customer.

List the line items on the invoice according to brand name. That way if there is a recall on one brand but not another, you don't find yourself having recall every feed that contains the general ingredients – just the ones that contain that brand of ingredient.

Last, use directions wouldn't necessarily apply to all custom feeds. Especially not the ones that were formulated by the customer. Those are pretty rare anymore, but they occasionally come in. Custom feeds that would require use directions are ones that contain ingredients like non-protein nitrogen, or premixes for TMRs that have high levels of selenium. Essentially, we are looking for use directions on feeds containing ingredients or nutrients that could cause a human or animal health or safety risk.

If a custom feed gets bagged off per the customer's request, please remember to attach a unique identifier to each individual bag of feed. If the customer requests a bulk delivery, then the feed only needs a copy of the one or more documents that contain all of the information shown in the example on your screen. [next slide]

Slide 36. I want to run through the unique identifiers one more time because those seem to be one of the easily forgotten pieces to labeling custom-mixed feeds.

When a customer orders their own feed, whether it is mill-formulated, formulated by a third-party, or something they picked themselves, a label is required. For bulk feeds, the label has to accompany the load. For bagged feeds, the main labels can accompany the load, as long as a unique identifier is attached to each bag.

Anything that is specific to the batch of feed at hand can be used on the unique identifier to associate the bags of feed to the invoice. If your inspector observes bagged feed on the dock or in the warehouse released for shipment without these identifiers, the product will be placed under Department holding order. [next slide]

Slide 37. Here are two examples of the way a Wisconsin manufacturer went about labeling bagged custom-mixed feed with unique identifiers. The mailing labels can be folded over the string that ties the poly bag shut, provided all the content remains legible. There is no wrong way to label a bag with a unique identifier, provided all of the required information is visible. [next slide]

Slide 38. The other piece I would like to reiterate related to the custom-mix format labels is the way the ingredients are listed on the invoice. Remember, that a custom-mix format label must list each individual ingredient out, with its inclusion rate, on the invoice. There cannot be one line item on the invoice that states the name of the feed, it must be each individual ingredient. Furthermore, each individual ingredient must be listed by the actual product name, not just the general ingredient name. The reason for that is potential recall purposes. If an ingredient is recalled, you'll have a better idea of which feeds used that ingredient and need to be recalled.

Hand-in-hand with listing the ingredients correctly on an invoice-style custom-mix label, is retention of the custom-mixed feed records. The formulation and labeling that apply for every custom-mixed feed your facility manufactures must be held for at least one year according to regulation. It is certainly your option to hold records for a longer period of time, and to retain more than just the custom-mixed feed records. [next slide]

Slide 39. With that, we'll open up the presentation to questions. First, let's go through the questions in the chat box. Remember, if you want to ask something very specific, please contact any of us directly based on the subject of your question.