

## **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: 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](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](https://datcp.wi.gov/Pages/About_Us/GuidanceDocuments.aspx)

#### **DEADLINE FOR SUBMISSION**

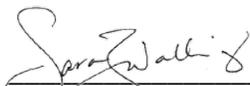
The comment period will run no fewer than 21 days after the publication of this document in the Administrative Register.

#### **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: 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.*

26 (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 medicated feed manufacturer webinar contains the most content of the three, and is tentatively planned to be a 90 minute presentation held in the late morning of February 19, March 4, March 11, and March 18, 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 - Medicated Feed Manufacturers

# Housekeeping and Agenda

- Speakers on mute
- Questions at end (30 min)
- Tonnage
- Sampling
- Inspections
- Drug calculations
- 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](http://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

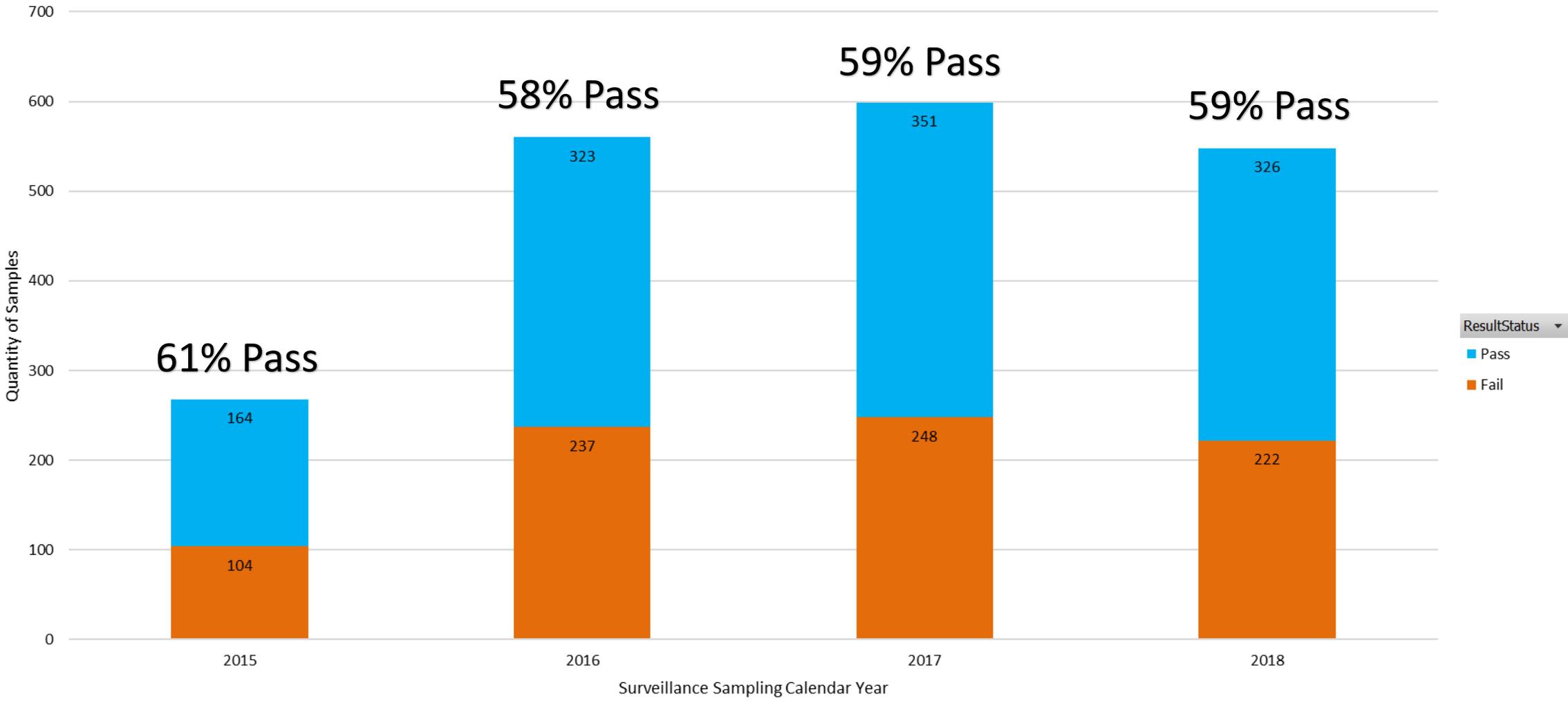
- Sample quantities were not representative in the past
- Conducted Six Sigma project to review quantities and goals to determine “knobs to turn” for representative samples
- 2015 - Now:
  - 2015 – approx. 370 samples
  - 2016 – approx. 600 samples
  - 2017 – approx. 600 samples
  - 2018 – approx. 600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

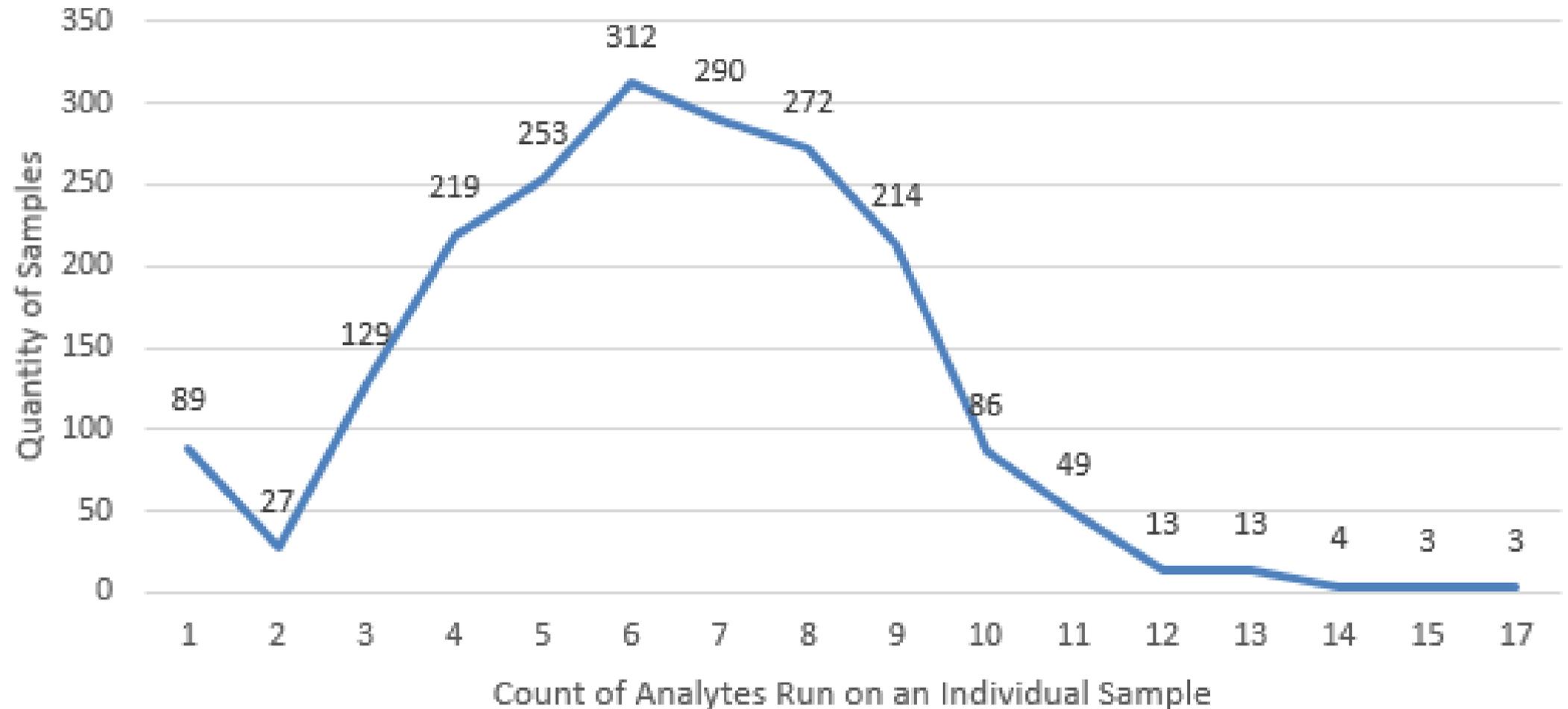
### Feed Surveillance Samples 2015-2018



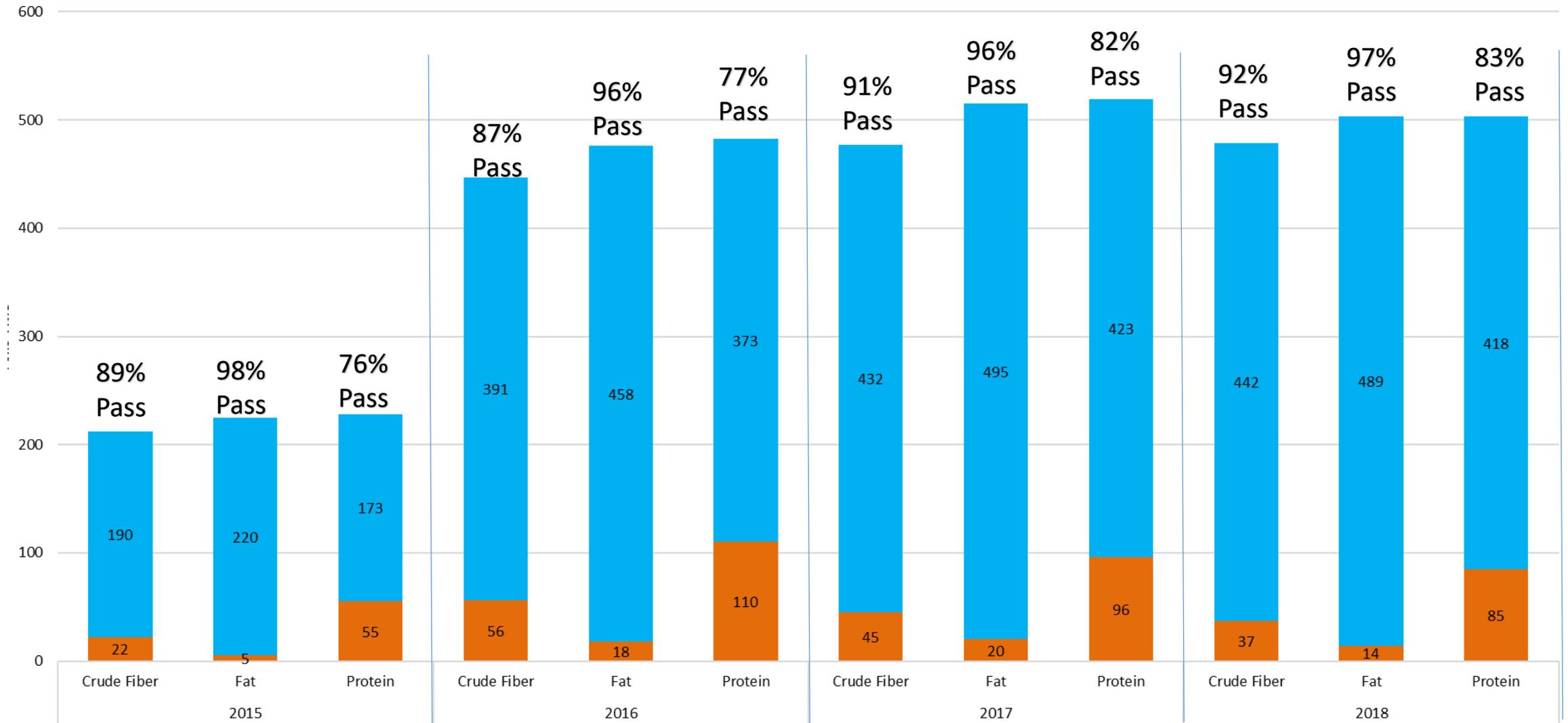
Years ▾ Quarters ▾ Sampling\_Date ▾

+ -

## Quantity of Analytes Run Per Sample 2015-2018

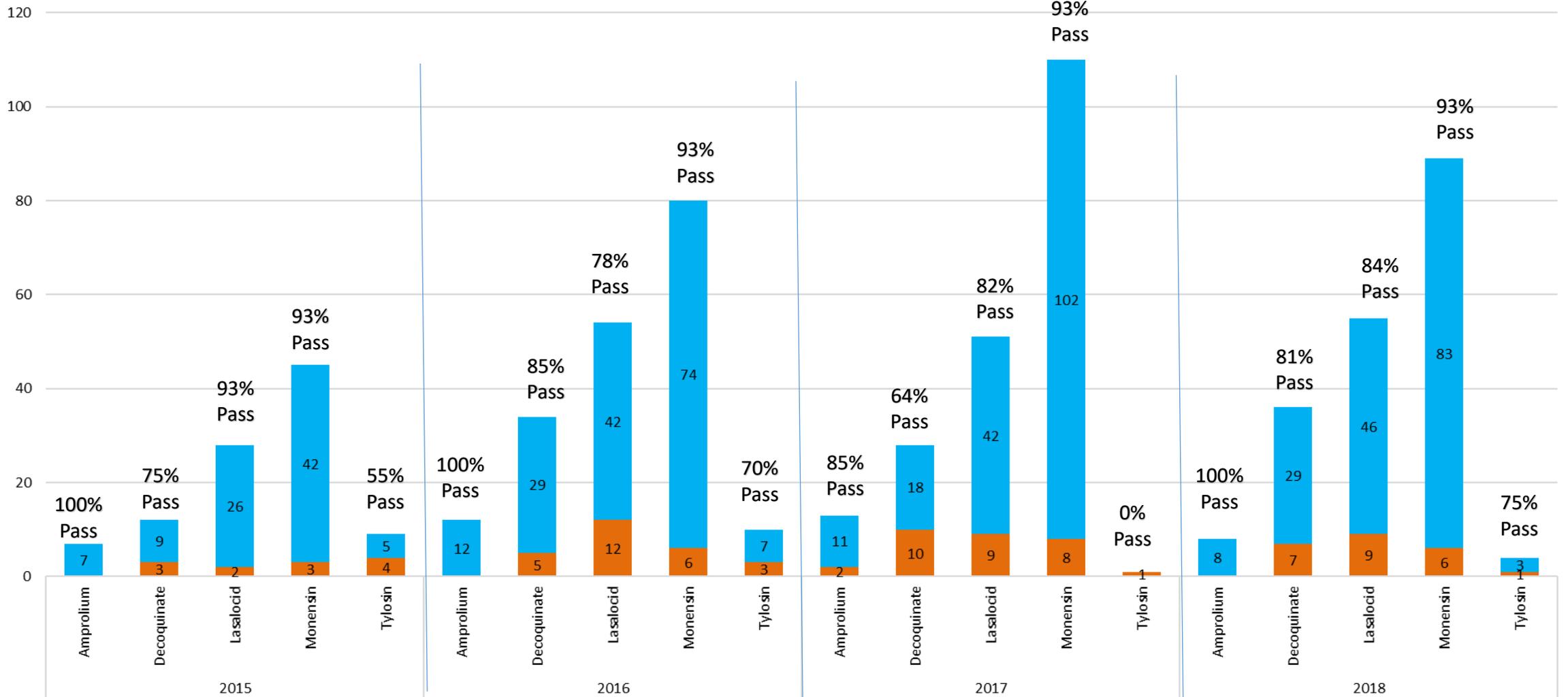


### Results by Analyte for Feed 2015-2018



Count of ResultStatus

### Results by Analyte for Feed 2015-2018



Years ▾ Analyte\_Desc ▾

+ -

# 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



# 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

# Five Key Aspects

- Licensing
- Cleanliness (buildings, equipment)
- Drug component controls
- 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.



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

A photograph of a cluttered storage room. On the left, there is a blue metal barrel with a red funnel on top, and a blue metal frame with various tools and equipment. In the center, a large brown paper bag is overflowing with debris. On the right, several more brown paper bags are stacked against a white door. A red fire extinguisher is mounted on the wall above the bags. The floor is concrete and has a large, dark, irregular water stain that extends from the doorway towards the center of the room. The doorway is open, showing a bright outdoor area with green grass and trees.

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



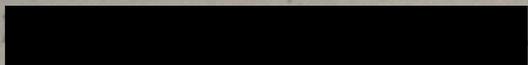
# Drug Components

- Scales and metering devices checked for accuracy
- Inventory Control
  - Stored and handled to preserve identity, strength, quality and purity
  - Keep drug label with drug
- Equipment cleanout

# Inventory Control

- A safeguard to ensure drugs are included at the correct levels, and a log of which feeds included the drug, in the case of an error.

Drug Component	Mill's Paper Inventory	DATCP Check
Rumensin 90	541.46# as of 11/12/15	541.43#



# DRUG PREMIX INVENTORY RECORD

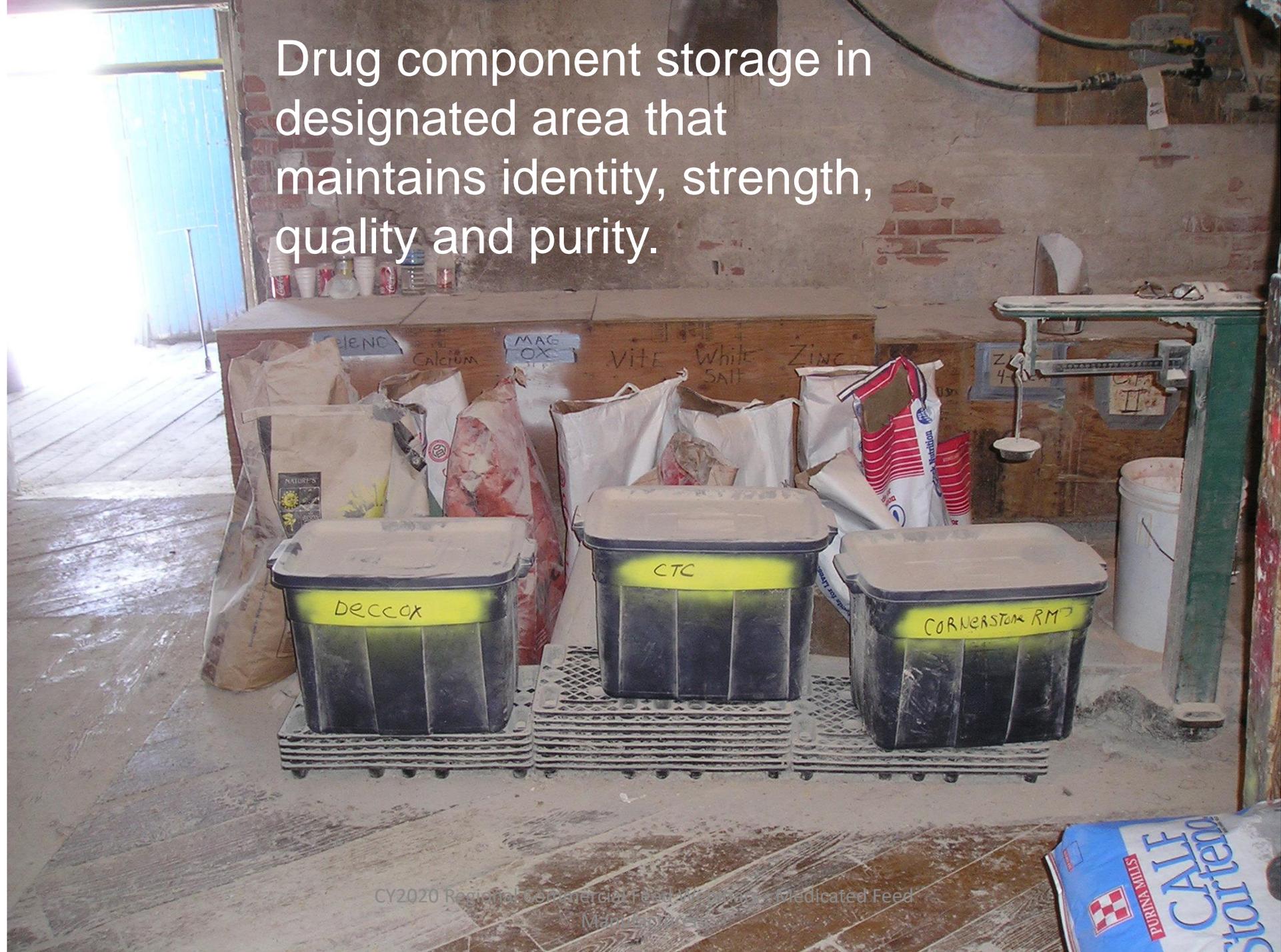
DRUGREC.DOC

DRUG PREMIX NAME: Rumorsin 90 gm DRUG POTENCY: 90 gm/Lb

MANUFACTURER: Elanco WEIGHT OF EMPTY BAG: 6.25

DATE	DRUG PREMIX LOT NUMBER	PRODUCT DRUG USED IN	BALANCE TO BEGIN (NET LBS)	WEIGHT REC'D NET LBS	✓	LBS. USED PER LOT	END BAL., NET CALC	GROSS WT LESS TARE	GROSS WT, INCL BAG	I N I T
<u>10/18/12</u>	<u>C940541</u>		<u>261<sup>75</sup></u>	<u>550</u>		<u>12</u>	<u>299<sup>25</sup></u>	<u>799<sup>5</sup></u>	<u>800<sup>25</sup></u>	

Drug component storage in designated area that maintains identity, strength, quality and purity.



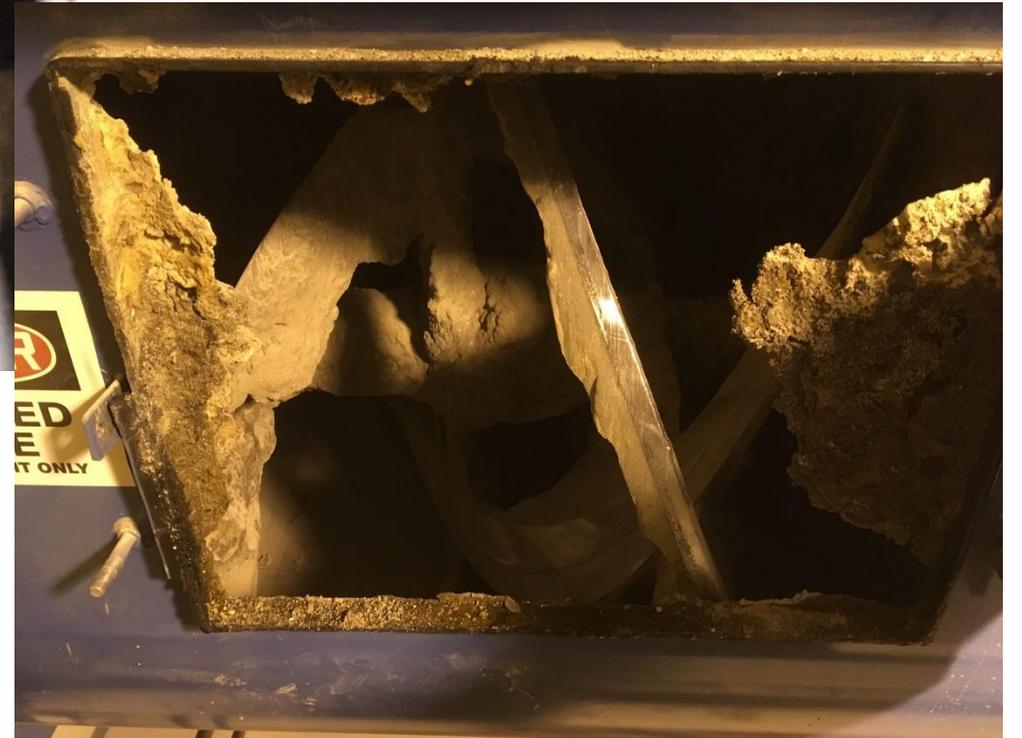
# Cleanout Procedures

- Adequate cleanout procedures to prevent unsafe contamination of medicated and non-medicated feeds
  - Sequencing
  - Flushing
  - Physical

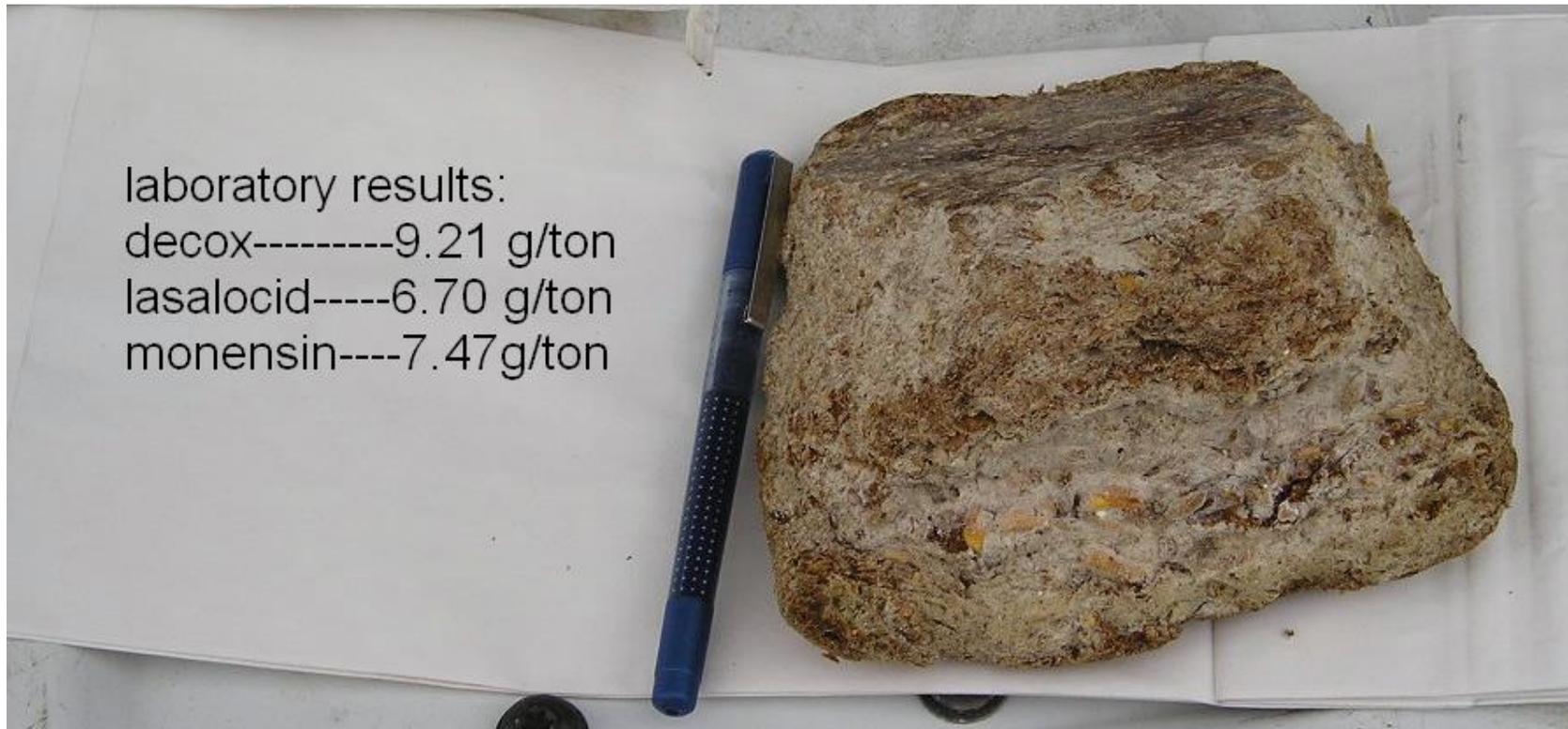
# Trucks



# Mixers



# Inadequate Cleanout



# GMPs: Records

## Production Records

Written records to document that production steps were met.  
Necessary to recall specific batches of feed.

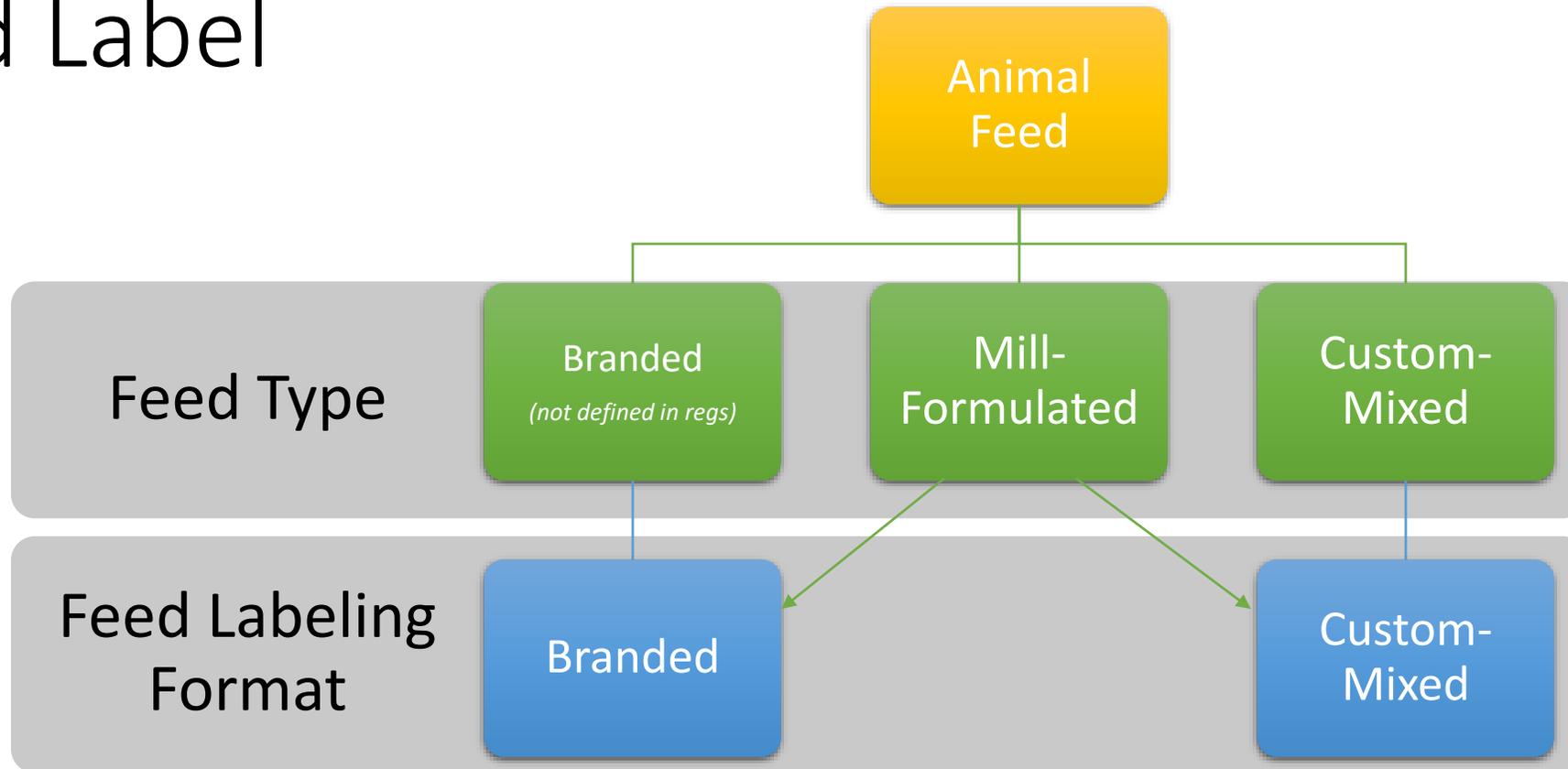
IF no written documentation, then no proof steps were completed.



# Labels

(5 min break)

# Feed Type v. Feed Label



# Medicated Feed Labeling

- **Required on all custom mixed and mill formulated medicated feeds:**
  - Word “Medicated” below or directly after name of feed,
  - Drug purpose (or “indication”),
  - Drug name, and drug level,
  - Adequate instructions to enable the safe and effective use (mixing or feeding directions),
  - All precautionary statements.

# Use of Drug Components

- Type A medicated articles and Type B medicated feeds must be used according to label directions
- Drug indication according to drug source?
- Drug level approved?
- Drug combination approved?
- Use directions adequate for safe and effective use?
- Precautionary statements adequate?

Brand Name

Product Name

Purpose Statement & Medicated claim

Drug Guarantee

Guaranteed Analysis

Ingredient Statement

Use Directions

Precautionary Statement (if required)

Responsible Party's Name & Address

Quantity Statement

**YOUR NAME FEEDS**



Start-Her  
Starter Calf Feed  
Medicated

Starter feed for dairy replacement heifers

For control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*

**Active drug ingredient**

Lasalocid .....30 grams /ton

**Guaranteed Analysis**

Crude Protein, minimum .....16%  
 Crude Fat, minimum .....4%  
 Crude Fiber, maximum .....4%  
 Acid Detergent Fiber, max. ....5.6%  
 Calcium, minimum .....0.8%  
 Calcium, maximum .....1.3%  
 Phosphorus, minimum .....0.65%  
 Selenium, minimum .....0.2 ppm  
 Vitamin A, minimum .....7000 IU/LB

**Ingredient Statement**

Grain Products, Plant Protein Products, Processed Grain By-Products, Urea, Calcium Lignin Sulfonate, Animal Fat, Vitamin A Supplement, D-Activated Animal Sterol (source of Vitamin D3), Vitamin E Supplement, Folic Acid, Ethoxyquin (a preservative), Ground Limestone, Dicalcium Phosphate, Salt, Copper Sulfate, Manganous Oxide, Zinc Oxide, Ferrous Sulfate, Cobalt Carbonate, Calcium Iodate, Sodium Selenite.

**FEEDING DIRECTIONS:**

Each pound of Start-Her contains 15 mgs of lasalocid. Hand feed enough Start-Her to provide 1 mg per 2.2 pounds of body weight. (i.e. provide 4.5 lb. to a 150 lb. animal) Maximum rate of 350 mg per day.

**CAUTION:** The safety of lasalocid in unapproved species has not been established. Do not allow horse or other equine access to feeds containing lasalocid, as ingestion may be fatal.

**YOUR NAME FEEDS**  
City, State, Zip

NET WT 50 LB (22.67 kg)

Medicated  
“branded”  
format

BLUE BIRD LABELING

bacitracin methylenedisalicylate

Type C medicated feed for beef steers & heifers fed in confinement for slaughter – Liver Abscess 70 (bacitracin Type C medicated feed)

For reduction in the number of liver condemnations due to abscesses in beef steers and heifers fed in confinement for slaughter.

**Active Drug Ingredient**

Bacitracin (as feed grade bacitracin methylenedisalicylate)\* ..... g/ton\*\*

**Guaranteed Analysis**

Crude Protein (Min) .....%  
 NPN<sup>a</sup> (Max) .....%  
 Crude Fat (Min) .....%  
 Crude Fiber (Max) .....%  
 Calcium<sup>a</sup> (Min) .....%  
 Calcium<sup>a</sup> (Max) .....%  
 Phosphorus<sup>a</sup> (Min) .....%  
 Salt<sup>a</sup> (Min) .....%  
 Salt<sup>a</sup> (Max) .....%  
 Sodium<sup>b</sup> (Min) .....%  
 Sodium<sup>b</sup> (Max) .....%  
 Potassium<sup>a</sup> (Min) .....%  
 Vitamin A<sup>a</sup> .....IU/lb

<sup>a</sup> Guarantee required only when nutrient added except when the feed is intended, represented or serves as a principal source of the nutrient.

<sup>b</sup> Sodium guarantee required only when total sodium exceeds that furnished by the maximum salt guarantee.

**Ingredients**

Feed ingredients, as defined by AAFCO, must be listed on the final printed Type C medicated feed label by their common or usual names in descending order or predominance by weight.

**Feeding Directions**

Administer continuously throughout the feeding period to provide 70 mg bacitracin per head per day. \_\_\_\*\*\* pounds of this cattle feed will medicate one animal.

**Manufactured By:**

Blue Bird Feed Mill  
City, State, Zip

Lot # \_\_\_\_\_

**NET WEIGHT ON BAG OR BULK**

\*Pennitracin MD is the proprietary name of bacitracin methylenedisalicylate formulation (Type A Medicated Article).

\*\*Label must show actual concentration of bacitracin, which will vary with consumption to provide 70 mg/head/day.

\*\*\*The following table provides examples of feeding rates and amount of drug per ton of feed. Third column represents number of pounds of feed that will medicate one animal.

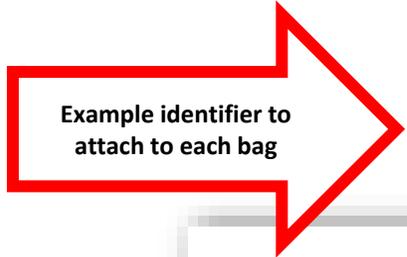
Drug level in feed (g/ton)	mg bacitracin/head/day	*** pounds of feed/head/day
5	70	28
7	70	10
10	70	14
20	70	7

# Non-medicated “branded” format

CY2020 Regional Commercial Feed Webinars - Medicated Feed  
Manufacturers

Brand Name	<p align="center"><b>YOUR NAME FEEDS</b></p> <p align="center">401's Special SHEEP FEED</p>  <p align="center">For breeding ewes.</p> <p align="center"><b>Guaranteed Analysis</b></p> <p>Crude Protein, minimum .....15.0%          (This includes not more than 1.0% equivalent          crude protein from non-protein nitrogen)          Crude Fat, minimum .....2.0%          Crude Fiber, maximum .....20.0%          Calcium, minimum .....0.8%          Calcium, maximum .....1.3%          Phosphorus, minimum .....0.35%          Salt, minimum .....0.35%          Salt, maximum .....0.85%          Copper, minimum .....5.0 ppm          Copper, maximum .....10.0 ppm          Selenium, minimum .....0.3 ppm          Vitamin A, minimum.....7000 IU/lb</p> <p align="center"><b>Ingredient Statement</b></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 D<sub>3</sub>), 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> <p align="center"><b>FEEDING DIRECTIONS</b></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> <p align="center"><b>Caution: Use as Directed. For Sheep Only.</b></p> <p align="center">Guaranteed by:          YOUR NAME FEEDS          City, State Zip</p> <p align="center">NET WT 50 lb (22.67 kg)</p>
Product Name	
Purpose Statement (and medicated claim if required)	
Drug Guarantee (if applicable)	
Guaranteed Analysis	
Ingredient Statement	
Use Directions	
Precautionary Statement (if required)	
Responsible Party's Name & Address	
Quantity Statement	

# Medicated "custom-mix" example



Example identifier to attach to each bag

Smith Dairy  
MEDICATED  
Inv #101015

Sugar Magnolia Feeds®  
100 W. Mill St.  
City, State Zip

# 101015

**Sold:** May 13, 2015

**Name of customer:**  
Jim Smith Dairy  
W234S3159 Ridge Rd  
City State Zip

MEDICATED

JSMITHCALFNOV04

**Feed Products:**

44% Soybean Meal	1700 lb
Brewers Dried Grain	800 lb
Corn Distillers Grain	700 lb
Whole Cotton Seed	270 lb
Ground Limestone	200 lb
Sugar Cane Molasses	150 lb
ABC White Salt	100 lb
University Dairy Premix	50 lb
Blue Bird 0.5% Deccox	30 lb

**Net weight:** 2 ton

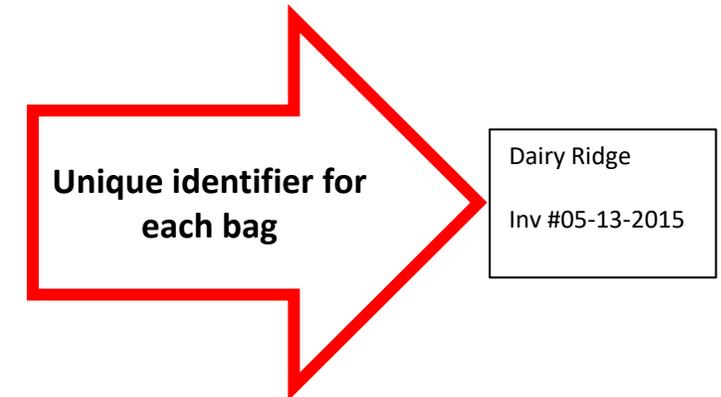
**Directions for use:** See attached medicated label.



CUSTOMER-FORMULA MEDICATED LABEL ATTACHMENT FOR INVOICE <b>101015</b> DATED <b>05/13/15</b>			TAKE TIME OBSERVE LABEL DIRECTIONS		
JIM SMITH DAIRY CALF CATTLE FEED MEDICATED COMPLETE FEED CONTAINING DECCOX™(DECOQUINATE) FORMULA # <b>JSMITHCALFNOV14</b>					
<b>STATEMENT OF PURPOSE</b>					
For the prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuerni</i> in cattle (including ruminating and non-ruminating calves and veal calves).					
<b>ACTIVE DRUG INGREDIENT</b>					
Decoquinatate			34.09 grams/ton 17.05 milligrams/pound		
<b>USE DIRECTIONS</b>					
Feed at a rate of 22.7 mg decoquinatate per 100 lb of body weight per day as indicated in the feeding chart below. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard.					
Cattle WT. (pounds)	decoquinatate required (mg)	lbs. To feed per day	Cattle WT. (pounds)	decoquinatate required (mg)	lbs. To feed per day
100	22.7	1.33	600	136.2	7.99
200	45.4	2.66	700	158.9	9.32
300	68.1	4.00	800	181.6	10.65
400	90.8	5.33	900	204.3	11.99
500	113.5	6.66	1000	227	13.32
<b>PRECAUTIONARY STATEMENTS</b>					
<b>WARNING:</b> Do not feed to cows producing milk for human consumption. <b>CAUTION:</b> Do not use in feeds containing bentonite. <b>LIMITATIONS:</b> Feed for at least 28 days during periods of coccidiosis exposure or when experience indicates that coccidiosis is likely to be a hazard.					
MANUFACTURED BY: BLUE BIRD FED MILL, ANY CITY, M ANY STATE 55555  Net Weight on Bag and/or Invoice					
DECCOX™ is a trademark of Alpha Pharma Inc.			label revision 12/01/16		

# Non-medicated “custom-mix” format

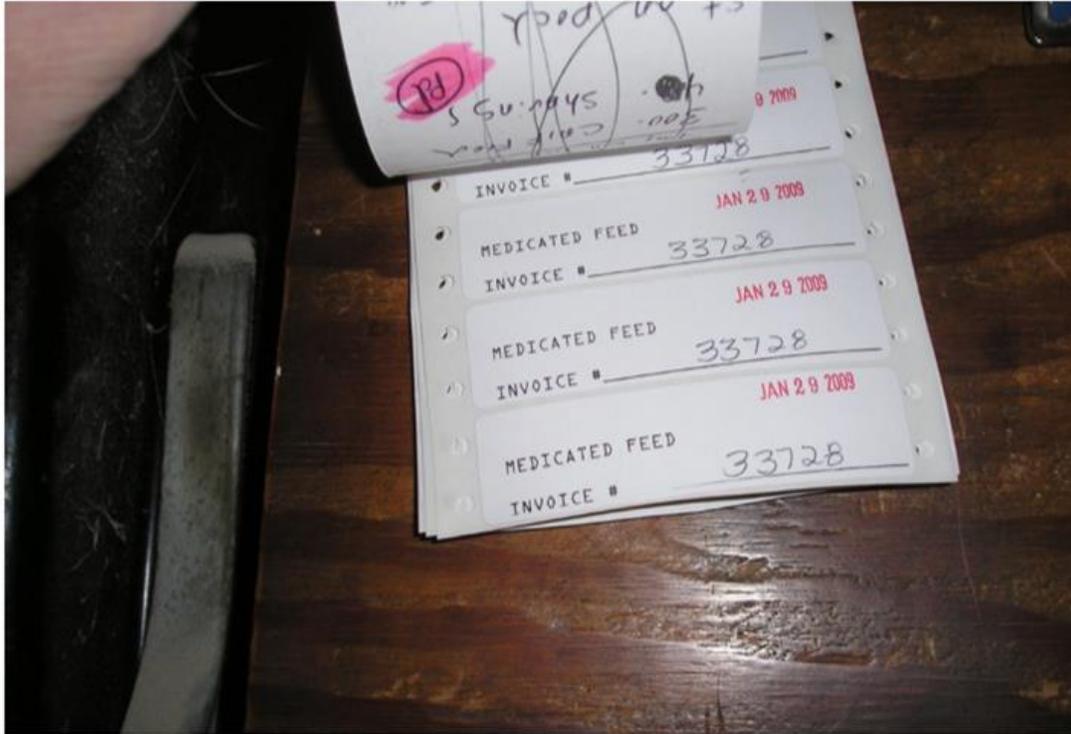
Sugar Magnolia Feeds® 100 W. Mill St. City, State Zip	
<b>Name of customer:</b> Dairy Ridge Farm W234S3159 Ridge Rd City State Zip	<b>Sold:</b> May 13, 2015
4-20-15 Dairy Ridge Dairy Complete	
<b>Feed Products:</b> 44% Soybean Meal Brewers Dried Grain Corn Distillers Grain Whole Cotton Seed Ground Limestone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



# Custom-mix feed both medicated and non-medicated

- Label each bag of custom mixed feed with an identifier that will associate each of those bags as a part of that batch and if the feed is medicated the word “medicated” must also be identified on each bag
- 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



Medicated



Non-medicated

# Custom-mix feed labeling

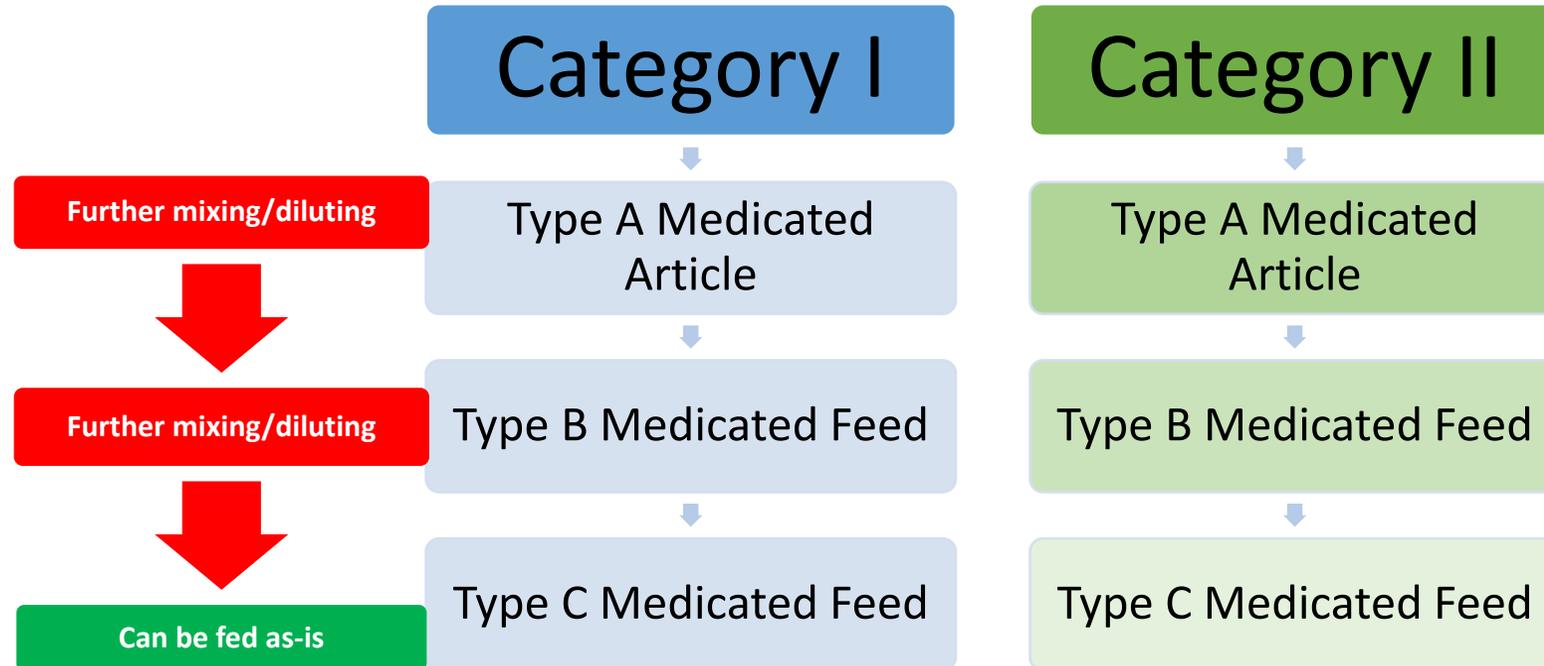
**Record the actual product name of the ingredients used on invoice style labels of custom mixed feed.**

For example:

- 44% ADM Soybean Meal v. soybean meal
- Redmond Salt v. salt
- 38% Heifer B275 v. Heifer pellet w/lasalocid

# Drug Components and Labels

# Medicated Feed



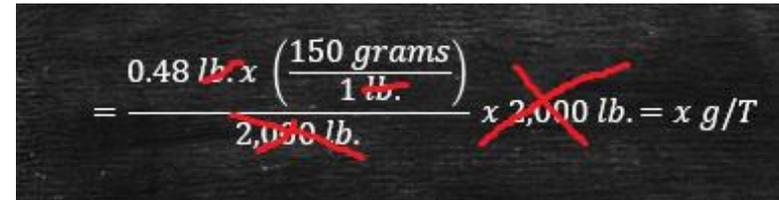
# Drug Levels

Formula calculations have to match the level identified on the tags

$$= \frac{0.48 \text{ lb.} \times \left( \frac{150 \text{ grams}}{1 \text{ lb.}} \right)}{2,000 \text{ lb.}} \times 2,000 \text{ lb.} = x \text{ g/T}$$

$$= 0.48 \text{ lb.} \times 150 \text{ g} = x \text{ g/T}$$

$$= 72.0 \text{ g/T}$$


$$= \frac{\cancel{0.48 \text{ lb.}} \times \left( \frac{150 \text{ grams}}{\cancel{1 \text{ lb.}}} \right)}{\cancel{2,000 \text{ lb.}}} \times \cancel{2,000 \text{ lb.}} = x \text{ g/T}$$

Note: Answer is grams per ton because the batch is one ton, therefore the calculation is for one ton.

# Drug Source

- Indications must include the uses at your mill
- Use the right level
  - Rumensin 90 is 90.7 g/lb.
  - Bovatec 91 is 90.7 g/lb.

Content borrowed  
from FDA/CVM



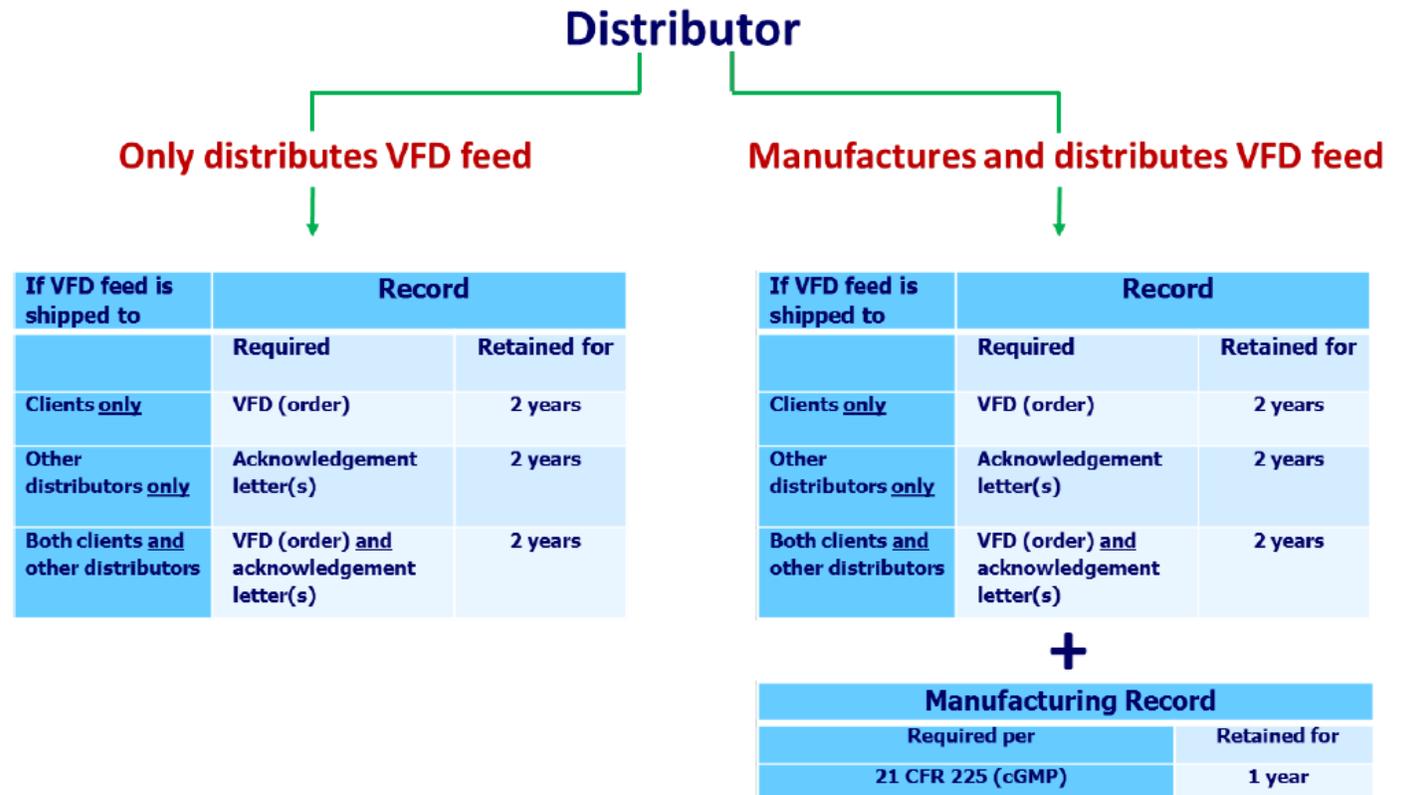
# Veterinary Feed Directives

# What is a VFD?

1. A drug
2. A document

# Record retention

- 2 year record retention
  - Veterinarian (ORIGINAL)
  - Client
  - Distributor



# VFD content: required

14 items:

1. Vet name/address/phone
2. Client name/address/phone
3. VFD issue date
4. VFD expiration date
5. VFD drug(s)
6. Species & class of animals
7. Qty of animals
8. Indication
9. Drug level & duration of use
10. Withdrawal time/special instructions/cautions
11. Number of reorders (if permitted)
12. "Use of feed containing this VFD drug in a manner other than as directed on the labeling is not permitted."
13. Affirmation of intent
14. Veterinarian signature

# Affirmation of intent

- (i) "This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs."
- (ii) "This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component." [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]
- (iii) "This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component."

Required in that the affirmation must be on the VFD

Optional in that only one of the three options must be on the VFD

# VFD content: optional

1. More specific description of the location of the treated animals
2. The approximate age or weight range of the animals
3. Any other information the veterinarian deems appropriate to identify the animals specified in the VFD

# Blue Bird Labels for VFDs, or any medicated feed

- DATCP templates
- [FDA Blue Bird Labels](https://www.fda.gov/animal-veterinary/medicated-feeds/blue-bird-labels) (<https://www.fda.gov/animal-veterinary/medicated-feeds/blue-bird-labels>)
- 21 CFR 558
- Medicatedfeed.com
- 2017 or later Feed Additive Compendium
- Brille Tagging Software
- Elanco Blue Birds: <https://www.elanco.us/feedmill>
- Pharmgate Blue Birds: <https://www.pharmgate.com/usa/blue-bird-labels/>
- Zoetis Blue Bird labels: <https://www.zoetisus.com/products/vfd/vfd-compliant-labels.aspx>

# Label requirement

- All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement:



## VFD Feed

**“Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.”**

# Questions?

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**CY2020 Commercial Feed Inspection, Sampling and Labeling Webinar Script**

- 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 as well. Today, we are discussing commercial feed requirements 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, how the feed program performs drug calculations, and last we'll go through the label requirements for 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 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 the 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 for his or her animals, and you as the manufacturer are not representing any nutritive guarantees for the 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 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 that sold the feed to the animal producer in Wisconsin, is responsible for reporting the tonnage and remitting the inspection fees. If the feed moved from California, to Wyoming, to Iowa, 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 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 big 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 samples. The bulk of our samples were run for 4 to 9 different analytes. We had some outliers where 3 samples was 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. Its 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. When we look at the results for the drug analytes, it is important to remember the results are attributable to much smaller sample size than the protein, fat and fiber. Monensin, which was run on 110 samples in 2017, had a 93% passing rate, whereas Tylosin had a 0% passing rate from running 1 sample. Not great data on the Tylosin. Generally speaking though, the medication analytes look reasonable, for the low quantities of them that did get collected and analyzed. Unfortunately, due to time constraints, this is the only data I'm going to run through today for surveillance sampling. If you would like to see additional data, please touch base with someone from the Department to can put in an open records request for the data. [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. Rather than run through these, I'll just let you know that they are also available on a handout that is available as one of the handouts 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]

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 medicated feed manufacturer inspection has five key aspects. The main things an inspector will look for are a current feed license, cleanliness of your buildings and equipment, adequate control of drug components, 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. Histoplasmosis is also suspected to cause a potentially blinding eye condition. 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. While walking through the production areas, your inspector will question you about scale calibration, inventory control procedures, and equipment cleanout procedures. Essentially, the inspector is going to want to know that your scales are routinely calibrated. Most facilities use a third party. Internal calibration can be acceptable, provided the most responsible party is able to adequately explain the process and frequency of the check. The inspector will also ask for a rundown of the inventory control procedures of the facility. As long as the procedures established are able to preserve the identity, strength, quality, and purity, you will have addressed most of the requirements. The other requirement is ensuring that all drug sources are used in accordance with the label. In medicated feeds, the label is the law. For example, if a Type B monensin 10 gram is labeled only for increased milk production efficiency in lactating and dry cows – that drug source cannot be used to manufacture a monensin feed any other purpose or species. I'll talk a little more about inventory control in a minute on the next slide. Last, when in the production area, the inspector will ask about your equipment cleanout procedures. We'll go into that in detail at several slides coming up. [next slide]

Slide 28. When in the drug storage area, the inspector will request a demonstration or discussion of your firm's inventory control procedures. It is vital that your facility can demonstrate maintenance of the identity and quality of every Type A and Type B drug source used in manufacturing. In addition, if your facility uses a Type C drug source to further manufacture feeds, the Department strongly encourages inventory control of the Type C source. The inventory control requirement comes from both Federal and state law.

In the Guidance for Industry #72 which outlines FDA's current thinking on compliance with non-licensed mill medicated feed good manufacturing practices, FDA says the key elements are continuous drug identification and protection, written inventory control, and adherence to label instructions.

In other words, continuous drug identification means the recording of lot numbers or some other specific identifying information such as dates, not just the names of the drug sources. Protection means we are looking for segregation so that a drug source doesn't get mistaken for a micro ingredient. Some facilities use a locked room to store drug sources, others use a designated area on the production floor such as one pallet, or one racking, segregated from other pallets and racking.

Written inventory control is the theoretical aspect to inventory control. Actual inventory control is the weight of the bag and drug source when set on the scale. The inspector will look to see the actual versus theoretical adequately demonstrates control, and that the two are compared with a frequency that would be able to mitigate the animal and human health and safety risk that could arise as a result of an over or under use of a specific drug source. For FDA licensed mills, part of that process would be choosing a level of "off" that would initiate a deeper investigation into why the actual and theoretical inventories do not align. We call that an established variance. While an established variance isn't required for non-FDA licensed mills, we encourage each facility to consider instituting an established variance as a proactive measure to be able to recall a very specific batch of feed quickly and efficiently if the drug inclusion was off or was the wrong drug source.

Finally, the requirements touch on the point we discussed in the last slide which was following the labeling of the drug source. Remember, in medicated feeds, the label is the law. All drug sources are used in accordance with the label.

The inspector is going to request an actual comparison of the theoretical to actual. They will want to witness you weigh three different drug sources, and then compare that weight to the theoretical inventory maintained on paper. If the two numbers do not balance or match, your inspector will expect you to be able to find out why there is a discrepancy. If there is still a discrepancy between the actual and theoretical, they will want it to be within the tolerance of your established variance.

Main points to consider when evaluating the effectiveness of your inventory control procedures include the amount of drugs your facility uses over a period of time – obviously, the more medicated feed you manufacture, the more frequently you would want to compare the actual and theoretical. The second point is the drug sources your firm uses – if Type A medicated articles are the primary sources used at your facility, then you would want to take that into consideration because an off could contribute a significantly higher or lower drug level to the resulting feed. [next slide]

Slide 29. Here is an example of a drug inventory record from a mill. The document records the name of the drug (Rumensin 90), the manufacturer (Elanco), the potency of the drug, and the weight of the empty bag. In addition, the drug premix lot number is recorded on every line, to ensure that each subsequently manufactured feed can be traced back to the original drug source.

Many facilities are starting to establish a procedure of weighing the bags before opening them. That's going to increase the integrity of their inventory control, because each bag always has a bit of a variance from the labeled bag weight. I've heard that more often than not, the drug source bag weights are over the labeled 50 or 55 pounds.

Over time, the overages from the manufacturer, and the bag weights themselves can contribute to an off. Keeping up with as many different contributors as possible proactively mitigates the risk of an off that cannot be explained to your inspector. [next slide]

Slide 30. Here you see an example of the storage procedures we described a couple slides ago, where the drugs are in a designated area of the production floor, where they cannot be mistaken for a micro ingredient. This is an acceptable storage method. [next slide]

Slide 31. After reviewing your inventory control procedures, 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 medicated feeds to avoid unsafe contamination of medicated and 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 medicated feed material in mixers, legs, bins, trucks, baggers and other equipment. The emphasis being on **prevention of unsafe carryover**.

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

Slide 32. 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'm hearing that medicated feed carries a static charge that clings to equipment better than previously thought. Firms that deliver medicated 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 cross-contamination. [next slide]

Slide 33. 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 34. 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 in a sheep feed. When sampled and run through our laboratory for drug content, you can see it came back with levels of deccox, lasalocid, and monensin. Unfortunately, this and many other chunks fell into the feed and was consumed by the sheep, ultimately leading to their death.

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. [next slide]

Slide 35. Production records serve two main purposes. The first purpose for production records is to enable your facility to conduct a recall of specific batches of feed should an issue arise with any ingredient used in the feed. Recently, with the creation of the Federal Reportable Food Registry, we hear about recalls related to copper levels, salt levels, and other issues, including medicated feed levels.

Another reason production records are required is related most specifically to medicated feeds. Production records help to ensure that sequencing, and even flushing, occur when medicated feeds and non-medicated feeds are produced in the same mixers. Remember that sequencing and flushing are two procedures, in addition to physical clean-out, that support a zero-carryover or a zero-cross contamination tolerance.

Typically, if it isn't written down on paper, then your inspector is hard pressed to have evidence to show that your facility completed the steps. Remember to keep track of production on paper so you are able to show your inspector that you do sequence and flush your mixers, where applicable. [next slide]

Slide 36. 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.

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 37. Before we go through the differences between medicated and non-medicated label requirements, let's talk about 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 a 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" with that 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 customer's request, using quantities specifically directed by the customer. Custom-mixed feeds do not have a nutritional guarantee for anything except the drug level, when it is a medicated feed.

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. Again, if it is a medicated feed, the drug level must be guaranteed and the paperwork accompanying the feed must contain the required use directions and precaution statements.

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. It's 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, let's walk through a few medicated feed specifics. [next slide]

Slide 38. One big thing to remember when it comes to labeling medicated feeds, regardless of the label format you're using: all of the label requirements for the medication apply. That includes four distinct parts: (1) the word "medicated" to be prominently displayed below or directly after the name of the feed; (2) the drug purpose or indication; (3) the drug name and level; and (4) adequate use directions for the safe and effective use of the feed and the precautionary statements.

All of the information required for a medicated feed that is specific to the drug – the drug purpose/indication, precautions, and use directions (in most cases) – are required to be copied verbatim from the FDA drug approval, conditional approval, or index listing. The only thing that varies, is the drug level.

You're going to see these requirements a couple more times before the end of the presentation. They are very important. Before we go into the specifics of labeling in general, I want to touch on a couple more medicated feed items. [next slide]

Slide 39. The content of this slide really plays more into good manufacturing practices, but it also plays into labels because it matters how a firm that manufactures Type B medicated feeds for further manufacture labels said Type B medicated feeds.

For both sides, firms manufacturing any medicated feed must follow the label. Some Type B medicated feeds are labeled for one, single indication or drug purpose. However, the drug may actually be approved for multiple uses or purposes. If the label only has one of the indications or purposes on it, then that single indication is the only reason that drug can be used in feed.

It is understandable to feel like the approved indications from FDA should just stand. However, with medicated feed, the label is the law. If a Type B monensin feed is labeled for increased milk production efficiency, it cannot be used for increased rate of gain or increased feed efficiency. A mix that will be labeled for increased rate of gain or increased feed efficiency must be manufactured from a different source of Type B monensin feed, that is labeled for those indications.

With that, prior to manufacturing a medicated feed, especially if the formula came from anywhere but in-house, take a minute to review the formula and indication. Make sure the indication is approved for that drug, at the level requested (and calculated according to the formula). If the formula calls for a drug combination, double check that the combination is allowed under the Federal approvals. Finally, ensure that the label intended to go with the feed contains adequate use directions and precautionary statements. Specifically, look for something to the effect of "feed X pounds per head per day or feed X pounds per pound of bodyweight per head per day". Use directions that say "feed according to your nutritionist's instructions" are not adequate.

Okay, now we are ready to get into the details of the actual label itself. [next slide]

Slide 40. This is an example of a medicated "branded" format label. Remember, in regulation, it is just referred to as a "commercial feed" label. Within the Department we call it a branded label to distinguish between this one and a custom-mixed label, since all feed is commercial feed in our world.

Notice there are 10 components to this label – the brand name, product name, purpose statement and medicated claim (also known as the drug purpose or drug indication), a drug guarantee, a nutrient guaranteed analysis, the ingredient statement, use directions, precautionary statements, the responsible party's name & address (or the manufacturers information), and the quantity statement.

Two slides ago, we discussed the medicated feed label components that are required, and consistent between the branded and custom-mixed labels – the word “medicated”, the drug indication, the drug guarantee, and the use directions and precautionary statements.

The rest of the label contents is related to the nutritional aspects of the feed. For example, the purpose statement identifies the species and class for which the feed is intended, or the species and weight ranges or ages for which the feed is intended. The guaranteed analysis outlines the nutrient values of the feed, specific to the species stated in the purpose. The rest of the information, the ingredient statement, manufacturer information, and net quantity, or truth in labeling type content – in order to provide full disclosure to the customer.

The different label components, as you see them on the screen, are laid out in a standardized format and order. That comes straight out of regulation, and is consistent across all states. That way, firms can use one label for a feed in multiple states; instead of developing one different label for each different state in which the single feed is distributed.

If you seek assistance with developing medicated feed labels, I encourage you to pull up the FDA Blue Bird labels online. Those labels are already formatted like the one on the screen, and essentially give you a template to follow. You just have to tweak the drug level, the guaranteed analysis values, the ingredient statement, and include quantities in the use directions, where applicable.

This is one example of a Blue Bird label from FDA’s website. It is essentially a template, just not a fillable form type template. In addition, it has a table at the bottom intended to help you complete the use directions with adequate information that is in compliance and within the requirements of the drug approval.

Now, if we remove the four medicated feed label components...[next slide]

Slide 41. We have a branded label for a non-medicated feed. It has the same format and order to the label components, it just doesn’t include the medicated feed information. Obviously, there are still feeding directions and, if applicable, precautionary statements on a non-medicated feed label. In this case, it is a feed containing a non-protein nitrogen source, so there are cautions related to the presence of the NPN.

The other components have the same purpose behind them as when they are printed on a medicated feed label – identifying the use of the feed, the nutritional values of the feed, the ingredients providing those nutrients, who made the feed, and how much of the feed is in the container.

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

Slide 42. First and foremost, custom-mixed feed labels come in a different format. There generally is not any nutritional guarantee behind the feed, aside from the drug level if the feed is medicated, so the purpose of the label is to disclose what the customer is getting in their mix. A custom-mixed feed label is literally a line-item invoice displaying 7 items if non-medicated, 10 items if medicated. 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. Then if the feed is medicated, there are those standard four requirements we discussed earlier: the word “medicated,” the drug name and drug level in the finished feed, the drug purpose or indication, and the use directions and the precautionary statements. The larger image on the left is an example of what a medicated feed custom-mixed feed invoice style label would look like.

In Wisconsin, you have access to one resource that other Ag Departments do not offer – the DATCP website contains templates developed in Microsoft Excel for you to use to label custom-mixed feeds that contain drugs. The templates available are not all-inclusive, however, they do encompass nearly all of the common drugs and drug indications for our state. The image on the right of your screen depicts the medicated feed content for a custom-mixed feed, except for the word “medicated” – which you can see in the center of the left image.

Finally, the last piece related to custom-mixed feeds is a bag identifier. Bulk feeds only need to be accompanied by the two documents depicted on the left and right of your screen. If a customer requests their feed to be bagged off, then each bag must have a unique identifier attached to it. Look by the red arrow in the upper left corner of your screen for an example. As you can see, the unique identifier doesn’t need to contain much – just enough information to tie it to a specific batch of feed, and the documents related to that feed. In this case, the firm used the customer name and the invoice number. The word medicated is a requirement only if the feed is medicated, and must be on every single bag. Some facilities have bags that are prestamped with the word “medicated”. If that’s the case, then the word medicated isn’t required to be on the unique identifier, although you certainly can add the word to the identifier if you prefer. *[next slide]*

Slide 43. Similar to branded labels, non-medicated feeds require the same label content for custom-mix format labels as the medicated, minus the medicated information. As we saw on the previous slide, the custom-mixed feed label is literally a line-item invoice displaying 7 items if non-medicated. 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.

Just as with the medicated feeds, non-medicated feeds labeled in the custom-mixed format require a unique identifier for bagged feed. The bulk feeds still only need to be accompanied by the single document depicted on your screen. *[next slide]*

Slide 44. 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.

Most important of all the content on a custom-mix format label, is the medicated information. The word “medicated”, the drug indication or purpose, the drug name and level, and the use directions and precautionary statements.

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 and, if applicable, the medicated feed information. 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 45. 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 46. The other piece I would like to stress related to the custom-mix format labels is the way the ingredients are listed on the invoice. Quickly, I will mention here 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. [next slide]

Slide 47. Now we're going to move on to the last part of our webinar – discussing drug components, or drug sources, and their labels. We mentioned earlier that the label is the law when it comes to feed-through animal drugs. Now we're going to dig a little deeper into the specifics. [next slide]

Slide 48. When we talk about, it is important to keep in mind the different types. First, there are category one and category two type drugs. The difference between the one and twos is the withdrawal period – a category two drug requires a withdrawal period at the lowest use level for at least one species in which they are used, OR the drug is regulated at a “no residue” basis or with a zero tolerance regardless of the withdrawal period status, because of carcinogenic concerns. You can remember the difference by attributing the double-u (W) that starts the word withdrawal to the “two” part of the type. A category two drug has a withdrawal at the lowest use level, or a zero tolerance for residue because of carcinogenic concerns.

Within both categories, there are Type A medicated articles, Type B medicated feeds, and Type C medicated feeds. A type A medicated article is just the drug with maybe a carrier. There is no nutritive intent behind the contents of package. The Type B medicated feed is a premix, that has some nutritive ingredients added to the drug, but in order to be fed to animals, the premix must be further diluted. The further diluted version of the Type B medicated feed could be another Type B medicated feed, or if diluted enough, it could be a Type C medicated feed. The type C medicated feed is the one that can be fed directly to animals.

There is often confusion between a Type B premix and Type C medicated feed. I've seen some mineral mixes that are formulated at a Type B level with feeding directions as a “top dress.” That can sometimes be okay, but not always – it depends on the drug approval. As the feed manufacturer, regulators look at you as the professional who knows, or has the resources to verify, that the drug level in a feed is appropriate for the intended use – whether that is to feed it directly to the animals, or to take it back to the farm and further mix it before feeding. [next slide]

Slide 49. When verifying drug levels, its always a good idea to take a second and calculate the drug level according to the formula as depicted in this slide. Sometimes formulas get updated or tweaked, and the labels are not updated to reflect the changes. It is really important to make sure we are taking that extra minute to perform this step.

I encourage you to take measures that will boost consumer confidence in our industry. Verifying that drug levels are spot on, and not under or overmedicated animals, regardless of the drug type, is one of those things that can easily be implemented and communicated as a proactive measure of judicious use of all drugs, not just antimicrobials.

Ideally, the drug level stated on the tag matches, or is really close to, the drug level calculated according to the formula. If you're using a Type A medicated article to mix a Type C medicated feed, and the inclusion rates are just too small to be accurate on the tag, you could consider using a Type B medicated feed instead, so that the inclusion rates are bigger and allow for more adjustment. The options on tweaking this scenario are multiple, it just really depends on the circumstances. [next slide]

Slide 50. Recall what we talked about earlier in slide 39 related to the label being the law. I'll repeat that the indication for which you are manufacturing a feed must be on the drug source label as an allowable use of the drug.

Furthermore, it is important that you are using the exact drug level according to the tag. It is really common for us to see firms manufacturing feed with Rumensin 90 and they are keying 90 g/lb as the drug source level. Rumensin 90 is actually 90.7 g/lb. With a drug that concentrated, that 0.7 g/lb makes a difference quickly. The same goes for Bovatec 91. It is not lasalocid at 91 g/lb, it is lasalocid at 90.7 g/lb.

While that may seem like an insignificant difference, if you think about it, it tends to have a snowball effect. If a type B medicated feed is manufactured as a premix using rumensin 90 calculated at 90 g/lb, where the goal is to have the premix end up at 1,440 g/ton, the feed will be included at a rate of 15.98 pounds per 2,000 pound batch. However, we just discussed that rumensin 90 is actually 90.7 g/lb. Recalculating the drug level using an inclusion rate of 15.98 pounds at 90.7 g/lb in a 2,000 pound batch, we figure out that the resulting feed will actually be at 1,449.39 g/ton. While that doesn't seem like a lot, any rounding errors that occur down the road when another facility uses the premix to manufacture a type C medicated feed will result in another off.

While a slight off does not seem like a big deal, if this was a tylosin Type C medicated feed, the window of approved levels is very small at 8-10 grams per ton. Or if the firm is trying to formulate a medicated feed at the very high end of the range of approved levels, they could end up having an unapproved drug level because of the off.

Long story short, keep the calculations in check using the level as reflected on the tag to assure your customers that your feeds meet guarantee. [next slide]

Slide 51. We have come to the last segment of our presentation related to Veterinary Feed Directives. After I go through this we'll open up the lines for questions and provide contact information for you to reach us if you prefer to have a private conversation related to your question(s). [next slide]

Slide 52. Hopefully all of this is mostly review for you. Please remember that the phrase VFD can be referencing a drug or a document. For purposes of this presentation, we're going to be talking about the VFD orders, or the document. [next slide]

Slide 53. Everyone has been very successful in properly retaining records for two years. That's one year longer than our typical medicated feed requirements related to non-VFD medicated feed labels and production records. [next slide]

Slide 54. There has been huge improvement with VFD orders reviewed as a part of our state inspections. VFD orders are generally including all of the 14 required components. There have only been a handful that received guidance from the Department – meaning we sent a letter to the veterinarian to remind them of all the required components that are supposed to be on the VFD order. Remember, distributing a feed containing a VFD drug without all the required VFD information is a violation of the feed rule. [next slide]

Slide 55. Remember to verify that the proper affirmation of intent box is checked, relating to combination feeds. A feed containing a pesticide for fly control is not considered a combination feed – the pesticide, when used in a medicated feed, is considered a food additive. The fly control is acceptable to use in the feed even if it is marked as “not to be used in combination with any other drug.” [next slide]

Slide 56. Veterinarians have commonly been including additional information on their VFD orders related to animal locations or size of the animals. Please just remember that you can decline to fulfill any VFD order as your right to decide to do business with any customer. However, you cannot require veterinarians to include the animal weights on the VFD order. That's not a requirement by law. [next slide]

Slide 57. This is just a second reminder that Blue Bird labels are available via a couple different resources to assist you with development of medicated feed labels, and verification of drug uses and levels. Most of you already know about the templates provided by the Department. Unfortunately, those templates are not all inclusive and take a long time to develop. If you need help for a different drug, you can Google “FDA Blue Bird Labels” and drill down to the drug manufacturer label template for a type B or type C medicated feed with any drug source.

You can also reference 21 CFR 558, the Federal regulations that contain drug approval information. However, the language is not always easy to understand, or read through in a limited amount of time.

Some quicker, more user friendly references include medicatedfeed.com, a web-based compilation of drug approval information and template tags. The Compendium, which must be at least 2017 or later, so that the changes from the veterinary feed directive regulations are in the document. I believe the Brille tagging software has some medicated feed information in it, and can help you out. I'm not very familiar with Brille, so I would more likely direct you to a resource I'm confident has the information you need like medicatedfeed.com, the compendium or the FDA Blue Bird labels webpage.

Last, some of the drug manufacturers offer blue bird labels – the same ones you'll find on the FDA website - on their websites. The downside to this resource is that the labels available are limited to those that the company manufacturers, it is not a comprehensive list. Still a good resource though! [next slide]

Slide 58. If you develop your own medicated feed tags, it is important to remember to double check that the VFD drug caution statement is on the label. The statement is only required on labels of VFD drugs like oxytetracycline, tylosin, and chlortetracycline. [next slide]

Slide 59. 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.