



Commercial Animal Feed Sampling Outreach Project

(Revision date: 01/2021)

Overview

The Wisconsin Department of Agriculture, Trade and Consumer Protection's (DATCP) commercial feed program is in place to assure the public and manufacturers that animal feed and feed ingredients are not contaminated, meet label guarantees, and are safe and effective for use. The program also serves to create a regulatory environment ensuring that all businesses may distribute their animal feed and feed ingredients fairly.

DATCP annually collects commercial feed samples to determine if the feed distributed in Wisconsin is meeting label guarantees. To do this, DATCP partners with in-house laboratory services to determine if the physical feed contains the nutrient levels stated on the label. Annual, routine surveillance sampling includes livestock feeds and specialty pet foods, as well as wild animal feeds. Pet food (food and treats for dogs and cats) was analyzed as a separate project due to the complex nature of dog and cat foods as a sole source diet.¹

DATCP conducted a sampling outreach project from 2018-2020 to communicate the feed sampling results with feed manufacturers. The data relayed included sampling results from 2015 to 2019. Overall, DATCP determined that 57% of feed samples passed analysis. As a result, DATCP not only conducted an outreach project to communicate the results to industry, but to also provide industry with resources for achieving a higher overall pass rate.

2013 Process Improvement Project

From 2012-2013, DATCP conducted a process improvement project to evaluate the procedures and quantities of the sampling program. The project included the following goals:

- Determine the appropriate number of feed samples to collect each year.
- Develop standard procedures and guidance to ensure the appropriate number of feed samples are successfully collected each year.
- Increase, by a minimum of 200%, the number of feed samples collected.

Based on information from the U.S. Department of Agriculture's (USDA) National Agricultural Statistics Service's (NASS) Wisconsin office, DATCP learned that a minimum of 200 samples would be needed, **per feed type** (such as dairy, swine, poultry, etc.), in order to say sample results are reflective of actual industry performance with 90% confidence. In light of this, DATCP was able to commit to a sampling program where the sampling quantity would be statistically meaningful, yet achievable within program resources.

¹ To learn about the 2017 Pet Food Sampling Project, visit <https://datcp.wi.gov/Documents/PetFoodSamplingReport2017.pdf>.

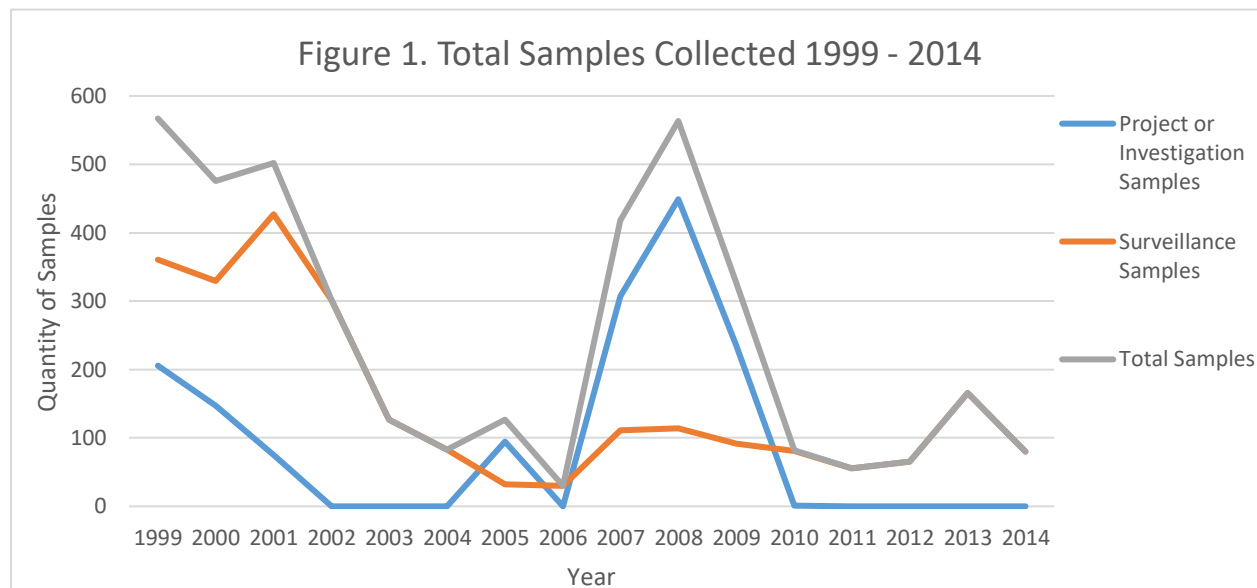
Program Planning

In 2014 and 2015, DATCP worked to create a sampling program plan that implemented the ideas from the process improvement project. In 2015, DATCP initiated an increase in sample collections with a goal of 600 samples, and incorporated the process improvement project discoveries described in the following sections.

Standardization of the Feed Sampling Season

The first step was to standardize the timing of the sample collection. Based on the seasonal workload of current field staff, this left late fall and winter as the best time to collect feed samples. Field staff are located around the state and are DATCP's boots on the ground working directly with the industry for compliance with state rules. Another consideration for timing was the laboratory capabilities. The laboratory also analyzes samples throughout the year for fertilizer, pesticides, and hemp. Based on workload, fall and winter were also the best time to work with the laboratory to analyze feed samples.

To maximize efficiency of collection and analysis, the feed program standardized the timing of collection and analysis of feed samples from approximately October 1 through mid-February annually.



Sample Diversity

Sampling data through 2011 was not readily available due to a change in the laboratory's data management software. The data that was available revealed two main challenges to statistically meaningful data. First, the data quantity was inadequate, averaging just short of 100 samples per year (see EES Samples trend line in Figure 1). Second, the data that was available from the samples collected demonstrated a lack of diversity in both labelers and type of feed.

	2012	2013	2014
<i>Total Samples Collected</i>	46	166	80
<i>Medicated Calf Complete/Concentrate Samples</i>	17	55	27
<i>Medicated Calf as Percent of All Samples</i>	37.0%	33.1%	33.8%

Different variables influence the data for feed sampling, such as types of species for which a feed is intended (cattle, swine, turkeys, etc.), types of feed (premix, complete, or supplement), and the multitude of ingredients used to manufacture the feed (like molasses, corn, vitamins, minerals, etc.). The data from 2012-2014 revealed a need for more diversity in the feeds sampled. The feed tonnage

and license data show that approximately 1,600 licensees distribute over five million tons of feed in Wisconsin annually. To accurately represent the feed in distribution by the licensees, DATCP would need to collect over 3,000 samples². The licensee population incorporates firms located in Wisconsin, outside of Wisconsin, and international firms. The 2012-2014 data summarized feed samples comprised of 38 different types of feed, manufactured by 118 different licensees, from facilities in about nine different states. Of the feed sampled in those three years, per Table 1, over one-third of the samples were medicated calf feeds.

Typically, a statistically meaningful sample size will incorporate all the different variations in order to be representative of the population. As mentioned previously, for the feed program, such a sample size would be around 3,000. To be more representative, the quantity would need to be even higher in order to include minor species, such as llamas, ratites (ostrich, emu), bison, farm-raised deer, and others. Moving forward, a goal would be to achieve diversity in variables with a quantity the available resources could accommodate. The new sampling program needed to incorporate as many different licensees as possible, and as many different types of feed as possible. According to NASS' standards, the data would still not be statistically representative, however, over time it would be useful in determining if firms were manufacturing commercial feed that could meet label guarantees.

The next step in the sampling project planning was to determine the total number of samples to be collected annually. The 2013 process improvement project established that 100 samples per year was inadequate. However, staffing and equipment in place would not support 1,000 or more samples. The feed program staff decided that if each of the 14 inspectors were to collect about 43 samples per year, for a total of 600 samples, the results would yield a data set that would be credible and within the means of the available resources.

Focused Feed Sampling Program

In 2015, DATCP began assembling new sampling work plans with the laboratory and for the field staff. To allow for workload adjustment, sampling started with 350 samples in 2015, and then moved to 600 samples in 2016.

The first part of the transition was an annual planning meeting with the laboratory. In June and July 2015, laboratory and program staff met to discuss the limiting factors to analysis. The primary limiting factor was the high-performance liquid chromatography (HPLC) system, one piece of equipment used to analyze certain drugs and amino acids. The system had the most restricted batch size (12-18 samples per batch) and took the longest to analyze, up to seven days for the analysis of amino acids. The secondary limiting factor was the sample preparation step where samples were ground and split into small, homogenous portions for analysis. Essentially, the laboratory would need to receive continual submissions of incoming samples throughout the sampling season in order to maximize equipment batch sizes during analysis.

The second part of the transition was work planning for field staff. DATCP assembled data from tonnage reporting to determine the sample diversity by species (Table 2). Using the desired quantities by species, per inspector, the program staff compiled a list of site visit assignments for each inspector to achieve diversity by labeler. Finally, all of the assignments were assembled into a work plan that allocated the different feed types across a twelve-week schedule, in an effort to support the laboratory in maximizing efficiencies.

The third part of the transition was training field staff on proper sampling procedures adopted from the Association of American Feed Control Officials (AAFCO) Inspector Handbook, and the work plan for the new sampling activities. In the past, samples were collected during an inspection. Going forward, field staff would sample independently of inspections, and focus on collecting samples by species and labeler.

²Estimated using five major species (cattle, horses, sheep, swine, poultry) x three types of feed (premix, complete, supplement) x 200 samples each = 3,000 samples.

Table 2. Wisconsin Feed Sampling Quantities

	2016	2017	2018	2019
Beef Feed	46.76	75	75	78.8
Bison	0	0	0	0
Broiler	24.97	0	0	0
Calf (Veal) Feed	49.41	0	0	0
Duck/Goose	0	21	23	21.18
Deer/Cervids	0	0	0	12
Dairy	277.72	95	96	91.57
Equine	27.88	49	50	48.11
Fish	0	0	0	0
Gamebirds	0	0	0	0
Layer	35.46	0	0	0
Llamas/Camelids	0	0	0	0
Mineral	0	58	58	56.68
Milk Replacer	0	20	19	16.7
Miscellaneous	0	73	69	64.23
Sm. Animal/Pet Food	66.79	0	0	0
Poultry	0	65	65	66.59
Ratites	0	0	0	0
Rabbit	0	18	19	20.24
Sheep/Goat	21.28	50	51	48.94
Swine	26.18	76	75	74.96
Turkey	23.56	0	0	0
Total	600	600	600	600

During the 2015 sampling season, field staff reported the following challenges:

- The timing of a facility manufacturing certain feeds wanted for sampling was not working and was causing delays because assigned sites did not always have the feeds available that staff were to collect.
- Field staff headquartered more than 60 miles from the laboratory were waiting to submit samples in order to limit the shipping and handling costs associated with mailing or delivering the samples to the laboratory.

In 2016 and forward, DATCP made changes to the sampling program to continue to maximize efficiencies while achieving the quantity and diversity objectives. This included the following adjustments:

- Weekly mailings and deliveries of sample submissions by the field staff to the laboratory.
- Shortened feed season of mid-September or October 1 through December 30 each year.
- No scheduling for sample collection, provided species and labeler diversity targets were met.

Sampling Data Analysis

Considerations

The same variables that determine a statistically meaningful sample of a population are also considered when reviewing data. One of the main variables in a feed sample are the feed ingredients. Feeds can include any combination of over 300 different, approved ingredients to provide animals with protein, fat, fiber, vitamins, and minerals. No single ingredient is the source of a single nutrient; it can provide a variety of nutrients, even at trace levels.

For example, corn might be added to a feed as a primary source of protein. The corn will still supplement trace levels of some fiber, vitamins and minerals. The more ingredients blended into a feed, the more sources of nutrients that are available to the animal from the feed. From a sampling perspective, laboratory analysis quantifies all nutrients in a feed, regardless of source. If a firm only guarantees the “added” sources of nutrients, the label does not quantify all sources of the nutrient in the feed. That can be an issue for minerals like selenium, which is necessary for the animal, but can be toxic in high quantities. Guaranteeing only added sources of a nutrient could result in not meeting the label guarantee because the laboratory analysis does not discern between added sources of a nutrient and background contributors of a nutrient – it quantifies the cumulative total bioavailable to the animal during digestion.

Another important part of evaluating the laboratory results is the nutrient variability in ingredients. For example, corn is a common ingredient in livestock feed. Corn has a crude protein value from just below 7% to over 9%, on an as-fed basis. Each year the U. S. Grains Council prepares an in-depth report of the corn harvest quality. On a national average, corn protein values average just over 8% but can vary across the country from 6-11%+ (see Figure 2). Within Wisconsin, analysis of corn from the 2019 harvest showed corn protein values to be at mid- to high- 6% (as fed).

Local corn harvests with lower than national average protein levels negatively impacts Wisconsin feed manufacturers who may use the national average to formulate their feed. While the low protein value can affect laboratory results, other ingredients in the feed may contribute to the protein level enough to meet the label guarantee. This kind of variability occurs with any ingredient, not just corn.

Expectations

With these considerations in mind, DATCP’s regulatory program must have a reasonable expectation for results. While it would not be impossible to achieve a 100% passing rate for sampling, it would not be

2019-2020 Corn Harvest Aggregate Protein Values in the United States



Figure 2. Reprinted from U.S. Grains Council. 2019/2020 Corn Harvest Quality Report. Washington, DC: U.S. Grains Council, 2020. <https://grains.org/wp-content/uploads/2019/12/USGC-Corn-Harvest-Quality-Report-2019-2020.pdf>. Accessed April 8, 2020.

reasonable. Even the most stringent quality assurance program would experience variations in nutrients within ingredients. It would be unreasonable to have a zero tolerance for deviations from the label guarantee. With that in mind, DATCP set a goal of an 85% average passing rate for overall sample results. The data analysis in the following paragraphs recognizes that on a per-analyte basis, most samples already meet the 85% goal.

Results

For a commercial feed sample to pass sampling analysis, every nutrient or medication (analyte) guaranteed on the accompanying feed label must pass. For some feeds, analysis of analytes not guaranteed occurs – such as copper in sheep feed – due to certain species’ sensitivities. Such unguaranteed nutrients must also pass for the overall sample to achieve a pass designation. Even if only one nutrient fails to meet the label guarantee or nutrient threshold established in regulation, then the entire feed sample receives a fail designation. Because of that and the other variables referenced earlier, not all feed samples will pass analysis.

From 2015-2019, the overall passing rate for commercial feed samples was 57% (Figure 3).

In 2017, DATCP conducted a pet food sampling project with 100 samples analyzed for a full nutrient profile of protein, fat, fiber, vitamins, minerals, and amino acids – up to 28 different nutrients. At the completion of the project, pet food had an 85% passing rate. Pet food experiences the same nutrient variability, quantity of ingredients, and multiple contributors of nutrients as livestock feed. DATCP needed more information to better understand the difference in passing rates between livestock feed and pet food.

Results per Analyte

A review of the sampling results by individual analyte for livestock feed provided better insight for a pass rate. The three primary analytes – crude fiber, fat, and protein – have on average about an 80% pass rate (Figure 4). Protein was the exception with an average below 80% in any given year. Even if combined, crude fiber, fat, and protein did not perform poorly enough across the five-year span to be one of the primary contributing factors to the 57% passing rate. The overall average passing rate, if commercial feed sample analysis only included protein, fat and fiber, would be 88.9%. However, DATCP analyzes multiple nutrients beyond protein, fat, and fiber, like minerals (such as calcium, selenium, etc.), drugs, and other nutrients that open the results up to more variability, which affects the overall pass rate.

Figure 3.

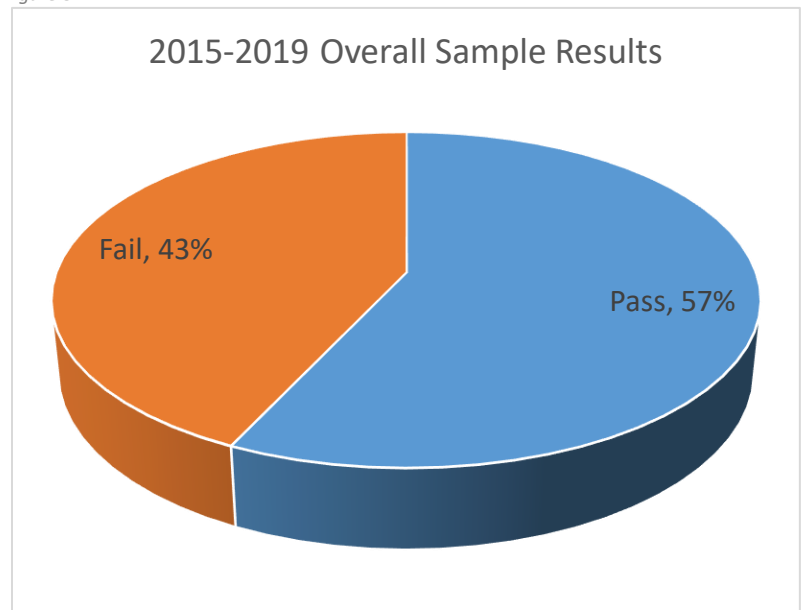
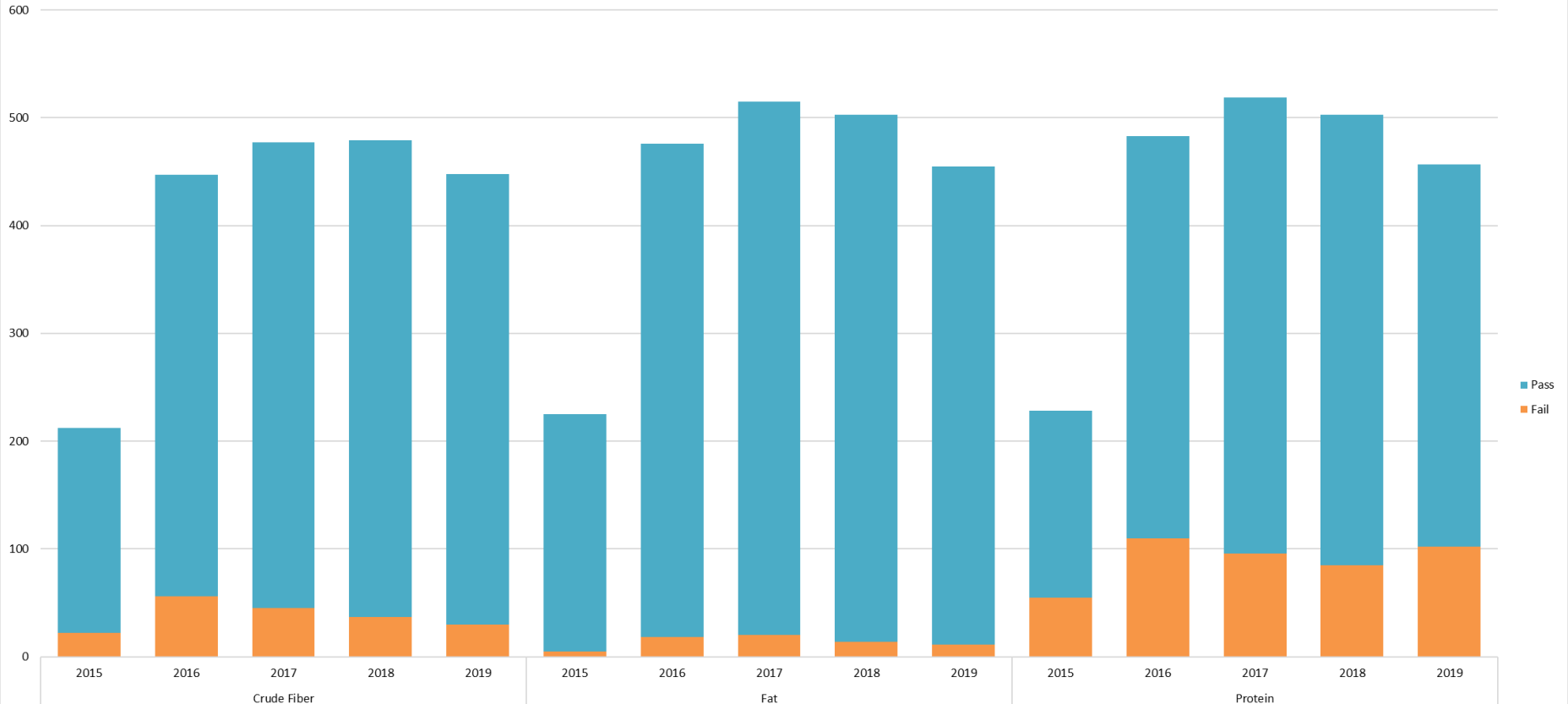


Figure 4. Protein, Fat and Crude Fiber Results, 2015-2019



Pass	190	391	432	442	418	220	458	495	489	444	173	373	423	418	355
Fail	22	56	45	37	30	5	18	20	14	11	55	110	96	85	102
% Pass	90%	87%	91%	92%	93%	98%	96%	96%	97%	98%	76%	77%	82%	83%	78%

Figure 5. Animal Drug Results, 2015-2019
(For Drugs with >5 Samples)

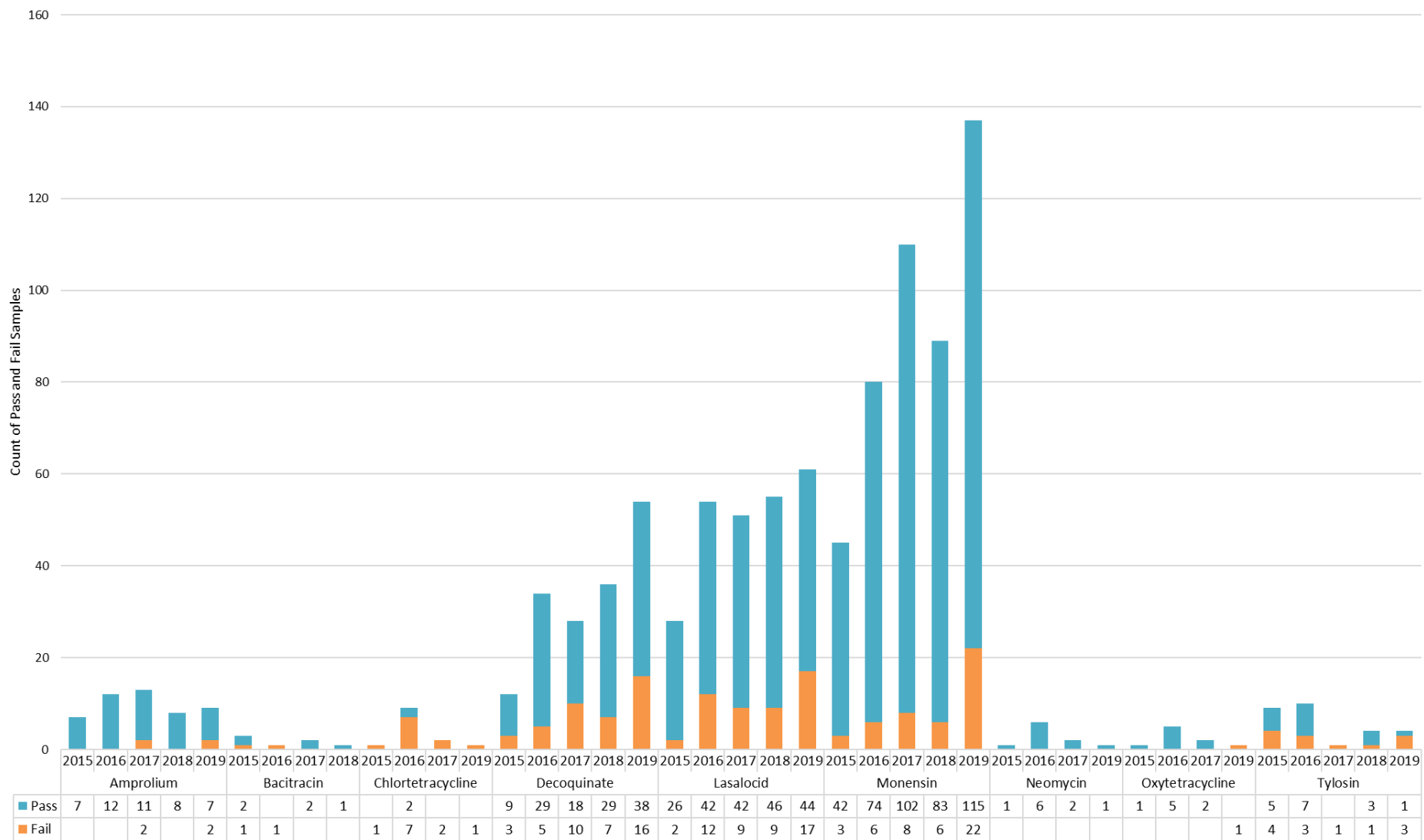
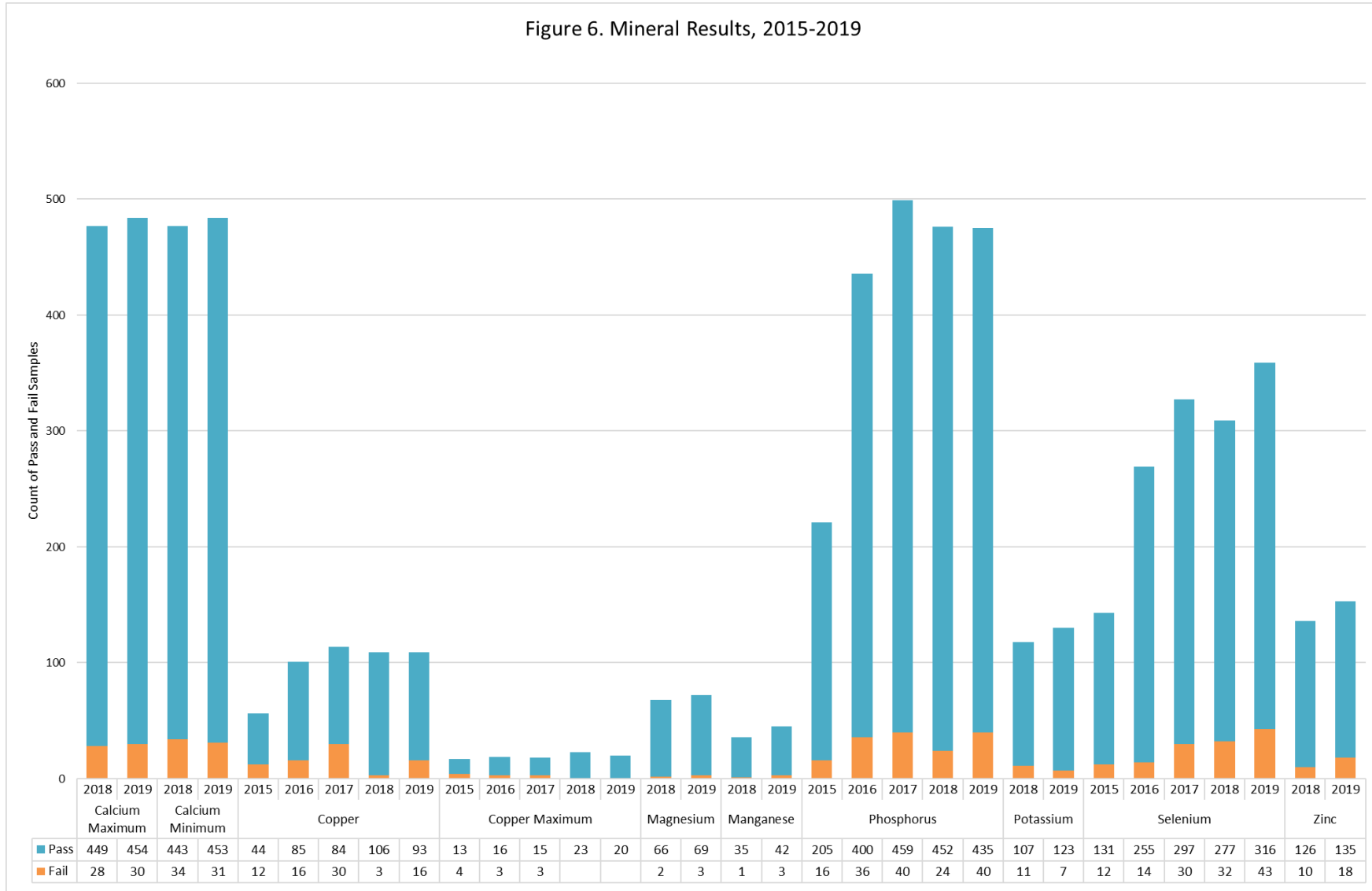


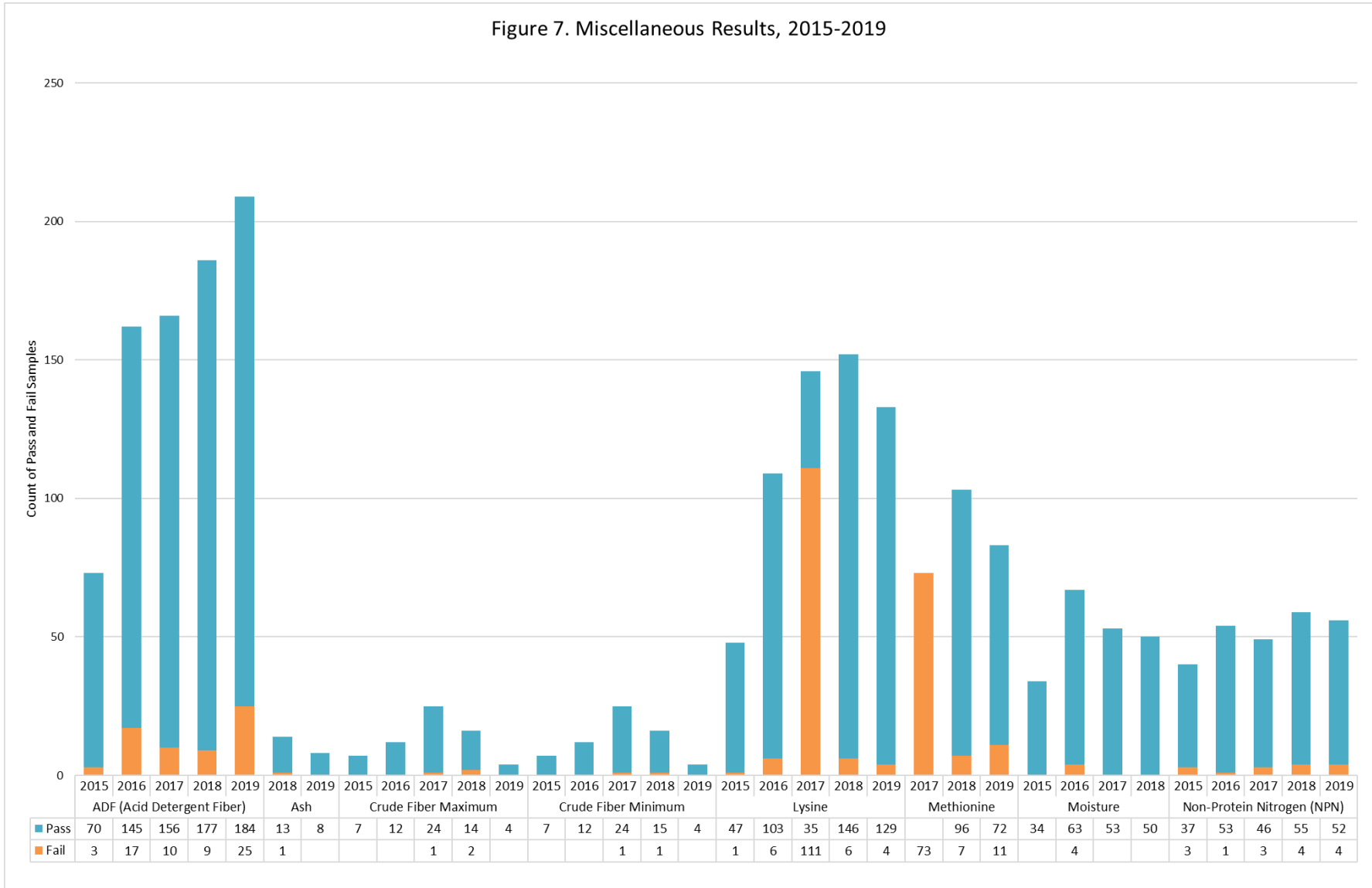
Figure 6. Mineral Results, 2015-2019



Note:

1. Copper analyte represents feeds with a guarantee for copper.
2. Copper maximum analyte represents sheep feeds without a label guarantee for copper. Passing status means the sample contained less than or equal to 20 parts per million (ppm) copper, per Wis. Admin. Code § ATCP 42.14(10)(i). Failing status means the sample contained more than 20 ppm copper.
3. Selenium is a minimum guarantee on feed labels. Complete feeds for chickens, swine, beef cattle and dairy cattle, as per 21 CFR §§ 573.920(c)(1), 573.920(g)(1)(i), and 573.920(h)(2), may not contain copper at a level higher than 0.3 ppm.

Figure 7. Miscellaneous Results, 2015-2019



Note:

- Acid detergent fiber guarantee is required on dairy feeds, sometimes included as option on equine and beef feeds.
- Ash and moisture are common to specialty pet foods.
- Crude fiber maximum and crude fiber minimum guarantees are specific to rabbit feeds.
- Lysine and methionine are amino acids. Lysine is required on swine and poultry feeds, methionine is required on poultry feeds only.
- Non-protein nitrogen guarantees are only required guarantees on ruminant feed labels where a source of non-protein nitrogen was added, such as urea.

The drug analysis data provides an area of potential improvement for samples collected, and with manufacturing feed (Figure 5). The drug analyte results are a smaller sample size than the protein, fat, and fiber. Monensin, the most common drug added to feed in Wisconsin, had an overall 90% passing rate from 2015-2019 (Table 3).

Table 3.

2015-2019 Overall Average Result, By Drug				
Drug	Fail	Pass	% Pass Rate	Total Samples
Amprolium	4	45	92%	49
Bacitracin	2	5	71%	7
Carbadox	1	3	67%	3
Chlortetracycline	11	3	15%	13
Decoquinatate	41	123	75%	164
Lasalocid	49	200	80%	249
Monensin	45	416	90%	461
Neomycin	0	10	100%	10
Oxytetracycline	1	8	89%	9
Penicillin	0	1	100%	1
Sulfamethazine	3	1	25%	4
Sulfathiazole	1	0	0%	1
Tylosin	12	16	57%	28

The other drugs tested were not sampled in representative quantities, but the data available - when the population size (the samples collected) was greater than two – identified the following analytes in need of improvement: chlortetracycline, decoquinatate, and tylosin. Of those three drugs, chlortetracycline and tylosin are veterinary feed directive (VFD) drugs, requiring veterinarian oversight in order to be fed to animals, making them less available for sample collection, yet not unavailable. Decoquinatate, however, is a readily available coccidiostat drug used to treat a microscopic parasite in the gastrointestinal tract of cattle. There was some industry feedback from the Manufacturer’s Report of Investigational Findings (MRIF) that one soybean meal supplier changed the anti-caking agent in their soybean meal from calcium carbonate to bentonite. Bentonite, an anti-caking agent approved for use in animal feed with certain limitations, is known to interfere with the availability of decoquinatate, for absorption by the animal, and for analysis in a laboratory. In other words, the bentonite will make the decoquinatate fail because it ties it up from detection in the laboratory. DATCP can look to collect more of the chlortetracycline, decoquinatate, and tylosin samples in the future to get a more representative data.

Similar to the other nutrients reviewed, on a per-analyte basis, the data shows average or above-average passing results for minerals (Figure 6). Based on these results, copper appeared to have an effect on passing results. On average, feeds labeled with a copper guarantee passed at an overall 84% passing rate. However, in 2015 copper passed at an average of 79%, and in 2017, at 74%. Looking at the copper maximum data, which represents sheep feed without added copper or with copper below 20 parts per million (ppm), only 2015 brought the long-term average down with a passing rate of 75%.

The miscellaneous analyte data demonstrate strong passing results across the board (Figure 7). The lysine and methionine results from 2017 that show a high fail rate are not valid since the analysis method for lysine and methionine broke sometime during the 2017 season. The entire data set must be considered invalid since the break could not be associated from the analysis of one specific sample forward. All of the data, outside of the 2017 lysine and methionine results, met or exceeded the 85% passing rate goal. The overall passing rate, when calculated without the 2017 lysine and methionine analysis results, is still 57%.

On a per-analyte (per-nutrient) basis, no specific analyte or handful of analytes experienced a level of poor performance that brought the overall passing rate down to 57%. The analysis did result in identification of a few nutrients as potential areas for additional sampling or improvement – protein, chlortetracycline, tylosin, decoquinatate, and copper.

Analysis Using Non-Nutrient Data

Container Type

Analysis of the data by the type of container the feed was sampled from revealed consistent pass results with the overall passing rate (Table 4). Bagged feeds or feeds packaged in 50-pound sacks, passed 57% of the time, nearly an identical result to the overall pass/fail rate. Bulk feed had a slightly higher pass rate at 62%. Feeds marked as unknown in container type were those feeds sold in buckets, pails, or smaller package sizes. Unknown packaged feeds passed at 49%. None of the container types demonstrated a pass rate markedly different from the overall pass rate.

Table 4.

Analysis by Container Type, 2015-2019

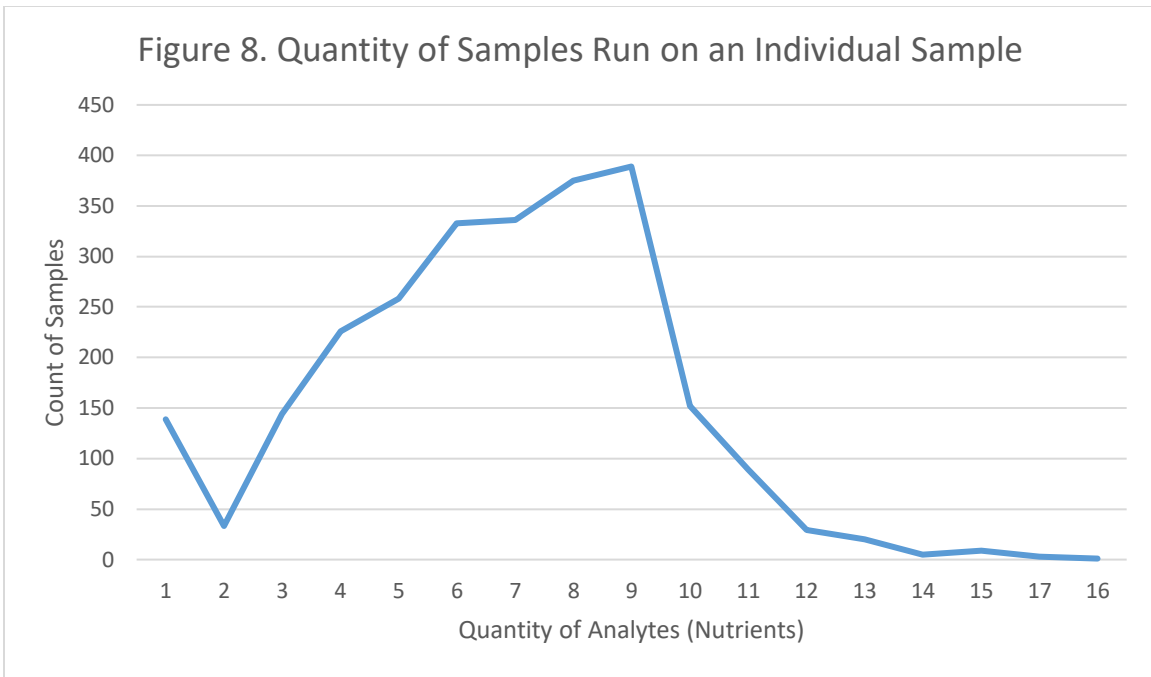
<u>Bagged Feed (n=2,169 samples)</u>	
Pass	57.08%
Fail	42.94%
<u>Bulk Feed (n=262 samples)</u>	
Pass	62.60%
Fail	37.40%
<u>Unknown (n=101 samples)</u>	
Pass	49.50%
Fail	50.50%

Intended Species

Analysis of feed samples by intended species, categorized first by medicated or non-medicated status, identified areas to focus on future sampling. Feed that fell below the 85% passing rate, with a sample size of 200 included complete medicated calf feed and complete non-medicated chicken feed as two areas where samples failed frequently. Overall, quantities of samples by intended species (Table 5) are not representative, and more data is necessary for an accurate assessment.

Analytes

The 2017 pet food project involved analysis of 100 samples for approximately 25 different analytes. In the sampling program, analysis included anywhere from one to 17 different analytes (Figure 8). The average sample was analyzed for about five to nine different analytes. While pet food samples are analyzed, on average, for three to five times the number of analytes, DATCP’s sampling project shows that these sample types have an 85% passing rate.



Within the failed surveillance sample dataset from 2015-2019, it is worth noting that 89.5% or 1,049 of the samples failed for only one or two analytes (Figure 9). All other available data analyzed thus far has failed to pinpoint a single problem area for failed samples. The count of failed analytes per sample could be the one thing that is most telling: livestock samples consistently fail for one inconsistent nutrient in a feed.

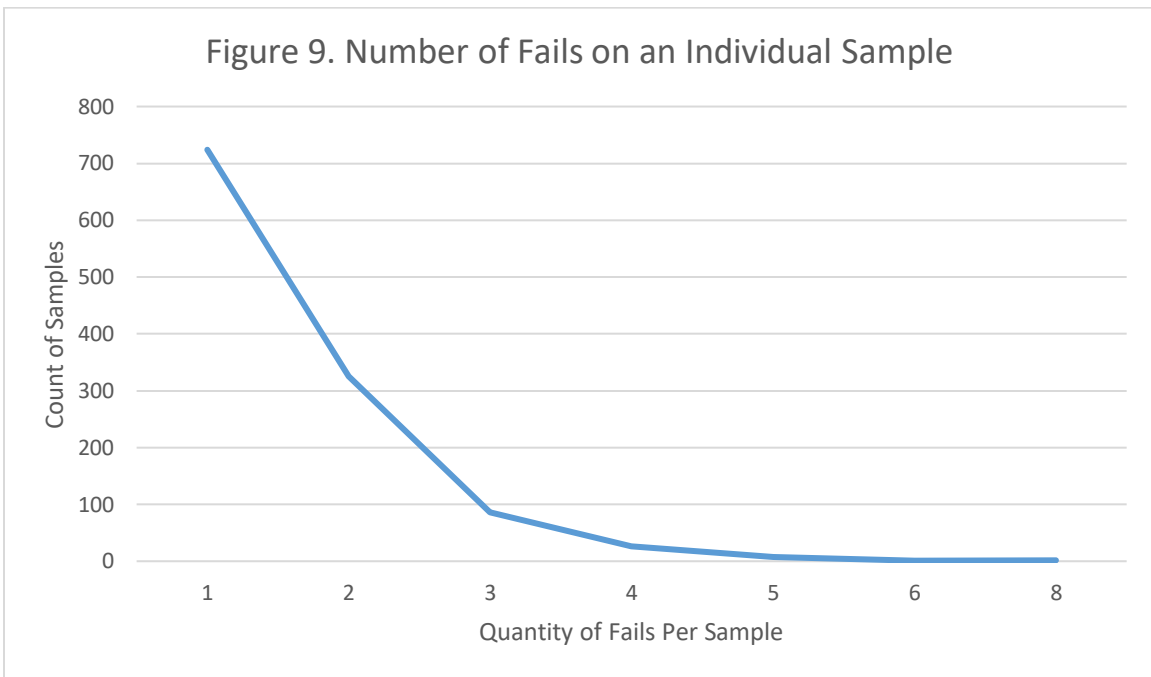


Table 5. 2015-2019 Results by Feed and Species Type (n=2,504)

<i>Feed Type by Species</i>	<i>Fail (Count)</i>	<i>Pass (Count)</i>	<i>Total (Count)</i>	<i>Fail %</i>	<i>Pass %</i>
Chicken Complete Feed	14	23	37	38%	62%
Medicated Beef Complete	53	32	85	62%	38%
Medicated Beef Concentrate	46	57	103	45%	55%
Medicated Calf Complete	108	100	208	52%	48%
Medicated Calf Concentrate	25	32	57	44%	56%
Medicated Chicken Concentrate	1	4	5	20%	80%
Medicated Dairy Complete	40	57	97	41%	59%
Medicated Dairy Concentrate	71	77	148	48%	52%
Medicated Horse Feed	1	6	7	14%	86%
Medicated Livestock Feed	3	4	7	43%	57%
Medicated Milk Replacer	8	24	32	25%	75%
Medicated Mineral Feed	28	22	50	56%	44%
Medicated Miscellaneous Feed	16	38	54	30%	70%
Medicated Mixed Feed	2	3	5	40%	60%
Medicated Premix	1	0	1	100%	0%
Medicated Sheep Complete	21	23	44	48%	52%
Medicated Sheep Concentrate	8	11	19	42%	58%
Medicated Swine Complete	7	5	12	58%	42%
Medicated Swine Concentrate	2	1	3	67%	33%
Medicated Turkey Complete	3	7	10	30%	70%
Medicated Turkey Concentrate	1	0	1	100%	0%
Medicated Veal Feed	0	1	1	0%	100%
Non-Medicated Beef Complete	14	17	31	45%	55%
Non-Medicated Beef Concentrate	9	5	14	64%	36%
Non-Medicated Calf Complete	24	23	47	51%	49%
Non-Medicated Calf Concentrate	9	12	21	43%	57%
Non-Medicated Chicken Complete	132	135	267	49%	51%
Non-Medicated Chicken Concentrate	9	17	26	35%	65%
Non-Medicated Dairy Complete	25	40	65	38%	62%
Non-Medicated Dairy Concentrate	45	68	113	40%	60%
Non-Medicated Horse Feed	77	119	196	39%	61%
Non-Medicated Milk Replacer	6	15	21	29%	71%
Non-Medicated Mineral Feed	46	52	98	47%	53%
Non-Medicated Miscellaneous Feed	104	253	357	29%	71%
Non-Medicated Mixed Feed	14	10	24	58%	42%
Non-Medicated Pet Feed	2	6	8	25%	75%
Non-Medicated Premix	3	5	8	38%	63%
Non-Medicated Sheep Complete	14	10	24	58%	42%
Non-Medicated Sheep Concentrate	5	6	11	45%	55%
Non-Medicated Swine Complete	58	87	145	40%	60%
Non-Medicated Swine Concentrate	6	15	21	29%	71%
Non-Medicated Turkey Complete	5	9	14	36%	64%
Non-Medicated Turkey Concentrate	0	1	1	0%	100%
Non-Medicated Veal Feed	0	3	3	0%	100%
Premix Veal Feed	1	1	2	50%	50%

Outreach

Instead of taking enforcement action on failed samples, DATCP initiated an outreach project in fall of 2018. The goal of the project was to communicate the surveillance sampling results to industry. Sampling data had not been publicly announced for decades. Outside of the performance of their own facility, most licensees were not aware of the poor overall passing rate.

Initially, DATCP met with the local trade association representatives to present the data. At the time of the first outreach, approximately 1,600 samples of livestock feed were in the dataset. The trade associations agreed to provide DATCP with outreach opportunities at meetings, while continuing to collect samples and increase the available data. DATCP presented to members of the Cooperative Network, Wisconsin Agri-Business Association (WABA), and held a webinar series in the spring of 2020 (Table 6).

Table 6. 2018-2020 Feed Program Presentations of Sampling Data	
Aug-18	Initial Trade Association Sampling Data Presentation
Jan-19	Wisconsin Agri-Business Assn (WABA) Classic Conference
Feb-19	Cooperative Network Wisconsin Farm Supply Committee Meeting
Apr-19	WABA Regional Feed Meeting in Appleton
May-19	WABA Regional Feed Meeting in Eau Claire
May-19	WABA Regional Feed Meeting in Wisconsin Dells
Feb-20	DATCP Medicated Feed Manufacturer Webinar
Feb-20	DATCP Non-Medicated Feed Manufacturer Webinar
Mar-20	(3) DATCP Medicated Feed Manufacturer Webinars

As industry learned about the commercial feed sampling statistics, speculation began as to a reason for the low passing rate. Ultimately, no single reason can be attributed to the failures. Instead, commercial feed licensees received a list of best practices for manufacturing a safe and quality animal food, developed by WABA consultant Wayne Nighorn of Agres Consulting, LLC. Nighorn presented the list of

Figure 10.

Feed Manufacturer’s Checklist for Safe and Quality Animal Food
<input type="checkbox"/> Regularly check nutrient values against label guarantees of mill-formulated feeds.
<input type="checkbox"/> When creating a label for a custom feed or floor stock feed, allow an adequate range for each minimum and maximum guarantee.
<input type="checkbox"/> Remember to update labels when updating formulas.
<input type="checkbox"/> Review mixing standard operating procedures (SOPs).
<input type="checkbox"/> The times are adequate for a homogenous mixture.
<input type="checkbox"/> The mixer is in good working order.
<input type="checkbox"/> Is the formula outdated for today’s ingredient types and premixes?
<input type="checkbox"/> Regularly update nutrient values in ration software.
<input type="checkbox"/> Check expiration dates – especially on feed-through medications and direct-fed microorganisms.
<input type="checkbox"/> Destroy expired products.
<input type="checkbox"/> Check inclusion rates to factor in degradation by time, temperature, and processing.

best practices at the 2019 Wisconsin Agri-Business Classic in January 2019. DATCP and WABA published the list of best practices for manufacturing a safe and quality animal food for further distribution (Figure 10).

At the conclusion of the 2020 webinar series, DATCP sent attendees a survey with questions about sampling. Feedback from the medicated feed manufacturers and non-medicated feed manufacturers revealed that 30 out of 33 respondents were very concerned or somewhat concerned about the overall passing rate of feed samples. Comments received as part of the survey expressed a desire by industry to see the passing rate improve, and that most mills are trying to make a safe and quality animal food. Two respondents even mentioned their efforts to implement an internal quality assurance sampling

program. One or two comments discussed the nutrient variability. Another comment mentioned the difficulty in collecting a good sample, particularly with texturized feeds over pelletized feeds. The particles can separate, and the farther a feed travels through bins and legs of the manufacturing equipment, the more the particles separate.

While communicating the sampling data was a goal, the primary goal was to communicate best practices to improve the manufacturing of commercial feed that meets label guarantees.

Next Steps

DATCP will continue to conduct surveillance sampling of complete feeds and premixes manufactured and distributed in Wisconsin. Due to the longevity of the 57% overall passing rate, DATCP is preparing to take measures to emphasize the need for improvement. State law [Wis. Stat. § 94.72(10)] authorizes the proper sample collection procedure for pursuit of enforcement action, should a commercial feed fail to meet label guarantees.

Current Enforcement

Currently, enforcement includes a written warning for failures that have an elevated human or animal health or safety risk, or a notice of potential violation for failures with a low human or animal health or safety risk. The written warning requires a written response from the labeler regarding the investigation into the failure using a DATCP form (Manufacturer's Report of Investigational Findings). The notice of potential violation does not require a response from the labeler.

The Manufacturer's Report of Investigational Findings received to-date have generated a bank of responses. The bulk of the responses can be summarized by four different reasons:

- Revised formula without updating the label, or vice versa
- Mixer distribution inadequate or inadequate mixing time
- Used nutrient values from national average or did not update nutrient values from year to year
- Incorrect inclusion of a specific ingredient

Responses like the four above prompted DATCP to conduct the outreach regarding the best practices in Figure 10. Implementation of the best practices at a minimum, and at best, pairing the best practices with a quality assurance sampling program, would be the ideal initial steps toward a higher overall passing rate.

Future Enforcement

Feed sampling outreach included communication about the incorporation of additional enforcement action(s). The purpose of the commercial feed program is to assure the public and manufacturers that animal feed and feed ingredients are not contaminated, meet label guarantees, and are safe and effective for use. Sample data is public information so it is important for industry to recognize how consumers may interpret data and ask questions about the safety and quality of Wisconsin commercial feed. DATCP will consider using a series of stepped enforcement to assist industry with achieving a higher overall passing rate.

The exact enforcement actions, and order of enforcement actions, will be dependent on the type and magnitude of violations found. The following paragraphs detail potential enforcement actions DATCP can use, in order of least to most severe.

Written Notices

Letters of potential violation and written warnings on many occasions have been an effective way to notify a facility of a feed label deficiency and to help gain compliance. DATCP will likely continue to use

letters of violation and written warnings, in accordance with the health and safety risk assessment discussed earlier.

Withdrawal from Distribution

Commercial feed regulations authorize temporary orders of product withdrawal from distribution [Wis. Stat. § 94.72(13)(b)]. The order can be temporary or permanent. A temporary withdrawal means the feed can be brought into compliance and subsequently released for distribution as animal feed. A permanent withdrawal means the product cannot be brought into compliance, and therefore must be disposed of in accordance with DATCP instruction.

Most commonly, mislabeled or unlabeled feed would be subject to a temporary order. The facility could properly label the feed and it would be released for distribution. Permanent withdrawals would occur specifically if a feed is not safe for consumption by animals, or if the feed would render the products produced by the animals consuming it to be unsafe for humans. Depending on the type of feed, DATCP would instruct the facility on the preferred method of disposal.

Change Conference

A change conference is a discussion between DATCP and licensee management regarding failed sampling results, and the corrective actions necessary to bring the company's samples into compliance. DATCP's sampling coordinator and program specialist, and possibly the appropriate field staff, meet with licensee management to discuss the sampling program, DATCP expectations, sample results specific to the company, and how sampling best practices can be incorporated to resolve possible manufacturing errors identified on past Manufacturer's Report of Investigational Findings forms.

Assurance of Voluntary Compliance Agreement

A voluntary assurance is a non-binding agreement in which the licensee takes the necessary steps to comply with regulations relating to manufacturing and/or labeling commercial feed. Both a DATCP representative and the feed licensee sign the voluntary assurance, in agreement to resolve outstanding compliance issues. A Voluntary assurance identifies the areas of deficiency from compliance with the law. The terms include itemized activities that the licensee must perform to experience a reduction in mislabeling occurrences.

Voluntary assurances will allow DATCP and licensee to collaborate regularly regarding the firm's sampling performance. DATCP's sampling coordinator will track and record activity under each specific point of the agreement, to assess compliance with the agreement. At the end of the season, DATCP's sampling coordinator and program specialist will conduct a review to determine if the licensee met the terms of the agreement, or if the voluntary assurance would be extended.

A voluntary assurance may, or may not, be the result of a change conference, depending upon the historical sampling performance of the firm.

Special Order

A special order involves a DATCP-filed complaint against a company experiencing a high level of mislabeled feed or for failure to take appropriate action to reduce the frequency of mislabeled feed. A special order dictates the type of action a facility must implement and follow in order to retain a commercial feed license. The special order differs from a voluntary assurance in that it is a binding agreement, and failure to meet the terms of the order can result in additional enforcement action such as revocation of the commercial feed license or a mandated temporary halt of manufacturing activities.

A special order is initiated by DATCP's investigation and compliance section in the Bureau Agrichemical Management, because of a formal investigation of violations by a company. The investigation would stem from multiple years of poor sampling performance by a single labeler or manufacturer of commercial animal feed, and/or an adulterated feed. Examples of adulterated feed include but are not limited to, medicated feed manufactured outside of the federally-approved use of a feed-through

animal drug, an unapproved drug combination in a medicated feed, or a nutrient toxicity or deficiency to the detriment of animals (such as toxic levels of copper in a sheep feed).

Penalties

Wis. Stat. § 94.72(14) authorizes DATCP to collect civil forfeitures or criminal penalties for violations. Only the most severe cases of poor performance would incorporate civil forfeitures or criminal penalties. For example, a feed responsible for sick or dead animals would be subject to monetary penalties.

Conclusion

Beginning in 2013, DATCP conducted a project to improve the sampling program for commercial feed. Today, the improvements have revealed other necessary improvements in both sampling data and sample results.

DATCP continues to collect a representative number of samples for more meaningful analysis of the safety and quality of commercial feed. Future efforts will focus on collecting feed data by intended species.

Works Cited

"Copper." National Research Council. 2005. *Mineral Tolerance of Animals: Second Revised Edition*, 2005. Washington, DC: The National Academies Press.

U.S. Grains Council. *2019/2020 Corn Harvest Quality Report*. Washington, DC: U.S. Grains Council, 2020. <https://grains.org/wp-content/uploads/2019/12/USGC-Corn-Harvest-Quality-Report-2019-2020.pdf>. Accessed April 8, 2020.