

Master of Public Health Field Experience Report

DRUG RESIDUE AVOIDANCE

by

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MPH Candidate

submitted in partial fulfillment of the requirements for the degree

MASTER OF PUBLIC HEALTH

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Abstract

Antibiotics are used in food-producing animals to treat, prevent, and control diseases caused by harmful bacteria. Administration of antibiotics, anthelmintics, pesticides, parasiticides, and other therapeutic chemicals to food-producing animals can result in a residue. A residue is defined by the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) as any compound or metabolite of a compound that is present in edible tissues from food animals because of the use of a compound in or on animals. Residues can be from the compound itself, its metabolites, or any other substances formed in or on food as a result of the compound's use. Any animal that receives any therapy that can result in residues cannot, by law, be sent to slaughter until the drug has been reduced to a specified level and deemed safe for human consumption. Drug concentrations above this level are illegal and known as violative residues. It is the responsibility of the producer to ensure the health, safety, and well-being of their animals while remaining in compliance with state and federal laws. Following labels and abiding by withdrawal times are crucial parts in protecting the food supply chain.

Diseases can have a devastating impact on animal welfare and production. Consumers have expressed concern regarding the health impact of drug residues in their food. These concerns include: toxicity, allergic or hypersensitivity reactions, carcinogenic, mutagenic or teratogenic effects, the potential for the development and transfer of antibiotic resistant bacteria, and consumer preference of “antibiotic free” products. To avoid these concerns, all drugs should be used according to label directions and in a judicious manner.

Drug residue avoidance begins by working with a veterinarian to put into place best management practices or “BMPs” and standard operating procedures or “SOPs” for a farm or operation. Following the formation of these BMPs and SOPs, all employees and stakeholders must be regularly trained and adherence to the BMPs and SOPs must be verified. Reading and following product-label directions, maintaining good records, and adopting a quality assurance program, all contribute to maintaining the safest food supply chain in the world. The Kansas Department of Agriculture

received a grant through the FDA with the goal to prevent violative drug residues in animal-derived foods produced in Kansas through educational training and outreach to livestock producers. This was accomplished through three communication strategies: brochures, PowerPoint slide sets, and online training modules. Specific educational materials were created for five different animal production segments: beef cattle, dairy cattle, swine, poultry, and small ruminants. Upon completion, these materials will be made available on the Kansas Department of Agriculture's website.

Subject Keywords: Drug; Residue; Public Health; Antibiotics; Food-Safety; Withdrawal Time; Toxicology; Meat; Milk; Egg; Animals; Humans; Consumers

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Acronyms & Abbreviations

FDA	Food and Drug Administration
CVM	Center for Veterinary Medicine
NRP	National Residue Program
USDA	United States Department of Agriculture
FSIS	Food Safety and Inspection Service
EPA	Environmental Protection Agency
FMIA	Federal Meat Inspection Act
PPIA	Poultry Products Inspection Act
EPIA	Egg Products Inspection Act
PMO	Pasteurized Milk Ordinance
VCPR	Veterinary-Client-Patient Relationship
AVMA	American Veterinary Medical Association
ELDU	Extra-Label Drug Use
AMDUCA	Animal Medicinal Drug Use Clarification Act
CFR	Code of Federal Regulations
MRL	Maximum Residue Level
FARAD	Food Animal Residue Avoidance Databank
ADI	Acceptable Daily Intake
VFD	Veterinary Feed Directive
BMPs	Best Management Practices
SOPs	Standard Operating Procedures
CODEX	Codex Alimentarius Commission

Chapter 1 - Field Experience Scope of Work

The Kansas Department of Agriculture (KDA) is an agency devoted to supporting the agriculture industry. The agency works on behalf of the entire agriculture sector, including farmers, ranchers, food establishments and agribusinesses, to protect both animal and human health, ensure a safe food supply, and regulate compliance of state laws. The organization is dedicated to promoting awareness of Kansas agriculture by providing the public with an accurate and reputable source of information.

KDA received a grant through the Food and Drug Administration (FDA) with the goal to prevent violative drug residues in animal-derived foods produced in Kansas through educational training and outreach to livestock producers. This is a cooperative agreement between the Kansas Department of Agriculture, Kansas State University Research and Extension, the Kansas State Veterinary Diagnostic Laboratory and the Beef Cattle Institute.

The purpose of this project was to create and disseminate educational materials with the goal to limit the occurrence of drug residues in animal-derived foods. This was accomplished through three communication strategies; brochures, PowerPoint slide sets, and online training modules. Specific educational materials were created for five different animal production segments: beef cattle, dairy cattle, swine, poultry and small ruminants. Upon completion, these materials will be made available on the Kansas Department of Agriculture's website.

The success of this prevention program will be determined by the number of individuals who watch the online training modules, attend presentations where the PowerPoint slide sets are used, or contact the organizations involved with questions or concerns.

Chapter 2

Learning Objectives

I have learned an extensive amount of knowledge regarding the issue of drug residues in foods of animal origin and how residues can be prevented and controlled. I have also learned about the effects residues have on the industry and regulations involved to ensure a safe and secure food supply. Lastly, I learned the best tools and communication strategies to educate producers on how to avoid drug residues.

Activities Performed

This project involved creating an outline of questions and specific topics regarding drug residues for use within the brochures, PowerPoint slide sets, and online training modules. After the content was established, a list of industry experts was assembled. Numerous industry professionals, veterinarians, extension agents, and livestock producers were contacted and each graciously agreed to provide valuable assistance to the project, specific to their area of expertise. Interviews, video footage, and species-specific information were acquired from participating individuals. It was my responsibility to create, design, and produce the informational brochures, PowerPoint slide sets, and online training modules.

Products Developed

1. Five species-specific brochures (beef cattle, dairy cattle, swine, poultry, and small ruminants). These brochures address some of the issues associated with drug residues and strategies to prevent residues in foods of animal origin.
2. Five PowerPoint slide sets (cow/calf, feedlot, dairy, swine, and poultry). These PowerPoint slide sets focus on the steps livestock producers can implement to prevent drug residues. These slide sets will be used by veterinarians, extension agents, and educators.
3. Five species-specific online training modules (beef cattle, dairy cattle, swine, poultry, and small ruminants). The modules primarily focus on ways producers can prevent drug residues on their operation. Avoidance strategies

such as identifying treated animals, keeping appropriate records, establishing and maintaining a valid veterinary-client-patient relationship, and following product-label directions were addressed in the modules.

The target audiences for this project are producers involved with treating and/or managing food-producing animals and veterinarians needing informative resources for client-education about best residue prevention practices.

Chapter 3 - Capstone Project / Culminating Experience

Background

Outbreaks of plague, disease, and illness have existed for centuries. The search for understanding the causes of these diseases has continued for many years. In approximately 1550 B.C., Egyptians used honey, lard, and lint for dressing wounds. Although, it was unknown at the time, honey contains substantial amounts of hydrogen peroxide which can kill bacteria. Many ancient cultures used mold, soil, and plants as remedies for illness or infection ("Ancient Times," n.d.). The Egyptians applied moldy bread to wounds and used plant extracts to treat infections. These remedies were believed to influence the spirits or the gods responsible for illness and suffering ("Ancient Times," n.d.). It is evident now that mold is a fungus that competes with bacteria; many antibiotics today are derived from fungi.

Explanations for disease causation have changed and evolved over time. Around the 1600s, there was the belief of "miasma" which was the idea that disease was caused by the presence of "bad air". This was thought to be due to organic decomposition of the Earth, producing gases that caused disease. Following the belief of miasma, was the belief of contagion, which attributed the transmission of disease between people by means of direct contact. Replacing the previous beliefs of miasma and contagion, the germ theory became a widely accepted explanation in the late 19th century. This theory hypothesized that specific microscopic organisms are the cause of specific diseases. This notion paved the way for finding an effective means to kill harmful microbes.

In 1904 a German physician, Dr. Paul Ehrlich, formed the idea that it could be possible to kill specific microbes, such as bacteria, that cause diseases without harming the body itself. Dr. Ehrlich believed similarly to a bullet being fired from a gun to hit a specific target, there could be a way to specifically target invading microbes. This became known as the "magic bullet" concept. Dr. Ehrlich was successful in creating this "magic bullet" when he discovered certain chemical dyes colored some bacterial cells but not others ("The History of Antibiotics," n.d.). This led to his discovery of the first

chemotherapeutic agent, Compound 606, responsible for providing an effective treatment for the endemic disease, Syphilis (A Brief History, 2010).

Following Ehrlich's discovery, penicillin the world's first antibiotic, was discovered by Alexander Fleming. It was nicknamed "the wonder drug" during World War II for its highly effective treatment of bacterial infections in war time casualties. Within a few years of availability, antibiotics had reduced the rate of death from infections in the United States by nearly 80 percent, from 280 to 60 deaths per 100,000 population (Spellberg, 2010).

Following the success of penicillin, other antimicrobial agents have been introduced and mass-produced for use not only in human medicine, but for animals as well. As time progressed, the cost of antibiotics decreased and they became practical to use in commercial livestock production (Bowen & Gustafson, 1997). The use of antibiotic therapy has transformed the ability to treat infections in animals and is an important tool to enhance animal health, animal well-being, and the economics of livestock production. In the past, antibiotic use in animals was not limited exclusively to treating disease, but was utilized to improve weight gain and feed efficiency, overcome parasitic infections, and for prophylactic purposes when disease risk is increased. Early examples of antibiotic use in animals were penicillin to treat bovine mastitis, streptomycin added to the diet of chicks to improve growth, and chlortetracycline to improve weight gain in chickens and reduce the amount of feed needed to bring broilers to market weight (Landers, Cohen, Wittum, & Larson, 2012).

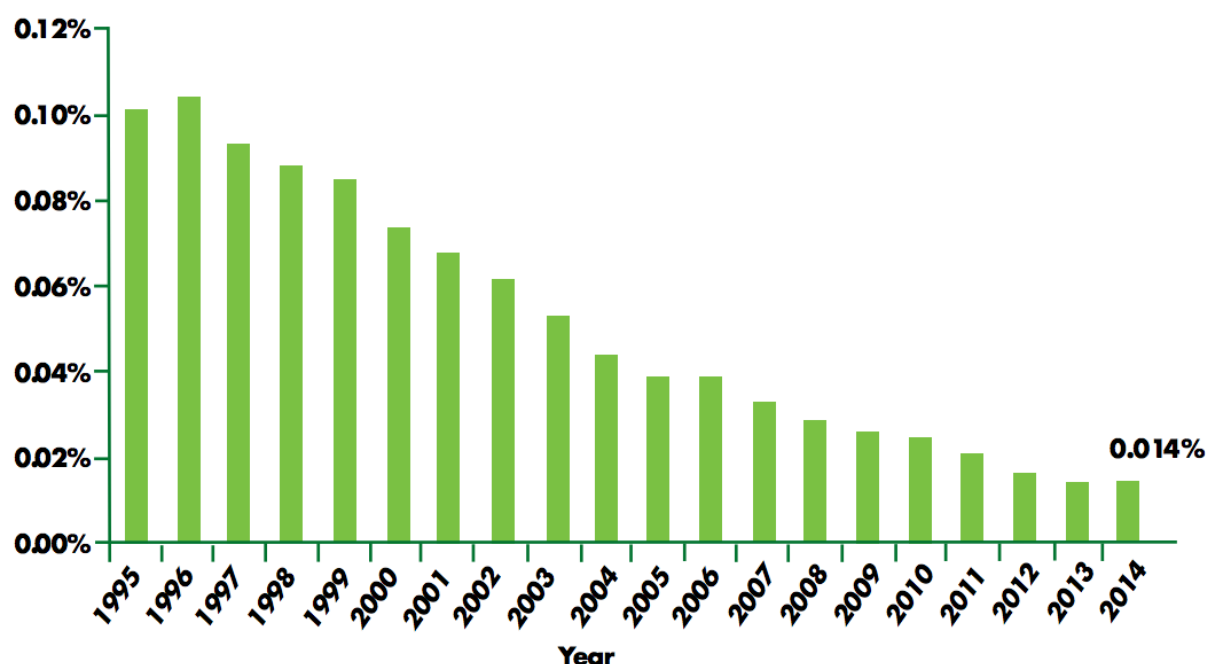
As the demand for meat has increased and technology has advanced, management practices have changed and food-animal production has intensified over the past 50 years (NRC, 1999). The number of US farms has decreased, while the density of animals on those farms have increased considerably (NRC, 1999). Production has become more efficient with a greater quantity of commodities produced by fewer animals (NRC, 1999). The goal of an efficient livestock operation is to raise animals or produce a product that will in turn result in a profit. This means that animals intended for market are free of disease and injury while gaining weight quickly and efficiently. Herd health management plans with detailed disease prevention and treatment protocols are instrumental for the success of a producer's farm or operation.

The use of antibiotics on a livestock operation benefits the producer by improved productivity, it enhances animal welfare by the effective treatment of sick animals, and it addresses consumer demand for a safe, inexpensive food supply. While there are strong incentives to appropriately use antibiotics to ensure only healthy animals enter the food supply and to enhance efficiency within the industry, the use of antibiotics is not without risk. Antibiotic resistance, drug residues, toxicity, and hypersensitivity reactions are all concerns that have increased with antibiotic usage. The focus of this project revolves around the concern of drug residues, which can affect human health through trace amounts of antimicrobial drugs present in meat, milk, or eggs.

Antibiotic residues in meat, milk, or eggs can occur for a variety of reasons including: failure to adhere to proper withdrawal regulations, extra-label use of animal drugs, or insufficient animal identification to prevent marketing of animals or animal-products until the withdrawal time has passed. Although residues found in animal-derived foods pose a relatively low risk, it is important that livestock producers are educated about the practices to avoid these residues. In 2014, the percentage of bulk milk tankers that reported a positive result for drug residues was 0.014% and this number has been on a consistent decline (Graph 1). This graph signifies a dramatic decrease over a 20-year period from an already low-level of occurrence.

Drug residue avoidance is an important topic to be addressed due to the potential risk to consumers and human health concerns. Through increased education and proper herd health management this small percentage will continue to decline. It is the responsibility of the livestock producer to ensure the health, safety, and well-being of their animals while remaining in compliance with state and federal laws.

Percent of Bulk Milk Tankers Positive for Drug Residues



Graph 1 Percent of Bulk Milk Tankers Positive for Drug Residues

Drug Residue

A residue is defined by FDA's Center for Veterinary Medicine (CVM) as any compound or metabolite of a compound that is present in edible tissues from food animals because of the use of a compound in or on animals. Residues can be from the compound itself, its metabolites, or any other substances formed in or on food as a result of the compound's use (21 CFR 500.82 (B), n.d.). Residues are not just limited to veterinary pharmaceuticals such as antibiotics and de-wormers. Other chemicals, insecticides, vaccines, or other products given or applied to food animals can be sources of residues. Drug residues refer specifically to veterinary pharmaceutical products such as antimicrobials and deworming products (NRC, 1999).

Any animal that receives any therapy that can result in residues cannot, by law, be sent to slaughter until the drug has been reduced to a specified level and deemed safe for human consumption. Drug concentrations above this level are illegal causing the food to be adulterated and known as a violative residue.

Drug Approval Process

A pivotal point in time for the laws surrounding the drug approval process was following the well-known thalidomide incident in Europe. Prior to this incident, the FDA did not place any regulations on drug approval or monitoring.

In 1953, Ciba, a pharmaceutical company based in Switzerland, was the first to synthesize thalidomide. This drug was intended to be used as an anticonvulsive agent; however, following lab tests the drug did not show the desired effect, so research on thalidomide was stopped. A few years later, in 1957, a West German pharmaceutical company re-examined the compound and found it worked as a sleep-aid with no apparent side effects. It became a popular sleeping pill and sold under the trade name Contergan. It was advertised as being “completely safe” for everyone, including pregnant women. Exacerbating the situation, an Australian obstetrician discovered the drug also alleviated morning sickness and began recommending off-label use to his pregnant patients. In addition to treating morning sickness, thalidomide was often combined with aspirin and used to treat just about everything from colds to asthma; some claimed it even helped treat loss of vision, diabetes, autoimmune disease, and some forms of cancer (Tantibanchachai, 2014). After only three years of being on the market, sales were competitive with those of aspirin. It was not long until the side effects were unveiled and disaster struck. The drug resulted in phocomelia, which is an interference in the development process causing shortened, absent, or flipper-like limbs. This devastating event has caused more than 10,000 birth defects worldwide, ultimately leading to the rigorous drug approval and monitoring systems in place today by the FDA.

Before the thalidomide incident there were no laws requiring physicians to keep records of the drugs they prescribed, nor were the physicians required to follow-up with their patients. The pressure of this thalidomide incident compelled Congress to pass in 1962 the *Amendments to the Federal Food, Drug and Cosmetic Act*. The 1962 Amendments stated that the sponsor company had to provide the FDA with a detailed outline of the study, monitor the progress of the studies, and continually report its findings to the FDA. Before these amendments, the FDA approved an average of 46.2

new single drug entities annually. In the decade after, that number dropped to 15.7 (Tantibanchachai, 2014).

There is now extensive regulatory oversight to ensure drugs approved for use are safe and effective. Extensive toxicology and pharmacology studies are required to demonstrate that consumers will not suffer harmful consequences from taking approved drugs. The pharmaceutical company applying for drug approval is responsible for providing CVM with scientific information and experimental data showing that the presence of residues from a compound in edible animal products is safe for consumers (NRC, 1999). Following the drug approval process, active surveillance and compliance programs are in place to ensure the proper use of antibiotics and the safety of the food supply.

Residue Testing

The United States Department of Agriculture's Food Safety and Inspection Service (USDA FSIS) protects public health by ensuring the supply of meat, poultry, and processed egg products are safe, wholesome, and do not contain violative residues (USDA FSIS, 2014). The National Residue Program (NRP) is a regulatory program administered by FSIS, designed to monitor, detect, reduce, and control violative residues in both domestic and imported food products (Muñiz Ortiz & O'Keefe, 2015). The NRP collects samples of livestock and poultry tissues at slaughtering establishments under its inspection authority and from import shipments at ports of entry. The samples are analyzed for the presence of unacceptable residue concentrations of animal drugs that might contaminate meat and other tissues (NRC, 1999).

This program involves three principal agencies: the Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). The FDA establishes tolerances for veterinary drugs and food additives, while the EPA establishes tolerances for registered pesticides. Each year the FSIS publishes a modified version of a Residue Sampling Plan known as the Blue Book and Residue Sampling Results known as the Red Book. These books outline the production classes sampled, the sample size, the drug classes that are tested for and

the results. The results indicate how many samples yielded a positive result or a violative residue, the production class the positives were found in, and the specific drug(s) used.

To narrow the effort of residue testing, the NRP operates using a three-tiered sampling system. Tier 1 is scheduled sampling aimed to collect a set number of random samples at the time of slaughter from the following production classes: beef cows, bob veal, dairy cows, steer, heifers, market hogs, sows, goats, young chickens, and young turkeys. The samples taken in the Tier 1 sampling plan is based on process to determine what samples need to be collected. This process begins with determining which compounds are a food safety concern. Once that determination has been made, algorithms are used to rank the selected compounds. These compounds are then compared with the appropriate production class establishing the number of samples that need to be collected (“Antibiotic Stewardship,” n.d.). This system allows FSIS to decide where available resources and testing efforts should be assigned.

Prior to 2012, FSIS tested 230 to 300 samples from each production class to obtain results that ensured a 90 or 95 percent probability, respectively, of detecting at least one residue violation (FSIS, 2017). In 2012, FSIS increased its sample size to about 800 samples for each of the nine major production classes tested under Tier 1. The number of samples collected is aimed at statistically identifying the occurrence of residues. It is based on the probability of detecting at least one violation. The table below provides the calculated number of samples required to ensure detection of at least one violation. For example, 780 samples are required to detect at least one violation with a 98% probability.

Percentage % Violative in the population (v)	Number of samples required to detect at least one violation in (n) samples with a probability (p)				
	0.90	0.95	0.98	0.99	0.9997
	Sample Size required "n"				
10	22	29	37	44	77
5	45	59	76	90	158
1	230	300	389	459	807
0.57	403	525	684	806	1,419
0.50	460	598	780	919	1,618
0.37	620	808	1,055	1,242	2,188
0.29	793	1,032	1,347	1,586	2,793
0.10	2,302	2,995	3,910	4,603	8,108

Table 1 Samples Required to Detect at Least One Violation

These sampling results can be used to identify producers most likely to market animals with violative levels of residues. Tier 2 samples are inspector-generated samples collected from animal carcasses of suspect animals that may contain violative residues. Suspect animals are considered high risk for violative residues. This is based on criteria such as incidence of past violations or questionable practices detected on the farm or processing site (NRC, 1999). Additionally, findings during ante-mortem or post-mortem inspection such as animals that display lameness, injection site lesions, or signs of illness are targeted for testing. Tier 3 is targeted sampling at the herd or flock level. A targeted testing program is used to determine the level of chemicals originating from the same farm or geographic region certain animals have been exposed to. This type of sampling is conducted in response to information obtained by the FDA and EPA regarding misuse of antimicrobial agents.

Despite changes in production practices, a consistent amount of meat is produced each year. According to the 2014 Residue Sampling Plan also known as the Blue Book, 33 million cattle (bulls, beef cows, dairy cows, heifers, steers, bob veal, formula-fed veal, non-formula-fed veal, and heavy calves), 112 million swine (market hogs, roaster pigs, boars/stags, and sows) and nearly 9 billion poultry (young chickens, mature chickens, young turkeys, mature turkeys, ducks, geese, and other fowl) were slaughtered in the U.S. yielding close to 110 billion pounds of meat. The 2015 Blue Book does not report these numbers. The 2016 Blue Book reported 29 million cattle,

112 million swine and nearly 9 billion poultry were slaughtered yielding approximately 99 billion pounds of meat. Most recently, the 2017 Blue Book reported 30 million cattle, 117 million swine and nearly 9 billion poultry were slaughtered in the U.S. yielding approximately 98 billion pounds of meat (NRP, 2016). These numbers are estimates for each production class in which FSIS has regulatory responsibility. In 2014, the amount of domestically-produced product consumed relative to the total for all of these production classes are 23.287% for cattle, 20.819% for swine, and 51.511% for poultry. This stays consistent as the 2016 percentage of product consumed relative to the total is 23.251% for cattle, 23.465% for swine, and 46.276% for poultry. Similarly, in 2017, 25.02% for cattle, 25.09% for swine, and 46.84% for poultry were the estimated consumption for each production class.

Results from the 2014 Red Book show that the tier 1 program collected 6,066 randomly selected residue samples (Table 2) and found a total of 12 lab-confirmed violations (Table 3) or 0.2 percent. Similarly, the 2015 Red Book results showed that domestic tier 1 program collected 6,445 samples with 12 violations or 0.2 percent. Lastly, the 2016 Red Book results show that domestic tier 1 program collected 7,067 residue samples and found 26 violations or 0.4 percent. The production classes sampled included: bovine (beef cows, bob veal, dairy cows, heifers, and steers); porcine (market swine, roaster swine, and sows); poultry (mature turkeys, young chickens, and young turkeys); and minor species (goats and sheep). Antimicrobial drugs are the majority of violations in scheduled sampling (NRP, 2016). In 2014 and 2015, the bob veal slaughter class contained the most residue violations found in Ceftiofur and by the multi-residue method (MRM), respectively. The MRM screening method screens for a variety of analytes, not just antibiotics, and can distinguish individual analytes even if multiple drugs are present in the same sample. In 2016, avermectins in goats was the most commonly detected antimicrobial agent, constituting seven of the twenty-six residue violations.

Slaughter Class	Number of Non-Detect Analytes	Number of Non-Violative Positives Analytes	Number of Lab Confirmed Violative Analytes	Total Number of Analyses Performed
Beef Cows	69,987	169	2	70,158
Bob Veal	49,304	74	9	49,387
Dairy Cows	69,011	151	-	69,162
Goats	11,648	-	-	11,648
Heifers	39,093	153	-	39,246
Market Swine	74,320	28	-	74,348
Mature Sheep	13,308	1	1	13,310
Sows	71,699	58	-	71,757
Steers	38,795	130	-	38,925
Young Chickens	69,863	9	-	69,872
Young Turkeys	68,311	16	-	68,327
TOTAL	575,339	789	12	576,140

Table 2 Total Number of Scheduled Samples Analyzed by Slaughter Class (2014)

Slaughter Class	Number of Non-Detect Samples	Number of Non-Violative Positives	Number of Lab-Confirmed Violative Samples	Total Samples
Beef Cows	721	7	1	729
Bob Veal	499	1	8	508
Dairy Cows	726	3	-	729
Goats	143	-	-	143
Heifers	406	12	-	418
Market Swine	774	1	-	775
Mature Sheep	157	-	1	158
Sows	744	4	-	748
Steers	408	6	-	414
Young Chickens	729	-	-	729
Young Turkeys	715	-	-	715
TOTAL	6,021	34	10	6,066

Table 3 Scheduled Sampling Results (2014)

A separate inspection effort from the NRP is made to prevent contaminated milk from entering the food supply. The Grade “A” Pasteurized Milk Ordinance (PMO) established by the FDA, is a set of minimum standards and requirements for regulating the production, processing, and packaging of Grade A milk (FARAD, 2017). Although jurisdiction is given to individual states, most states adopt the PMO standards as a minimum. Milk is tested on the farm, in the bulk tank by the trucker, and at the plant. All milk tankers are screened for beta-lactam drug residues while other drug residues are screened by using a random-sampling program.

DRUG	AMOXICILLIN	AMPICILLIN	CEFTIOFUR	CEPHAPIRIN	CLOXACILLIN	PENICILLIN
TOLERANCE	10 ppb	10 ppb	100 ppb ²	20 ppb	10 ppb	5 ppb
SCREENING TEST						
CHARM SL BETA LACTAM TEST	5.6	8.5	77	13.7	50 ⁷	3.6
CHARM 3 SL3 BETA LACTAM TEST	8.4	8.0	79	20.0	8.6	3.8
DELVOTEST P 5 PACK (VISUAL)	4.6	4.0	ND ³	8.2	NA ¹⁴	2.1
NEW SNAP BETA LACTAM TEST KIT	7.3	5.8	12	11.7	50 ⁷	3.0

Table 4 Milk Residue Screening Detection Tests

Table 4 shows the milk residue screening detection tests. The type of test run depends on how many samples need to be run, the species, and the sensitivity of the test. The Charm SL test takes approximately 8 minutes and is for raw commingled cattle, goat, sheep, and water buffalo. The Charm SL3 test takes 3 minutes and is only for cattle. Both of the Charm tests feature a test strip and following incubation are placed in a reader interpretation machine; a negative number corresponds to a negative test result and a positive number corresponds to a positive test result. The Delvotest contains 96 wells, allowing for multiple samples to be ran at once. It takes approximately two and a half hours, yellow indicates a negative result and purple

indicates a positive result. The Delvotest is for only cattle milk. Lastly, the SNAP test takes approximately 10 minutes and is run for cow, camel, or goat milk. The results are compared against a control. If the sample spot is lighter than the control then it is positive, if the sample spot is darker then it is a negative result. All positive test results in any species require a laboratory-confirmed test.

If a violative residue is detected in food-producing animals at slaughter, FSIS will notify the producer and other parties involved. These products are considered adulterated and subject to condemnation. Any animal that tests positive for a violative residue does not enter into the food supply chain. First time violators will receive a notification letter. Repeat violators will be subject to injunction and are included in the Residue Repeat Violator List maintained by the FSIS (USDA FSIS, 2014). This list contains the names and addresses of producers who have more than one residue violation in a 12-month period in animals presented for slaughter (Figure 1). This list is updated weekly and intended to aid inspectors in discovering residue tolerance violations before they reach consumers. FSIS also maintains a similar list intended to precaution livestock marketers when marketing animals from owners or operations on the repeat violator list.

FSIS RESIDUE VIOLATION INFORMATION SYSTEM

August 04, 2017

09:58:31

WEEKLY RESIDUE REPEAT VIOLATOR FOR USE BY FSIS INSPECTION PROGRAM PERSONNEL

Part I: This part is intended to assist Inspection Program Personnel to identify producers with more than one residue violation in the last 12 months either in the same establishment or different establishments.

Source Name By State	Plant Name / ID	Sample ID / Date Collected / Tags	Tissue	Residue	Value (ppm)	Tolerance
JOSE NUNES FARMS P.O. BOX 1210 LOS BANOS, CA 93635	LRN PROCESSORS, INC. 130 N SANTA FE GRADE RD. NEWMAN, CA 27300 M	101491627 09/26/16 BOB VEAL BACK TAGS 93DM 0310	KIDNEY	NEOMYCIN	17.86	7.2
		101487009 09/19/16 BOB VEAL BACK TAGS 93DM2553	KIDNEY	NEOMYCIN	384.01	7.2
S & S DAIRY 1499 EDMINSTER ROAD STEVENSON, CA 95374-9715	LRN PROCESSORS, INC. 130 N SANTA FE GRADE RD. NEWMAN, CA 27300 M	101561728 12/26/16 BOB VEAL EAR TAGS 345400	KIDNEY	TETRACYCLINE	24.78	12
	CARGILL MEAT SOLUTION CORPORATION 3115 S. FIG AVE. FRESNO, CA 00354 M	101473417 09/02/16 COWS - DAIRY BACK TAGS 93FA3941 OTHER HT # 20225, LOT # 179	LIVER	FLUNIXIN	0.322	.125
TRI BAK DAIRY 13076 AVENUE 368 VISALIA, CA 93292-9530	CARGILL MEAT SOLUTION CORPORATION 3115 S. FIG AVE. FRESNO, CA 00354 M	101563151 12/27/16 COWS - DAIRY BACK TAGS 93EH3900 OTHER HT # 271148, LOT # 1552	KIDNEY	DESFUROYLCEFTIOFUR	3.460	.4
		101521665 11/01/16 COWS - DAIRY BACK TAGS 93EH3356 OTHER HT # 10900 , LOT# 145	KIDNEY	PENICILLIN	0.769	.05
TRANSPORT P. A. B. BOUFFARD 4755 ROUTE 143 HATLEY, QUEBEC, CN J0B 4B0 PHONE: 819-838-4401	JBS SOUDERTON INC. 249 ALLENTOWN ROAD SOUDERTON, PA 01311 M	101702366 06/08/17 COWS - DAIRY NONE	KIDNEY	PENICILLIN	0.495	.05
		101553908 12/14/16 COWS - DAIRY EAR TAGS 124000108206061 BANGLES 108206061	LIVER	TILMICOSIN	3.639	0

RPT23

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Figure 1 Residue Repeat Violator List (2017)

If the evidence shows blatant misuse, use of unapproved or banned drugs, issuing false guarantees, or multiple misdemeanor counts the result will be prosecution. FSIS enforces these tolerances through its various control programs authorized by the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA).

The tests used by FSIS in the NRP have been improved and are more sensitive for detecting chemical and drug residues than prior to 2012. The new multi-class testing method allows samples to be simultaneously analyzed for many different drugs, reducing the time needed and the need for class-specific confirmation tests. The specific detection limit is between 5-500 parts per billion for veterinary drugs and 5-50 ppb for pesticides. Increasingly sensitive analytical tests are causing the detectable zero

to become smaller and smaller. The analytical testing methods can now detect parts per trillion and parts per billion as opposed to parts per million. There are certain substances for which the FDA has established a zero-tolerance policy, meaning there must be complete absence of residual amounts; the entire drug that has been administered must be completely eliminated. Clenbuterol and Chloramphenicol are examples of zero-tolerance drugs. Both drugs are illegal in food-producing animals and prohibited from human food entirely, because they pose a significant health risk. Due to higher sensitivity tests, these agents are avoided because zero-tolerance is becoming harder and harder to achieve. It can be concluded that if these drugs were administered to production animals, there will nearly always be detectable residues, but such residues would be at an extremely low concentration.

In summary, in-plant FSIS inspectors collect and analyze samples at the time of slaughter for the presence of unacceptable residue concentrations of veterinary drugs that might contaminate meat or other tissues (NRP, 2016). If a positive test result is obtained, the carcass is held until a laboratory-confirmed test has verified the result. If the confirmatory test comes back positive the animal is marked condemned and does not enter the food supply. Violations are referred to the FDA for investigation and enforcement action.

Human Health Hazards

Diseases can have a devastating impact on animal welfare and production. Animal health affects food-safety and food-safety affects public health. Consumers have expressed concern regarding the health impact of drug residues in their food. These concerns include: toxicity, allergic or hypersensitivity reactions, carcinogenic, mutagenic or teratogenic effects, the potential for the development and transfer of antibiotic resistant bacteria, and consumer preference of “antibiotic free” products.

Depending on the type of adverse effect, some violative levels of drugs in products of animal origin pose a greater risk to public health than others. On average, the U.S. meat industries produce 100 billion pounds of meat each year. In all the samples taken by FSIS each year approximately 0.2 percent are found positive with a

violative residue. This shows that while the occurrence of drug residues is minimal, there is room for improvement.

The ingestion of residue via food can cause direct adverse toxic effects such as organ damage or tumor development. The term toxicity describes a toxin's effect in terms of potency. It is the amount of a substance that can cause damage to an organism. It can refer to the whole organism or a substructure such as the cell (cytotoxicity) or an organ such as the liver (hepatotoxicity).

One of the main concerns related to drug residues are allergic or hypersensitivity reactions. These reactions result from an overresponse of the immune system to the standard dose of a drug (Sylvia, 2014). Penicillin and other beta-lactam antibiotics are the most commonly recognized substances that can prompt serious allergic reactions.

There is also the potential for cancer, reproductive, or developmental related effects as well. A carcinogen is any substance capable of causing cancer. A mutagen is the potential of a gene mutagen or chromosome breakages as a result of a drug or environmental chemical that may affect human fertility (Beyene, 2015). A teratogen refers to a drug or chemical agent that produces a toxic effect on the embryo or fetus. These are all concerns, but without any known direct foodborne connections.

The use of antibiotics is the single most important factor leading to antibiotic resistance. Resistance involves increasing the prevalence of bacteria that have a mechanism to block the inhibitory or killing effects of antibiotics. In human medicine, antibiotics are prescribed at an alarmingly high rate and are among the most commonly prescribed drugs used in human medicine. However, up to 50% of all the antibiotics prescribed for people are not needed or are not optimally effective as prescribed (CDC, 2013). Antibiotic use in livestock has the potential to create resistant bacteria that is then transmitted to humans through food-borne pathogens. Companion animals also have the possibility of spreading drug-resistant bacteria to their owners through the direct contact they have to humans.

Some consumers believe products labeled "antibiotic free" are safer and healthier than conventionally raised products. In an entirely "antibiotic free" market, livestock producers would carry a financial burden of no longer having the tools needed to treat sick animals. Under normal circumstances, animals treated for a disease would

later be sent to market and sold for a profit. This profit would be returned back to the producer. In the scenario of an “antibiotic free” saturated market, any animal in need of medical treatment that does not naturally overcome illness would be euthanized and therefore would not enter the food supply for human consumption. The money invested in those animals would be wasted, making it a financial loss for the producer. The number of healthy animals making it to the slaughter facilities would significantly decrease. Since the supply would decrease, but the demand would presumably stay the same, prices would increase. The inability to use antibiotics when necessary would contribute to already existing health disparities, by limiting the access to healthy food, for low-income people. These individuals would be unable to purchase products of dietary importance such as meat or milk due to the increase in prices. It is important that sustainable practices in the industry such as the judicious use of antibiotics are utilized to help meet the needs of a growing population and to supply everyone a nutritious and inexpensive food source.

Veterinary-Client-Patient Relationship

Over-the-counter or nonprescription medicine allows for easy access and convenience, but fails to provide third-party monitoring of drug use. Whereas prescription drugs require oversight by a medical professional. A prescribed medication increases the likelihood that a drug is given to the correct patient, for the correct illness, and that it is administered properly, and according to label. It is now required by the Veterinary Feed Directive that all medically important veterinary drugs are prescribed by a veterinarian within the confines of a valid veterinary-client-patient relationship.

A Veterinary-Client-Patient Relationship or VCPR is a relationship that exists when a veterinarian is familiar enough with a livestock operation to be able to take responsibility for making clinical judgments regarding animal health. According to the American Veterinary Medical Association, a veterinarian in a VCPR makes medical judgments, accepts responsibility for providing the herd's livestock with medical care, keeps a written medical record, advises the livestock producer about the benefits and risks of different treatment options, provides oversight of treatment and helps to assure that emergency care can be provided if the need should arise (VCPR, 2017). The client

agrees to maintain records and follow the instructions of the veterinarian. The value of a VCPR is critical to the health of an animal. Without an established relationship with a veterinarian, livestock producers cannot legally use any drugs in an extra-label manner. A valid VCPR can improve animal productivity, enhance animal health and well-being, and decrease the risk of drug residues.

Extra-Label Drug Use

The 1994 Animal Medicinal Drug Use Clarification Act (AMDUCA) enacted by Congress provided veterinarians acting within a VCPR the ability to legally prescribe medication in an extra-label manner when the health of an animal is threatened or suffering and/or death may result from failure to treat (ELDU, 2017). Regulations regarding ELDU are covered in the Code of Federal Regulations (CFR) and maintained by the FDA which has a list of drugs that are prohibited for ELDU for food-producing animals. The following agents are not allowed to be used in an extra-label manner in any food-producing species: Chloramphenicol, Clenbuterol, Diethylstilbesterol (DES), Fluoroquinolones, Glycopeptides, Medicated feeds, Nitroimidazoles, and Nitrofurans (FARAD, n.d.).

Extra-label drug use or ELDU is the use of an approved drug in a manner that is not in accordance with the approved label directions (AMDUCA, 2014). The use of a drug in a manner that is different from the label instructions can be in regard to the disease being treated, route of administration of the drug, dosage of the drug, or the treatment regimen. Any deviation from the label (ELDU) is only permitted under the direct guidance and supervision of a licensed veterinarian that has an established Veterinary-Client-Patient Relationship (VCPR) with the animal(s) being treated.

When a veterinarian prescribes extra-label use of a veterinary pharmaceutical, the withdrawal time of that drug will change. In order to comply with AMDUCA the veterinarian must establish an extended withdrawal time that is supported by scientific evidence. The Food Animal Residue Avoidance Databank (FARAD) is a national database that serves as a resource to protect our nation's food supply. This databank allows veterinarians to seek expert assistance. FARAD gathers and analyzes scientific reports, publications, and other resources in conjunction with kinetic modeling to

determine an appropriate revised drug withdrawal time. FARAD offers a searchable database of previously determined withdrawal interval recommendations by FARAD for drugs used extra-label called the WDI Lookup. Another feature offered is the ability to calculate future withdrawal dates using FARAD's Withdrawal Date Calculator (WDC). Lastly, FARAD offers a searchable database called the Veterinarian's Guide to Residue Avoidance Management (VetGRAM) that provides a comprehensive database of all regulatory information (tolerance, withdrawal time, etc.) for all approved drugs in food animals. This is a resource for veterinarians to prescribe extra-label with accurate adjusted withdrawal times (FARAD, n.d.).

Withdrawal time

A withdrawal time is established for each specific pharmaceutical product given to a food-producing animal with consideration for the safety of the food product consumer. During the drug approval process the following are used to calculate an established withdrawal time: No observable adverse effect level (NOAEL), acceptable daily intake (ADI), safe concentration, and tolerance.

NOAEL is the level of exposure to the drug at which no adverse effects on an animal's health is detected. Once established, a safety factor is then applied, often decreasing the NOAEL by up to a thousand-fold. This safety factor results in a relatively large safety margin when used according to label and when withdrawal times are followed. The NOAEL is multiplied by the average body weight of a human, resulting in the total acceptable daily intake (ADI). This is the average consumption of eggs, milk, or other animal tissues a person can ingest throughout the course of their life with no adverse effects. This is to ensure long-term consumption of the food product will not result in any negative effects. This measurement is known as the safe concentration; it is how much of the drug can be in the eggs, milk, or edible tissues. The safe concentration applies to all residues including parent compounds and metabolites of the chemical or drug.

The tolerance level uses a portion of the residue called a marker residue. A marker residue's concentration decreases in a known relationship to the level of total residues in the eggs, milk, or other animal tissues ("Veterinary Drug Residues", n.d.).

This level depends on the product (thickness of fluid), dosage form (volume of injection), route of administration, location of infection, and size of the animal. The tolerance is a partial of the total residue and constitutes a percentage. For example, if the safe concentration is 0.2 mcg of drug per gram of tissue and the marker residue constitutes half of the total residues, the tolerance would become 0.1 mcg/gm for muscle ($0.2 \times 50\%$). To be considered safe for human consumption, drug concentrations in the edible tissues must be below the tolerance level. These levels are established during the drug approval or pesticide registration process and are listed in the U.S. Code of Federal Regulations (Title 21 for veterinary drugs and Title 40 for pesticides) (NRP, 2016). Tolerance violations indicate that the amount of residue present exceeds the maximum legal limit allowed in food or safe concentration. This happens when an effective withdrawal time is not followed.

Similar to the tolerance level is the maximum residue level (MRL). The MRL is not used in the U.S. rather it is an accepted approximation of the tolerance used by other countries and by the Codex Alimentarius Commission. Additionally, the CVM uses what is known as a safe level. This level is based on available safety data and intended to serve as a guide for estimating the safety of residues in meat or milk when no official tolerance level exists. Generally, safe levels are assigned only when residues appear in meat or milk because of an unapproved use of an animal drug and because a formal tolerance level does not exist (NRC, 1999).

A withdrawal time is the period of time between when a drug is administered and when drug concentrations are below the tolerance level. It is the time needed for the residue to reach a safe concentration as defined by the tolerance level (Beyene 2015). This is when an animal can be slaughtered and it is safe to consume edible products from that treated animal. Violations indicate the amount of residue present exceeds the maximum legal limit allowed in food or milk. The withdrawal time only applies if the drug is used according to label. If a veterinarian authorizes use of a drug in an extra-label manner, he/she must also establish an extended withdrawal time.

The withdrawal time is set in regards to how the drug moves through the animal's body, or pharmacokinetics. The factors that influence this are the rate of absorption from the site of administration, the distribution of the drug from the blood out into the

tissue, the metabolism of the drug, and the rate of elimination from the blood (Beyene, 2015). Withdrawal time is based on the concentration of a drug falling below the tolerance level in a target animal tissue or organ. The target tissue or organ used to determine violative residues are most commonly the muscle, liver, kidney, or fat. These tissues are typically eaten in large amounts, function as storage sites, or facilitate the process of elimination from the body. As the primary tissue, this is the site where the drug is eliminated at the slowest rate and will display a residue for the longest amount of time.

If a violative residue is found in the target organ, the whole carcass is discarded. There are drugs that have a muscle tolerance level as opposed to the target organ. If a violative residue is found in an organ, but not in the muscle, the muscle would not be discarded and it would be deemed safe.

Veterinary Feed Directive

FDA Guidance's 209 and 213 revisions came into effect January 1, 2017 making it illegal for medically important antibiotics to be used to promote growth in food animals. These new standards require a Veterinary Feed Directive (VFD) and veterinary oversight when administering certain antibiotics in animal feed. A VFD is a written document provided by a licensed veterinarian, which authorizes the use of a VFD drug in or on animal feed in accordance with label directions approved by the FDA. This requires not only a signed consent form, but a valid VCPR. The purpose of the VFD is enhance responsible antibiotic use via increased veterinary oversight.

Prevention Practices

It is the responsibility of the producer to ensure the health, safety, and well-being of their animals while remaining in compliance with state and federal laws. Producers can take the following steps to prevent drug residues. Violative residues are often a result of human management errors such as failure to maintain records or follow proper withdrawal times. Below is a list of drug residue prevention practices:

1. Establish a valid veterinary-client-patient relationship

2. Implement a herd health management plan (quarantine, vaccinate, etc.)
3. Read and follow all label directions (including withdrawal times and proper drug administration)
4. Seek veterinary guidance to establish appropriate extended withdrawal times for extra-label usage of approved drugs
5. Identify treated animals
6. Keep records that include the identification of the animal(s) treated, treatment date, the product used, dosage and who administered it, and withdrawal time
7. Train and educate animal caretakers, employees, etc. by providing clear instructions and follow-up
8. Adopt a quality assurance program (proper animal handling, injection site techniques, etc.)
9. Provide proper nutrition
10. Implement a biosecurity plan (clean feeders, clean manure and bedding, clean equipment, supply fresh water, etc.)

Best management practices or “BMPs” and standard operating procedures or “SOPs” are important aspects of disease prevention. All employees and stakeholders must be regularly trained and adherence to the BMPs and SOPs must be verified. Reading and following product label directions, maintaining good records, and adopting a quality assurance program that encompasses a wide array of topics from drug storage, administration techniques, and humane animal handling practices, all contribute to maintaining the safest food supply chain in the world.

Chapter 4 - Core Area Competencies

The following are core competencies required in Kansas State University's Masters of Public Health program. These courses provided a multi-disciplinary approach with a solid foundation of knowledge that is necessary to successfully complete a field experience project.

Biostatistics

MPH 701 *Fundamental Methods of Biostatistics*, STAT 703 *Introduction to Statistical Methods for the Sciences*, and STAT 705 *Regression and Analysis of Variance* aided in my knowledge of data interpretation and analysis. These courses covered descriptive statistics, basic probability theory, hypothesis testing, and linear regressions. This knowledge proved to be useful in my literature review and will be invaluable in my future career.

Environmental Health Sciences

MPH 802 *Environmental health sciences* provided a broad overview of the sources of toxicity in the environment and risks and hazards associated with each of them. This understanding allowed me to be effective when determining individuals at high-risk for negative health consequences due to drug residues.

Epidemiology

DMP 708 *Introduction to Veterinary Epidemiology* and DMP 854 *Intermediate Epidemiology* provided me with the terminology I would need to understand topics related to disease, food-safety, and animal/human health. This course taught how to quantify disease occurrence and disease transmission, the implications for individual and population health management, and how to measure disease frequency and risk factors. DMP 854 *Intermediate Epidemiology* helped me to understand how to draw appropriate inferences from epidemiologic data by identifying strengths and limitations of a dataset.

Health Services Administration

MPH 720 *Administration of Health Care Organizations* demonstrated to me the importance of understanding the health care system. It provided a comprehensive overview of the health care system and how that system responds to economic, social/ethical, political/legal, technological, and ecological environments.

Social and Behavioral Sciences

This core competency course broadened my understanding of factors that influence health care. MPH 818 *Social and Behavioral Bases of Public Health* emphasized the relationships among health outcomes, health behaviors, and social/political/environmental structures. In order to effectively communicate to the public about the importance of drug residue avoidance, it is vital to understand the target audience and what influences their opinions, attitudes, and behaviors. MC 750 *Strategic Health Care Communication* introduced me to various communication theories and the challenges associated in health communication and promotion. It addresses the relationship between consumers and health professionals by examining the interpersonal, intrapersonal, organizational, and societal-level health communication processes.

Chapter 5 – Conclusion

While our nation has the safest food supply chain in the world, there is potential for error and room for improvement. Agriculture production practices utilize certain compounds that if used incorrectly may pose a public health hazard. The use of antibiotics, anthelmintics, pesticides, and other drugs in food-producing species are an integral part to the process of raising food animals. Veterinary drugs are used not only to treat, control, and prevent disease, but also to benefit animal welfare by helping to ensure healthy and well-nourished livestock. Properly administered veterinary drugs can also benefit food-safety and public health by improving the health of livestock and decreasing the likelihood of a sick animal entering the food supply chain.

Management errors are often the cause of residues. Regulations are in place that if followed should effectively ensure the absence of drug residues. One method to address management shortfalls is effective education. Drug residue avoidance strategies should be clearly understood by all livestock producers. Residue prevention practices are simple and contribute not only to drug residue avoidance but also to maintaining a healthy and profitable herd.

There has been a continuous and coordinated effort between government agencies, veterinarians, and livestock producers to protect public health before an antibiotic is ever used on an animal. Programs are in place such as the National Residue Program, the Pasteurized Milk Ordinance, and the Veterinary Feed Directive to regulate the use of antibiotics and monitor drug residues through a rigorous, extensive process of sampling, testing, notification, and enforcement.

References

- Abdelmajid, N., Mr. (2015, December). National Residue Program for Meat, Poultry, and Egg Products: 2014 Residue Sampling Results. Retrieved August 16, 2017, from <https://www.fsis.usda.gov/wps/wcm/connect/2428086b-f8ec-46ed-8531-a45d10bfef6f/2014-Red-Book.pdf?MOD=AJPERES>
- Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). (2014, December 9). Retrieved June 24, 2017, from <https://www.fda.gov/animalveterinary/guidancecomplianceenforcement/actsrulesregulations/ucm085377.htm>
- Aminov, R. I. (2010). A Brief History of the Antibiotic Era: Lessons Learned and Challenges for the Future. Retrieved June 21, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3109405/>
- Ancient Times. (n.d.). Retrieved June 16, 2017, from <http://amrls.cvm.msu.edu/pharmacology/historical-perspectives>
- Beyene, T. (2015). Veterinary Drug Residues in Food-animals Products: Its Risk Factors and Potential Effects on Public Health. *Veterinary & Science Technology*, 7(1), 4-7. doi:10.4172/2157-7579.1000285CFR - Code of Federal Regulations Title 21. (n.d.). Retrieved June 16, 2017, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=500&showFR=1>
- Food Animal Drug Residue Avoidance & Databank Home Page | FARAD. (n.d.). Retrieved June 24, 2017, from <http://www.farad.org/>
- FSIS. (2014, April 16). Retrieved June 16, 2017, from <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get->

answers/food-safety-fact-sheets/production-and-inspection/fsis-import-procedures-for-meat-poultry-and-egg-products/fsis-import-procedures

Germ Theory. (n.d.). Retrieved June 16, 2017, from <http://ocp.hul.harvard.edu/contagion/germtheory.html>

Gustafson, R., & Bowen, R. (1997). Antibiotic use in animal agriculture [Abstract]. *Journal of Applied Microbiology*, 83, 531-541. Retrieved June 21, 2017, from <http://onlinelibrary.wiley.com/store/10.1046/j.1365-2672.1997.00280.x/asset/j.1365-2672.1997.00280.x.pdf?v=1&t=j4781k4f&s=88ab333cdb2ba6f4ad94208031eb0b569ee52916>

Extra-label Drug Use and AMDUCA: FAQ. (n.d.). Retrieved June 13, 2017, from <https://www.avma.org/KB/Resources/FAQs/Pages/ELDU-and-AMDUCA-FAQs.aspx>

Muñiz Ortiz, J. G., Dr., & O'Keefe, M., Ms. (2015, March). United States National Residue Program for Meat, Poultry and Egg Products. Retrieved June 24, 2017, from <https://www.fsis.usda.gov/wps/wcm/connect/04c818ed-9bb1-44b2-9e3f-896461f1ffb9/2015-Blue-Book.pdf?MOD=AJPERES>

Muñiz Ortiz, J. G., Dr., & O'Keefe, M., Ms. (2014, June). National Residue Program for Meat, Poultry, and Egg Products: 2014 Residue Sampling Plans. Retrieved August 16, 2017, from <https://www.fsis.usda.gov/wps/wcm/connect/533beea8-1bcf-468e-a13b-531232b2af2f/2014-Blue-Book.pdf?MOD=AJPERES>

National Research Council (US) Committee on Drug Use in Food Animals. (1999, January 01). Food-Animal Production Practices and Drug Use. Retrieved June 16, 2017, from <https://www.ncbi.nlm.nih.gov/books/NBK232573/>

- National Research Council *The Use of Drugs in Food Animals: Benefits and Risks*. (1999). Washington D.C.: The National Academies Press.
doi:<https://doi.org/10.17226/5137>
- Landers, T. F., Cohen, B., Wittum, T. E., & Larson, E. L. (2012). A Review of Antibiotic Use in Food Animals: Perspective, Policy, and Potential. Retrieved June 16, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3234384/>
- Latest news. (n.d.). Retrieved June 16, 2017, from <http://www.fao.org/fao-who/codexalimentarius/en/>
- Science Museum. Brought to Life: Exploring the History of Medicine. (n.d.). Retrieved June 16, 2017, from <http://www.sciencemuseum.org.uk/broughttolife/techniques/germtheory>
- Society, M. (n.d.). The history of antibiotics. Retrieved June 21, 2017, from <https://www.microbiologysociety.org/education-outreach/antibiotics-unearthed/antibiotics-and-antibiotic-resistance/the-history-of-antibiotics.html>
- Solensky, R. (2017, May). Patient education: Allergy to penicillin and related antibiotics (Beyond the Basics). Retrieved June 24, 2017, from <https://www.uptodate.com/contents/allergy-to-penicillin-and-related-antibiotics-beyond-the-basics>
- Spellberg, B. 2010. The antibacterial pipeline: Why is it drying up, and what must be done about it? In *Antibiotic resistance: Implications for global health and novel intervention strategies: Workshop summary*. Washington, DC: The National Academies Press. Pp. 299–332.
- Sylvia, L. M. (2014). *Allergic and Pseudoallergic Drug Reactions*. McGraw Hill Education.

Tantibanchachai, C. (2014, April 01). The Embryo Project Encyclopedia. Retrieved August 14, 2017, from <https://embryo.asu.edu/pages/us-regulatory-response-thalidomide-1950-2000>

The National Residue Program for Meat, Poultry, and Egg Products. (2016, March 8). Retrieved June 24, 2017, from <http://www.pewtrusts.org/en/research-and-analysis/reports/2016/03/the-national-residue-program-for-meat-poultry-and-egg-products>

U.S. Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013. Atlanta: U.S. Department of Health and Human Services. 2013. <https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>

USDA FSIS. (2014, April 16). Retrieved June 24, 2017, from <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/fsis-import-procedures-for-meat-poultry-and-egg-products/fsis-import-procedures>

VCPR: The Veterinarian-Client-Patient Relationship. (n.d.). Retrieved June 24, 2017, from <https://www.avma.org/KB/Resources/Reference/Pages/VCPR.aspx>

Veterinary Drug Residues in Food: Glossary of Terms. (n.d.). Retrieved August 02, 2017, from <http://www.fao.org/fao-who-codexalimentarius/standards/vetdrugs/glossary/en/>

Appendix 1 - Participating Individuals

Dairy

Hildebrand Dairy – Melissa Reed
Kansas Department of Agriculture – George Blush
Kansas Veterinary Diagnostic Laboratory – Dr. Gregg Hanzlieck
Dairy Farmers of America – Peyson Shields, David Darr and Dr. Fabian Bernal
Jim Lauderdale
Food Armor – Dr. Katie MrDutt

Beef

Cattle Empire - Dr. Dave Sjeklocha
Beef Producer - Paige Pratt
Assistant Professor/Extension Beef Veterinarian - Dr. AJ Tarpoff
American Angus Association – Ryan Ruppert

Poultry

Associate Professor - Dr. Scott Beyer
Nutritionist - Jeff May
Good Shepherd Poultry Ranch, Producer - Frank Reese

Small Ruminants

Goddard Goat Farm, Producer - Noah Goddard
Terabithia Goat Farm, Producer - Becky Thorpe
Veterinarian - Joan Bowen
Veterinarian - Joan Dean Rowe
Extension/Field Veterinarian - Patty Scharko
Kansas State University Sheep & Meat Goat Center
Ebert Sheep Farm – Jeff Ebert

Exhibition

Producer - Dale Lanham
Producer - Brian Creager
Kansas State Fair - Susan Sankey
Kansas Livestock Association – Matt Teagarden
Nebraska State Fair – Bill Angell

Swine

Professor/Extension Specialist - Dr. Mike Tokach
Sabetha Vet Clinic - Dr. Jeff DeMint
Kansas Pork Association - Jodi Oleen

Food and Animal Residue Avoidance Databank (FARAD)

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Appendix 2 – Species-Specific Brochures

VETERINARY FEED DIRECTIVES

What is a VFD drug?

A Veterinary Feed Directive (VFD) drug is a drug intended for use in or on animal feed that is limited to use under the professional supervision of a licensed veterinarian.

What is a VFD?

A VFD is a written (nonverbal) statement issued by a licensed veterinarian that authorizes the use of a VFD drug in or on animal feed.

How are VFDs related to drug residue?

VFDs are part of the FDA's strategy to reduce the amount of drug residue in meat. It is an action to protect public health by phasing out the use of medically important antimicrobials in food animals for production purposes (e.g., to enhance growth or improve feed efficiency), and to bring the therapeutic uses of such drugs (to treat, control, or prevent specific diseases) under the oversight of licensed veterinarians. It is the goal of the VFD to promote the judicious use of medically important antimicrobial drugs in food animals.

For more information on VFDs visit:
vfdinfo.org

Kansas Department of Agriculture

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agriculture.ks.gov/animalhealth

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KANSAS DEPARTMENT OF
AGRICULTURE

serving the state's largest industry

Drug Residue Avoidance Beef



Kansas
Department of Agriculture



INTRODUCTION

The beef industry is committed to producing a safe, wholesome and affordable beef product of the highest quality.

It is through the dedication and commitment of all who participate in the food supply chain to ensure animals are healthy and free from disease.

Antibiotics should be used appropriately to prevent residues from occurring in cattle sent to market.

DRUG RESIDUE

Drug residue refers to the presence of veterinary drugs or pesticides in meat. Residues found in beef above the tolerable levels most often occur due to the following:

- uninformed drug use by small segments of the animal industry,
- failure to adhere to proper withdrawal regulations,
- extra-label use of drugs, and
- lack of animal identification or traceability.

There are regulations to ensure that no residues beyond the government prescribed tolerance levels enter the food supply chain.



ILLEGAL DRUG RESIDUE

An "illegal drug residue" is any drug found above the allowable range in an animal sent to slaughter.

IMPORTANCE OF DRUG RESIDUE

Contaminated meat is a major concern for human health. Any adulterated product may result in **drug residue allergies** and/or the development of **antibiotic resistant bacteria**.

Producers found guilty for illegal drug residue may face the following:

- financial penalties,
- criminal penalties,
- refusal at sale barns and packing facilities, or
- negative public perception.



RESIDUE MONITORING

Residues in fresh meat are monitored by the Food Safety Inspection Service through the National Residue Program (NRP). The NRP helps prevent the entry of animals containing violative residues of pesticides, drugs or potentially hazardous chemicals into the food chain through monitoring and enforcement. Random samples are tested for monitoring the national residue incidence.

PREVENTION PRACTICES

Veterinary Client Patient Relationship

It is important for a producer to have an ongoing relationship with an accredited veterinarian. This helps to ensure the veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and need for medical treatment.

Keep Good Records

Record keeping is simply a good business practice. Thorough records will inspire consumer confidence and demonstrate control over risk factors that have residue potential. Should your operation get cited for a residue violation and you believe it is a case of mistaken identity, good records are your best evidence that the animal in question does not belong to you.

Avoid Extra-Label Drug Use (ELDU)

ELDU is the use of an animal drug in a manner that is different from label instructions in regard to the disease being treated, route of administration of the drug, dosage of the drug or recommended treatment regimen. It is important to follow all labeled directions and withdrawal dates. All extra label drug usage must be under the supervision of a licensed veterinarian.

Injection Technique

Administer the shot in the neck area. Inject subcutaneously when possible. Inject in a clean area. Take into account route of administration, size of animal, location of injection, volume of injection and thickness of fluid when selecting a needle size. Use disposable syringes and do not use bent needles.

VETERINARY FEED DIRECTIVES

What is a VFD drug?

A Veterinary Feed Directive (VFD) drug is a drug intended for use in or on animal feed that is limited to use under the professional supervision of a licensed veterinarian.

What is a VFD?

A VFD is a written (nonverbal) statement issued by a licensed veterinarian that authorizes the use of a VFD drug in or on animal feed.

How are VFDs related to drug residue?

VFDs are part of the FDA's strategy to reduce the amount of drug residue in meat. It is an action to protect public health by phasing out the use of medically important antimicrobials in food animals for production purposes (e.g., to enhance growth or improve feed efficiency), and to bring the therapeutic uses of such drugs (to treat, control, or prevent specific diseases) under the oversight of licensed veterinarians. It is the goal of the VFD to promote the judicious use of medically important antimicrobial drugs in food animals.

Chickens producing eggs for human consumption are considered food animals regardless of the type of operation.

For more information on VFDs visit:
vfdinfo.org

<http://vfdinfo.org>

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KANSAS DEPARTMENT OF AGRICULTURE

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Drug Residue Avoidance Poultry



INTRODUCTION

The poultry industry is a dynamic and highly specialized industry. This large commercial industry is heavily influenced by the slightest of changes in economic factors such as feed, availability and cost. Each year billions of chickens are raised in both commercial and backyard settings as a source of food, for both meat and eggs.

Antibiotics are used in poultry as a means to prevent and treat disease.

Due to public concerns over the widespread use of antibiotics, some producers have started eliminating the use of antibiotics in order to produce and market "antibiotic free" chicken.

DRUG RESIDUE

Drug residue refers to the presence of veterinary drugs or pesticides in the animal's body tissues.

These substances enter into an animal's body by the following routes: feed, water, injections, external treatments or by accident. The residue may remain in the tissue several months.

Intensive poultry production have tended to increase the risk of food contamination due to the rapidly growing fast-food industry and the demand for increasing meat production. Several antibiotics have been employed for animal treatment.

The risk of violative drug residues can be minimized if treatment protocols are carefully followed and approved drugs are used for the class of animal being treated.

ILLEGAL DRUG RESIDUE

An "illegal drug residue" is any drug found above the allowable range in an animal sent to slaughter.

IMPORTANCE OF DRUG RESIDUE

Contaminated meat and eggs are a major concern for human health. Any adulterated product may result in **drug residue allergies** and/or the development of **antibiotic resistant bacteria**.

Producers found guilty for illegal drug residue may face the following:

- financial penalties,
- criminal penalties,
- refusal at sale barns and packing facilities, or
- negative public perception.

BACKYARD POULTRY DILEMMA

The backyard poultry industry is faced with the challenge that there are very few drug products on the market for egg-laying hens in non-commercial settings. Most of the FDA approved medications for laying hens are designed to meet the needs of large scale operations. A drug product used beyond what is specifically stated on the approved FDA label is 'extra-label.'

A commonly used medication for treating chickens are "dewormers." There are very few dewormers labeled for all classes of chickens and are often in the form of medicated feeds or premixes which increase the difficulty for use in small flocks. It becomes difficult to ensure the dose of the product is accurate and that they actually consumed the product.

PREVENTION PRACTICE TIPS

- 1 Disinfect the coop**
First clean all surfaces with an effective detergent. Many disinfectants require at least 30 minutes to destroy infectious organisms and should be completely dry before use.
- 2 Quarantine, if necessary**
An unhealthy chicken should be immediately quarantined and accurately diagnosed in order to prevent the further spread of disease.
- 3 Vaccinate**
Vaccination should be performed on birds if they are transported on/off the premises regularly and for disease treatment.
- 4 Keep chickens clean**
Minimize/eliminate the entry of new chickens into your flock and limit contact with visitors.
- 5 Be aware of the top chicken diseases**
In general sick chickens are less active, have a retracted neck close to its body and an unkempt appearance. However, not all diseases have the same appearance. It is important to be aware of common diseases and their corresponding symptoms.

VETERINARY FEED DIRECTIVES

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Drug Residue Avoidance Small Ruminants



INTRODUCTION

The small ruminant industry is committed to generating safe and high-quality products. Consumers are able to benefit in many ways from the small ruminant industry by the production of meat, wool, milk and other by-products.

Quality assurance programs have been created to maximize consumer confidence and acceptance of these products. Standard operating procedures are a key implementation of these programs that help to increase the effectiveness of proper management practices and decrease the potential for disease and drug residues.

DRUG RESIDUE

Drug residue refers to the presence of veterinary drugs or pesticides in either meat or milk.

If a drug is found to be above the established tolerance limit, this becomes violative and threatens the safety of our food.

Well-defined goals and standards are paramount for quality assurance programs to ensure each product is suitable for its intended use.



ILLEGAL DRUG RESIDUE

An "illegal drug residue" is any drug found above the allowable range in an animal sent to slaughter.

IMPORTANCE OF DRUG RESIDUE

Contaminated meat and milk is a major concern for human health. Any adulterated product may result in **drug residue allergies** and/or the development of **antibiotic resistant bacteria**.

Producers found guilty for illegal drug residue may face the following:

- financial penalties,
- criminal penalties,
- refusal at sale barns and packing facilities, or
- negative public perception.



There are very few medications approved for use in goats and sheep. Animals that are treated should be removed from the milking string in accordance with the pharmaceuticals withdrawal time to prevent drug residues in the milk.

If there is no withdrawal time for this drug in the specified animal, they should be removed from the milking string for the duration of their lactation.

Detection of drug residues may result in milk rejection. Producers can both stay within the law and treat their animals if they abide by extra-label drug use (ELDU) procedures and work closely with a licensed veterinarian within a valid veterinarian client-patient relationship (VCPR).

PREVENTION PRACTICES

Veterinary Client Patient Relationship

It is important for a producer to have an ongoing relationship with an accredited veterinarian. This helps to ensure the veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and need for medical treatment.

Keep Good Records

Record keeping is simply a good business practice. Thorough records will inspire consumer confidence and demonstrate control over risk factors that have residue potential. Should your operation get cited for a residue violation and you believe it is a case of mistaken identity, good records are your best evidence that the animal in question does not belong to you.

Avoid Extra-Label Drug Use (ELDU)

ELDU is the use of an animal drug in a manner that is different from label instructions in regard to the disease being treated, route of administration of the drug, dosage of the drug or recommended treatment regimen. It is important to follow all labeled directions and withdrawal dates. All extra label drug usage must be under the supervision of a licensed veterinarian.

Injection Technique

Administer the shot in the neck area. Inject subcutaneously when possible. Inject in a clean area. Take into account **route of administration**, **size of animal**, **location of injection**, **volume of injection** and **thickness of fluid** when selecting a needle size. Use disposable syringes and do not use bent needles.

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Drug Residue Avoidance Swine



INTRODUCTION

The swine industry encompasses both live swine (hogs and pigs) and the production of pork.

Antibiotics and other feed additives are widely used in the swine industry for increased feed efficiency, growth promotion and treatment of diseases which confer the reduction of mortality and morbidity.

There are two major concerns related to their use: drug residue and drug resistance.

The focus of this pamphlet will be on drug residue prevention which continues to be a challenge in the pork industry due to its complex nature.

DRUG RESIDUE

Drug residue refers to the presence of veterinary drugs or pesticides in the animal's body tissues.

These substances enter into an animal's body by the following routes: feed, water, injections, external treatments or by accident. The residue may remain in the tissue several months.

The risk of violative drug residues can be minimized if treatment protocols are carefully followed and approved drugs are used for the class of animal being treated.



ILLEGAL DRUG RESIDUE

An "illegal drug residue" is any drug found above the allowable range in an animal sent to slaughter.

IMPORTANCE OF DRUG RESIDUE

Contaminated meat is a major concern for human health. Any adulterated product may result in **drug residue allergies** and/or the development of **antibiotic resistant bacteria**.

Producers found guilty for illegal drug residue may face the following:

- financial penalties,
- criminal penalties,
- refusal at sale barns and packing facilities, or
- negative public perception.

DRUG USE

Sulfa drugs or sulfonamides are one of the most commonly used drugs in pig feeds.

Sulfa residues have been found in the livers of slaughtered swine. Extensive testing and research has demonstrated, sulfa residue is not due to illegal drug use or improper withdrawal time. It is the result of cross-contamination between medicated and non-medicated feeds.

Therefore, a high importance is placed on the flushing and cleaning methods of producers that mix their own feed.

RESIDUE PREVENTION CHECKLIST

- ✓ Establish a Veterinary Client Patient Relationship
- ✓ Adopt a Quality Assurance Program
- ✓ Supply fresh water
- ✓ Clean feeders
- ✓ Clean manure and bedding
- ✓ Clean equipment to prevent cross-contamination
- ✓ Practice proper injection site techniques
- ✓ Identify individually treated animals
- ✓ Keep good records
- ✓ Practice proper feed mixing practices
 - ✓ Read and follow label instructions
 - ✓ Use proper dosage
 - ✓ Follow established withdrawal times
- ✓ Avoid using feeders for both medicated and non-medicated feed whenever possible
- ✓ Do not mix hogs receiving sulfa with market animals
- ✓ Prevent delivery errors
 - ✓ Clearly mark medicated and non-medicated bins and feeders

Appendix 3 – Power Point Slide Sets

Drug Residue Avoidance in Cow/Calf Operations



Cow/Calf Segment

The beef industry is committed to producing a safe, wholesome and affordable beef product of the highest quality.

It is through the dedication and commitment of all who participate in the food supply chain to ensure animals are healthy and free from disease.

Antibiotics should be used appropriately to prevent residues from occurring in cattle sent to market.

Animal Drug Residue Concerns

- Consumer health risk
- Consumer preference
- Production loss for the producer (lost milk product, lost animal)
- Legal action against the producer (violative illegal residues)

Drug Residue vs. Illegal Drug Residue

"Drug residue" refers to the presence of veterinary drugs or pesticides in meat.

"Illegal drug residue" is any drug found above the allowable range in an animal sent to slaughter.



Animal Drug Residue Concerns

- Consumer health risk
- Consumer preference
- Production loss for the producer (lost milk product, lost animal)
- Legal action against the producer (violative illegal residues)

Drug Residue

Residues found in beef above the tolerable levels most often occur due to the following:

- uninformed drug use by small segments of the animal industry
- failure to adhere to proper withdrawal regulations
- extra-label use of drugs
- lack of animal identification or traceability

There are regulations to ensure that no residues beyond the prescribed tolerance levels enter the food supply chain.

What are the consequences of Illegal Drug Residue?

Producers who are found guilty of illegal drug residue may face the following:

- financial penalties
- criminal penalties
- refusal at the sale barn and packing facilities
- negative public perception



Human Health Risk Issues

In the beef industry, contaminated meat is a major concern for human health. Any adulterated product may result in the following:

- Drug residue allergies
- Development of antibiotic resistant bacteria
- Potential for cancer, reproductive or developmental effects
- Hormone-related risks

Residue Testing and Monitoring

Residues in fresh meat are monitored by the Food Safety Inspection Service through the National Residue Program (NRP).

The NRP helps prevent the entry of animals containing violative residues of pesticides, drugs or potentially hazardous chemicals into the food chain through monitoring and enforcement.

Random samples are tested for monitoring the national residue incidence

Cow/calf Drug Use

It is vital that cow/calf producers have a close working relationship with a large animal veterinarian in their area.

- To help ensure prudent drug use
- Decrease antibiotic use
- Improve treatment success
- Decrease risk of residues

Prevention Practices

- Veterinary Client Patient Relationship
- Good Record Keeping
- Avoid Extra Label Drug Use
- Proper Injection Techniques



Veterinary Client Patient Relationship

It is important for a producer to have an ongoing relationship with an accredited veterinarian. This helps to ensure the veterinarian has assumed responsibility for making medical judgements regarding the health of the animal and need for medical treatment.



Record Keeping

Records should include: treatment date, animal identification, name of employee administering the drug, drug administered, weight of animal, route of administration, disease being treated, withdrawal time and the first date the animal can be sent to slaughter.

Records should be kept at least two years.

Avoid Extra-Label Drug Use

Extra-label drug use (ELDU) is the use of an animal drug in a manner that is different from label instructions in regard to:

- the disease being treated
- route of administration of the drug
- dosage of the drug
- the recommended treatment regimen

It is important to follow all labeled directions and withdrawal dates.

Injection Technique

Things to consider when giving an injection include:

- Administer the shot in the neck
- Inject subcutaneously when possible
- Make sure the injection site is clean
- Use the proper size needle based on: the location, route of administration, volume of injection and the thickness of the fluid
- Do **NOT** use bent needles



What is a Veterinary Feed Directive (VFD)?
And
What is their part in drug residue avoidance?

What is a VFD?

A VFD is a written (nonverbal) statement issued by a licensed veterinarian that authorizes the use of a VFD drug in or on animal feed.



How are VFDs related to drug residue?

VFDs are part of the FDA's strategy to reduce the amount of drug residue in meat. It is an action to promote the judicious use of medically important antimicrobial drugs in food animals.



Summary

Failing to practice good residue avoidance can lead to financial penalties and a poor public perception on the beef industry. Good management practices, along with following withdrawal times on VFDs, help to reduce residues at the packing facilities.

Remembering the prevention checklist and tips like having a good VCPR, practicing accurate record keeping, avoiding ELDU, and having proper injection site techniques result in better meat quality.

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Drug Residue Avoidance in Dairy Cattle



Dairy Industry

- Committed to producing safe and wholesome products
- High-quality milk and dairy products
- Continuous evaluation of quality management practices and disease prevention protocols
- Top priority: judicious use of antibiotics
- Many precautions are taken so contaminated milk or meat never enter the food supply chain

Drug Residue vs. Illegal Drug Residue

"Drug residue" refers to the presence of veterinary drugs or pesticides in meat. In dairy cattle, drug residue can also be found in the milk.

"Illegal drug residue" is considered to be any drug found in an animal sent to slaughter that is above the allowable range.



What are the consequences of Illegal Drug Residue?

Producers who are found guilty of illegal drug residue may face the following:

- financial penalties
- criminal penalties
- refusal at the sale barn and packing facilities
- negative public perception



Human Health Risk Issues

In the dairy industry, contaminated milk is a major concern for human health. Any adulterated product may result in the following:

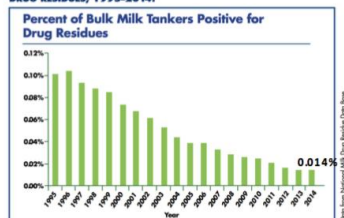
- Drug residue allergies
- Development of antibiotic resistant bacteria
- Potential for cancer, reproductive or developmental effects
- Hormone-related risks

Residue Testing and Monitoring (Milk)

The Grade A Pasteurized Milk Ordinance requires that all bulk milk tanks be sampled and analyzed for beta-lactam drug residues before the milk is processed.

Positive test results lead to the mandatory testing of raw milk samples from each farm which supplied raw milk for that truckload.

Figure 1. PERCENT OF BULK MILK TANKERS POSITIVE FOR DRUG RESIDUES, 1995-2014.



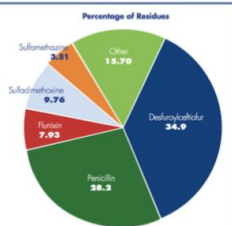
Residue Testing and Monitoring (Meat)

In the dairy industry, culled cows are sent to meat packing facilities. Like beef cattle, these cows must follow all protocols set forth by the industry.



Figure 2. PREVALENCE OF DRUG RESIDUES IN CULL DAIRY COWS APRIL 2014-MARCH 2015

Data from USDFASIS National Residue Program Quarterly Reports, Violations from Inspector-Generated In-Plant Screening Program



Prevention Practices

- Veterinary Client Patient Relationship
- Good Record Keeping
- Avoid Extra Label Drug Use
- Proper Injection Techniques



Veterinary Client Patient Relationship

It is important for a producer to have an ongoing relationship with an accredited veterinarian. This helps to ensure the veterinarian has assumed responsibility for making medical judgements regarding the health of the animal and need for medical treatment.



Record Keeping

Should your operation get cited for a residue violation and you believe it's a case of mistaken identity, good records are your only evidence that the animal in question does not belong to you.

Records should include: treatment date, animal identification, name of employee administering the drug, drug administered, weight of animal, route of administration, disease being treated, withdrawal time and the first date the animal can be sent to slaughter.

Records should be kept at least two years.

Avoid Extra-Label Drug Use

Extra-label drug use (ELDU) is the use of an animal drug in a manner that is different from label instructions in regard to:

- the disease being treated
- route of administration of the drug
- dosage of the drug
- recommended treatment regimen

It is important to follow all labeled directions and withdrawal dates.



Injection Technique

Things to consider when giving an injection include:

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- Inject subcutaneously when possible
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How are VFDs related to drug residue?

VFDs are part of the FDA's strategy to reduce the amount of drug residue in the meat. It is an action to promote the judicious use of medically important antimicrobial drugs in food animals.



Summary

Failing to practice good residue avoidance can lead to financial penalties and lead to poor public perception of the dairy industry. Good management practices along with following withdrawal times on VFDs helps reduce residue at milking and packing facilities. Remembering tips like having a good VCPR, practicing accurate record keeping, avoiding ELDU and having proper injection site techniques results in better milk and meat quality in the end.

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Drug Residue Avoidance in Poultry



Poultry Industry

The poultry industry is a dynamic and highly specialized industry.

This large commercial industry is heavily influenced by the slightest of changes in economic factors such as feed, availability and cost. Each year billions of chickens are raised in both commercial and backyard settings as a source of food, for both meat and eggs.

Commercial vs. Backyard

Backyard:

- Less than 100 birds per household
- Increased space per chicken
- Specialized production
- Allows birds to: scratch, forage, peck and have outdoor exercise
- Low productivity
- High mortality rates (due to lack of technical know-how and access to key inputs)
- Requires a large amount of land
- Can be weather dependent

Commercial:

- More than 100 birds per operation
- Meets the demand of both meat and eggs
- Increases production
- Highly efficient system which saves land, feed, labor and other resources
- Continuous production year round
- Creates potential health risks, animal abuse and harmful to the environment
- Faces global competition and is largely dependent on access to cheap inputs and improvements in production and marketing efficiency

Both commercial and backyard operations have to use nationally approved medications (antibiotics) regularly to keep the poultry birds free from diseases.

Drug Residue vs. Illegal Drug Residue

"Drug residue" refers to the presence of veterinary drugs or pesticides in meat or eggs.

"Illegal drug residue" is any drug found above the allowable range in an animal sent to slaughter.



Reasons for antibiotic use:

- Increased feed efficiency
- Increased growth promotion
- Treat and prevent disease
- Overcome parasitic infections
- Alleviate pain from an injured bird



Drug Residue Concerns:

- Chickens particularly those in a non-commercial setting may inadvertently consume materials that contain drug products. *(Example: chickens eating manure from an animal that has recently been treated with medication)*
- Need to be aware of the potential contaminants.
- Chickens treated with drugs can be absorbed and distributed to various parts of the body.

Human Health Risk Issues

Any adulterated product may result in the following:

- Drug residue allergies
- Development of antibiotic resistant bacteria
- Potential for cancer, reproductive or developmental effects
- Hormone-related risks

Industry Action:

Programs and industry implementations:

- Hazard Analysis Critical Control Points
- USDA and FDA inspections (testing and monitoring), tolerance limits and withdrawal times are used to safeguard against potential risk to humans.
- Veterinary Feed Directives

These safe concentrations are determined in scientific studies designed to determine how much drug a human can be exposed to over the duration of his/her lifetime without any adverse effects.

Note: Chickens producing eggs for human consumption are considered food animals regardless of the type of operation.

Industry Action:

Large segments of the industry are making production management changes based on consumer concerns in order to meet the demand. Some producers have started eliminating the use of antibiotics in order to produce and market "antibiotic free" chicken.

"Are the changes being made to satisfy consumer demand good, bad or indifferent for the animals and the industry?"

Common Drug Residues in Poultry:

- Chloramphenicol is the most prominent antibiotic residue in eggs. It can persist in yolk for up to 66 days, depending on the dosage. Sulphadimidine and arsanilic acid have been found as residues in egg albumen.
- FDA gives minimum withdrawal periods prior to slaughter: 5 days for many drugs, 3 days for tetracyclines and 10 days for sulfaquinoxaline.
- Vaccination for the control of coccidiosis is becoming more popular, thus eliminating the risk of residue carry-over in poultry products.
- Hormones are no longer used in poultry production.

Backyard Poultry Dilemma

- Very few drug products are on the market for egg-laying hens in non-commercial settings
- Dosing instructions may not be suitable for smaller flocks
- Results in the potential for 'extra-label' drug use
- A common medication are "dewormers" (in the form of medicated feeds or premixes)
- Difficult for small flocks to ensure the dose of the product is accurate and that they actually consumed the product

What are the consequences of Illegal Drug Residue?

Producers found guilty of illegal drug residue may face the following:

- financial penalties
- criminal penalties
- refusal at the sale barn and packing facilities
- negative public perception



Residue Testing and Monitoring

Residues in fresh meat are monitored by the Food Safety Inspection Service through the National Residue Program.

Random samples are tested for monitoring the national residue incidence.

Prevention Practice Tips

1. Disinfect the coop

Clean all surfaces with an effective detergent. Many disinfectants require at least 30 minutes to destroy infectious organisms and should be completely dry before use.

2. Quarantine, if necessary

An unhealthy chicken should be immediately quarantined and accurately diagnosed in order to prevent the further spread of disease.

Prevention Practice Tips

3. Vaccinate

Vaccination should be performed on birds if they are transported on/off the premises regularly and for disease treatment.

4. Keep chickens clean

Minimize/eliminate the entry of new chickens into your flock and limit contact with visitors.

Prevention Practice Tips

5. Be aware of the top chicken diseases

In general sick chickens are less active, have a retracted neck close to its body and an unkempt appearance. However, not all diseases have the same appearance. It is important to be aware of common diseases and their corresponding symptoms.

Veterinary Client Patient Relationship

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How are VFDs related to drug residue?

VFDs are part of the FDA's strategy to reduce the amount of drug residue in the meat. It is an action to promote the judicious use of medically important antimicrobial drugs in food animals.

Summary

Failing to practice good residue avoidance can lead to financial penalties and a poor public perception on the poultry industry. Good management practices, along with following withdrawal times on VFDs, help to reduce residues. Remembering tips like keeping chickens clean, disinfecting the coop, quarantine and vaccinate (if necessary) and being aware of the top chicken diseases result in a better quality product.

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Drug Residue Avoidance in Swine



Swine Industry

The swine industry is a vertically integrated industry which encompasses both live swine and the production of pork. The demand for pork products has **inclined** in recent years, because of this the industry has met the need by becoming more efficient.

Antibiotics are used to both to treat disease and increase efficiency of the pigs.

Drug Residue vs. Illegal Drug Residue

"Drug residue" refers to the presence of veterinary drugs or pesticides in meat.

"Illegal drug residue" is any drug found above the allowable range in an animal sent to slaughter.

Reasons for antibiotic use:

- Increased feed efficiency
- Increased growth promotion
- Treat and prevent disease



Animal Drug Residue Concerns

- Consumer health risk
- Consumer preference
- Production loss for the producer (lost milk product, lost animal)
- Legal action against the producer (violative illegal residues)

Industry Action:

- The U.S. National Residue Program administered by the USDA and Food Safety and Inspection Service is a program that identifies, ranks and tests for chemical contaminants in meat, poultry and egg products.
- Residue monitoring has been stepped up significantly to help monitor more closely the increased incidence of illegal residues found at slaughter.
- Agencies such as the FDA work to remove harmful substances from the market. (Example: Carbadox)

What are the consequences of Illegal Drug Residue?

Producers found guilty of illegal drug residue may face the following:

- financial penalties
- criminal penalties
- refusal at the sale barn and packing facilities
- negative public perception

Commonly used drugs:

- Sulfa drugs or sulfonamides
- Tetracyclines
- Pleuromutilin (Tiamulin)
- Macrolide (Tylosin)
- Lincosamides (Lincomycin)

Sulfonamides

Sulfa residues have been found in the livers of slaughtered swine. Extensive testing and research has demonstrated, sulfa residue is not due to illegal drug use or improper withdrawal time. It is the result of cross-contamination between medicated and non-medicated feeds. Therefore, a high importance is placed on the flushing and cleaning methods of producers that mix their own feed.

Residue Prevention Checklist

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| ■ Establish a Veterinary Client Patient Relationship | ■ Practice proper feed mixing practices |
| ■ Adopt a Quality Assurance Program | ■ Read and follow label instructions |
| ■ Supply fresh water | ■ Use proper dosage |
| ■ Clean feeders | ■ Follow established withdrawal times |
| ■ Clean manure and bedding | ■ Avoid using feeders for both medicated and non-medicated feed whenever possible |
| ■ Clean equipment to prevent cross-contamination | ■ Do not mix hogs receiving sulfa with market animals |
| ■ Practice proper injection site techniques | ■ Prevent delivery errors |
| ■ Identify individually treated animals | ■ Clearly mark medicated and non-medicated bins and feeders |
| ■ Keep good records | |

Things to consider: *when choosing a medication*

- Bioavailability
- Dosage
- Pig feeding behavior

Veterinary Client Patient Relationship

VCPR is an ongoing relationship with an accredited veterinarian.

It helps to ensure the veterinarian has assumed responsibility regarding the health of the animal.

Record Keeping

Records should include: treatment date, animal identification, name of employee administering the drug, drug administered, weight of animal, route of administration, disease being treated, withdrawal time and the first date the animal can be sent to slaughter.

Records should be kept at least two years.

Avoid Extra-Label Drug Use

Extra-label drug use (ELDU) is the use of an animal drug in a manner that is different from label instructions in regard to:

- the disease being treated
- route of administration of the drug
- dosage of the drug
- the recommended treatment regimen

It is important to follow all labeled directions and withdrawal dates.

Injection Technique

Things to consider when giving an injection include:

- Administer the shot in the neck
- Inject subcutaneously when possible
- Make sure the injection site is clean
- Use the proper size needle based on: the location, route of administration, volume of injection and the thickness of the fluid
- Do NOT use bent needles



What is a Veterinary Feed Directive (VFD)?
And
What is their part in drug residue avoidance?

What is a VFD?

A VFD is a written (nonverbal) statement issued by a licensed veterinarian that authorizes the use of a VFD drug in or on animal feed.



How are VFDs related to drug residue?

VFDs are part of the FDA's strategy to reduce the amount of drug residue in the meat. It is an action to promote the judicious use of medically important antimicrobial drugs in food animals.

Summary

Failing to practice good residue avoidance can lead to financial penalties and a poor public perception of the swine industry. Good management practices, along with following withdrawal times on VFDs, help to reduce residues at the packing facilities. Remembering the prevention checklist and tips like having a good VCPR, practicing accurate record keeping, avoiding ELDU, and having proper injection site techniques result in better meat quality.

Contact Us

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(785) 564-6601 or (785) 564-6778
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vfdinfo.org



Drug Residue Avoidance in Feedlot Cattle



Kansas
Department of Agriculture

Feedlot Segment

The beef industry is committed to producing a safe, wholesome and affordable beef product of the highest quality.

It is through the dedication and commitment of all who participate in the food supply chain to ensure animals are healthy and free from disease.

Antibiotics should be used appropriately to prevent residues from occurring in cattle sent to market.

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Drug Residue

Residues found in beef above the tolerable levels most often occur due to the following:

- uninformed drug use by small segments of the animal industry
- failure to adhere to proper withdrawal regulations
- extra-label use of drugs
- lack of animal identification or traceability

There are regulations to ensure that no residues beyond the prescribed tolerance levels enter the food supply chain.

What are the consequences of Illegal Drug Residue?

Producers who are found guilty of illegal drug residue may face the following:

- financial penalties
- criminal penalties
- refusal at the sale barn and packing facilities
- negative public perception



Human Health Risk Issues

In the beef industry, contaminated meat is a major concern for human health. Any adulterated product may result in the following:

- Drug residue allergies
- Development of antibiotic resistant bacteria
- Potential for cancer, reproductive or developmental effects
- Hormone-related risks

Residue Testing and Monitoring

Residues in fresh meat are monitored by the Food Safety Inspection Service through the National Residue Program (NRP).

The NRP helps prevent the entry of animals containing violative residues of pesticides, drugs or potentially hazardous chemicals into the food chain through monitoring and enforcement.

Random samples are tested for monitoring the national residue incidence.

Feedlot Drug Use

Commonly used antimicrobials in feedlot cattle include: Penicillin, tetracyclines, trimethoprim-sulfonamides, erythromycin and others

Feedlot cattle are typically treated for common diseases during the early part of the feeding period and therefore have 75 to 200 days to eliminate the drug from the body.

Prevention Practices

- Veterinary Client Patient Relationship
- Good Record Keeping
- Avoid Extra Label Drug Use
- Proper Injection Techniques



Veterinary Client Patient Relationship

It is important for a producer to have an ongoing relationship with an accredited veterinarian. This helps to ensure the veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and need for medical treatment.



Record Keeping

Records should include: treatment date, animal identification, name of employee administering the drug, drug administered, weight of animal, route of administration, disease being treated, withdrawal time and the first date the animal can be sent to slaughter

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