

REPORT OF THE USAHA/AAVLD COMMITTEE ON FOOD AND FEED SAFETY

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The Committee met on October 19th at the Sheraton Hotel in Kansas City, Missouri, from 1:30 pm until 5:45 pm. There were 11 members and 31 guests present. Dr. McDonough introduced himself and Vice Chair Dr. Shultz. Then he provided the committee with an overview of the current issues facing the United States in part due to the global nature of the challenges; the "One Health" concept provides us with the framework in which to consider the food safety continuum as sharing in the interdependence of human-animals-and the environment. The recent European "horsemeat scandal" highlighted the dangers of long supply chains, greed leading to food adulteration with cheaper horsemeat, the related issues of damaged consumer confidence, inaccurate food ingredients labels, and international participation. Brief mention was made of the spillover of wildlife disease into human populations and their animals (brucellosis in feral swine affecting hunting dogs; the growing Ebola epidemic in Africa and the issues of the international trade in bushmeat derived from African wildlife such as fruit bats). Severe drought in the Western states has led to concerns for using alternative water sources for livestock (e.g., reclaimed human sewage water), including any risks that this practice may pose. Dr. McDonough briefly went over the following issues, i.e., sign the attendance sheet indicating whether attendees were either committee members and/or desired to join the committee; he discussed developments within the USAHA and the AAVLD to align the committee mission statement with new strategic plans within both organizations (requiring ongoing committee discussion). A brief overview was given of the agenda for the meeting.

Presentations & Reports

Overview of Multistate Foodborne Outbreaks

Stacey A. Bosch, DVM, MPH, DACVPM, Epidemiologist and CDR, U.S. Public Health Service, Outbreak Response and Prevention Branch, Division of Foodborne, Waterborne and Environmental Diseases, Centers for Disease Control and Prevention (DHHS/CDC/OID/NCEZID/DFWED/ORPB)

Dr. Bosch reviewed the major outbreaks of foodborne disease occurring in the United States during 2013-2014. She described the changing landscape of foodborne disease from predominantly localized to more large scale outbreaks encompassing many more cases and wider distribution of those cases. She went on to describe the process for investigating multistate foodborne outbreaks, including the role of PulseNet in the evaluation of bacterial strains, the typical timeline for reporting illnesses (Salmonella was used as an example) as being part of an outbreak (usually 2-4 weeks), and the role of the CDC Outbreak Response Team in evaluating outbreaks.

Dr. Bosch then presented an overview of the 2013-2014 multistate foodborne outbreaks. The following pathogens are screened by laboratories, i.e., *E. coli*, *Salmonella spp*, *Listeria monocytogenes*, *Campylobacter spp*, *Shigella sonnei*, and others. During 2013, a total of 221 multistate clusters were investigated or an average of 35 clusters/week (range:29–41). Of these clusters 187/221 (85%) are typically selected for intensive follow-up. During 2014, 191 total clusters were investigated (as of the date 10/15/14). There is a seasonality to foodborne outbreaks attributed to environmental temperatures, i.e., fewer outbreaks during the cooler fall and spring months. New food vehicles are being identified in multistate outbreaks such as Tahini sesame paste, cucumbers, dog food, raw cookie dough, and pine nuts. Food vehicles and associated pathogens were outlined for 18 outbreaks.

Recent trends indicate that non-bacterial pathogens are involved in outbreaks, too, e.g., *Cyclospora cayentensis* was the agent in 2 large foodborne outbreaks in the United States in 2013–2014. In 2013 – 631 ill, 25 states, likely 2 separate outbreaks (salad mix from Guanajuato, Mexico and fresh cilantro from Puebla, Mexico); 2014 – 133 ill in TX, linked to fresh cilantro from Puebla, Mexico. Hepatitis A was part of a large foodborne outbreak in the United States in 2013 - 165 ill in 10 states; Hepatitis A was linked to pomegranate arils imported from Turkey that was part of a frozen organic antioxidant berry mix, and to frozen organic pomegranate kernels.

Since 2011, 3 multistate outbreaks of *L. monocytogenes* linked to soft cheeses made with pasteurized milk have occurred; contamination occurred in the production facility where unsanitary conditions were cited. The practice of cutting and repackaging cheese leads to cross-contamination. Due to this practice occurring in distribution centers, stores, and in people's refrigerators, product identification and traceback are a big challenge; this has been a particular problem with artisanal cheeses.

A review of the poultry outbreaks during 2011-2014 showed that 6 multistate outbreaks of *Salmonella* infections linked to poultry products occurred:

- *Salmonella* Hadar: Turkey burgers
- *Salmonella* Heidelberg: Ground turkey
- *Salmonella* Heidelberg: Chicken livers
- *Salmonella* Heidelberg (2): Brand A chicken products
- *Salmonella* Heidelberg: Mechanically-separated chicken

Multiple outbreak strains were resistant to several commonly prescribed antibiotics: Although these antibiotics are not typically used to treat *Salmonella* blood infections or other severe *Salmonella* infections, antibiotic resistance can be associated with increased risk of hospitalization in infected individuals.

A review of Shiga toxin-producing *E. coli* that more non-O157 outbreaks were identified, i.e., O121, O145, O26, O111, O104, and others. New food vehicles were identified such as frozen snack foods, hazelnuts, and Lebanon bologna; raw flour was the suspected ingredient in 2 outbreaks (cookie dough O157:H7 in 2009 and frozen snack foods O121 in 2013). However, the “usual suspects” are still being found in outbreaks, i.e., ground beef, leafy greens (mixed salads, spinach, romaine lettuce, cabbage), and raw sprouts.

2011-2012 FERN Collaboration Microbiology Study

Renate Reimschuessel, VMD, PhD, Director: Veterinary Laboratory Investigation and Response Network, Center for Veterinary Medicine, Office of Foods and Veterinary Medicine, Office of Research (DHHS/FDA/CVM/OFVM/CVM/OR - Vet-LIRN)

Dr. Reimschuessel discussed the results of a collaborative study done with FERN laboratories to evaluate pet feeds for bacterial pathogens: *Salmonella*, *Listeria*, *E. coli* O157H7, and generic *E. coli*. The goals of the study were to increase proficiency and capacity and to get data on pet feeds. A total of 6 FERN FDA laboratories participated (FL Dept of Agriculture and Consumer Services, MI Dept of Agriculture, MN Dept of Agriculture, NC Dept of Agriculture, OH Dept of Agriculture, WA Dept of Agriculture). Results of the study have been published in the journal *Foodborne Pathogens and Disease* 11(9) in 2014,

Jerky Pet Treat Adverse Events: Descriptive Epidemiology

Lee Anne M. Palmer, VMD, Supervisory Veterinary Medical Officer, FDA Center for Veterinary Medicine, Office of Foods and Veterinary Medicine, Office of Surveillance Compliance; Team Leader: Adverse Event Review Team, (DHHS/FDA/CVM/OFVM/CVM/OSC/VPS)

Dr. Lee Anne Palmer presented an update and review of the jerky pet treat (JPT) problems. What are jerky pet treats? JPT consist of dried chicken, dried duck, dried sweet potato or yams, and variations (such as jerky wrapped yams, sweet potatoes, rawhides). Ingredients in treats usually consist of meat, often contain glycerin and +/- seasonings, usually without preservatives; treats are shelf stable for months at room temperature and most product is irradiated. Most product is foreign/imported, due to cheaper source materials (white meat chicken), and the fact that other cultures prefer the dark meat for human consumption.

History of JPT's - the jerky pet treat (JPT) issue came to the attention of FDA CVM in the summer of 2007 after the melamine incident was coming to a close. Blog reports appeared after a major retailer withdrew a brand of chicken JPT from shelves and it was stated that trace melamine was detected, but not confirmed by FDA. On 9/13/2007, the AVMA issued an alert regarding illness and consumption of JPT (specifically chicken), and then on 9/14/2007, the ACVIM issued an alert: ACVIM Diplomats were reporting primarily small breed dogs presenting with acquired Fanconi syndrome following consumption of JPT from China. By early September 2007, FDA had received approximately 70 complaints (reports) of illness involving 95 dogs. The FDA issued a caution to consumers on 9/26/2007, after which report numbers increased further. In total, during 2007, FDA received approximately 180 complaints of canine illness with a reported history of consumption of JPT (~21 were reports of acquired Fanconi syndrome).

The Australian Experience with Chicken Jerky – Australian reports from September 2007 spoke of an acquired Fanconi “outbreak” starting September 2007. Reports of 108 cases of acquired Fanconi were reported in Australia associated with consumption of the same brand of chicken jerky treats imported from China (Kramar Supa Naturals) (Reference: MF Thompson, LM Fleeman, AE Kessell, LA Steenhard, Australian Vet Journal 91(9): 368-373, 2013). The CJT were introduced to the market two weeks prior to the first reports, with a median onset of 12 weeks. The product was withdrawn from the market about 16 months later and reporting declined. With the introduction of a “budget version”: Kramar Supa Naturals Chicken Breast Bites in 2009, cases appeared again and the product was withdrawn quickly.

The Canadian Veterinary Journal in June 2011 contained a notice: “Recently, several veterinarians in Ontario have reported cases of dogs that have been showing signs similar to Fanconi syndrome. All dogs in the reported cases had been fed chicken jerky treats that were manufactured in China. Signs of Fanconi syndrome can include decreased appetite, decreased activity, vomiting, and increased water consumption and/or increased urination. Blood tests may show increased urea nitrogen and creatinine. Urine tests may indicate Fanconi syndrome (increased glucose). The problem is that this can be confused with diabetes.”

Dr. Palmer presented the methods of reporting pet food related adverse effects, including the FDA's Safety Reporting Portal. Consumer complaints are taken by FDA Consumer Complaint Coordinators (CCC) located in district offices. They may alert CVM or request guidance; the CVM monitors consumer complaints collected by CCC's (www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators). She presented the CVM information processing for pet food and animal feed, as well as case definitions for each body system.

What is Fanconi syndrome? This syndrome includes proximal renal tubular dysfunction in which glucose, amino acids and electrolytes fail to be reabsorbed and pass into the urine leading to clinical signs of increased thirst and urination, metabolic acidosis and eventually renal failure. There can be Genetic based disease: i.e., Basenji dogs are usually affected between the ages of one and five years. In the US, 10% of Basenjis are found to have glycosuria; disease in Labrador Retriever is suspected, too?

Acquired Fanconi Syndrome/acquired proximal renal tubulopathy any: may occur at any age, may resolve with treatment (genetic forms don't resolve).Glycosuria, aminoaciduria, +/- azotemia (all may resolve). It is

considered uncommon in dogs, and the potential causes may include: heavy metals (lead, mercury, cadmium), Lysol, nitrobenzene, maleic acid, ethylene glycol; medications: outdated tetracyclines, gentamycin, azathioprine, valproic acid, salicylates; and Disease states: Leptospirosis, hepatic copper storage hepatopathy. Reports from the University of Pennsylvania indicate that acquired Fanconi occurs in younger dogs, often small breeds, often after opening a new bag. Aminoaciduria outlasts the glucosuria, and aminoaciduria may start high and normalize. In contrast, genetic forms don't resolve, they worsen.

Normally the kidney reabsorbs 100% of glucose; however, for dogs affected by Fanconi Syndrome, reabsorption of glucose can decrease markedly, even down to 39-65%. Thus almost all dogs affected by Fanconi Syndrome exhibit glucose in the urine coupled with normal blood sugar concentrations. Dr. Palmer gave examples of cases and their laboratory results.

Geographic locations: reports have been received from all 50 states, and 5 Canadian provinces. Besides the large number of reports from Florida, California and Texas, there does not seem to be a geographic distribution pattern that lends clues to etiology. Reports tend to coincide with the distribution of the US population, and a greater proportion of Fanconi like syndrome/FLS reports from Florida may be due to interest and awareness among specialists.

Case-control Study with the CDC: In May 2014, FDA and the CDC collaborated on a study of cases reported to FDA of sick dogs compared with "controls". The goal was to compare foods eaten by both groups and determine if sick dogs are eating more jerky. "Sick dogs" included diagnosis of Fanconi (or Fanconi Like Syndrome(FLS) and dogs ≤5 yrs. with renal failure. This study is still ongoing. Study is still ongoing.

The 2012 Inspections: in April 2012, FDA inspected 5 jerky pet treat facilities in China. Firms were selected based on both the number and severity of illness reports. Valuable information was obtained regarding manufacturing operations, ingredients and raw materials used, processing, packaging, quality control, sanitation, and product testing. The FDA identified concerns on record keeping practices of several inspected firms. The inspections resulted in AQSIQ seizing products and suspended exports to the U.S.

Some take home points: Pets can be sentinels for broader food issues because they have a more limited diet generally with less variety. As far as Acquired Fanconi:

- Urine samples – treat eaters
- Small breed dogs affected, but not limited to those
- Withdrawal of treats and institute support therapy
- The signs may resolve
- Report cases to FDA

AAVLD Update on CVM's Jerky Pet Treat Investigation: Diagnostic Sample and Product Testing

Renate Reimschuessel, VMD, PhD, Director: Veterinary Laboratory Investigation and Response Network, Center for Veterinary Medicine, Office of Foods and Veterinary Medicine, Office of Research (DHHS/FDA/CVM/OFVM/CVM/OR - Vet-LIRN)

Dr. Reimschuessel presented an update of the Vet-LIRN activities: prior to 2010, the Vet-LIRN did not exist. Back then the FDA relied on the medical history as is with no opportunity to request additional information. In contrast the Vet-LIRN has funds to request further diagnostic workup by the owner's veterinarian and a Vet-LIRN network laboratory. The focus is on Animal Diagnostics and not product testing. Usually the Office of Regulatory Affairs does product testing for regulatory action if routine testing has not identified a Root Cause; in 2011 the Vet-LIRN began to assist by conducting INVESTIGATIONAL TESTING of consumers' jerky products. They used product collected from the consumer's bag, conducted tests trying to identify or eliminate toxicants. The idea was to think about the big picture rather

than individual cases. It was noted that no individual owner's product can be tested for all the potential toxicants. Aggregate data is needed for the investigation.

For the product testing we first developed a list of toxicants that could cause the clinical signs in the dog or cat patient. The Vet-LIRN also needed to develop a budget and write contracts and cooperative agreements to get the testing done. Getting such funding in place can take up to a year, so products being tested now were collected a year ago. They try to collect product from cases where there are the fewest complicating factors to reduce variables during data interpretation, i.e., cases without pre-existing medical issues, cases ingesting only 1 type of treat, and cases with a good veterinary medical history.

There are quite a few challenges when faced with testing jerky products (JPT), here are just a few, e.g.; sample size – some tests require more sample than others; how many tests should one run per sample/case, Additional analytes are often requested due to new findings, which means either renegotiating an existing contract or developing a new contract; some methods don't work for jerky and need to be developed; testing can be quite expensive – especially when looking for unknowns; working within a government setting has its own challenges, too.

The Vet-LIRN developed a testing plan for the jerky treats, that Dr. Reimscheussel presented. Again the choice of tests done on each product depend on the clinical signs, amount of product available and previous testing results.

Dr.Reimschuessel discussed the importance of negative data: sometimes a first step to understand a problem is to identify what it is NOT; how many negative test results do you need before you eliminate that particular toxicant? (i.e. metals); what about positive data? If you find something does it necessarily mean that it is the cause of the illness? (i.e. in very, very tiny amounts). Metals – when Vet-LIRN began product testing, metals had been tested, but only on about 10 samples. Since then the LIRN has tested over 100 samples for various toxic metals using 3 different screens (the third was done to test for S which wasn't on the first 2 screens). They have concluded that metals are probably not involved in these illnesses, but may need to test some additional products since new products come on the market and those haven't been tested. Positive data – extremely low levels of antibiotics and one antiviral (amantadine) have been detected in jerky – but their contribution to the illnesses is questionable. Of the testing done during the investigation, most of the tests were negative or within the expected levels. Several brands tested positive for Antiviral drugs (Amantadine). Early on, we had a few samples positive for DEG, EG and PG. PG is allowed to be used in animal food. Concentrations of EG and DEG were very low at levels not considered to be toxic. Several samples tested positive for antibiotic residues which were found in very low levels and are not considered to be of concern. These findings are similar to the findings of NYSDAM which initiated nationwide recall of several different brands of treats. Several microbiology tests were positive but these findings are not considered to be a root cause of JPT related problems. Compositional analysis showed that several types of treats from several brands were mislabeled for glycerin. Several samples were mislabeled for species.

They looked at the physical characteristics of the treats by soaking the treats and stomaching them, and some of them remained very tough after the treatments. One hypothesis related to the Gastrointestinal (GI) illnesses was –“Is the toughness of the product contributing?” They has one case where a necropsy was done in a dog that had eaten jerky 3 days before death, but nothing else since then. Intact jerky product was found in the dog's stomach. So they designed a study where jerky was rehydrated on shakers and after 7 days the samples were still very tough. They also put jerky pieces in a stomacher that smashes samples; some products disintegrated but others remained intact even after 90 min. The results of this study showed that many products are very tough and resist mechanical disruption, so they concluded that some of the mild GI upsets could be due to the physical properties of jerk. They recently had a case where the dog ate 3.5 lbs. of treats and developed severe hemorrhagic gastritis and melena. Upon necropsy the stomach was ulcerated and full of blood. This, of course, was an extreme case, but serves to show that jerky physical properties can cause GI problems.

The Vet-LIRN tests diagnostic samples; the Vet-LIRN's mission really is focused on the diagnostic sample testing, to provide FDA with more information on consumer complaint cases. They consider diagnostic

samples testing as the very important tool for understanding the root cause of the JPT reported problems. They could also potentially help to understand if there is an idiopathic reaction to JPT (or some of the ingredients) in some dogs. They began collecting samples in 2012. Samples included: Urine (urinalysis, Franconia panel), Clinical chemistry, fecal cultures, necropsies, tissues (toxicology, histopathology, culturing, Raman analysis of crystals, etc.).

Consumer complaints reporting death are of great concern to FDA, thus it is very important for them to follow up with as complete an investigation as possible. Last year the Vet-LIRN really focused on these reports. The results of necropsy exam of 71 deaths reported to FDA indicated that 37 of these were not related to jerky, i.e., 22 dogs died of renal problems, 4 of liver disease and 3 of GI problems. They are having further diagnostics done on the renal cases to get a better idea about the nature of the lesions to better understand the etiologies that may be involved.

Necropsies are important to identify the true cause of death, to determine the nature of the lesions associated with potential jerky related deaths, to correlate similar lesions with associated products, and to focus efforts for product testing. They have also focused a large effort on doing Fanconi testing on dogs presenting with glycosuria. Of the 170 dogs tested so far 107 were positive (63%). They conducted follow up testing on 59 of these and 47 of those animals near (80%) were positive approximately 2 months after the first test. Seventeen of these dogs were tested a third time (4-6 months later) and 11 of these were positive (65%). Many were clinically normal at this point. The "take home message" – even if glycosuria has resolved, it is worth testing these animals. QUESTION- are some animals predisposed to renal problems and pushed over the edge by jerky type treats or are the results of testing showing prolonged effects? Most of the small breeds (Chihuahua, Shiz Zu, Maltese, mini/toy Poodle, Yorkie and Pomeranian. Shih Tzu) have ~80% of the tested animals positive (sometimes they test GI cases and/or housemates – so not all are symptomatic – but most of these we have a reason to suspect that they are Fanconi positive).

What you can do? Report cases to FDA (<http://www.safetyreporting.hhs.gov>); get a good feeding history including: exact Name (get the bag), when first fed? when was it last fed?, how many per day?, any other treats? what is usual diet? Also get the all of medical records of the patient including drug usage. (drugs?), Be sure to do your routine work up so you don't miss a lot of diseases that can explain the animal's signs, e.g., Leptospirosis, Addison's Disease, Cushing's Disease, medication – NSAIDS, immune mediated hemolytic anemia, neoplasia, congenital renal dysplasia, etc. If the Vet-LIRN requests diagnostic samples, for GI cases – fecal routine usually already done, but the Vet-LIRN may want cultures – refrigerate, don't freeze, get fresh samples; Renal cases – urine sample - get as much as possible (>10 ml) and don't insert dipstick (contaminates), but freeze ASAP; for Necropsies – refrigerate the body, but they will work with frozen bodies if that is all that is available.

Update: Preventive Controls for Animal Food- FDA Food Safety Modernization Act

Dr. Daniel G. McChesney, Director, Office of Surveillance and Compliance (DHHS/FDA/CVM/OFVM/CVM/OSC)

Dr. McChesney provided an update and discussion of the Food Safety Modernization Act (FSMA). The law was needed because of Globalization (15 percent of U.S. food supply is imported); the Food supply is more high-tech and complex (more foods in the marketplace, and there are new hazards in foods not previously seen); there are Shifting demographics (growing population, about 30% of individuals are especially "at risk" for foodborne illness).

What is so historic about the law? Involves the creation of a new food safety system with a broad prevention mandate and accountability, also it is a new system of import oversight; it emphasizes partnerships, and farm-to-table responsibility; plus it was developed through a broad coalition.

The current view is that the food and feed supply is very safe; it is a global supply system that is reactive to problems; that the inspection of all facilities by the FDA on a reasonable frequency is impossible, and

lastly that the current system while good, cannot keep up. In contrast the FSMA directs FDA to build a new, modern food safety system that includes standards all must follow for preventing food safety problems; and also provides the FDA with tools for gaining high rates of compliance with those standards. To meet the vision, the FDA will Promulgate new regulations that will provide the standards for protecting food from farm-to-table, will develop guidance with and for the regulated industry to enhance understanding of what is needed to protect food, will provide for a common understanding of how to comply with the standards through training, and then will develop and apply the tools for gaining high rates of compliance with the standards. Also to meet the vision industry itself must be primarily responsible for food safety, must implement risk based preventive measures at all appropriate points, and must manage supply chains to assure appropriate measures are being implemented as part of routine practice.

Who is covered? Facilities that manufacture, process, pack or hold human or animal food. In general, facilities required to register with FDA under sec. 415 of the FD&C Act are covered; the act applies to domestic and imported food, although some exemptions exist and modified requirements are being proposed.

Summary of the FSMA's requirements: to establish, for the first time, Good Manufacturing Practices for animal food, to establish Hazard Analysis and Risk-Based preventive controls; each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods.

Comments and Outreach by the FDA: Comment period closed March 31, 2014, and over 2100 comments were received. The FDA has pulled and reviewed some of the larger comments, but they are still reviewing all of the comments. They have had 3 town meetings, plus numerous listening sessions with industry groups have been held including AFIA, NGFA, PFI, GMA, Brewers Assoc., UEP, NCC, NTF, United Fresh. There have also been letters from Congress, particularly related to coverage of breweries' spent grains.

What is the definition of the "Farm"? Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" would include establishments that:

- (1) Pack or hold raw agricultural commodities
- (2) pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership and
- (3) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

The implications of the farm definition are that there is no evidence that the safety of animal food varies with feed mill model (independent, contract farming operations, fully vertically integrated operations). The FDA is requesting comment on whether feed mills associated with fully vertically integrated operations should be required to register; the FDA is requesting comment on how to value the animal food being fed when no sales are involved for the purpose of determining whether they would be a very small business.

More information is available on the Web site: <http://www.fda.gov/fsma> that has a subscription feature available; you can also send questions to FSMA@fda.hhs.gov.

Raw Milk: Politics and Policy

Shelley Mehlenbacher, DVM, Assistant State Veterinarian, Vermont Agency of Agriculture

Dr. Mehlenbacher presented the topic of raw milk consumption and the regulatory aspects of raw milk outbreaks.

Raw Milk Associated Outbreaks in Vermont:

during 2010 there were three outbreaks in Vermont. Outbreak #1-Guests and workers at a B&B provided raw milk developed symptoms consistent with *Campylobacter*. Two were children; one experienced febrile seizures that required emergency care. They were suspect for *Campylobacter* but no confirmatory tests

were performed. Outbreak #2 - Inmates at a work camp painting fences at a dairy were offered raw milk by the dairy farm owner. Five of ten inmates on the work crew developed diarrhea and tested positive for Campylobacter. Outbreak #3- during a school field trip to a dairy farm, students were offered raw milk; 10 students and one teacher developed diarrhea.

From 2003 to 2013, 215 Vermonters with Campylobacter infections reported consuming raw milk.

The History of Raw Milk Sales in Vermont:

- Sales prior to 2008
 - Max of 25 quarts per day at the farm
- 2008 statutory change
 - Raised to 50 quarts per day/ 350 quarts per week
 - Requirement of basic cleanliness
- 2009 statutory change to a two tier system
 - Tier I – up to 350 quarts/week
 - Tier II – 351 to 1120 quarts/week
 - Allowed for delivery
 - Added requirements and accountability
- 2011 – fluid milk for personal consumption only
- 2014 statutory change
 - Allows delivery to farmers markets for Tier II producers

Note that “personal consumption” is defined as milk that is ingested by the consumer and members of the consumer’s household or nonpaying guests. It does not include taking raw milk products to a social function or otherwise distributing the products made.

Tier I and Tier II Requirements: allow raw milk producers to sell directly to consumers without requiring a milk handler’s license. Requirements for both Tiers:

- Animal Health testing
- Customer inspection
- Sanitation –
 - Clean animals and environment
 - Potable water – bacteriological testing every three years
- Milk tested for antibiotic residue
- Record keeping
- Farm signage and product labeling
- Temperature – cooled to 40F within 2 hours after milking

Record keeping and reporting:

(A) A producer shall collect one composite sample of unpasteurized milk each day and keep the previous 14 days’ samples frozen. The producer shall provide samples to the agency if requested.

(B) A producer shall maintain a current list of all customers, including addresses, telephone numbers, and email addresses when available.

(C) The producer shall maintain a list of transactions for at least one year which shall include customer names, the date of each purchase, and the amount purchased.

(2) Labeling. Unpasteurized (raw) milk shall be labeled as such, and the label shall contain:

(A) The date the milk was obtained from the animal.

(B) The name, address, zip code, and telephone number of the producer.

(C) The common name of the type of animal producing the milk (e.g. cattle, goat, sheep) or an image of the animal.

(D) The words "Unpasteurized (Raw) Milk. Not pasteurized. Keep Refrigerated." on the container's principal display panel, and these words shall be clearly readable in letters at least one-eighth inch in height and prominently displayed.

(E) The words "This product has not been pasteurized and therefore may contain harmful bacteria that can cause illness particularly in children, the elderly, and persons with weakened immune systems and in pregnant women can cause illness, miscarriage or fetal death, or death of a newborn." on the container's principal display panel and clearly readable in letters at least one-sixteenth inch in height.

Animal Health Testing for Tier I and Tier II requires:

- Annual health exam by a licensed veterinarian
- Current rabies vaccination performed by a licensed veterinarian
- Official identification
- Brucellosis testing – producer expense
- Adult cattle 24 month of age and older
- Initial blood test
- Annual BRT on a sample of milk
- Adult goats/sheep 12 months of age and older - annual blood test
- Annual tuberculosis test – producer expense
- All adult animals in the herd

Milk testing for Tier II:

- A producer shall have unpasteurized milk tested twice per month by a U.S. Food and Drug Administration accredited laboratory. Milk shall be tested for the following and the results shall be below these limits:
 - (i) Total bacterial (aerobic) count: 15,000 cfu/ml (cattle and goats);
 - (ii) Total coliform count: 10 cfu/ml (cattle and goats);
 - (iii) Somatic cell count: 225,000/ml (cattle); 500,000/ml (goats).

Agency Implications: Delivery to Farmers Markets:

- Both Tier I and Tier II may deliver to customers if the milk is presold and they meet the common requirements and additional requirements.
- Inspection needed at Farmers Markets
 - Ensure compliance with regulations
- Other product at markets
 - Scales
 - Apples
 - Meat
 - Eggs
- Lack of resources
 - Number of inspectors
 - Budget to cover salaries
- Most markets on weekends/after work hours
 - Overtime for inspectors

Agency implications: Animal Health Testing Policy: the Statute:

'Unpasteurized milk shall be derived from healthy animals which are subject to appropriate veterinary care, including tuberculosis and brucellosis testing and rabies vaccination, according to accepted testing and vaccinations standards as established by the agency.'

There has been some push back on the Agency testing policy; it is viewed as unfair and burdensome. The Agency added the Brucellosis Ring Test option in place of blood testing for maintenance in January of 2014.

Dr. Mehlenbacher discussed the “penalty matrix” of fines for first compliance action and additional compliance actions in the same area of violation. The Agency implications of the Compliance Policy:

- Why have written compliance policies? Serve to keep penalties fair and consistent; consistently set (monetary amounts; actions needed for the non-compliant individual)
- Required by law – the Supreme court case regarding written policies (Algers)
- Not generally shared with external stakeholders (Agency actively provided the raw milk policy; huge push back on policy and what is in statute)
- External input on an internal policy (Motor vehicle fines)

Why the Controversy?:

- Raw milk regulations taken more personally
- Lack of a company buffer between producer and regulator
Processing plant serves as the interface between the public and the producers
- Raw milk producers in charge of their own recalls
High bacterial counts
High somatic cell counts
- Morphs into a small farm vs large farm issue
- PMO does not work as a regulatory framework
Assumptions made that milk will go to further processing (pasteurization; aged – cheese)

Advocacy Group Activity:

- Press for changes to the law every legislative session
 - Once law passed – repeated call for more changes
 - Retail sales goal
- Advocacy activities more pronounced in an election year
 - Agency serves as evil entity
 - Provides a focus for fund raising efforts
- Completely opposite reaction from our tissue residue penalty

Tissue Residue Penalty:

- 6 V.S.A. § 2744a. Drugs
 - (b)(1) No producer shall sell livestock for slaughter which contains any drug or drugs in excess of tolerances established by the United States Food and Drug Administration in the Code of Federal Regulations.
 - (2) In the event that livestock intended for slaughter is found to contain a drug or drugs in excess of levels established by the United States Food and Drug Administration in the Code of Federal Regulations at the time of sale, the secretary may assess an administrative penalty not to exceed \$1,000.00 for each violation.
 - (c) Before issuing an order or administrative penalty under this section, the secretary shall provide the producer and the handler or dealer an opportunity for hearing. (Added 1991, No. 232 (Adj. Sess.), § 2; amended 1997, No. 88 (Adj. Sess.), § 2; 2003, No. 42, § 2, eff. May 27, 2003; 2011, No. 39, § 1, eff. May 19, 2011.)
- Penalty set at highest allowable amount:
 - \$1000 per animal or drug

Tissue Residue Penalties:

- Offenders tend to be conventional dairies
Opt for payment versus hearing
Disappointing from a preventive aspect
No outcry or public request for input on the penalty
- Why the difference in compliance policy outcry?
Different population of people
Raw milk producers:
 1. More likely to engage in on-farm slaughter

2. Keep cows longer
3. Less likely to cull and send to a slaughter plant
4. More organic certification?

Lead residues in animal products from exposed cattle.

Karyn Bischoff, DVM MS, AVCT, Director and Senior Research Associate, Clinical Toxicology Laboratory, Animal Health Diagnostic Center, College of Veterinary Medicine, Ithaca, NY 14882

Dr. Bischoff discussed the issue of lead and lead dust in the farm environment. Lead is a ubiquitous environmental contaminant and most species are susceptible to toxicosis. Acute Pb poisoning is commonly diagnosed in cattle and can be associated with large ingestions of Pb from a point-source by a few animals. However, environmental Pb contamination or feed contamination can lead to chronic exposure of a large number of animals who may appear clinically unaffected. We wanted to determine if products from chronically exposed cattle contained Pb residues. Only 11 of 94 cattle with detectable blood Pb concentrations had clinical signs of toxicosis. Clinical and subclinically lead-exposed cattle had blood lead half-lives ranging from 3 to 577 days (n=44). Our laboratory followed a Pb-exposed dairy herd for 2.5 years (n = 32). Lead was detectable in the milk of some cattle throughout the study period. The bulk tank Pb concentration was 100 ppb early in the study, and the highest milk Pb concentration from an individual cow was 466 ppb. Though the data is unpublished, we have sampled a small number of Pb exposed and recovered (n = 5, blood Pb < 10 µg/dL) and cattle with high blood Pb concentrations (n =4, blood Pb > 35 µg/dL) of varying purposes and ages and from a variety of farms. Soft tissue lead concentrations were low (< 10 ppm) in recovered cattle, and ranged from 17 to >1000 ppm in cattle with high blood Pb concentrations. Bone Pb concentrations ranged from 1 to 22 ppm in recovered cattle and up to 122 ppm in cattle with high blood Pb.

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Committee Business:

During the Business meeting, we discussed the goal of responding to the AAVLD and the USAHA offices concerning their request to align the committee's mission statement with the newly written strategic plans of both organizations. We also talked about the need to continue the discussions throughout the year

(between national meetings) perhaps via a quarterly conference call. The Committee had no resolutions this year.