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Extension Toxicologist

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"IN THIS ISSUE "

TOXICOLOGY TIDBITS

VETERINARY NOTES

E. Coli Victims Didn't Wash Their Hands

Wisconsin State health officials have, according to this story, determined that 13 people who contracted *E. coli* O157:H7 at a county fair early this month visited animal barns or a petting zoo, **then ate without washing their hands.**

Herb Bostrom, director of the state Bureau of Communicable Diseases was cited as saying that those who became sick touched manure or touched an item that came into contact with manure, adding, "It's not bad luck. It's bad hygiene. If you go into an animal barn and don't wash your hands, you're going to get sick."

The story says the state examined 52 water samples and six manure samples from the Ozaukee County fairgrounds and found no trace of *E. coli*. Officials determined the bacteria did not come from food or drinks provided at the fair or from any ponds on the fairgrounds. The story further explains that more than 220 people filled out a questionnaire about their experiences at the fair, held Aug. 1-5. Their answers led officials to pinpoint the barns and zoo, although not any exact source of the bacteria.

REF: Associated Press, via FSNET, August 22, 2001

Tularemia --- Oklahoma, 2000

In June 2000, seven cases of tularemia were reported to the Oklahoma State Department of Health (OSDH) over an 18-day period. This report summarizes clinical and epidemiologic information from the investigation of the 11 cases, presents three case reports to illustrate different risk factors for tularemia, and underscores the danger of delayed diagnosis of tularemia and the risk for acquiring tularemia in laboratory settings. Physicians should consider tularemia in ill persons with fever who reside in or visit areas where the disease is endemic and who have been exposed to ticks or carcasses or tissue from rabbits or other animals.

Possible *F. tularensis* exposures for nonfatal cases included known tick attachment within 14 days of illness onset (three patients), possible environmental tick exposure (three patients), skinning rabbits (two patients), and laboratory exposure (one patient). One person who died had possible tick exposure; the exposure for the other fatal case was undetermined.

Case Reports:
Case 1. On June 16, 2000, a 64-year-old man was found comatose in his home and taken to a local emergency department (ED). In the ED, he had evidence of acute renal failure, and pulmonary infiltrates were seen on his chest radiograph. He had a history of fever of unknown duration, generalized muscle weakness, cough, hemoptysis, anorexia, and fatigue. The patient's condition deteriorated and, because he had a history of training dogs, intravenous doxycycline was started for a possible tickborne illness. The patient died on June 29. On July 14, *F. tularensis* was isolated from blood culture.

Case 2. On July 3, 2000, a 51-year-old female microbiologist presented to an ED with a 10-day history of fever, headache, myalgia, loss of appetite, abdominal tenderness, painful respiration, and sharp pain in the upper right quadrant of her back. She was diagnosed with possible food poisoning and given a 10-day course of oral levofloxicin. Approximately 14 days before becoming symptomatic, she had worked with the blood culture bottles and plates obtained from case 1 in the hospital laboratory. When *F. tularensis* was isolated in case 1 specimens, case 2 was notified about a potential exposure to the organism. The patient recovered completely. None of the three other laboratory workers who had contact with case 1 specimens reported illness.

Case 3. On September 1, 2000, an 11-year-old girl with a 2-day history of fever (103 F [39.4 C]), painful adenopathy, headache, and muscle aches was taken to a hospital. On physical examination, she had cellulitis of the forearm and an enlarged axillary lymph node. Her peripheral blood count was normal. She was treated for cellulitis of undetermined etiology with an oral cephalosporin. When she did not improve after 3 days, she was taken to her regular physician who suspected tularemia and ordered serologic tests. The girl had a hobby of sewing together tanned rabbit hides to make blankets, and a week before illness onset she had skinned and tanned a rabbit killed by the family dog.

Editorial Note: *F. tularensis* is transmitted to humans by direct contact with or ingestion of infected animal tissues, through the bite of infected arthropods, by consumption of contaminated food or water, or from inhalation of aerosolized bacteria. It also is a potential bioterrorism agent. The occurrence of seven cases over a 2-week period in Oklahoma prompted an investigation of exposures, including the possibility of a bioterrorism event; however, the

exposure history, clinical presentations, and geographic distribution of cases were compatible with natural transmission. In addition, the strains involved in this cluster were genetically similar to those previously acquired in the state.

Tularemia occurs throughout North America, but during 1985-1994, 55% of cases in the United States were reported from Arkansas, Missouri, and Oklahoma. The incidence of tularemia in the United States and in Oklahoma has declined markedly since the 1940s, and national incidence has remained between 0.05 and 0.15 cases per 100,000 population since 1965. Reasons for the increase in cases in 2000 are unknown.

Tularemia has a broad clinical spectrum and may be overlooked in the differential diagnosis of patients with suspected infectious diseases, particularly when the typical ulcer is absent. Delayed diagnosis and late administration of effective antibiotic therapy result in increased morbidity and mortality. Tularemia should be included in the differential diagnosis of any patient in an area where the disease is endemic who has unexplained febrile illness and exposure to ticks, biting flies, or animal tissue.

For the entire report link to: http://www.cdc.gov/mmwr//mmwr_wk.html

REF: *Morbidity and Mortality Weekly Report*, 50(33), August 24, 2001.

Survey of Domestic Fresh Produce: Interim Results

In May 2000, FDA initiated a 1000 sample survey focused on high-volume domestic produce that is generally consumed raw. The stated objective was to collect 125 samples of each of the following commodities: cantaloupe, celery, cilantro, green onions, loose-leaf lettuce, parsley, strawberries, and tomatoes, and to analyze each for the presence of *Salmonella* and *E. coli* 0157:H7. It was also determined that all samples (with the exception of strawberries due to the lack of a validated testing method) would be analyzed for the presence of *Shigella*.

The survey is currently being conducted and is scheduled for completion by the end of September 2001. This document is intended to serve as an update of the results of analyses performed by FDA thus far.

The Domestic Produce Survey is the domestic compliment of the Imported Produce 1000 Sample Survey. For more information regarding procedural details of the Domestic Produce Survey, you may wish to view the Domestic Produce Sampling Assignment (DOEP #00-16).

Interim Results as of June 30, 2001; http://www.cfsan.fda.gov/~dms/prodsur8.html

Samples analyzed: 728
Samples violative: 11
Violation rate: 1.5%

REF: U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, June 30, 2001.

California Issues Warning on Consuming Raw Oysters from the Gulf Coast

The sixth illness since June in California linked to the consumption of raw oysters from the Gulf Coast was announced today by State Health Director Diana M. Bontá, R.N., Dr.P.H. She reminded individuals with weakened immune systems not to eat raw oysters harvested from Louisiana, Alabama, Florida, Mississippi and Texas.

Oysters harvested from these states, especially during the warmer months of April through October, may be contaminated with the bacteria *Vibrio vulnificus*, which can cause severe illness and death. Since 1983, 58 *Vibrio vulnificus* infections have been reported to the California Department of Health Services (CDHS), including 38 that resulted in death. When the source of contaminated oysters could be traced, they were all harvested from the Gulf Coast.

Vibrio vulnificus naturally inhabits estuaries and marine environments and is not associated with environmental pollution.

Individuals with chronic liver disease are especially susceptible to *Vibrio vulnificus* infections. Others at higher risk of severe infection who are warned not to eat raw oysters include those with cancer, AIDS or other conditions that weaken or compromise the immune system.

Since the bacteria is killed by heat, CDHS recommends that oysters be thoroughly cooked to decrease the risk of infection. Consumers are advised that oysters eaten raw (on the half shell or in cold Campechana), or marinated (as in ceviche), undercooked, lightly steamed or prepared as oysters Rockefeller may also pose a health risk.

Vibrio vulnificus infections can cause fever, chills and sometimes abdominal pain, generally within 24 hours of eating contaminated shellfish. Death can occur within two to three days.

Since 1991, CDHS has required restaurants, markets and other retail establishments that sell Gulf Coast oysters to conspicuously display a warning about the risk of eating this product. Regulations prohibit retailers from receiving raw oysters if their origin is not clearly identified. They also are required to maintain records to allow for the rapid identification of shellfish sources that are linked to illnesses. Consumers should ask the retailer or oyster supplier where the oysters were harvested.

The safety of shellfish is regulated in California by CDHS, which participates in the Interstate Shellfish Sanitation Conference (ISSC) to develop a national program to provide safe shellfish to consumers. The ISSC was formed in 1982 to foster and promote shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry and the academic community. During the 2001 Interstate Shellfish Sanitation Conference in July, a control plan was adopted to reduce illnesses and deaths associated with the consumption of raw oysters contaminated with

Vibrio vulnificus. The plan includes an education program directed at high-risk individuals coupled with industry efforts to control bacteria levels through post-harvest processing.

CDHS warns consumers that all foods of animal origin pose some risk when eaten raw. To reduce the risk of illness, high-risk individuals are advised to cook all foods of animal origins or purchase products that have been processed to enhance safety.

http://www.dhs.ca.gov

REF: California Department of Health Services Press Release, 54-01, August 13, 2001.

School Pest Management Bill Gets Senate Approval

In a surprise move, the Senate June 19 approved by unanimous consent school pest management legislation. The School Environment Protection Act (SEPA), sponsored by Sen. Torricelli (D-N.J.), would amend the Federal Insecticide, Fungicide, and Rodenticide Act and set federal policy on the exposure of school children to pesticides.

SEPA, which drew immediate praise from industry and public interest groups, would require each states lead pesticide regulatory agency to submit to the EPA a model school pest management plan. The EPA would review these plans to ensure they are consistent with the new statutory requirements.

States would then distribute information about their plans to local school districts, which would have 12 months to adopt the model plan. School districts would be required to designate a contact person for all information regarding pesticide use in the district. Schools would be barred from applying pesticides to a room or area that is occupied by students. They would be required to establish a 24 hour reentry interval for rooms or areas that were treated by broadcast application, baseboard spraying, tenting or fogging, unless a product label specified a different reentry interval. The school district or school must send a notice to parents at the beginning of each school year and the middle of the school year describing the district's pest management program, potential pest problems, the name and phone number of the contact person, and information about notification registry. The school district would create a registry of those who want advance notice of pesticide use, and schools would have to provide 24 hour advance notice of such use. The posting of signs would also be required both at a central location and at the site of application. They would be required to be posted 24 hours in advance of pesticide applications.

"Parents will now be armed with the knowledge they need to protect their children from potentially harmful pesticides when they send them to school," Torricelli said. "It is an enormous and hard fought victory for the health of our children." The National Pest Management Association, which helped broker compromise language for the legislation, lavished praise on SEPA. "We're delighted with it," Robert Rosenberg, NPMA's director of government affairs, said. "We think it's good legislation."

The legislation “represents a straightforward approach to promote school pest management practices that minimize risk to children and notify and provide safety information to parents and school staff when pesticides are used in the schools,” said Jay Feldman, executive director of Beyond Pesticides. “This important [legislation] strikes a balance between the right of parents to receive notification prior to the application of a pesticide in their child’s school with the need to protect the public health of children from harmful pests through the appropriate use of effective and proven EPA registered pesticide products,” said Warren Stickle, president of the Chemical Producers and Distributors Association (CDPA). “We believe it will play an instrumental role in continuing to protect public health in schools.” The CPDA was also involved in the negotiations over the compromise language. (Pesticide & Toxic Chemical News, Vol .29, No. 35, June 25, 2001.)

REF: *Oklahoma Cooperative Extension Service Pesticide Reports*, August 2001.

CDC Releases New Guidelines on Fluoride Use to Prevent Tooth Decay

The Centers for Disease Control and Prevention (CDC) today issued new recommendations for fluoride use in the current day environment of widespread use of bottled waters and availability of a host of fluoride-containing products. Fluoride is a well-known preventive for tooth decay. "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States" provides guidance to dental and health care providers, public health officials and the general public on the best practices in using fluoride to prevent tooth decay. A work group of fluoride experts evaluated the scientific evidence for the various fluoride products used in the United States.

"Fluoride is needed throughout the lifespan to prevent and control tooth decay. Better use of fluoride can lead to considerable savings in public and private resources and continue the tremendous advances we've made in reducing tooth decay," said CDC Director Dr. Jeffrey Koplan. Fluoridation of community drinking water, which began in the late 1940s, and use of other fluoride products, are credited for the dramatic reductions in tooth decay experienced by U.S. residents. In 1999, the CDC included water fluoridation in its list of 10 great public health achievements of the 20th century. Studies show that fluoride prevents the formation, slows the progression, and even reverses newly-forming cavities. "Although these declines have been dramatic, there are still some areas of the country that are not receiving the benefits of water fluoridation," Koplan added.

Key recommendations for fluoride use include the following:

- Continue and expand fluoridation of community drinking water. Water fluoridation in the proper amounts (0.7-1.2 parts per million [ppm]) has been accepted as a safe, effective, and inexpensive method of preventing tooth decay. Adding fluoride to municipal drinking water also is an efficient strategy to reduce the inequalities in dental disease among Americans of all social strata. All persons should know whether or not their primary source of drinking water has an optimal level of fluoride. Approximately 100 million Americans currently do not receive the benefit of fluoridation.
- Frequent use of small amounts of fluoride. Daily and frequent exposure to small amounts of fluoride will best reduce the risk of tooth decay for all age groups. The recommendations strongly support drinking water with

optimal levels of fluoride and following self-care practices such as brushing at least twice a day with fluoridated toothpaste.

- Use supplements and high concentration fluoride products judiciously. Fluoride supplements for children may best be prescribed for those who are at high risk for decay and who live in communities that have a low fluoride concentration in their drinking water. High concentration fluoride products, such as professionally applied gels, foams, and varnishes, also may best benefit children who are at high risk of decay.
- Parents should monitor the fluoride intake of children younger than six years old. The first six years of life are an important period for tooth development. Overuse of fluoride during this period can result in enamel fluorosis, a condition that may appear as white lines or spots on the teeth. Monitoring fluoride sources by parents can reduce the occurrence of white spots while preventing early tooth decay. Children under age six should use only a "pea-sized" amount of fluoride toothpaste; parents should consult their child's doctor or dentist concerning use of fluoride toothpaste for children under age two.
- Label bottled water with the fluoride concentration. Increased labeling of bottled waters on a voluntary basis will allow consumers to make informed decisions on their fluoride intake.
- Educating health professionals and the public. Collaborative efforts by professional organizations, public agencies and suppliers of oral care products are needed to encourage behavior change to facilitate improved, coordinated use of fluoride products and regimens currently available.
- Further research. Additional studies are needed to learn more about fluoride use and evaluate the current cost-effectiveness of fluoride modalities (i.e., toothpastes, mouth rinses, supplements, gels, and varnishes).

"With multiple sources of fluoride available to us, we want to ensure that every family member gets fluoride in the right amount, in the right place, and at the right time," stated Dr. William R. Maas, director of CDC's Division of Oral Health (DOH). "These new recommendations will provide the framework for effective and efficient fluoride use in today's environment of multiple sources of fluoride."

The complete report is available at the CDC Web site: www2.cdc.gov/mmwr/ or visit the DOH website at: www.cdc.gov/nccdphp/oh/

REF: CDC Press Release, August 16, 2001.

Toxicology Tidbits

Stronger Consumer Information Program, Scientific Advisory Panel Meeting Announced for CCA-Treated Wood

Throughout the summer consumers can expect to find improved safety handling information when using wood pressure-treated with chromated copper arsenicals (CCA), a wood preservative that contains arsenic. EPA has completed its review of a plan developed by the American Wood Preservers Institute (AWPI) to strengthen information available to consumers for CCA-treated wood, which is widely used for many outdoor applications including decks, fences, posts, picnic tables, docks and playground equipment. The expanded consumer information program begins immediately, and by early fall will include labeling on all pieces of CCA-treated lumber, in-store displays and additional information available to the public.

"Now consumers will understand that this treated wood contains arsenic," said Stephen Johnson, EPA Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances. "I am pleased that the public discussions about CCA-treated wood resulted in a commitment by the industry to include end-tag labeling, in-store bin stickers and signs, and a new toll-free hotline and web site," added Johnson.

CCA, a chemical containing arsenic, is used to pressure-treat wood to protect it against decay and insect damage. EPA learned that the previous consumer awareness program was not adequately informing the public, and in May the Agency asked the wood preservative industry and the public to propose ways to expeditiously enhance the existing consumer awareness program to ensure adequate information reaches consumers. EPA's comments on the AWPI proposal are available at: www.epa.gov/pesticides .

EPA will hold a public meeting of the Scientific Advisory Panel during the week of Oct. 22 to invite scientific peer review on the Agency's hazard assessment and methodologies for calculating children's potential exposure in playgrounds where equipment is made from CCA-treated wood. The children's assessment is one aspect of the Agency's comprehensive reassessment of CCA, which is currently underway and will be released for public review in 2002. EPA will also carefully evaluate the success of the voluntary consumer information program as part of the overall reassessment of CCA. While details of the upcoming meeting are not finalized, it is expected to be held in the Washington DC area. Further information on the meeting will be posted shortly at: www.epa.gov/scipoly/sap

REF: EPA Press Release 103, JULY 3, 2001.

News from the California Department of Pesticide Regulation (CDPR)

UPDATING FUMIGANT DEVELOPMENTS

DPR has updated a status report and overview of fumigants. The report includes plans to conduct air monitoring for methyl bromide, 1-3D (Telone), metam sodium, and chloropicrin during the 2001 use season; the status of risk assessments and evaluations of those fumigants; prospective alternative fumigants, and other details. www.cdpr.ca.gov/docs/dprdocs/methbrom/srfpindx.htm

DPR has adopted regulations to designate the fumigants dazomet and metam-potassium as restricted materials,

allowing County Agricultural Commissioners to take precautions against offsite movement of the fumigant breakdown product MITC.
www.cdpr.ca.gov/docs/legbills/recntadop.htm

DPR has adopted emergency regulations to make technical corrections in the buffer zones and application equipment for methyl bromide applications.
www.cdpr.ca.gov/docs/legbills/emergregs.htm

REVAMPING ADVISORY COMMITTEES

DPR plans to reorganize two advisory committees that advise the Director on pesticide issues. The goal is to better define the roles of the Pest Management Advisory Committee (PMAC), a group of nongovernmental stakeholders, and the Pesticide Registration and Evaluation Committee (PREC), an interagency group.
www.cdpr.ca.gov/docs/legbills/r01-008.htm

TRACKING ENFORCEMENT ACTIONS

DPR's Enforcement Branch recently put county civil penalty and other administrative actions online to improve public access. This summary information includes agricultural and structural civil penalties, as well as suspensions and revocations of county registrations, private applicator certificates, and restricted materials permit cases closed since January 1, 1999. Lists are updated quarterly. Online reference data also allow the public to determine the county in which the action occurred, and the code section involved. Individuals and companies are listed in alphabetical order.
www.cdpr.ca.gov/docs/enfcmpli/admnacts/cvlpnlty.html

DPR has also proposed regulations to specify pesticide use reporting and record keeping requirements for licensed pest control businesses that work on public school sites. Record keeping was mandated by the Healthy Schools Act.
www.cdpr.ca.gov/docs/legbills/r01-005.htm

IMPROVING ILLNESS REPORTING

DPR and the California Poison Control System (CPCS) have teamed up to improve reporting of pesticide-related illnesses. Under a $105,000 DPR contract, CPCS phone operators will take reports of suspected pesticide illness from emergency responders and physicians for referral to county investigators. DPR's goal is to gather more illness data and investigate incidents more promptly.

GOING INTO PRINT

DPR staffers have authored a peer-reviewed article that describes well water sampling in California to detect pesticide residues from non-point source applications. The article summarizes sampling protocols, data collection procedures, and analytical results for the presence of pesticides in ground water developed by DPR.
www.cdpr.ca.gov/docs/empm/pubs/ehapref.htm

Sprouts Infected Thousands in Late 1990's

Sprouts from contaminated alfalfa and clover seeds were responsible for a series of outbreaks of gastrointestinal illness and urinary tract infections in the late 1990s, according to researchers at the California Department of Health and the Centers of Disease Control and Prevention in Atlanta, Georgia. Dr. Janet C. Mohle-Boetani of the Division of Communicable Disease Control in Berkeley, California, and colleagues were cited as reporting in the August 21st issue of the *Annals of Internal Medicine* that as currently produced, "sprouts can be a hazardous food. Seeds can be contaminated before sprouting, and no method can eliminate all (disease-causing organisms) from seeds." The research team recommends that seed and sprout growers make efforts to reduce contamination, and that people with weak immune systems avoid sprouts altogether.

Mohle-Boetani and her colleagues investigated five outbreaks of salmonellosis and one outbreak of *E. coli* O157 that occurred in California between 1996 and 1998. During this period, half of all disease outbreaks in the state that crossed county lines were associated with alfalfa or clover sprouts. The investigators confirmed infections in 600 people and estimate that approximately 22,800 people suffered gastrointestinal illness or urinary tract infections related to sprouts. The outbreaks killed two people.
(*Annals of Internal Medicine* 2001;135:239-247)
http://www.annals.org/issues/current/abs/200108210-00008.html

REF: Fsnet, August 23, 2001

VETERINARY NOTES.....

USDA/FSIS Residue Testing Policy

The Food Safety and Inspection Service (FSIS) is announcing its intention to harmonize its procedures with those of the Food and Drug Administration (FDA) with respect to the target tissue/marker residue policy in testing animal tissues for residues of new animal drugs. FSIS has reviewed its approach regarding the disposition of carcasses containing residues and has determined that its approach is not consistent with FDA's approach. To ensure that meat containing unsafe levels of chemical residues is not being released into commerce, FSIS intends to modify its approach to testing and disposition of carcasses for violative residues to be more consistent with FDA's target tissue/marker residue policy.

Background

When a new animal drug is given to an animal, some of the parent drug and resulting metabolites remain in the

animal as residues. A new animal drug is defined under 21 CFR 510.3(g) and examples of "newness" are specified in 21 CFR 510.3(i). For new animal drugs approved prior to 1976, tolerances were assigned for each of the edible tissues. Collection and testing of multiple tissues is routine for these new animal drugs. As each tissue is tested, it is either released or condemned, depending on whether it is found to have an acceptable level of residue.

Since 1976, FDA has been establishing tolerance levels for new animal drugs using a "marker residue." The term "marker residue" is defined in the Food and Drug Administration's (FDA) Center for Veterinary Medicine's Guideline, "General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals," (CVM Guideline #3, http://www.fda.gov/cvm/guidance/guideline3toc.html) as being the residue selected for assay whose concentration is in a known relationship to the total residue of toxicological concern in the last tissue to deplete to its permitted concentration.

These marker residues serve as a sentinel for the levels of all residues associated with that drug (parent and metabolites) in all edible tissues of the food animal. CVM's Guideline 3 defines target tissue as being the edible tissue selected to monitor for residues in the target animals, including, where appropriate, milk or eggs. When the FDA-approved conditions of use for a new animal drug are followed, the concentration of marker residue in the target tissue should be below the target tissue tolerance when the animal is sent to slaughter. To establish an appropriate tolerance for the marker residue, FDA must know the relationship between the concentration of the marker residue in the target tissue and the concentrations of total residues in each of the edible tissues (CVM Guideline 3). FDA obtains this information from the drug's sponsor who, in submitting a New Animal Drug Application (NADA), includes total residue depletion and metabolism studies with radiolabeled compound in species for which approval is sought (CVM's Guideline 3). The target tissue is usually liver, kidney, or fat because residues generally deplete from these tissues more slowly than from other tissues, i.e., muscle tissue.

In those cases where FDA has established a marker residue tolerance in target tissue, when the marker residue in the target tissue depletes to a concentration equal to or less than the target tissue tolerance (based on the total residue depletion and metabolite data), it can be reliably anticipated that the concentration of total residue in each edible tissue has reached its respective permitted safe concentration. In other words, when the concentration of the marker residue is at or below its tolerance in the target tissue, the entire carcass is considered safe to eat, without additional testing of the individual edible parts of the animal carcass. Similarly, if the level of the marker residue in the target tissue exceeds the tolerance, FDA will consider the entire carcass to be adulterated, because the residue in the target tissue is imputed to the rest of the animal.

In addition, for 15 new animal drugs, FDA has specifically established tolerances for residues found in muscle tissue and analytical methods for detecting those residues. Therefore, the muscle tissue may be released for human consumption if it meets the muscle residue tolerance level. This is true even when the marker residue tolerance in the target tissue has been exceeded. The target tissue, however, would be condemned. In this situation, documenting that the drug residues in muscle are less than the muscle tolerance will only demonstrate that the muscle tissue is safe, and does not imply that any other part of the animal carcass is safe, except in those few instances where muscle has been designated to be the target tissue.

FSIS Practice

FSIS regulations regarding residues state that "* * *Animal drug residues are permitted in meat and meat food products if such residues are from drugs which have been approved by the Food and Drug Administration and any such drug residues are within tolerance levels approved by the Food and Drug Administration * * *" (9 CFR 318.20). FSIS has not strictly applied FDA's marker residue/target tissue approach in determining whether drug residues are within tolerance levels.

Specifically, FSIS has condemned only the organ with a violative residue level and has conducted a laboratory analysis of the muscle tissue to determine whether the muscle portion of the carcass can be salvaged. This has been the practice even for residues of those new animal drugs for which FDA has not established a tolerance or testing methodology for the muscle tissue. Historically, if no drug residue was detected in the muscle, FSIS released the muscle portion of the carcass for human consumption.

FSIS's practice has generated on-going questions regarding whether or not the muscle or other organs are safe. FSIS has referred these questions to FDA, which addresses them on an ad hoc basis.

FSIS needs to modify its procedures to be consistent with the determinations that underlie FDA's approach. Therefore, for those new animal drugs for which FDA has established a marker residue tolerance in a specified target tissue without establishing a tolerance for a residue in muscle and an official analytical method for muscle residues, FSIS will only test the target tissue that is identified in FDA regulations. If the residues found in the target tissue exceed the FDA tolerances, FSIS will condemn the entire carcass. If FDA has also established a tolerance for a residue in muscle and an official analytical method for muscle residues, FSIS will test the muscle using the official methodology to determine whether the concentration of residues in the muscle is at or below the muscle tolerance. If acceptable, FSIS will permit the release of the muscle. For those new animal drugs for which a marker residue tolerance in a specified target tissue has not been identified, FSIS will continue to collect and monitor multiple edible tissues.

FSIS is aware that the change in its procedures announced in this notice will affect the industry. To ensure that animals do not have violative amounts of residues, establishments may change their purchasing practices. Establishments should consider incorporating controls into their HACCP plans to avoid exceeding residue tolerances. Exceeding residue tolerances may result in the condemnation of more product than is currently being condemned. FSIS invites comment on this impact and will welcome any cost data. FSIS will consider these data and consider in what ways it may lessen the impact.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and provide copies of this *Federal Register* publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on-line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, *Federal Register* notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

DATES: Comments may be submitted by no later than September 5, 2001. FSIS will review comments and address them in another notice. That notice will announce when the procedural changes addressed in this notice are effective.

ADDRESSES: Submit one original and two copies of written comments to: FSIS Docket Clerk, Docket # 00-026N, Room 102, Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250-3700. All comments received in response to this notice will be considered part of the public record and will be available for viewing in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel L. Lazenby, Acting Director, Technical Analysis Staff, Office Policy, Program Development and Evaluation; (202) 205-0210.

REF: *Federal Register*, 66(151), August 6, 2001.

USDA/FSIS Residue Testing Procedures

The Food Safety and Inspection Service (FSIS) is changing the action it will take when livestock or poultry are presented for slaughter at official establishments that come from producers and others who have previously marketed such animals with violative levels of drug, pesticide, or other chemical residues ("chemical residues"). FSIS will no longer test livestock and poultry carcasses at official establishments for chemical residues until a specific number of the carcasses consecutively test negative for violative chemical residues (i.e., FSIS "5/15" policy). Instead, FSIS will post on its website the names and addresses of the sellers of livestock and poultry who the Food and Drug Administration has determined are responsible for the repeated sale of livestock or poultry that contain violative levels of chemical residues. FSIS believes that this action will help better ensure that meat and poultry products distributed in commerce are not adulterated with violative residues. FSIS is taking this action partly in response to a request from certain industry groups.

Background

The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers. This program among other things helps to prevent the distribution in commerce of adulterated products of livestock and poultry. Under the FMIA and the PPIA, it is illegal to sell or transport, offer for sale or transportation, or receive for transportation, in commerce, meat and poultry products that are capable of use as human food that are adulterated (21 U.S.C. 458(a)(2)(A) and 610(c)(1)). Meat and poultry products are considered adulterated under the FMIA and PPIA if they bear or contain illegal amounts of drugs, pesticides, and other chemicals (21 U.S.C. 453(g)(1), (g)(2), and (g)(3) and 601(m)(1), (m)(2), and (m)(3)).

Both the FMIA and the PPIA include requirements for Federal inspection. They prohibit the sale, transportation, offer for sale or transportation, or receipt for transportation, in commerce, of meat and poultry products that are required to be inspected unless they have been inspected and passed (21 U.S.C. 458(a)(2)(B) and 610(c)(2)).

Meat and poultry products prepared at establishments that operate solely within a State are effectively subject to the same inspection requirements and adulteration prohibitions discussed above. These requirements and prohibitions are imposed pursuant to a State inspection program or by the FMIA and PPIA as a result of the designation of a State for Federal inspection (21 U.S.C. 454(c)(1) and 661(c)(1)).

Since the 1960's, the public and private sectors have tried to meet the challenges presented by various types of

product adulteration that organoleptic examination generally cannot detect. The control of chemical residues in meat and poultry products is a particularly appropriate subject for an improved regulatory approach that involves a well-integrated and seamless, prevention-oriented farm-to-table strategy.

At the Federal regulatory level, efforts to prevent residue-related food safety problems principally involve, in addition to FSIS, the Food and Drug Administration (FDA), acting under the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321 et seq.), and the Environmental Protection Agency (EPA), acting under the FFDCA, the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 et seq.), and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.). FDA and EPA establish, respectively, what, if any, levels of animal drug and pesticide residues in food are safe, and thus can legally remain in the tissue of livestock and poultry. EPA also may make recommendations regarding what level, if any, of other chemical hazards that may be associated with substances that occur in meat and poultry products as a result of environmental contamination are safe. These levels are known as action or tolerance levels. FSIS enforces the tolerance and action levels set by the EPA and FDA to ensure that meat and poultry products do not contain levels of animal drugs, pesticides, or other chemicals above the level that is considered safe.

At slaughter, FSIS looks for indications of illegal chemical use or exposure and collects livestock and poultry carcass samples for residue analysis. The analytical components of the Agency's residue control activities are collectively known as the "National Residue Program" (NRP). Initiated more than 30 years ago, the NRP has generally been a success. It has been instrumental in reducing the incidence of such residue violations as sulfamethazine in market hogs. The most recent NRP reports are the "1999 FSIS National Residue Program" and the "Domestic Residue Data Book National Residue Program 1998" (referred to informally as the "Blue Book" and the "Red Book", respectively.)

The prevention of illegal chemical residues in the food supply is an integral aspect of maintaining a high level of food safety. As part of FSIS' inspection program to screen for violative levels of chemical residues in livestock and poultry carcasses to ensure that meat and poultry products are not adulterated, Agency inspection program personnel sample meat and poultry carcasses at official establishments and submit the samples for testing to determine whether they contain violative drug, pesticide, or other chemical residues.

If it is confirmed that a carcass contains a violative drug, pesticide, or other chemical residue, the Slaughter Operations Staff at FSIS' Technical Service Center (TSC) opens a case file about this matter and initiates an investigation to determine who is the violator. A violator is defined as a firm or person, (e.g., farmer, hauler, auction market) who sells livestock or poultry for slaughter that contains violative levels of drugs, pesticides, or other chemical residues. If the TSC staff is able to obtain from the official establishment the name of the producer (e.g. farmer) of the livestock or poultry, the TSC sends an "FSIS Violation Notification Letter" to this person. The letter provides the results of the residue tests taken and requests that the producer submit five animals to FSIS for residue testing at a designated official establishment.

The TSC staff informs the appropriate FSIS personnel at the designated official establishment to sample the carcasses of animals presented for slaughter by the producer. There is no specific time period in which these carcasses must be presented. The case file remains open until five consecutive carcasses from animals presented for slaughter by the producer test negative for violative residues.

If the TSC staff is not able to obtain the name of the producer who supplied the violative livestock or poultry carcass to the official establishment, then inspection program personnel are instructed to sample 15 carcasses from animals provided by the auction, market, or buyer that had previously supplied livestock or poultry to the official establishment that had been found to contain violative chemical residues. Inspection program personnel will select carcasses from three or more different lots for sampling and testing. There is no specific time period in which these carcasses must be presented. The case file remains open until 15 consecutive carcasses from animals presented for slaughter test negative

for violative residues.

The sampling and testing undertaken at official establishments of a specified consecutive number of carcasses of livestock or poultry that contained violative chemical residues is known as FSIS' "5/15" residue policy.

Under an October 1984, Memorandum of Understanding with FDA, when FSIS finds violative drug, pesticide, or other chemical residues in livestock or poultry, FSIS transmits to FDA information, including the name of the official establishment where the livestock or poultry that was presented for slaughter was confirmed positive for violative chemical residues and information about the violator. This information is transmitted via the Residue Violation Information System (RVIS). RVIS is a nationwide interagency computer information system that was designed by FSIS in cooperation with FDA to handle pertinent regulatory information related to residue violations.

FDA uses the information it receives from RVIS to conduct an investigation of the violator to determine whether the violator is a repeat violator. A repeat violator is an individual or firm who sells an animal for slaughter whose carcass is found to contain a violative level of a drug, pesticide, or other chemical residue within a 12-month period after having received a FSIS Violation Notification Letter.

On July 27, 2000, the American Meat Institute, the Livestock Marketing Association, the National Livestock Producers Association, the National Cattleman's Beef Association, and the National Meat Association wrote to FSIS and requested that the Agency make certain changes in how it responded to residue violations by sellers of livestock. The associations stated that they were particularly interested in reducing the sales of market cattle that contained violative levels of animal drug residues. The associations requested that FSIS terminate its "5/15" policy "in favor of a more meaningful cooperative program with FDA." They contended that FSIS' "5/15" policy was not an effective deterrent for firms or persons who knowingly and repeatedly sold medicated livestock.

In place of FSIS' "5/15" policy, the associations requested that FSIS publish and disseminate a list that contains the names and addresses of the sellers of livestock that FDA has investigated and determined to be responsible for more than one residue violation in a 12-month period (repeat violators). The associations recommended that these violators remain on the published list for a period of one year following a "responsible party" designation by FDA, and that this time period be extended another twelve months for each subsequent residue violation for which the seller was determined to be responsible.

FSIS has reviewed the associations request. FSIS has determined that the list requested may more effectively prevent, than its current "5/15" policy does, the distribution of meat products that are adulterated with violative levels of chemical residues. FSIS has also determined that this type of list may also more effectively prevent, than the current "5/15" policy does, the distribution of poultry
products that contain violative chemical residues. FSIS believes that its current "5/15" policy may not be the best way to deter the repeated sale of livestock and poultry with violative chemical residues because, once a producer is notified about a residue violation, it is not difficult for a seller of livestock and poultry to temporarily present animals for slaughter that do not contain violative drug, pesticide, or other chemical residue levels. FSIS also believes that the suggested approach is more consistent with the approach embodied in HACCP than is the "5/15" policy.

Therefore, FSIS will implement the change requested by the associations not only in regard to persons who have marketed livestock with violative chemical residues, but also in regard to persons who have marketed poultry that contain violative chemical residues. In cooperation with FDA, FSIS will make a list of repeat chemical residue violators publicly available by posting a list of repeat violators on the FSIS Homepage (www.fsis.usda.gov). The list will contain the names and addresses of the sellers of livestock and poultry that FDA has investigated and determined to be responsible for more than one drug, pesticide or other chemical residue violation in a 12-month period. The names and

addresses of violators will remain on the list for a year from the time of being listed. For any subsequent violation, the time period will be extended by a year from the time of that subsequent violation.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and provide copies of this *Federal Register* publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on-line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, *Federal Register* notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

DATES: The new procedures will be effective September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Daniel L. Lazenby, Acting Director, Technical Analysis Staff, Office of Policy, Program Development, and Evaluation, FSIS, U.S. Department of Agriculture, Room 409, Cotton Annex, 300 12th Street, SW., Washington, DC 20250, (202) 205-0210.

REF: *Federal Register*, 66(151), August 6, 2001.

1999 National Residue Data

USDA's Food Safety and Inspection Service posted the 1999 National Residue Data Book (The "Red Book") on its Web site. The National Residue Program requires domestic monitoring and special project samples to be collected from carcasses of food animals and egg products to be analyzed for drug, pesticide, or environmental residues.

http://www.fsis.usda.gov/OPHS/red99/index.htm

REF: EdNet, Aug 27, 2001.

Outbreaks of Multidrug-Resistant Salmonella Typhimurium Associated With Veterinary Facilities --- Idaho, Minnesota, and Washington, 1999

The Centers for Disease Control received reports in 1999 from three state health departments of outbreaks of multidrug-resistant *Salmonella* serotype Typhimurium infections in employees and clients of small animal veterinary clinics and an animal shelter. *Salmonella* infections usually are acquired by eating contaminated food; however, direct contact with infected animals, including dogs and cats, also can result in exposure and infection. This report summarizes clinical and epidemiologic data about these outbreaks and reviews methods of reducing the likelihood of *Salmonella* transmission in veterinary settings by avoiding fecal-oral contact.

Idaho -- During September-October, the Idaho Department of Health and Welfare identified through routine surveillance an outbreak of *Salmonella* infections among employees of a small animal veterinary clinic. The index patient reported caring for several kittens with diarrhea 1 or 2 days before illness onset; stool specimens were not cultured and the kittens died. All 10 ill employees ate meals in the clinic and had no common exposures outside the clinic.

Minnesota -- The Minnesota Department of Health (MDH) routinely receives animal *S.* Typhimurium isolates from the Minnesota Veterinary Diagnostic Laboratory. In 1999, MDH tested *S.* Typhimurium isolates from nine cats and seven humans that were indistinguishable by PFGE. All isolates were resistant to ampicillin, chloramphenicol, streptomycin, sulfamethoxazole, and tetracycline (R-type ACSSuT).

Washington -- Through laboratory-based surveillance and patient interviews, the Washington State Department of Health detected in late 1999 an outbreak of *Salmonella* infections associated with a small animal veterinary clinic. One ill person was a clinic employee and the two others recently had brought their cats to the clinic, one for elective surgery and the other for a urinary tract infection. The cats developed diarrhea after their discharge from the clinic and the owners subsequently became ill. The clinic was the only common exposure reported by the three ill persons.

Editorial Note: Although most of the estimated 1.4 million *Salmonella* infections that occur each year in the United States are transmitted through food, *Salmonella* also is transmitted through exposure to contaminated water, reptiles, farm animals, and pets. It is unknown how the human patients in these outbreaks became infected with S*almonella;* however, the inadvertent ingestion of animal feces or food contaminated with animal feces may have occurred as the result of suboptimal sanitation and hygienic practices in the veterinary facilities. Many cats in these facilities had a diarrheal illness that also may have contributed to *Salmonella* transmission. Even after recovery from an acute episode of *Salmonella* gastroenteritis, fecal shedding of *Salmonella* can occur and may last several months. In addition, the use of antimicrobial agents in veterinary facilities may have contributed to transmission of multidrug-resistant *Salmonella* by lowering the infectious dose needed for ingestion to cause illness in animals and increasing the likelihood of transmission to humans. Although outbreaks of multidrug-resistant *Salmonella* with human and animal illness have been reported in large animal veterinary facilities (e.g., horse clinics) outbreaks associated with small animal facilities are rare. The outbreaks described in this report demonstrate that small animals shed *Salmonella* and that small animal facilities can serve as foci of transmission for *Salmonella* to other animals and humans.

To prevent salmonellosis, persons should wash their hands before eating and after handling food. Immunosuppressed persons should avoid animals aged <6 months and animals with diarrhea. Veterinary

workers should wash their hands after handling pets, especially after handling feces. These workers can further reduce their exposure to feces by wearing rubber or disposable gloves, and by removing gloves and washing their hands immediately after finishing a task that involves contact with animal feces. Although there have been no reports of *Salmonella* transmission through splash exposures, workers might consider taking measures to reduce splashes of feces to the mouth when hosing or cleaning a kennel. All surfaces contaminated with feces should be cleaned and disinfected. No eating should be allowed in animal treatment or holding areas.

For the entire report link to: http://www.cdc.gov/mmwr//mmwr_wk.html

REF: *Morbidity and Mortality Weekly Report*, 50(33), August 24, 2001.

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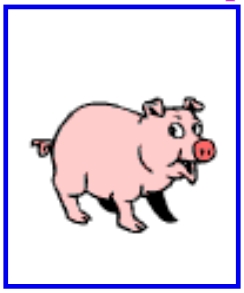

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