## Cooperative Extension --- University of California, Davis



# **Environmental Toxicology Newsletter**

"Published Occasionally at Irregular Intervals"

~ Dr. Arthur L. Craigmill ~ Extension Toxicologist

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PET FOOD RECALL WEBSITE



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**Unintentional Poisoning Deaths - United States, 1999-2004** 

In 2004, poisoning was second only to motor-vehicle crashes as a cause of death from unintentional injury in the United States. Nearly all poisoning deaths in the United States are attributed to drugs, and **most drug poisonings result from the abuse of prescription and illegal drugs**. Previous reports have indicated a substantial increase in unintentional poisoning mortality during the 1980s and 1990s. To further examine this trend, CDC analyzed the most current data from the National Vital Statistics System. This report summarizes the results of that analysis, which determined that **poisoning mortality rates in the United States increased each year from 1999 to 2004, rising 62.5% during the 5-year period. The largest increases were among females (103.0%), whites (75.8%), persons living in the southern United States (113.6%), and persons aged 15-24 years (113.3%).** Larger rate increases occurred in states with mostly rural populations. Rates for drug poisoning deaths increased 68.3%, and mortality rates for poisonings by other substances increased 1.3%. The largest increases were in the "other and unspecified," psychotherapeutic, and narcotic drug categories. The results suggest that more aggressive regulatory, educational, and treatment measures are necessary to address the increase in fatal drug overdoses.

Mortality data for 2004 were collected from the National Vital Statistics System. Unintentional poisoning deaths that occurred during 1999-2004 included overdoses of illegal drugs and legal drugs taken for nonmedical reasons, poisoning from legal drugs taken in error or at the wrong dose, and poisoning from other substances (e. g., alcohol, pesticides, or carbon monoxide). Adverse effects of legal drugs taken in the proper doses and as directed were not included in this analysis.

The number of unintentional poisoning deaths increased from 12,186 in 1999 to 20,950 in 2004. The annual age-adjusted rate increased 62.5%, from 4.4 per 100,000 population in 1999 to 7.1 in 2004. The increase among females, from 2.3 to 4.7 per 100,000 population (103.0%), was twice the increase among males, from 6.5 to 9.5 per 100,000 population (47.1%). Among males, rates among whites, American Indians/Alaska Natives, and Asians/Pacific Islanders all increased approximately 50%. Rates among black males were highest in 1999 but did not increase. Among females, rates among whites more than doubled, whereas nonwhites had smaller increases or decreased. Overall, rates increased 75.8% among whites, 55.8% among American Indians/Alaska Natives, 27.4% among Asians/Pacific Islanders, and 11.2% among blacks. Rates among non-Hispanics increased more than rates among Hispanics for both sexes. Among all sex and racial/ethnic groups, the largest increase (136.5%) was among non-Hispanic white females. Among all age groups, the largest increase occurred among persons aged 15-24 years (113.3%). In 2004, the highest rates were among persons aged 35-54 years, who accounted for 59.6% of all poisoning deaths that year.

The increase in poisoning mortality occurred almost exclusively among persons whose deaths were coded as unintentional drug poisoning, for which the rate increased 68.3%. The rate for poisoning deaths attributed to other substances increased 1.3%. By 2004, drug poisoning accounted for 19,838 deaths, 94.7% of all unintentional poisoning deaths. Among types of drug poisoning, the greatest increases were in the "other and unspecified" drug, psychotherapeutic drug, and "narcotic and hallucinogen" drug categories.

Editorial Note: Unintentional drug poisoning mortality rates increased substantially in the United States during 1999-2004. Previous studies, using multiple cause-of-death data, have indicated that the trend described in this report can be attributed primarily to increasing numbers of deaths associated with prescription opioid analgesics (e.g., oxycodone) and secondarily to increasing numbers of overdoses of cocaine and prescription psychotherapeutic drugs (e.g., sedatives), and cannot be attributed to heroin, methamphetamines, or other illegal drugs.

The mortality increases might be the result of greater use and abuse of potentially lethal prescription drugs in recent years, behaviors that are more common among whites than nonwhites. The substantial increase in deaths among persons aged 15-24 years is consistent with substantial recent increases in recreational prescription drug

and cocaine use among adolescents and young adults.

Studies by state health agencies have reported recent increases in prescription-drug-poisoning mortality in rural communities, despite historically higher rates in urban areas. The South and Midwest regions, which had the largest relative and absolute increases among regions in this study, are the most rural regions of the country. Further research is needed to determine how differences in drug use, drug-abuse-control measures, and demographic characteristics (e.g., race/ethnicity) contribute to this pattern.

Effective response to increasing fatal drug overdoses requires strengthening regulatory measures to reduce unsafe use of drugs, increasing physician awareness regarding appropriate pharmacologic treatment of pain and psychiatric problems, supporting best practices for treating drug dependence, and potentially modifying prescription drugs to reduce their potential for abuse. State agencies that manage prescription-monitoring programs should use such systems to proactively identify 1) patients who abuse drugs and fill multiple prescriptions from different health-care providers and 2) providers whose prescribing practices are outside the standards of appropriate medical care. Both federal and state prevention measures should be evaluated periodically to determine their effectiveness.

REF: MMWR Weekly Report, February 9, 2007 / 56(05);93-96.



#### Foodborne Botulism from Home-Prepared Fermented Tofu California, 2006

In December 2006, the Orange County Health Care Agency (OCHCA) and California Department of Health Services (CDHS) were notified of two potential cases of foodborne botulism in an older Asian couple. This report summarizes the subsequent investigation, which identified home-prepared fermented tofu (soybean curd) as the source. The public should be aware of the risk for botulism when preparing fermented tofu at home.

Botulism is a toxin-induced paralytic illness characterized by cranial nerve palsies and descending flaccid paralysis. Treatment is based on supportive care and administration of botulinum antitoxin; recovery can take from weeks to months. Foodborne botulism results from eating foods containing botulinum toxin. Although rare, foodborne botulism is a public health emergency because of the potential severity of illness and exposure of many persons to contaminated food.

On November 28, 2006, a woman aged 67 years had onset of double vision, followed the next day by bilateral ptosis. An ophthalmologist attributed these symptoms to long-standing diabetes mellitus. On December 4, she visited her primary-care physician because of double vision, ptosis, dizziness, difficulty swallowing, slurred speech, drooling, and right arm weakness. Physical examination revealed limitation of upward gaze, bilateral ptosis, sluggish tongue movement, and mild right upper extremity weakness.

The woman's husband, aged 75 years, reported 3 days of worsening double vision, dizziness, and difficulty swallowing. On physical examination, he also had mild right ptosis and sluggish tongue movement.

Both patients were admitted to an intensive care unit. On December 5, physicians suspected foodborne

botulism, notified OCHCA, and collected clinical specimens for testing. CDHS dispatched botulinum antitoxin to the hospital, and it was administered to the couple. Both patients were hospitalized for more than 1 week with no further symptom progression. Botulinum toxin was not detected in serum or stool samples from the patients. However, *Clostridium botulinum* type A was detected in enrichment cultures of the stool samples of both patients. Both patients have some blurred vision but otherwise have recovered.

On December 5, OCHCA visited the couple's home and identified multiple potential sources of intoxication. OCHCA interviewed the patients using photos of home-prepared food items to overcome the language barrier and identify the most suspect food. The patients reported they recently had been eating a new batch of home-prepared fermented tofu. Although both had eaten fermented tofu from this batch every day, the woman ate more than her husband. CDHS Microbial Diseases Laboratory found both *C. botulinum* type A and botulinum toxin type A in the fermented tofu samples, which had a pH of 6.8.

The tofu was a commercially packaged product purchased at a retail market. In the home, the tofu was boiled, towel dried, and cut into cubes. The cubes were placed in a bowl, covered with plastic wrap, and stored at room temperature for 10-15 days. The tofu was then transferred to glass jars with chili powder, salt, white cooking wine, vegetable oil, and chicken bouillon to marinate at room temperature for 2-3 more days. Finally, the fermented tofu was stored and eaten at room temperature.

*C. botulinum* spores exist widely in the environment, but proper food-preparation practices inhibit spore germination and toxin production. Environmental conditions that facilitate spore germination and growth include a pH >4.6, anaerobic conditions, low salt or sugar content, and temperatures >39.2 F (>4 C). In the case described in this report, the growth of *C. botulinum* and production of toxin might have been facilitated by several factors: 1) the almost neutral pH of the fermented tofu, 2) boiling the tofu, potentially creating an anaerobic environment, and 3) room temperature (approximately 68-77 F) storage of the product for days during and after preparation.

The wife reported she has lived in the United States for more than 25 years and, during this time, has prepared fermented tofu using the same recipe she learned as a student in Taiwan. Preparation of this batch was not notably different, and the reason for contamination this time is not clear.

This is the first U.S. report of botulism caused by eating home-prepared fermented tofu. Historically, most foodborne botulism cases in the United States result from consumption of improperly prepared home-canned foods. However, fermented foods, including fish, seal, and whale, also have been associated with botulism. Fermented tofu is popular in Asia, and homemade fermented bean products, including tofu, are the most common foods causing botulism in China. During 1958-1989, home-fermented bean products were associated with 63% of approximately 2,000 cases of botulism in China. Clinicians, public health workers, and the public should be advised that home preparation of fermented tofu can result in foodborne botulism.

REF: MMWR Weekly Report, February 9, 2007 / 56(05);96-97.



#### Summary of Results from the California Pesticide Illness Surveillance Program - 2005

Executive Summary: The California Department of Pesticide Regulation's Pesticide Illness Surveillance Program (PISP) seeks to identify any health effect caused by pesticides. While DPR strives to collect as many individual reports on illnesses and injuries as possible, within resource constraints, our primary goals are to identify high-risk situations that warrant regulatory action; and to promote pro-active, health-protective measures, especially for those individuals who regularly face the highest pesticide exposure risks.

The 2005 PISP summary continued to capture a wide range of pesticide illnesses in California, with 1,323 cases investigated (compared to 1,238 investigations in 2004). Investigation confirmed pesticide exposure as a potential causal factor in 911 cases in 2005, compared to 828 cases in 2004.

Two significant points of interest emerge from the 2005 data. First, a full one-third of the investigations involved a single incident: A field fumigation in Monterey County allowed irritant vapors to escape into a suburban neighborhood. The incident graphically demonstrated the potential impacts of pesticide drift, and underscored the need for strong restrictions to prevent situations that may lead to drift injuries.

The second point of interest involves a sharp decline in the number of non-occupational injury reports. Apart from the Monterey incident, only 70 non-occupational cases were investigated in 2005, nearly a ten-fold decline from some recent years.

An obvious explanation is related to DPR budget cuts four years ago. At that time, DPR was unable to take over a federally funded project with the California Poison Control System (CPCS), which monitors emergency calls for toxic exposure information. DPR annually received hundreds of CPCS-mediated pesticide illness reports until 2002, when federal funding for the project was exhausted. By late last year, the improved condition of DPR's budget allowed the Department to fund resumption of the project.

DPR also continues to work with the Office of Environmental Health Hazard Assessment (OEHHA) on a pilot project to improve physician reporting of pesticide cases. While state law requires such reporting, compliance has been spotty for years, despite extensive DPR efforts to inform the medical community of its responsibilities. With federal funding, DPR and OEHHA are working to integrate pesticide reporting into a statewide, internet-based system. The project now under development also involves cooperation with local health officials and agricultural commissioners in three pilot counties.

The number of suspected pesticide injuries to farm field workers in 2005 - 132 cases involving drift, 28 residue -- declined in comparison to 2004, with 180 and 68 cases, respectively.

This continues a long-term decline since the 1980s, when more than 350 workers were injured in some years. However, DPR continues to seek further improvements in field safety, such as worker notification rules.

Link: http://www.cdpr.ca.gov/docs/whs/pdf/hs1869.pdf



#### **DPR Launches Toll-Free Phone for Complaints**





Californians who have pesticide complaints can now call one toll-free phone number for help, the <u>California</u> Department of Pesticide Regulation announced.

The new service, 1-87PestLine (1-877-378-5463), transfers callers to their County Agricultural Commissioner's Office with recorded information in English and Spanish.

"Our goal is to help people with their pesticide problems as quickly as possible," said DPR Director Mary-Ann Warmerdam. "The 1-87PestLine is an important innovation that will help us and our local partners, the County Agricultural Commissioners, enforce pesticide laws and protect the public.

"Despite previous DPR outreach efforts, many people seem to be unaware of how to report pesticide complaints, or whom to call," said Warmerdam. "The new 1-87PestLine will speed up reporting and response time. This could be especially helpful for illness investigations."

The new, toll-free service was launched as DPR released its latest annual summary of pesticide illness reports. The 2005 illness summary found 911 individual cases related to pesticide exposure. Of these, 647 were agricultural and 263 were non-agricultural. (One case could not be classified.)

That compares to 828 total cases in 2004. Some 390 were agricultural, 438 non-agricultural.

Non-occupational injury reports have been on the decline since 2002, when federal funding ran out for a project that linked DPR to reports from the California Poison Control System. The system, which provides emergency responders with information on toxic exposures, led DPR to hundreds of pesticide cases annually. Many involved home accidents. Thanks to an improved outlook for DPR's budget, the Department restarted the project with its own funds in October 2006.

DPR has long recognized that consumer injuries and complaints are less likely to be reported, either because people do not know how to file a complaint or do not seek medical treatment for an injury. When medical help is sought, DPR has found that physicians often fail to report non-occupational cases to local health officers.

In the agricultural sector, pesticide drift remains a significant source of injuries, the 2005 DPR summary showed. The largest drift investigation in 2005 involved release of chloropicrin during a farm field fumigation adjacent to a neighborhood in Salinas. A total of 324 injuries were related to that mishap.

Earlier this year, Warmerdam set a DPR goal to "aim for zero" major incidents such as the Salinas drift case. Such incidents may involve several victims who require medical attention, or just one person if hospitalization

occurs (excluding suicide attempts). Significant environmental and property damage are other examples of major incidents.

"DPR's 1-87PestLine service is another tool that will help us 'aim for zero', " said Warmerdam. "Later this year, we will also produce two new print guides for the public. One will help people involved in pesticide emergencies. The second will help people understand DPR's regulatory work, and how they can participate in setting pesticide policies."

The toll-free number will be listed under "Pesticide" in the state government pages of phone books statewide. DPR will also sponsor public service announcements, handouts, and other materials featuring a 1-87PestLine logo during the next 18 months. The Department also is asking local agencies, worker advocates, and environmental groups to help publicize 1-87PestLine.

A statewide summary of pesticide illnesses in 2005, is available at <a href="www.cdpr.ca.gov/docs/whs/2005pisp.htm">www.cdpr.ca.gov/docs/whs/2005pisp.htm</a>

Individual county illness statistics for 2005 are available at <a href="www.cdpr.ca.gov/docs/">www.cdpr.ca.gov/docs/</a> pressrls/2007/2005illnesstable.pdf.

DPR researchers emphasize that these statistics alone are not an indicator of the effectiveness of pesticide regulation at the local level. Illness statistics are compiled and summarized statewide to analyze illness trends and help determine whether existing safeguards are sufficient.

REF: CDPR News Release, February 28, 2007 (07-02)



#### FDA Statement on European Aspartame Study

FDA has completed its <u>review</u> concerning the long-term carcinogenicity study of aspartame entitled, "Long-Term Carcinogenicity Bioassays to Evaluate the Potential Biological Effects, in Particular Carcinogenic, of Aspartame Administered in Feed to Sprague-Dawley Rats," conducted by the European Ramazzini Foundation (ERF), located in Bologna, Italy. FDA reviewed the study data made available to them by ERF and finds that it **does not support ERF's conclusion that aspartame is a carcinogen.** Additionally, these data do not provide evidence to alter FDA's conclusion that the use of aspartame is safe.

Aspartame was first approved in the United States in 1981 and is one of the most widely used artificial sweeteners. When metabolized by the body, aspartame is broken down into two common amino acids, aspartic acid and phenylalanine, and a third substance, methanol. These three substances are available in similar or greater amounts from eating common foods.

Upon first learning of the ERF study results, FDA requested the data from ERF to evaluate the findings. On February 28, 2006, the agency received only a portion of the study data requested. In June 2006, FDA asked ERF to provide the remainder of the study data initially requested and also offered to review pathology slides from the study. ERF did not submit additional data to FDA and did not agree to FDA's review of the pathology slides.

FDA could not conduct a complete and definitive review of the study because ERF did not provide the full study data. Based on the available data, however, we have identified significant shortcomings in the design, conduct, reporting, and interpretation of this study. FDA finds that the reliability and interpretation of the study outcome is compromised by these shortcomings and uncontrolled variables, such as the presence of infection in the test animals.

Additionally, the data that were provided to FDA do not appear to support the aspartame-related findings reported by ERF. Based on our review, pathological changes were incidental and appeared spontaneously in the study animals, and none of the histopathological changes reported appear to be related to treatment with aspartame. FDA believes that additional insight on the study findings could be provided by an internationally-sponsored pathology working group examination of appropriate tissue slides from the study.

Considering results from the large number of studies on aspartame's safety, including five previously conducted negative chronic carcinogenicity studies, a recently reported large epidemiology study with negative associations between the use of aspartame and the occurrence of tumors, and negative findings from a series of three transgenic mouse assays, **FDA finds no reason to alter its previous conclusion that aspartame is safe as a general purpose sweetener in food.** 

REF: CFSAN/Office of Food Additive Safety, April 20, 2007.



## **DPR Plans New Restrictions on 2 Fumigants, Offers More Public Input on Risk Decisions**

The <u>California Department of Pesticide Regulation</u> will impose new restrictions on <u>two fumigants</u> to prevent drift incidents and injuries in farm fields and neighborhoods.

By fall, DPR will put additional controls on metam-sodium and metam-potassium. Both pre-plant fumigants break down into a volatile gas that may cause eye and respiratory irritation. Several major drift incidents related to these chemicals have occurred in recent years.

"Strong efforts by our local partners, the County Agricultural Commissioners, have already reduced the number of incidents involving these fumigants," said DPR Director Mary-Ann Warmerdam. "Now we want to improve on that with new controls, based on a scientific foundation, that reinforce our 'zero tolerance' policy for pesticide injuries."

Warmerdam said the fumigant rules also would serve as pilot project for more public involvement in DPR risk management decisions. In the past, DPR issued local use recommendations to agricultural commissioners without formal public input. There is no statutory requirement to do so.

"The Schwarzenegger Administration wants fair and equitable environmental decisions," said Warmerdam. "People who hold an environmental and economic stake in pesticides deserve a voice in DPR's decision-making

process. We already consult with industry and environmental advocates. We've also launched an environmental justice project in a rural, agricultural community. Opening our risk management process is another logical step for an environmental agency that is responsive to public needs and concerns."

DPR will hold public workshops in May and accept written comments through June. The new restrictions will initially take the form of recommended permit conditions for County Agricultural Commissioners. That will allow implementation this year. Next year, DPR will put restrictions into formal, statewide regulations that are subject to public hearings.

More than 14 million pounds of metam-sodium was applied in California in 2004 and about 13 million pounds in 2005. Metam-potassium use totaled about 851,000 pounds in 2004 and 1.9 million pounds in 2005. The fumigants are used to treat weeds and other pests in vegetable fields before crops are planted.

New controls under consideration include:

- Extended buffer zones up to one-half mile, depending on application method, rate of application, acreage treated, and other factors.
- Special pre-application notification for sensitive sites (schools, homes, hospitals, farm worker housing)
  within 300 feet of the edge of a buffer zone; more restrictive controls on applications within one-quarter
  mile of sensitive sites.
- English and Spanish warning signs to warn workers in adjacent farm fields, if buffer zones extend into those fields.

Acreage and application rate limits on other fumigants will be addressed next month, when DPR proposes new rules for seven fumigants to meet clean air standards.

Tighter controls on metam-sodium and metam-potassium began with interim DPR permit conditions after drift incidents in the late 1990s. County Agricultural Commissioners also invoked their own permit conditions in recent years.

In 2004, DPR completed a risk assessment for MITC (methyl isothiocyanate), a breakdown chemical of metam-sodium and metam potassium. MITC may cause eye and respiratory irritation with brief exposure at relatively low levels.

DPR's risk assessment led the Department to support new measures to reduce the risk of acute exposures and illness. DPR decided to focus on soil injection and irrigation sprinkler uses, since they are the primary agricultural application methods. Other uses will be examined later.

#### **Public comment details:**

Workshop and comment sessions will be held May 30 at the Tulare County Agricultural Commissioner's Office, Agricultural Building Auditorium, 4437 South Laspina St., in Tulare. The first session runs from 1 to 3:30 p.m. and the repeat session from 7 to 9:30 p.m.

Written comments will also be accepted until June 30. Letters should be addressed to Linda O' Connell, DPR, P.O. Box 4015, Sacramento, CA 95812. Send e-mails to <a href="loconnell@cdpr.ca.gov">loconnell@cdpr.ca.gov</a>, or fax comments to 916-445-4280, attention Linda O' Connell.

For more on proposed permit conditions, see: <a href="www.cdpr.ca.gov/docs/dprdocs/methbrom/fum\_regs.">www.cdpr.ca.gov/docs/dprdocs/methbrom/fum\_regs.</a> htm#metamsodium

REF: http://www.cdpr.ca.gov/docs/pressrls/2007/070426.htm



#### **Avian Influenza and Food**

The highly pathogenic H5NI strains of avian flu which are transmitted from wild birds to domestic poultry are currently transmissible to humans only with great difficulty, as a result of close direct contact with live or dead infected birds. This is probably because the receptors for H5N1 in humans are deep in the lungs but not in the nose, throat or upper respiratory tract.

When H5N1 is present in poultry, the virus can be present in meat and eggs from affected birds. However, if poultry meat is handled with good hygiene and meat or eggs are properly cooked (the same precautions needed to avoid bacterial food poisoning) there is no risk to humans consuming them.

The worst case scenario for human health is if H5N1 mutates into a form which, while retaining its virulence, could attach to receptors in the nose, throat or upper respiratory tract. The mutated virus could then be more easily caught by humans and transmitted from human to human, leading to a global pandemic. Such an event could theoretically occur by genetic recombination if a person suffering from flu caused by a 'normal' human strain of influenza virus acquired an H5N1 virus, which itself had little capacity to infect humans. The World Health Organization, UN Food and Agriculture Organization, EU Commission and many national governments are making plans to try to avert or cope with such an eventuality.

Following poultry outbreaks of H5N1 avian flu in many countries, an outbreak of H5N1 at a turkey farm in the UK in early February 2007 has proved to be essentially identical to the strain that occurred in two flocks of geese in Hungary in late January 2007, and investigations have concluded that the most plausible vector was imported semi-processed raw turkey meat from Hungary; that there was no evidence that any meat entered the UK food chain from the restricted zones in Hungary; and that the risk to the health of the workers in the processing plant, or the wider poultry farm was very low.

Institute of Food Science and Technology The complete document can be downloaded from: <a href="http://www.ifst.org/uploadedfiles/cms/store/ATTACHMENTS/AvianInfluenzaandFood.pdf">http://www.ifst.org/uploadedfiles/cms/store/ATTACHMENTS/AvianInfluenzaandFood.pdf</a>

REF: Veterinary News, January-March 2007



#### **Annual Summary Calendar Year 2005**

This summary of results for 2005 is the 15th Annual Summary of the U.S. Department of Agriculture (USDA) Pesticide Data Program (PDP). In 1991, USDA was charged with designing and implementing a program to collect data on pesticide residues in food. The responsibility for this program was given to USDA's Agricultural Marketing Service (AMS).

**Results:** During 2005, PDP tested fresh and processed fruit and vegetables, soybeans, wheat, milk, heavy cream, pork, bottled water, and drinking water for various insecticides, herbicides, fungicides, and growth regulators. Of the 14,749 total samples collected and analyzed, 10,154 were fruit and vegetable commodities including apples, cantaloupe, cauliflower, eggplant, grapes, grapefruit, fresh and frozen green beans, lettuce, oranges and orange juice, pears, fresh and dried plums (prunes), strawberries, watermelon, and winter squash. PDP also tested 668 soybean (plus 306 for a soybean rust/aphid special survey), 674 wheat, 746 milk, 369 heavy cream, 704 pork, 378 bottled water, and 750 drinking water samples.

Excluding drinking water, approximately 84 percent of all samples tested were from U.S. sources, 14 percent were imports, 1 percent was of mixed origin, and approximately 1 percent was of unknown origin. Approximately 21 percent of the orange juice samples were of mixed national origin.

Overall, 73 percent of fresh fruit and vegetables and 61 percent of processed fruit and vegetables showed detectable residues. More residues were detected in fresh produce than in processed products and grains. Residues detected in dairy products and pork samples were primarily low level residues of unavoidable environmental contaminants, including DDE p,p' and dieldrin. Additionally, low levels of diphenylamine were detected in dairy products.

Excluding drinking water, 34 percent of samples tested contained no detectable pesticides [parent compound and metabolite(s) combined], 30 percent contained 1 pesticide, and 36 percent contained more than 1 pesticide. Low levels of environmental contaminants were detected in cantaloupe, cauliflower, green beans, heavy cream, lettuce, milk, pork, watermelon, and winter squash at concentrations well below levels that trigger regulatory actions.

Excluding samples for which no tolerances are set (bottled water and drinking water), residues exceeding the tolerance were detected in 0.2 percent of the 13,621 samples tested in 2005 – 25 samples with 1 residue each. A tolerance is the maximum amount of a pesticide residue allowable on a raw agricultural commodity. Established tolerances are listed in the Code of Federal Regulations, Title 40, Part 180. Residues with no established tolerance were found in 4.2 percent of the samples (570 samples with 1 residue each, and 2 samples with 2 residues each). In most cases, these residues were detected at very low levels and some residues may have resulted from spray drift or crop rotations. PDP communicates these findings to FDA when they are reported by testing laboratories.

In finished drinking water, PDP detected low levels (measured in parts per trillion) of some pesticides, primarily widely used herbicides. Forty-eight different residues were detected in the untreated intake water and 43 in the treated water. The majority of pesticides, metabolites, and isomers included in the PDP testing profiles were not detected. None of the detections in the finished water samples exceeded established EPA Maximum Contaminant Levels (MCL) or Health Advisory (HA) levels or established Freshwater Aquatic Organism (FAO) criteria.

This publication, the PDP database file for 2005, and annual summaries and database files for previous years are available on the PDP Website at:

http://www.ams.usda.gov/pdp

**REF**: <u>USDA/AMS</u> website



#### **♦ TOXICOLOGY TIDBITS ♦**

#### **FDA Safety Alerts**

FDA is warning consumers of the dangers of drinking raw milk, or milk that has not been pasteurized. Raw milk potentially contains a variety of harmful bacteria including *Salmonella*, *Listeria*, and *E. coli* O157:H7. Government figures show that between 1998 and 2005, unpasteurized milk was responsible for 1,007 illnesses, 104 hospitalizations, and two deaths.

REF: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01576.html



#### **U.S. FDA Press Release on Contact with Baby Turtles**

The Food and Drug Administration (FDA) is urgently reminding the public that contact with baby turtles can pose a serious health risk to infants, small children, and adults with impaired immune systems as they can be natural hosts to Salmonella, a group of bacteria that can cause severe illness and death. Recently, a four-week old infant in Florida died of infection traced to Salmonella pomona, a bacteria that was also found in a pet turtle in the home.

Salmonella is the genus name of a number of bacteria commonly associated with food poisoning from contaminated or undercooked foods, and salmonellosis is the disease the bacteria can cause. Salmonella can be found on the outer skin and shell surfaces of the turtles causing salmonellosis for those handling turtles without properly washing their hands after handling the animals.

#### FDA is reminding parents and others who care for children of the following:

- The sale of turtles with a shell less than four inches long is illegal. Exceptions to FDA's regulation include sales of these turtles intended for export only or for bona fide scientific, educational, or exhibitional purpose;
- Salmonella infection can be caused by contact with turtles in petting zoos, parks, child day care facilities and other locations; and
- It is important to wash hands thoroughly with soap and water after handling or touching turtles and their housing.

In the early 1970's, it was determined that pet turtles, particularly red-eared sliders, were responsible for an estimated 280,000 cases of salmonellosis each year in the United States. In 1975, FDA banned the sale of turtles with a shell less than four inches long as a necessary public health measure. FDA has repeatedly emphasized the risks of turtle-associated salmonellosis because of a resurgence in the sales of such turtles in the last four years. The public health impact of turtle-associated salmonellosis in humans is an estimated 74,000 cases in the United States per year.

Salmonella infection can be transmitted either directly from contact with the turtle or its feces, or indirectly through the

animal's water. Turtles with Salmonella usually do not appear to be sick. Their feces do not always contain the bacteria, therefore a single negative test does not prove they are Salmonella-free.

Although anyone can acquire a salmonellosis infection, the risk is highest in infants, young children, the elderly, and others with lowered natural resistance to disease. Pregnancy, cancer, chemotherapy, organ transplant, diabetes, and liver problems pose particular risks. Gastrointestinal symptoms following Salmonella exposure begin in 6 to 72 hours (usually 12 to 36 hours) and generally last for two to seven days.

For more information on FDA's regulation of turtles, please see the following: http://www.fda.gov/cvm/turtleregs.htm.

REF: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01604.html



#### Ag Health Study Examines Pesticide Exposure, Diseases

The Agricultural Health Study (AHS) is the largest, most comprehensive study of agricultural health conducted in the United States. Almost 90,000 people are participating in the Agricultural Health Study - about 31,000 from North Carolina and 59,000 from Iowa. Participants include certified private pesticide applicators (farmers) and their spouses in North Carolina and Iowa and certified commercial pesticide applicators (5,000) in Iowa only.

Another important feature of the Agricultural Health Study is that it is one of the largest health studies of rural women ever conducted. About 3% of pesticide applicators in the study are women (1,359). Over half of the farmers' spouses are active in farm work, including mixing and applying pesticides.

The credibility of this study and the resulting research findings are high. AHS results were first released in late 2005 and new information was released in late 2006 and March 2007. The study will continue for at least another 10 years. Some individuals have been participating in the study for more than 14 years.

#### **General Health Status of Agricultural Applicators**

Previous studies of agricultural health indicated that farmers are healthier than the general population in some respects. For example, they live longer and are less likely to die from heart disease. Farmers are less likely to die of some cancers such as lung, esophagus, bladder and colon, probably because farmers are more physically active and less likely to smoke. For example, in the general population 28% of males and 23% of females smoke, while among the pesticide applicators studied, 17% of males and 10% of females smoke.

#### **Data Collection on Study Participants**

When the applicators and spouses were enrolled, the study collected detailed information about their health, their lifestyles (smoking, drinking, etc.), and medical history through a series of surveys. Participants were asked details about their pesticide practices, application methods, use of personal protective equipment, crops and livestock raised and other safety practices. The surveys also asked participants about potential environmental exposures. Between Iowa and North Carolina, a large percentage of applicators and their families are participating: 83% of eligible private applicators enrolled, 74% of spouses enrolled and 47% of commercial applicators enrolled.

The study made three general comparisons. First, investigators are comparing applicators and spouses to people in the general population of Iowa and North Carolina to see if there are differences in the cancer rates. Second, scientists compared applicators or spouses who have cancer or other diseases to those who don't to see if there are pesticide exposure or other factors that may have contributed to the disease. Third, the scientists also are comparing applicators or

spouses using a particular pesticide to those not using it to see if there are any differences in the risk of cancer or other health problems. These comparisons can be made for types of farm exposures other than pesticides.

For the full report link to: <a href="http://cropwatch.unl.edu/archives/2007/crop6/ahs\_study.htm">http://cropwatch.unl.edu/archives/2007/crop6/ahs\_study.htm</a>

REF: Nebraska Crop Watch Newsletter (University of Nebraska), April 6, 2007



#### **Does FDA Have A Phone Number for Food Safety Information?**

**Yes.** For general food safety questions, call the FDA Food Safety Hotline at **1-800-723-3366**. If the situation is critical, phone FDA's **emergency number**, (301) 443-1240, which is staffed 24 hours a day.

However, if your questions involve **meat or poultry products**, call the U.S. Department of Agriculture's hotline at **1-800-535-4555**.

For more on food safety, see <a href="http://www.foodsafety.gov">http://www.foodsafety.gov</a>

REF: FDA News Digest, 2/12/07



### Joint News Release: FDA and USDA Determine Swine Fed Adulterated Product USDA to Compensate for Depopulation

The USDA Food Safety and Inspection Service (FSIS) and the U.S. Food and Drug Administration (FDA) notified State authorities that swine fed adulterated product will **not be approved to enter the food supply**. Based on information currently available, FDA and USDA believe the likelihood of illness after eating pork from swine fed the adulterated product would be very low; however, the agencies believe it is prudent to take this measure.

FDA determined that a shipment of rice protein imported from China was contaminated with melamine and melamine-related compounds. The product was imported during the week of April 2, 2007 by Wilbur-Ellis, an importer and distributor of agricultural products. The rice protein was used in the production of pet food and a byproduct was used to produce animal feed.

The contaminants in question include melamine and melamine-related compounds, including cyanuric acid, the combination of which is a potential source of concern in relation to human and animal health. Scientific research indicates that melamine alone, at detected levels, is not a human health concern. However, no scientific

data exist to ascertain the effects of combining melamine and melamine-related compounds. Therefore, a determination has not yet been made regarding the safety of the product.

Because the animal feed in question was adulterated, USDA cannot rule out the possibility that food produced from animals fed this product could also be adulterated. Therefore, USDA cannot place the mark of inspection on food produced from these animals.

USDA is offering to compensate producers who euthanize swine that were fed the adulterated product. USDA is authorized to use Section 32 funds to restore farmers' purchasing power. USDA is also offering the expertise and assistance of Animal and Plant Health Inspection Service (APHIS) personnel in carrying out depopulation activities, to ensure animals are euthanized and disposed of in accordance with Federal and State laws.

FDA and FSIS are coordinating with State authorities in eight states where the adulterated feed is known to have been purchased. Eight pork producers in the states of California, Kansas, North Carolina, New York, Oklahoma, South Carolina and Utah are known to have purchased the feed. These combined operations involve approximately 6,000 hogs. All of the animals are currently being held under state quarantines in CA, NC, NY and SC. In KS, OK and UT producers agreed to hold the animals until further notice. Authorities are also in contact with a feed mill in Missouri that might have received adulterated feed.

Pork and pork products derived from animals that were fed the adulterated product will also be destroyed. In CA and UT, pork from federally inspected plants is being held under FSIS direction. In SC, a state inspected plant is voluntarily holding swine that were fed the adulterated product. FSIS, FDA and state authorities are in the process of determining whether any meat from animals that were fed the adulterated product has entered commerce. If that has occurred, FSIS will work with states and industry to take the appropriate action.

FDA and FSIS are continuing the effort to trace the adulterated feed. If additional producers are identified who fed the adulterated product to animals, they will also be offered compensation by USDA for depopulation and disposal.

REF: FDA website, April 26, 2007



#### **ASPCA Dispels Common Misconceptions Related to Poisons**

The American Society for the Prevention of Cruelty to Animals reminds veterinarians and pet owners of the more common misconceptions related to poisons. The ASPCA reports the following:

**False**: If eaten poinsettias are deadly.

Poinsettia ingestions typically induce only mild to moderate irritation in the gastrointestinal tract of pets. Keeping the plant out of reach to avoid stomach upset is a good idea, but pet owners don't need to banish poinsettias from their homes for fear of a fatal exposure.

**False**: Swiffer WetJets contain an ingredient similar to antifreeze, and causes liver failure in dogs. When used according to label directions, the ingredients in Swiffer WetJets are safe around pets and will not cause liver damage at product concentrations. Despite a similar-sounding name, the propylene glycol n-butyl ether or propylene glycol n-propyl ether found in Swiffer differs substantially from ethylene glycol, the potentially toxic ingredient present in most antifreeze products, which can cause kidney, not liver, failure.

**False:** Salt can be used to induce vomiting.

It was once believed that giving pets a spoonful of salt was an effective means of making them regurgitate potentially harmful substances. However, salt is not a reliable emetic and could actually lead to a sodium ion poisoning if too much were ingested.

**True:** Macadamia nuts cause dogs to lose the use of their hind limbs.

Dogs that consume roughly one gram of macadamia nuts or more per pound of body weight can develop lethargy, vomit, or suffer from an increased body temperature, progressing to loss of coordination, tremors, and profound weakness primarily in the hind limbs. So far, dogs are the only species known to experience these effects. Usually these clinical effects resolve completely in 24 to 48 hours with minimal management.

**False:** Greenies pet treats are deadly to dogs, causing intestinal blockage when swallowed. Although the safety of Greenies remains controversial, the ASPCA reported that Greenies do not pose a higher risk for gastrointestinal tract obstruction compared with other edible chew products.

**True:** Pennies are poisonous if ingested.

United States pennies minted after 1982 contain 99.2% zinc (and 0.8% copper) by weight. Although an essential trace nutrient, zinc is a concern because ingestions of substantial amounts can cause damage to the kidneys, liver, red blood cells, and gastrointestinal tract. As a result of the high zinc content, pennies minted after 1982 are considered to be potentially toxic if swallowed.

To learn more, visit the ASPCA's Animal Poison Control center online at <a href="www.aspca.org/apcc.">www.aspca.org/apcc.</a>

REF: JAVMA, March 1, 2007.



#### **Mercury in Fish and Shellfish Brochure**

What You Need to Know About Mercury in Fish and Shellfish is a free brochure that offers advice to women who might become pregnant, women who are pregnant, nursing mothers and young children about what fish to avoid due to high mercury content. Developed by the Food and Drug Administration and the Environmental Protection Agency, the brochure also offers guidance on the nutritional benefits of fish and shellfish.

For more information, visit: www.cfsan.fda.gov

REF: Nutrition Perspectives, Jan/Feb 2007.



#### **Residential Misting Systems**

EPA's new Web fact sheet on outdoor residential misting systems, also known as mosquito misting systems, will help consumers decide if residential pesticide misting systems are appropriate for their home, understand safety precautions for using outdoor misting systems, find related information on a variety of methods for mosquito control, and understand the role of the EPA and state agencies in regulating misters. EPA developed this fact sheet because an increasing number of households have purchased timed-release outdoor residential misting systems to control mosquitoes and other insects around the home. However, advertisers, the media, and other sources sometimes provide information about misting systems that is difficult to understand or might conflict with other information. The new Web page describes outdoor residential misting systems and discusses the pesticides used in the systems, their safety and effectiveness, and the regulatory authority of EPA and state governments regarding misting systems. The Outdoor Residential Misting Systems fact sheet is available on EPA's Web site at: http://www.epa.gov/pesticides/factsheets/misting\_systems.htm

REF: Chemically Speaking, April 2007



## State Health Officer Advises Consumers Not to Eat Some Shellfish and Viscera of Sardines, Anchovies, and Crab from 5 Southern California Counties

Consumers should **not** eat sport-harvested species of bivalve (two-shelled) shellfish, sardines and anchovies or the organs, or viscera, of sport-harvested or commercially sold lobster or crab taken from the coast of **Los Angeles, Orange, San Luis Obispo, Santa Barbara and Ventura** counties because they may be contaminated with domoic acid, a naturally occurring toxin that can cause human illness, State Public Health Officer Dr. Mark Horton warned. **Dogs, cats, birds and other household pets are also susceptible to domoic acid poisoning and should not be fed these products.** 

The California Department of Health Services (CDHS) has detected elevated levels of domoic acid in sardines and mussels from the coast in these five counties. Other seafood, including bivalve shellfish such as oysters, clams and scallops and the viscera of anchovies, crab and lobster, have not been tested, but could also contain dangerous levels of toxin. Crab viscera is commonly known as "crab butter" and lobster viscera is called "tomally."

This advisory is in addition to the current quarantine on the sport-harvesting of mussels along the entire California coastline that took effect April 20.

Domoic acid was first identified in 1991 in samples of mussels, razor clams and other seafood at several locations along the Pacific Coast, including California. No known cases of human poisoning from this toxin are

known to have occurred in California. CDHS includes testing of domoic acid and other marine toxins in its biotoxin monitoring program.

Symptoms of domoic acid poisoning include vomiting, abdominal cramps, diarrhea, headache, disorientation, seizures and loss of short-term memory. Severe cases may be fatal or result in permanent short-term memory. Older individuals and individuals with impaired kidney function are more vulnerable to the toxic effects of domoic acid.

This warning does not apply to commercially caught bivalve shellfish, which are sold by certified harvesters and dealers and subject to frequent mandatory testing. State law prohibits the sale or offering for sale for human consumption of any clams, mussels, scallops or oysters, except by state-certified commercial shellfish harvesters or dealers. Shellfish sold by certified harvesters and dealers are subject to frequent mandatory testing.

For more information, consumers can call CDHS' toll-free "Shellfish Information Line," which includes updates on shellfish biotoxins and quarantines, at **1-800-553-4133**.

REF: California Department of Health Services Press Release, April 27, 2007.



#### Early Onset of Warm Weather Triggers an Early West Nile Virus Season

Unusually high temperatures throughout California in March triggered an earlier than normal start to the West Nile virus (WNV) season, State Public Health Officer Dr. Mark Horton warned today.

"Mosquitoes that carry West Nile virus are breeding earlier this year due to warm weather," Horton said.
"While no predictions can be made about the severity of West Nile virus this season, Californians should begin taking precautions to protect themselves from mosquito bites by eliminating all sources of standing water that can support mosquito breeding and applying insect repellent containing DEET."

WNV was first detected in California five years ago. So far this year, no human cases of WNV have been identified. However, the virus has been detected in mosquito pools, sentinel chickens or horses in eight counties: Imperial, Los Angeles, Orange, Riverside, Santa Clara, San Diego, Sonoma and Stanislaus.

In 2006, a total of 292 human WNV infections, including seven deaths, were reported in the 54 counties that detected WNV activity. Of the 58 horses that also tested positive for WNV, 24 died or were euthanized. WNV is transmitted to humans and animals through a mosquito bite. Mosquitoes become infected when they feed on infected birds.

Governor Arnold Schwarzenegger has invested a total of \$15 million over the last two years to enhance mosquito control efforts. This funding has supplemented the resources of existing mosquito control programs statewide and expanded efforts in areas of the state not covered to combat WNV. This investment in equipment and other products to control mosquitoes continues to benefit mosquito control efforts this year.

Horton reminded Californians of three simple ways to protect themselves from WNV:

- DEET Apply inspect repellent containing DEET, picaradin or oil of lemon eucalyptus according to label instructions. Repellents keep the mosquitoes from biting you. DEET can be used safely on infants and children 2 months of age and older.
- DAWN AND DUSK Mosquitoes that carry WNV bite in the early morning and evening so it is
  important to wear repellent at this time. Make sure that your doors and windows have tight-fitting screens
  to keep out mosquitoes. Repair or replace screens with tears or holes.
- DRAIN Mosquitoes lay their eggs on standing water. Eliminate all sources of standing water on your property, including flower pots, old car tires, rain gutters and pet bowls. If you have a pond, use mosquito fish or commercially available products to eliminate mosquito larvae.

California's WNV Web site – <u>www.westnile.ca.gov</u> – has been updated to make it easier for the public to find the latest information on WNV activity in the state. In addition to reporting all dead birds, Californians are encouraged to report dead tree squirrels, three types of which have tested positive for WNV in California: the Western Gray, Fox and Eastern Gray. The Web site also includes information on the most common birds found with WNV. Dead birds and squirrels can be reported on the Web site or by calling (877) 968-2473.

REF: California Department of Health Services Press Release, April 23, 2007.



#### **Avoiding RWIS While Swimming**

With spring and summer months and an increase in outdoor activities right around the corner, it is time to start thinking about swimming safety issues. Most people think first of concerns over children drowning in neighborhood pools or lakes, but there are also risks of illness from swimming in public areas. Illnesses caused by *E. coli* and other pathogens are often associated with foods such as undercooked meats and raw vegetables, but can also be spread by ingesting water that is contaminated with them. Illnesses caused by pathogen transmission in swimming pools are often referred to as recreational water illnesses, or RWIs, and become a concern especially for children and families who swim in public pools or lakes in the summer.

The Centers for Disease Control and Prevention (CDC) defines RWIs as illnesses spread by swallowing, breathing, or contacting contaminated water in swimming pools, hot tubs, lakes, rivers, or oceans. These illnesses can cause diarrheal, respiratory, skin, ear, and neurologic infections, although the most commonly reported RWI symptom is diarrhea. Since 1978, the CDC has collected information on RWI outbreaks in the United States. The most common causes of RWI outbreaks are *Cryptosporidium*, *E. coli*, *Giardia*, *Shigella*, and *Norovirus*, pathogens usually linked to contaminated foods.

The CDC has found that most outbreaks of diarrhea associated with swimming pools and lakes occur during the summer months, and that cases have increased since 1985. The 10 or so diarrheal illness outbreaks linked to public swimming pools each year are thought to be just the tip of the iceberg. Among the pathogens of concern, *E. coli* is sensitive to chlorine, and thus more often causes illness in lakes or other swimming areas where chlorine is not added. *Cryptosporidium*, however, is resistant to chlorine and can survive in chlorinated

swimming pools. When young children in diapers, especially those with diarrheal illness, swim in public areas, these pathogens can contaminate the water and spread to others who accidentally swallow swimming water.

As part of the ongoing research about RWIs, the CDC has interviewed parents about the safety risks of swimming, and has found that most are not aware that swimming can cause illness through ingestion of contaminated water. Many parents indicated that they believe a pool is safe and clean when they smell chlorine at around the pool area. Some pathogens, however, can live for hours or even days in chlorinated pools, even those that are well-maintained. Because swimming is a very popular warm-weather activity especially for children, parents indicated in the interviews that they would like to have better education and more information about RWIs and how they are spread.

The CDC has responded by providing detailed information about swimming risks and illness prevention, targeted towards the general public and available at the CDC website. These recommendations to promote healthy swimming are outlined as "PLEAs" for both swimmers and parents of young children.

#### The "PLEAs" for swimmers are:

- Please don't swim when you have diarrhea.
- Please don't swallow the pool water, and avoid getting water in your mouth.
- Please practice good hygiene.

#### The three "PLEAs" for parents are:

- · Please take your kids on bathroom breaks or check diapers often.
- Please change diapers in a bathroom and not at poolside.
- · Please wash your child thoroughly with soap and water before swimming.

The CDC encourages parents to use these guidelines and to consider RWIs as much a part of safe swimming education as the prevention of drowning and swimming-related injuries. RWI illness prevention becomes most important now, as the summer months and swimming weather draw near.

REF: Colorado State University Cooperative Extension Safefood News - Spring 2007, Vol 11 (3).





FARAD Public Access to be Closed Effective May 15th Due to Lack of Funding The members of the <u>Food Animal Residue Avoidance Databank [FARAD]</u> program reluctantly announce the suspension all interactive activities as of the end of business on Tuesday, May 15, 2007, due to lack of continued federal funding. FARAD has been funded through the USDA since 1982 on a yearly basis. The FARAD databases and staff will be maintained temporarily in the hope that stable and long term funding is obtained. Expert mediated extra label veterinary drug use advice will be discontinued and the toll-free number (1-888-US-FARAD) and web access will be unavailable.

In the event of a major food or feed contamination incident (like the melamine incident), FARAD will attempt to assist state and federal veterinarians with contamination mitigation if time and staffing allow.

(FARAD has worked behind the scenes duriung the "pet food crisis" to determine the possibility of residues in the food animals (swine and chickens) which were also exposed to melamine.)

**REF:** FARAD website



#### FDA Removes Hydrogen Peroxide from the List of Low Regulatory Priority Aquaculture Drugs

The Food and Drug Administration (FDA) is announcing today the removal of hydrogen peroxide from the list of Low Regulatory Priority Aquaculture Drugs identified in the Program Policy and Procedures Manual Guide 1240.4200 http://www.fda.gov/cvm/Documents/LRPDrugs.pdf.

FDA, under enforcement discretion, had previously not objected to the use of hydrogen peroxide to control fungi on all species and life stages of fish, including eggs; however, hydrogen peroxide is now the subject of an FDA-approved new animal drug application with the trade name 35% PEROX-AID <a href="http://www.fda.gov/cvm/">http://www.fda.gov/cvm/</a> <a href="http://www.fda.gov/cvm/">CVM\_Updates/perox-aid.htm</a>. Therefore, the only approved hydrogen peroxide product that can be used in fish production is 35% PEROX-AID. There is no longer any enforcement discretion for the use of hydrogen peroxide to control fungi on all species and life stages of fish, including eggs, or for its use to treat any other fish disease.

Aquaculture producers raising fish for human food consumption should not use drug compounds other than the approved product because it can be unsafe for your fish. In addition, the effectiveness of unapproved drug compounds is questionable.

The FDA is also reminding food animal producers to read veterinary drug labels carefully and follow label directions to help avoid causing illegal residues in their products.

REF: FDA website, May 2, 2007.



#### FDA Clarifies Extra-label Use of Medicated Feed in Minor Species Per CPG #615.115

FDA's Center for Veterinary Medicine (CVM) is clarifying the Compliance Policy Guide (CPG) section 615.115 entitled, "Extra-Label Use of Medicated Feeds for Minor Species" in order to ensure proper use of medicated feed in minor species. CVM has received a number of inquiries relative to the proper use of the CPG. The inquiries have revealed some common points of confusion regarding the appropriate interpretation of the principles specified in the CPG.

The following conditions, in addition to all other stipulations in the CPG, have to be satisfied in order to ensure proper use of medicated feed in minor species:

- **Veterinarian involvement.** Any extra-label use of medicated feed in minor species per this CPG requires involvement of a licensed veterinarian within the confines of a valid veterinarian-client-patient relationship. The veterinarian is expected to make a written recommendation for the extra-label use of medicated feed based on a recent diagnosis of an active disease for which no other drug treatment is approved.
- **Treatment only use.** Medicated feed may be considered for treatment only when the health of animals is threatened and suffering or death would result from failure to treat the affected animals.
- No production use. Extra-label use of medicated feed for production purposes is not allowed.
- No feed reformulation or relabeling. Once manufactured and labeled as approved for use in a major species, the feed cannot be either reformulated to meet nutritional needs of the intended minor species or relabeled as such.

Comments on the CPG may be submitted any time to: FDA's Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments should be identified with the full title of the CPG and Docket number 99D-2638.

REF: FDA website, May 4, 2007.



