Cooperative Extension --- University of California, Davis



Environmental Toxicology Newsletter

"Published Occasionally at Irregular Intervals"

~ Dr. Arthur L. Craigmill ~ Extension Toxicologist

Vol. 24 No. 3 -- November 2004

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Lead Poisoning from Ingestion of a Toy Necklace --- Oregon, 2003

Although ingestion of dust from lead-based paint is the most common source of lead exposure among children in the United States, lead also can be present in unsuspected objects. Ingestion of these objects can result in elevated blood lead levels (BLLs). This report describes an investigation by the Deschutes County Health Department and the Oregon Department of Human Services of lead poisoning in a boy who swallowed a medallion pendant from a necklace sold in a toy vending machine. The investigation resulted in a nationwide recall in September 2003 of the implicated toy necklace.

In July 2003, a boy aged 4 years was taken to a physician in Oregon after several days of abdominal cramping, vomiting, and diarrhea without fever. His symptoms resolved until 1-2 weeks later when he had another bout of vomiting and abdominal pain. He was returned to his physician, and his condition was diagnosed as probable viral syndrome and anemia of undetermined etiology. Two days later he was brought to the emergency department with worsening symptoms, including constipation and inability to eat or sleep because of his abdominal pain. An abdominal radiograph showed a metallic object in the stomach with no evidence of obstruction. Initially, the object was believed likely to pass on its own; however, on the next day, an abdominal computerized tomography showed the object more superiorly located. Endoscopy was performed, resulting in retrieval of a medallion pendant (along with a quarter) from the boy's stomach.

Three days later, the boy returned with edema of the left cheek and gingiva, suggesting either a dental abscess or excessive biting of the cheek. Concern that the cheek bite might have been caused by a seizure prompted testing of his BLL. The boy was admitted to the pediatric intensive care unit for intravenous chelation therapy. Subsequently, neurodevelopmental, cognitive, and speech therapy evaluations of the boy all showed appropriate development.

An environmental investigation of the boy's home, which was built in 1996, did not reveal any additional sources of lead exposure. A sibling, aged 6 years, had a BLL of <5 µg/dL.

The medallion retrieved from the boy's stomach was **reportedly purchased from a toy vending machine in Oregon**, approximately 3 weeks before it was retrieved. The state environmental quality lab found the **medallion's contents to be 38.8% lead** (388,000 mg/kg), 3.6% antimony, and 0.5% tin. Similar medallions purchased from toy vending machines in other areas of Oregon were found to have similar high proportions of lead (44% and 37%). These medallions are round, measuring approximately 7/8 of an inch in diameter, gray in color, with a symbol on one side. State health officials notified the U.S. Consumer Product Safety Commission; a national voluntary recall was announced on September 10, 2003, of approximately 1.4 million of the metal toy necklaces. A distributor of the medallions reported that they had been manufactured in India and distributed throughout the United States. Oregon health officials cautioned that more of the medallions might still be sold in vending machines in the state.

FIGURE. Medallions from recalled toy necklaces that were sold in vending machines in Oregon and linked to lead poisoning



Photo/Oregon Department of Human Services

REF: MMWR. June 18, 2004 / 53(23):509-511



Lead Poisoning Associated with Ayurvedic Medications Five States, 2000-2003

Although approximately 95% of lead poisoning among U.S. adults results from occupational exposure, lead poisoning also can occur from use of traditional or folk remedies. Ayurveda is a traditional form of medicine practiced in India and other South Asian countries. Ayurvedic medications can contain herbs, minerals, metals, or animal products and are made in standardized and nonstandardized formulations. During 2000-2003, a total of 12 cases of lead poisoning among adults in five states associated with ayurvedic medications or remedies were reported to CDC. This report summarizes these 12 cases.

Case Reports

New Hampshire. A woman aged 37 years with rheumatoid arthritis visited an emergency department (ED) with diffuse abdominal pain, nausea, and vomiting of 6 days' duration. Her blood lead level (BLL) was $81 \mu g/dL$ (geometric mean BLL = $1.75 \mu g/dL$ for U.S. population aged ≥ 20 years), and her zinc protoporphyrin (ZPP) concentration was $286 \mu g/dL$. (normal: $<35 \mu g/dL$). She reported ingesting five different traditional medications (two powders and three tablets) obtained from an ayurvedic physician in India for her rheumatoid arthritis. Analysis of the two powders revealed 17,000 and 12,000 parts per million (ppm) lead, respectively, and 60-100 ppm lead in the three tablets. She began oral chelation therapy; 1 week after completion, her BLL was $35 \mu g/dL$. Her two children, aged 6 and 7 years, had BLLs of 5 and 3 $\mu g/dL$. She reported restarting ayurvedic medications 2 weeks previously. She agreed to stop taking the medications, and her physician decided against chelation therapy.

California. A woman aged 31 years visited an ED with nausea, vomiting, and lower abdominal pain 2 weeks after a spontaneous abortion. One week later, she was hospitalized for severe, persistent microcytic anemia. A heavy metals screen revealed a BLL of 112 µg/dL; a repeat BLL 10 days later was 71 µg/dL, before initiation of oral chelation therapy. A ZPP measurement performed at that time was >400 µg/dL. Her husband's BLL was 6 µg/dL. No residential or occupational lead sources were identified, but the woman reported taking nine different ayurvedic medications prescribed by a practitioner in India for fertility during a 2-month period, including one pill four times daily. She discontinued the medications after an abnormal fetal ultrasound 1 month before her initial BLL. Analysis of her medications revealed 73,900 ppm lead in the pill taken four times daily and 21, 65, and 285 ppm lead in three other remedies. Her BLL was 22 µg/dL when she was tested 9.5 months after the initial BLL testing.

A man aged 34 years was evaluated twice in an ED for back pain and abdominal pain. A screen for heavy metals revealed a BLL of $80 \mu g/dL$. He was hospitalized for chelation therapy and disclosed that he had been taking ayurvedic medications prescribed by a practitioner in India to increase fertility. He had discontinued use the previous day. The 10 preparations included pills, powders, and syrups, most of which were not labeled. He had taken one type of tablet once daily for 3 months; samples of one of these tablets contained **78,000 ppm** lead. A second variety of pill contained 36 ppm lead. A home investigation revealed no other sources of lead. His BLL was 17 $\mu g/dL$ when tested 7.5 months after the initial BLL test.

Massachusetts, New York, and Texas. Nine additional cases were reported from Massachusetts, New York, and Texas. The median age of patients was 52 years; five patients were female. The five women were taking the medications for arthritis (one), menstrual health (one), and diabetes (three). The four men were taking the medications for arthritis (one) and diabetes (three).

EDITORIAL NOTE: Although the majority of cases of lead poisoning in adults result from occupational exposures, use of traditional or folk medications also can cause lead poisoning. In the United States, lead exposure in adults has decreased substantially during the preceding two decades because of removal of lead from gasoline and regulation of lead exposure in the workplace. Nevertheless, 10,658 cases of BLLs $\geq 25 \mu g/dL$ in adults (aged ≥ 16 years) were reported from the 35 states that provided data to the program in 2002. Certain traditional or folk medications used in East Indian, Indian, Middle Eastern, West Asian, and Hispanic cultures contain lead and other adulterants. In this report, the majority of persons affected were of Asian Indian or other East Indian descent. Several ayurvedic and other traditional medications do not contain lead; however, lead content has ranged from 0.4 to 261,200 ppm in certain common ayurvedic preparations. Certain branches of ayurvedic medicine consider heavy metals to be therapeutic and encourage their use in the treatment of certain ailments.

Symptoms of lead toxicity in adults often vary and are nonspecific; these include abdominal pain, fatigue, decreased libido, headache, irritability, arthralgias, myalgias, and neurologic dysfunction ranging from subtle neurocognitive deficits to a predominantly motor peripheral neuropathy to encephalopathy. The number and severity of symptoms typically increase as BLLs increase; however, the toxic effects of lead can occur without overt symptoms. Primary management of lead toxicity is source identification and exposure cessation. In adults, chelation therapy usually is reserved for patients with substantial symptoms or signs of lead toxicity or BLLs of >80 µg/dL.

Culturally appropriate educational efforts are needed to inform persons of the potential health risks posed by these remedies, particularly in populations in which traditional or folk medication use is prevalent. For remedies known to contain lead or to be possibly adulterated with lead, educational materials should state the potential health effects. Young children and fetuses of pregnant women are at added risk for the toxic effects of lead, particularly because of the use of these products to treat infertility in women.

REF: MMWR, July 9, 2004 / 53(26);582-584



Childhood Lead Poisoning from Commercially Manufactured French Ceramic Dinnerware New York City. 2003

Lead poisoning adversely affects children worldwide. During 1999-2000, an estimated 434,000 children aged 1-5 years in the United States had elevated blood lead levels (BLLs) \geq 10 μ g/dL. Glazes found on ceramics, earthenware, bone china, and porcelain often contain lead and are a potential source of lead exposure. Children are especially vulnerable to the neurotoxic effects of lead. Exposures to lead in early childhood can have adverse effects on the developing nervous system, resulting in decreased intelligence and changes in behavior. In addition, certain behaviors (e.g., thumb sucking) place children at greater risk for exposure to lead. In 2003, the New York City Department of Health and Mental Hygiene's Lead Poisoning Prevention Program (LPPP), and the Mount Sinai Pediatric Environmental Health Specialty Unit (PEHSU) investigated a case of lead poisoning in a boy aged 20 months. This report summarizes that case investigation, which identified ceramic dinnerware imported from France as the source of lead exposure. This case underscores the susceptibility of children to a toxic exposure associated with 1) the high proportion of time spent in the home and 2) dietary habits that promote exposure to lead leached from ceramic ware.

In July 2002, the patient's lead exposure was first identified when a routine lead screening at age 12 months revealed a BLL of 15 µg/dL, which exceeds CDC's level of concern (>10 µg/dL). Follow-up at age 15 months documented a BLL of 18 µg/dL. The child's

pediatrician provided guidance to the child's parents on lead hazards. A private environmental testing company confirmed the absence of lead-based paint in the family's home by using x-ray fluorescence. However, at age 18 months, the child's BLL increased to 23 µg/dL. In February 2003, LPPP completed a comprehensive investigation of the child's home and assessed the child's routine daily activities and physical environment and found no lead paint hazards, although concern was raised by an LPPP investigator about the ceramic dinnerware used regularly by the child. A home lead test was conducted by the family and revealed that the ceramic dinnerware was positive for lead.

In March 2003, the child was referred to Mount Sinai PEHSU for a secondary evaluation. A plate from the dinnerware also was submitted for evaluation, and PEHSU requested assistance from the Food and Drug Administration (FDA) to test the plate. The sample plate appeared to be in good condition and had no visible cracks or signs of wear. The plate was tested for lead by using an FDA protocol, whereby lead is extracted from the food contact surface. The ceramic plate released 29.6 μ g/mL of lead into the leaching solution, a level exceeding the FDA compliance guideline of <3 μ g/mL.

The child was home full time and consumed all meals and beverages using the dinnerware. Because of concerns about lead exposure to other family members, BLLs of the child's mother and grandmother also were assessed. Results for both were $<5 \mu g/dL$, substantially lower than the child's BLLs. The family was advised to discontinue use of the dinnerware. On follow-up at age 23 months, the child's BLL had decreased to $8 \mu g/dL$.

The particular brand of dinnerware identified in this investigation is no longer sold in the United States. However, plates of this brand are available online and might still be available for sale in discount stores, flea markets, and online auctions. Additional tests will be conducted on plates from the same manufacturer to determine the extent of the problem. A complete listing of dinnerware that has been restricted for importation into the United States is available at http://www.fda.gov/ora/fiars/ora_import_ia5208.html.

Editorial Note: When investigating lead poisonings, examining the most common sources of lead exposure (e.g., occupational exposures or lead-based paint) is a critical first step; after these sources are ruled out, other sources should be investigated. Traditionally, more concern has been raised about the presence of lead glazes in homemade ceramics than in manufactured dinnerware. The case described in this report illustrates how imported, commercially manufactured dinnerware also should be considered as potential sources of lead exposure.

Lead can leach out of ceramic ware when the glaze is improperly fired or when the glaze has broken down because of wear from daily usage, particularly after repeated use in a microwave or dishwasher. Chips and cracks in ceramic ware also allow leaching of lead. When lead is released into food and drink from ceramics, hazardous levels can contaminate food substances and expose children and adults to toxic levels. Children's risk for such exposures is compounded by their diets, especially their frequent consumption of acidic juices (e.g., orange and apple juices) that promote leaching of lead from ceramics.

REF: MMWR, July 9, 2004, 53(26).



Exploratory Data on Furan in Food

FDA has updated its data on the amount of furan found in food products. "The presence of furan is a potential concern because, based on high-dose animal tests, furan is considered possibly carcinogenic to humans." Full Notice

During investigations relating to review of a petition for the use of irradiation in certain foods, FDA scientists identified the substance furan in a number of foods that undergo heat treatment, such as canned and jarred foods. The presence of furan is a potential concern because, based on high-dose animal tests, furan is considered possibly carcinogenic to humans.

What consumers should understand

Consumers should not view the furan levels as an indicator of furan exposure, or as the "risk" of eating certain foods. First, furan levels alone do not equate to furan exposure requires consideration of both furan levels, and the amounts of food that consumers eat. Second, estimates of furan exposure take into account not single food items, but the wide variety of foods found in a range of diets. Third, the scope of data is too limited to properly consider potential sources of variation in measured furan levels, such as variability between different units or lots of food and the effect of consumer cooking practices on furan levels.

FDA is presenting this data to inform the public of its progress and to help stimulate research into the formation of furan in food. The results reflect furan levels detected in samples of individual food products. For more information link to: http://www.cfsan.fda.gov/~dms/furandat.html

REF: http://www.cfsan.fda.gov/~dms/furandat.html



Trichinellosis Associated with Bear Meat New York and Tennessee, 2003

Trichinellosis is a parasitic infection caused by tissue-dwelling *Trichinella* roundworms and is associated traditionally with ingestion of pork from infected domestic swine. As a result of improvements in swine production, trichinellosis has declined steadily in the United States. However, infection also can result from eating the meat of wild animals. During 1997-2001, a total of 72 cases of trichinellosis (median: 12 cases annually; range: 11-23 cases) were reported to CDC; the majority of these infections were associated with eating wild game, predominantly bear. This report describes three cases of trichinellosis associated with eating undercooked bear meat reported from New York and Tennessee in 2003.

Case Reports

New York. In December 2003, the New York State Department of Health was notified of a trichinellosis case in a man aged 54 years. The patient had been hospitalized in a tertiary care center in early November with a 3-week history of diaphoresis, fever, weakness, tachycardia, diarrhea, an 8-pound weight loss, and dry cough. The patient reported eating approximately 2 pounds of nearly raw bear meat during several meals 2 weeks before onset of symptoms. The meat had come from a custom slaughter house in upstate New York and

file:///CI/My%20Stuff/ucdnl/UCD2004/nltrNovember041.htm (4 of 16) [11/19/2004 11:10:15 AM]

had been frozen for approximately 1 week before ingestion. Because of suspicion of trichinellosis infection, albendazole and corticosteroids were administered. Weakness and fatigue persisted through late December 2003. The patient recovered fully by February 2004.

The New York State Department of Environmental Conservation (NYSDEC)'s Wildlife Pathology Unit recovered nine packages of bear meat from multiple bears from the patient's freezer and identified *Trichinella* spp. larvae in five of the seven packages examined. Muscle digestion with artificial gastric juice yielded 0.5-48.0 larvae per gram of bear meat. The remaining two packages of meat were examined by the U.S. Department of Agriculture (USDA), which identified *Trichinella nativa* by polymerase chain reaction (PCR).

Tennessee. In November 2003, the Tennessee Department of Health received a report of two cases of trichinellosis. In early October, a man aged 38 years and a woman aged 54 years were admitted to a hospital with 7-day and 14-day histories of fever, respectively, chills, headache, myalgias, arthralgias, and facial swelling. Serum obtained from both patients tested positive for *Trichinella* antibodies, and both were started on a course of albendazole and corticosteroids. Both patients have recovered fully.

Questioning of the patients revealed that, in late August 2003, the man had shot a black bear (*Ursus americanus*) in Canada. The bear was field dressed, and selected meat was packed on ice for transport to Tennessee. On August 31, the man and woman prepared and cooked the bear meat on an outdoor grill for themselves and four other persons. The man and woman ate their steaks medium rare; the four others ate their steaks well done. The remaining meat was packaged for storage in a household freezer, and the family continued to consume the meat during September.

Editorial Note: Undercooked wild game has emerged in recent years as a predominant source for infection with *Trichinella*. During 1997-2001, of the 52 (72%) U.S. cases in which a source of infection was known or suspected, pork products were associated with 21 (40%) cases, and wild game was associated with 31 (60%), including 29 cases linked to bear meat. In Canada, the majority of trichinellosis outbreaks during the previous three decades were attributed to eating meat from wild animals.

Increasing local bear populations combined with the popularity of bear hunting in the northeastern United States and Canada might contribute to increased cases of *Trichinella* infection. In 2003, in New York state, a record number of approximately 1,850 bears were reported killed by hunters. NYSDEC provides information about trichinellosis and proper cooking instructions for wild game with each bear-hunting license issued. However, the **meat from hunted animals often is given away and eaten by persons who are unaware of the need to cook the meat thoroughly enough to kill larvae.** Multiple exposures also can occur when bear meat is served at wild game parties. Whereas freezing at specified temperatures kills *T. spiralis* larvae in pork, *T. nativa* is a freeze-resistant species that remains viable after freezing, even for months or years. The three cases described in this report were the result of eating improperly cooked bear meat infected with *T. nativa*.

To prevent future cases of trichinellosis, health-education messages should target wild game hunters who are most at risk for *Trichinella* infection. Information on the parasite and proper cooking should be made available at points of wild game distribution, such as custom butchers and game meat processors. To prevent trichinellosis, **consumers should be advised to monitor for an adequate cooking temperature of 160 F** (71 C) and observe the color and texture of the meat during cooking. A change in color from red to dark gray throughout and a change in texture such that muscle fibers are easily separated from each other are indicators that meat has been rendered safe to eat. However, game meats such as bear are very dark, making interpretation of color changes difficult; for these, adequate cooking might be better judged by texture and temperature. **USDA recommends a higher temperature to allow for different cooking methods (e.g., microwave cooking) that might result in uneven temperature distributions throughout the meat.**

REF: MMWR, July 16, 2004 / 53(27);606-610



Surveillance Data from Public Spa Inspections United States, May-September 2002

Approximately 5 million public and private hot tubs, whirlpools, and spas are used in the United States. Extensive spa use combined with inadequate maintenance contribute to recreational water illnesses (RWIs) caused by pathogens such as *Pseudomonas* spp., *Legionella* spp., and *Mycobacterium* spp.. In the United States, local environmental health inspectors periodically inspect public spas to determine their compliance with local or state health regulations. During inspections for regulatory compliance, data pertaining to spa water chemistry, filtration and recirculation, and management and operations are collected. This report summarizes spa inspection data from six sites in the United States during May 1-September 1, 2002. The findings underscore the utility of these data for public health decision-making and the need for increased training and vigilance by operators to ensure high-quality spa water for use by the public.

Data from 5,209 inspections of spas were collected from the Florida Department of Health, Bureau of Water Programs (n = 4,463); the Los Angeles County Recreational Water Program, California (n = 588); the City of St. Paul Office of License, Inspections, and Environmental Protection, Minnesota (n = 53); the Wyoming Department of Agriculture (n = 49); the Allegheny County Department of Health, Pennsylvania (n = 35); and the St. Louis County Department of Public Health, Minnesota (n = 21). The sites selected were a convenience sample of spa inspection programs with computerized data available. The data were merged into a database, including date of inspection, water chemistry data (e.g., disinfectant residual and pH level), mechanical system data (e.g., operating filters and water turnover rates), and policy and management data (e.g., record keeping and operator training). A violation was noted when an inspection item was not in compliance with state or local regulations. Other inspection items (e.g., support facilities and injury control) were not addressed in this analysis.

A total of 5,378 violations were documented during the 5,209 inspections; 2,736 (52.5%) inspections occurred in spas for which the location (e.g., hotel or motel) was known. Approximately half (56.8%) of the inspections (2,958 of 5,209) had one or more violations (median: one; range: one to eight). Eleven percent (500 of 4,533) of inspections resulted in the immediate closing of spas, pending correction of the violation item(s). Water chemistry violations constituted 50.7% of all violations (2,725 of 5,378); followed by filtration and recirculation systems, 32.2% (1,732 of 5,378); and policy and management, 17.1% (921 of 5,378). Various violations for policy and management issues were documented; during inspections, 23.3% (162 of 695) of spa operators lacked required training, and 12.7% (654 of 5,153) had inadequate record keeping. For the 52.5% of inspections for which spa location could be ascertained, a range of violations occurred. For known locations collecting disinfectant residual data, the highest percentages of violations occurred in campgrounds (21.9%) and hotel/motel spas (19.6%). The percentage of inspections that documented pH level violations, which can compromise disinfectant efficiency, ranged from 14.1%-16.2% in known locations. Of those inspections that revealed violations that warranted spa closure, the highest percentages also were in campgrounds (15.1%) and hotel/motel spas (12.2%).

Editorial Note: Environmental health inspections can identify weaknesses in the management and inspection of spas. In this report, the proportions of spa inspections in violation of local ordinances (56.8%) or requiring immediate closure (11.0%) are similar to those documented for public swimming pools (54.1% and 8.3%, respectively). The inspections document a gap in the training of spa operators; more than 20% of spa inspections cited operators who had not received adequate training. These data emphasize that spa operators can protect the health of users by adhering to maintenance procedures and obtaining appropriate training; regular public health enforcement of these items is necessary. The findings also demonstrate the utility of maintaining spa inspection data in a computerized format that can be analyzed routinely and used to evaluate spa inspection programs.

Poor disinfectant and pH control, high temperatures that quickly dissipate disinfectant, small water volumes, poor hygiene, high bather loads, inadequate maintenance, and opportunities for environmental contamination of the water can lead to proliferation and to pathogen contamination in the spa environment. RWIs spread through spa use are typically skin and respiratory infections in contrast to gastrointestinal illnesses commonly associated with full-body recreational activities found in swimming pools. During 1999-2000, a total of 13 reported outbreaks of infectious diseases, affecting 183 persons, were attributable to public and private spa use.

The high temperature of water in spas makes them particularly vulnerable to depletion of disinfectant, which facilitates pathogen amplification. Pathogens such as *Pseudomonas* spp. can multiply rapidly when the disinfectant residual falls below 0.5 mg/L or the pH rises above 8.0. Pathogens also can reside in biofilm layers that form in spa pipes and surfaces, where they can be protected from disinfection, which necessitates routine scrubbing and maintenance to decrease biofilm formation. Because domestic acquisition of *Legionella* spp. appears to be travel-related, venues (e.g., campgrounds and hotels or motels) should pay particular attention to operator training and maintenance of their spas.

Additional information and health communication materials designed to reduce the spread of RWIs are available at http://www.cdc.gov/healthyswimming.

REF: MMWR http://www.cdc.gov/



NTP-CERHR Expert Panel Report on the Reproductive and Developmental Toxicity of Acrylamide

The National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) provides timely, unbiased, scientifically sound evaluations of human and experimental evidence for adverse effects on reproduction and development caused by agents to which humans may be exposed. Acrylamide was selected for expert panel evaluation because of recent public concern for human exposures through its presence in some prepared foods, especially starchy foods cooked at high temperatures, such as French fries and potato chips. Acrylamide is used in the production of polyacrylamide, which is used in water treatment, pulp and paper production, and mineral processing. Polyacrylamide is also used in the synthesis of dyes, adhesives, contact lenses, soil conditioners, cosmetics and skin creams, food packaging materials, and permanent press fabrics. Acrylamide is a known health hazard. It has been shown to induce neurotoxicity in highly exposed workers and in cases of acute poisoning. In animal studies, exposure to acrylamide has been shown to cause cancer and adverse effects on reproduction and fetal development.

Expert Panel Conclusions:

- 1. Considering the low level of estimated human exposure to acrylamide derived from a variety of sources, the Expert Panel expressed negligible concern for adverse reproductive and developmental effects for exposures in the general population.
- 2. The Expert Panel expressed minimal concern for acrylamide-induced heritable effects in the general population. The Expert Panel recognizes that dose-response information for these effects is limited.*
- 3. Recognizing the broad range of occupational exposure estimates for acrylamide, the occurrence of neurotoxicity in some occupational settings, and the concurrent expression of neurotoxicity and reproductive toxicity in some experimental animal studies, the Expert Panel expressed some concern for adverse reproductive and developmental effects, including heritable effects, for exposures in occupational settings.
- 5.5 Critical data needs are defined as tests or measurements that could provide information to substantially improve an assessment of human reproductive and developmental risks. The items listed below under exposure and effects are considered by the Panel as critical data needs:

Section 1: Chemistry, Use and Human Exposure

- Occupational exposures need to be better defined, especially for high-exposure groups.
- The linkage between external exposure and hemoglobin and sperm adduct concentrations needs to be carefully assessed in humans. Research is needed to reconcile the discrepancy between estimates of exposure based on adducts in the general smoking and non smoking population and estimates of exposure based on dietary exposures.
- Subpopulation differences in exposures need to be characterized, especially ingestion of high contamination foods by young adults.
- Research is needed to explore susceptible subpopulations based on metabolic genotypes for enzymes involved in the metabolism of acrylamide.

Section 2: Developmental Toxicity

• There are no critical data needs for developmental toxicity. Acrylamide has been examined in two species using multiple routes of administration, and no further studies are recommended.

Section 3: Reproductive Toxicity

- A study to identify biologically relevant adducts and their relationship to reproductive toxicity by techniques such as the use of knock-out mice for CYP2E1 is needed to determine the role of acrylamide metabolism in genetic damage.
- A study is needed to define dose-response relationships for heritable alterations in male germ cells; direct assays of germ cells are preferable to breeding studies.
- A reproductive epidemiology study in occupationally exposed male workers to determine the relationship between external exposure and internal biomarkers of exposure, male reproductive health, including direct assays of sperm integrity, and neurobehavioral effects.
- * Drs. Dale Hattis and John Favor did not concur with the Expert Panel's "minimal concern" for heritable effects in the general population. Drs. Hattis and Favor concluded that a higher level of concern, i.e., some concern, was justified based on the expectation that a portion of the acrylamide-induced genetic damage in germ cells could exhibit a linear dose-response relationship at low exposure levels. Because of ubiquitous acrylamide exposure to the general population, such a linear component of the dose response could, in their judgment, produce appreciable numbers of adverse effects.

REF: National Toxicology Program, US Department of Health and Human Services, http://cerhr.niehs.nih.gov/news/acrylamide/final_report.pdf, June 2004



Illness Associated with Drift of Chloropicrin Soil Fumigant into a Residential Area - Kern County, California, 2003

Chloropicrin is the fourth most commonly used soil fumigant in California. Exposure to chloropicrin causes eye and respiratory tract irritation, vomiting, and diarrhea. This report describes an investigation by the California Department of Pesticide Regulation (CDPR) and the Kern County Agriculture Commissioner (KCAC) into illnesses associated with the offsite drift of chloropicrin in Kern County. A total of 165 persons experienced symptoms consistent with chloropicrin exposure. The findings underscore health risks associated with fumigants and the usefulness of procedures adopted in California to ensure both prompt identification of exposure events and timely notification of the affected public.

On October 3, 2003, an agricultural pest control service began applying 100% chloropicrin at a concentration of 80 pounds/acre to 34 acres of fallow land in Kern County. Chloropicrin was injected 17-18 inches into the soil; a weighted board was used to compact the soil,

treating 18 acres. That evening, residents living one quarter mile west of the application site experienced irritant symptoms. The Kern County Fire Department (KCFD) was contacted to investigate; however, darkness, distance from the treated field, and absence of chloropicrin odor prevented firefighters from identifying the source of the irritation. Records from a weather station approximately 7 miles southeast of the application site indicated low wind speeds and stable atmospheric conditions but also that the wind direction had changed that evening, blowing from the field toward the residential dwellings.

The next day, chloropicrin was applied to the remaining 16 acres. A 60-foot, chloropicrin-free buffer was maintained around the perimeter of the field because workers noted a persistent odor when they arrived. Residents one quarter mile west and south of the field complained about irritant symptoms that evening. Residents notified KCFD; several responding firefighters experienced eye irritation. The wind had changed again that evening and begun blowing from the field toward the residential dwellings. Suspecting a pesticide release. KCFD notified KCAC. The field was recompacted, and the odor ceased.

On October 6, KCAC notified CPDR about the incident. KCAC and CDPR conducted in-person interviews at 35 households located approximately one quarter mile west and south of the field and at a day care center; additional interviews were conducted on October 15. The 35 households and day care center had a total of 172 persons present during the exposure period. Representatives from each household and the day care center were interviewed by using a standardized questionnaire. In addition, five workers involved with the fumigation were questioned informally, and KCFD records were reviewed to identify affected firefighters.

The investigation determined that 165 persons reported symptoms compatible with illness caused by chloropicrin; median age of the persons was 16 years (range: 3 months-63 years). Nearly all (99%) had irritant symptoms (e.g., eye or upper respiratory); nine (5%) received medical evaluations. Seven had persistent respiratory symptoms when interviewed 11 days after the event. Follow-up medical care was limited because most of the affected persons lacked health insurance.

Exposures were retrospectively estimated by using a standard air dispersion model. Estimated 1-hour average chloropicrin air concentrations in areas south and west of the field ranged up to 0.20 parts per million (ppm). Peak-to-mean extrapolations indicated that peak concentrations might have exceeded 1 ppm. The Occupational Safety and Health Administration permissible exposure limit and the National Institute for Occupational Safety and Health (NIOSH)-recommended exposure limit is 0.10 ppm averaged during 8 hours. However, extrapolations from animal studies suggest 0.0044 ppm as a safe level for a 1-hour environmental exposure.

According to KCAC, a possible cause of the offsite drift was failure to contain the chloropicrin adequately after applications. After the incident, KCAC imposed new restrictions on chloropicrin applications, including prohibition of applications within one quarter mile of an occupied structure and mandatory use of a heavy-duty tarp or water seal for applications within one half mile of such structures.

The findings in this report are subject to at least two limitations. First, this report is limited by an imprecise estimate of reported cases. Some affected persons likely were not interviewed, leading to an underestimation. Conversely, false-positive cases cannot be excluded because some self-reported symptoms might not have been related to exposure. Second, environmental measurements were not conducted to confirm chloropicrin exposure.

Adequate chloropicrin containment measures are needed to prevent similar community outbreaks. In addition, when outbreaks occur, measures are needed to prevent the community distress that arises when government authorities do not provide timely information regarding the emergency response and follow-up investigation findings. In 2003, CDPR developed procedures to respond to incidents involving offsite drift of pesticides. This approach might be useful in other jurisdictions where offsite pesticide drift can occur.

REF: MMWR, Volume 53, No. 32, August 20, 2004



DPR Announces Regulations for Methyl Bromide Use

The California Department of Pesticide Regulation announced new methyl bromide regulations to limit levels of the fumigant that may remain in the air for several weeks. These new "seasonal exposure" rules for methyl bromide are the first in the nation, and they take effect immediately.

The regulations enhance health protection for workers and others who may potentially be exposed to multiple applications over several weeks. DPR has found no imminent health hazard to communities from seasonal exposures to methyl bromide in recent years, based on air monitoring of high-use areas.

The new regulations give DPR and County Agricultural Commissioners authority to "ensure that ambient air concentrations of methyl bromide do not exceed an average daily non-occupational exposure of nine parts per billion (9 ppb) in a calendar month." This air standard includes a 100-fold margin of safety and is based on a large body of scientific data. Until now, there has been no subchronic (seasonal) exposure regulatory standard for methyl bromide anywhere in the United States.

A seasonal daily average of 9 ppb equates to use of about 270,000 pounds of methyl bromide within a township (six-square-mile area) in one month. In recent years, no township in California has reached that poundage level, based on pesticide use reports.

The 9 ppb standard will be maintained through the use of buffer zones, strict application methods, and, if necessary, limits on use. DPR plans to hold a workshop to refine its methods for determining use limitations.

As approved by the state Office of Administrative Law, the rules also strengthen and clarify DPR restrictions on farm field fumigations first imposed in 2000. Some specific provisions:

- -- In addition to mandatory buffer zones, anyone who lives within 300 feet of a buffer zone perimeter shall receive advance notice of the fumigation.
- -- When a school property is within 300 feet of a buffer zone perimeter, a fumigation must be completed at least 36 hours before school goes into session.
- -- Fumigation work restrictions are clarified to include supervisors, and include requirements for respirators, as well as limited work hours and workdays.

DPR previously adopted regulations aimed at limiting short-term (24-hour) exposures to methyl bromide in the air to no more than 210 ppb. While maintaining that short-term standard, the seasonal (four-to-eight-week) standard of 9 ppb addresses average daily exposures for children or other individuals deemed most sensitive. The seasonal standard for adults is an average daily exposure of 16 ppb. (One part per billion is equivalent to one second of time in about 32 years, or one drop of liquid in a full tanker of a gasoline delivery truck.)

At public hearings on the seasonal exposure regulations, some industry advocates argued for exposures levels of up to 36 ppb for children and 64 ppb for workers, based on a single study. Environmentalists favored a 1 ppb level for seasonal exposures. DPR's risk assessment had already concluded that 1 ppb was acceptable for long-term (chronic) exposures.

DPR based its decisions on numerous scientific studies and extensive air monitoring conducted since the early 1990s. DPR scientists completed a risk assessment for methyl bromide in 1999 and sent their scientific document to the National Academies of Science (NAS) for review and comment. A NAS panel endorsed DPR's findings for short-term exposure action levels.

In 2000, DPR imposed new regulations for methyl bromide that included buffer zones, advance notification for field fumigations, and other protections. The rules were based on the 210 ppb standard for short-term exposures. No regulatory action level was set for seasonal file:///Cl/My%20Stuff/ucdnl/UCD2004/nltrNovember041.htm (7 of 16) [11/19/2004 11:10:15 AM]

exposures, due to a lack of data indicating seasonal exposure risk.

When additional air monitoring showed seasonal air levels that sometimes exceeded an average of 1 ppb per day, DPR scientists then began to review data and assess the need for additional regulatory safeguards. The NAS panel supported DPR's approach. The panel also recommended an additional toxicology study to establish subchronic (seasonal) action levels for methyl bromide exposure.

DPR's methyl bromide regulations have been the subject of lawsuits by both environmental and agricultural interests. To resolve that litigation, DPR agreed to reassess the regulations' potential economic impact on farmers, and to consider seasonal exposure standards. The rules imposed in 2000 were readopted as emergency regulations, pending approval of the new rules that just went into effect.

DPR pesticide use reports show methyl bromide applications in California fell from more than 15 million pounds in 1999 to 6.5 million pounds in 2002. Factors contributing to the decline include increasing DPR restrictions, use of other fumigants, research on less-toxic alternatives supported by DPR, the U.S. Environmental Protection Agency, the University of California, and industry; and reductions mandated by the federal Clean Air Act.

For the text of DPR's regulations, see www.cdpr.ca.gov/docs/legbills/recntadop.htm

REF: Department of Pesticide Regulation News, November 4, 2004.



♦ TOXICOLOGY TIDBITS ♦

New Foodborne Illness Guide

Americans' vulnerability to foodborne illness has been highlighted by large outbreaks in recent years. To increase awareness, an updated educational guide for health care professionals on how to identify, treat, and prevent foodborne illnesses, as well as consumer tips for patients, has been prepared by a group of professional associations and government agencies.

The free, easy-to-read guide, **Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health Care Professionals**, is a revision of a publication originally done in 2001. The updated version contains five new sections on new and remerging foodborne illnesses, as well as charts, scenarios, and a continuing medical education section.

After microbes that produce illness are swallowed, they pass through the stomach into the intestine, attach to the cells lining the intestinal walls, and begin to multiply. According to the Centers for Disease Control and Prevention (CDC), some types of microbes stay in the intestine, some produce a toxin that is absorbed into the bloodstream, and some can directly invade the deeper body tissues. The symptoms produced, including diarrhea, abdominal cramps, and nausea, depend greatly on the type of microbe. It is rarely possible to say which microbe is likely to be causing a given illness unless laboratory tests are done to identify the microbe, or unless the illness is part of a recognized outbreak.

"Recent concerns about hepatitis A and norovirus outbreaks have emphasized the need for health professionals to be vigilant for foodborne pathogens, and this need is further emphasized by concerns about intentional contamination of food," says David Acheson, M.D., director of the Food Safety and Security Staff at the FDA's Center for Food Safety and Applied Nutrition.

More than 75 percent of foodborne illness deaths are caused by just three pathogens: salmonella, listeria, and toxoplasma. Greater understanding of foodborne illnesses by nurses and other front-line health care providers is also important for early detection. Collaborators on the primer include the American Medical Association (AMA), American Nurses Association-American Nurses Foundation, the CDC, the FDA's Center for Food Safety and Applied Nutrition, and the U.S. Department of Agriculture's Food Safety and Inspection Service.

Health care professionals can request a free copy of the primer by visiting the AMA Web site. Consumer tips on food safety also are available at this site.

REF: FDA Consumer Magazine, July-August 2004



Lead Contamination in Candy

Some Mexican candy sold in the United States has been associated with lead contamination, and the FDA is advising that it would be prudent to not allow children to eat these products. The health effects of elevated lead levels in children are well documented and can result in learning deficiencies and delayed mental and physical development.

The FDA has compiled information indicating that candy containing significant amounts of chili powder may contain higher lead levels than other types of candy, such as candy that contains predominantly sugar. Examples of chili-containing products include lollipops coated with chili and chili seasoning sold in packets as a snack item. The FDA believes that contamination of chili powder may be occurring at certain steps in the manufacturing process. Also, tamarind, a popular Mexican candy item, can become contaminated with lead if it is sold in poorly made glazed ceramic vessels that release lead from the glaze into the candy. The FDA will be working with Mexican government and industry personnel on this issue and plans to establish more stringent guidance for considering regulatory action against candy containing lead.

REF: FDA Consumer Magazine, July-August 2004



FDA Alerts Consumers About Adverse Events Associated With "Permanent Makeup"

The Food and Drug Administration (FDA) is alerting the public to a number of reported adverse events associated with individuals who have undergone certain micropigmentation procedures, a form of tattooing, used to apply "permanent makeup" for lip liner, eyeliner, or eyebrow color. The adverse events are associated with certain ink shades of the Premier Pigment brand of permanent makeup inks, which are manufactured by the American Institute of Intradermal Cosmetics, doing business as Premier Products, in Arlington, TX. FDA is currently investigating this matter.

To date, FDA has been made aware of more than 50 adverse events and is investigating additional reports sent to the manufacturer. Reactions that have been reported include swelling, cracking, peeling, blistering, and scarring as well as formation of granulomas (chronically inflamed tissue mass associated with an infection) in the areas of the eyes and lips. In some cases, the effects reported caused serious disfigurement, resulting in difficulty in eating and talking.

In July 2003, the manufacturer reported to FDA its intent to remove five of its ink shades from the market, based on six adverse events that had been reported. However, FDA has obtained additional reports of adverse events involving ink shades that were not included in the firm's removal effort. While the investigation continues, FDA is alerting consumers about associated adverse event reports received about Premier Products ink shades identified on the FDA website at: http://www.cfsan.fda.gov/~dms/cos-tat2.html.

FDA considers intradermal tattoos (including permanent makeup) cosmetics and considers the pigments used in the inks to be color additives requiring premarket approval under the Federal Food, Drug, and Cosmetic Act. However, FDA has not traditionally regulated tattoo inks or the pigments used in them. The actual practice of tattooing is regulated by local jurisdictions.

As FDA continues its investigation, the agency urges consumers and healthcare providers to continue to report adverse reactions from tattoos, including permanent makeup, to FDA as well as to state and local health authorities. Contact information for your nearest FDA district office is available online at http://www.fda.gov/ora/fed_state/Small_business/sb_guide/regions.htm and in the blue pages of your local phone directory. Reports of adverse reactions may be reported also to FDA's Emergency Operations Center at 301-443-1240 or Center for Food Safety and Applied Nutrition (CFSAN) Adverse Events Reporting System (CAERS) at (301) 436-2405 or email at <a href="https://cxeecs.org/center-cen

For related information, see Tattoos and Permanent Makeup http://www.cfsan.fda.gov/~dms/cos-204.html.

REF: FDA website T04-20, July 2, 2004



New Surgeon General's Report Expands List of Smoking-Related Diseases

A new report on smoking and health released by U.S. Surgeon General Richard H. Carmona, M.D., M.P.H., shows for the first time that smoking causes diseases in nearly every organ of the body. Published 40 years after the surgeon general's first report on smoking-which concluded that smoking was a definite cause of three serious diseases-this newest report finds that cigarette smoking is conclusively linked to many other diseases and conditions.

"We've known for decades that smoking is bad for your health, but this report shows that it's even worse than we knew," Carmona said in releasing the report in May 2004. "The toxins from cigarette smoke go everywhere the blood flows."

According to the report, smoking kills an estimated 440,000 Americans each year. On average, men who smoke cut their lives short by 13.2 years, and female smokers lose 14.5 years. The economic toll exceeds \$157 billion each year in the United States-\$75 billion in direct medical costs and \$82 billion in lost productivity.

In 1964, the surgeon general's report announced medical research showing that smoking was a definite cause of cancers of the lung and voice box (larynx) in men and chronic bronchitis in both men and women. Later reports concluded that smoking causes other diseases, such as cancers of the bladder, esophagus, mouth, and throat; cardiovascular diseases; and reproductive effects.

The new report, titled *The Health Consequences of Smoking: A Report of the Surgeon General*, expands the list of illnesses and conditions linked to smoking. The new illnesses are cataracts, pneumonia, acute myeloid leukemia, abdominal aortic aneurysm, stomach cancer, pancreatic cancer, cervical cancer, kidney cancer, and periodontitis.

Statistics indicate that more than 12 million Americans have died from smoking since the 1964 report of the surgeon general. Another 25 million Americans alive today will most likely die of a smoking-related illness.

REF: www.surgeongeneral.gov



Alcohol-Attributable Deaths and Years of Potential Life Lost --- United States, 2001

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Excessive alcohol consumption is the **third leading preventable cause of death in the United States** and is associated with multiple adverse health consequences, including liver cirrhosis, various cancers, unintentional injuries, and violence. To analyze alcohol-related health impacts, CDC estimated the number of alcohol-attributable deaths (AADs) and years of potential life lost (YPLLs) in the United States during 2001. This report summarizes the results of that analysis, which indicated that approximately 75,766 AADs and 2.3 million YPLLs, or approximately 30 years of life lost on average per AAD, were attributable to excessive alcohol use in 2001. These results emphasize the importance of adopting effective strategies to reduce excessive drinking, including increasing alcohol excise taxes and screening for alcohol misuse in clinical settings.

To read the full article link to: www.cdc.gov

REF: MMWR, September 24, 2004 / 53(37);866-870



Recent Health Warnings from the California Department of Health Services

West Nile Virus has Spread to 48 of California's 58 Counties

West Nile virus (WNV) has been detected in seven more counties and the number of Californians who have tested positive for the virus has climbed to 249, including a Los Angeles County man who died, State Public Health Officer Dr. Richard Joseph Jackson announced. The number of deaths in California from WNV infections is now six.

"Even though West Nile virus has not been detected yet in all 58 counties, the evidence shows that it is widespread in California and we all need to be vigilant about avoiding mosquito bites," Jackson said. "In addition to personal protection, I encourage all Californians to eliminate sources of standing water in their yards that support mosquito breeding and avoid mosquito-infested areas at dusk and dawn when mosquitoes are most active."

A Merced County man tested positive for the virus in August, which was the first evidence of the virus in that county. In addition, tests of dead birds this week confirmed that WNV has spread to Madera, Napa, Nevada, Siskiyou and Trinity counties. The virus was also detected for the first time in Colusa County after a horse tested positive.

Of the six Californians who have died from WNV infections, three were from Los Angeles County, two from San Bernardino County and one from Orange County. WNV infections were reported in the following counties: San Bernardino, 96; Los Angeles, 81; Riverside, 51; Orange, eight; Kern, four; Fresno, two; and one each in Butte, Imperial, Lassen, Merced, Tulare, Ventura and Yolo. WNV human infections also were reported for the first time this week in Butte and Lassen counties.

WNV has also infected 122 horses, of which 60 have died. Since horses are susceptible to WNV and a vaccine for horses is available, horse owners are advised to contact their veterinarians about timely vaccinations.

Most individuals who are infected with WNV will not experience any illness. Up to 20 percent of individuals will have only mild to moderate symptoms, such as fever, headache and body aches. Less than 1 percent of individuals will develop serious neurologic illness such as encephalitis and meningitis. The elderly and those with lowered immune systems are more susceptible to serious illness.

WNV is generally transmitted to humans and animals through a mosquito bite. Mosquitoes become infected when they feed on infected birds. Individuals can reduce their risk of mosquito-borne diseases by taking these precautions:

- · Avoid spending time outside when mosquitoes are most active, especially at dawn and the first two hours after sunset.
- When outdoors, wear long pants and long-sleeved shirts.
- Apply insect repellent containing DEET according to label instructions.
- Make sure that doors and windows have tight-fitting screens. Repair or replace screens that have tears or holes.
- Eliminate all sources of standing water, which can support mosquito breeding.
- Contact your local mosquito and vector control agency if there is a significant mosquito problem where you live or work, especially if you know of abandoned swimming pools or spas.

The state's current interagency surveillance system for WNV includes testing of dead birds, mosquitoes, sentinel chickens, horses and people. Jackson asked the public to assist in the extensive monitoring effort for the virus by reporting any crows, ravens, magpies and jays that have been dead for less than 48 hours. Reporting can be done online by visiting the West Nile virus Web site at: http://www.westnile.ca.gov/. Individuals should take note of the bird's location and condition before reviewing the Web site for further instructions, including assistance with identifying the type of bird found. Birds with signs of decomposition or maggot infestation are not acceptable for testing. While there is no evidence that people can get WNV from handling live or dead infected birds, individuals should not attempt to catch or handle them. If the local agency is unable to pick up the bird, individuals should use gloves, a shovel or newspaper to put it in a plastic bag and place it in the trash. Priority for bird testing is being given to those areas where WNV has not yet been detected.

For the year to date, WNV has been found in 1,726 dead birds, 616 "pools" of mosquitoes and 263 sentinel chickens.

The current surveillance program to monitor for WNV in California has been established by the California Department of Health Services (CDHS) in collaboration with the University of California, Davis, California Department of Food and Agriculture, local mosquito and vector control districts, local health departments and other state and local agencies.

For more information about WNV in California or to report dead birds online, visit CDHS' Web site at http://www.westnile.ca.gov/.

REF: Issued: August 20, 2004

State Health Department Advises Consumers About Lead in Seasonings Imported from Mexico

State Public Health Officer Dr. Richard Joseph Jackson warned that lead has been found in four seasonings imported from Mexico: Lucas Limon, Lucas Acidito, Super Lucas and Super Jovy Chili Powder.

Lead from food and other environmental sources accumulate in the body. Elevated levels of lead can cause serious health problems, but even relatively low levels can cause learning disabilities and behavioral problems in children, Jackson said.

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Testing by the California Department of Health Services (CDHS) found that the products contained levels of lead that exceed the federal and state regulatory standard of 0.5 parts per million (ppm) for candy. There is no regulatory health standard for lead levels in seasonings.

CDHS, which detected the lead in the products during random testing of 172 samples of candies, gums and candy ingredients/seasonings, has shared its findings with the U.S. Food and Drug Administration (FDA) and will be working with the manufacturers and FDA to reduce the level of lead in these products. The results are on CDHS' Web site at http://www.dhs.ca.gov/fdb/

The lead analysis results of the four individual brands of seasonings are:

- Lucas Limon 0.039 ppm, 0.16 ppm, 0.48 ppm, 0.53 ppm, 0.56 ppm, and 1.1 ppm lead.
- Lucas Acidito 0.23 ppm, 0.36 ppm, 0.50 ppm, and 0.56 ppm lead.
- Super Lucas 0.13 ppm, 0.39 ppm, 0.58 ppm, and 0.93 ppm lead.
- Super Jovy Chili Powder 0.47 ppm, and 0.63 ppm lead.

Lucas Limon is packaged in a 0.87-ounce cylindrical container with a green label, with a prominently displayed logo of a goose head wearing glasses on top of a yellow circle. Lucas Acidito is packaged in a 1.5-ounce cylindrical container with a prominently displayed logo of a goose head wearing glasses on top of a purple circle. Super Lucas is packaged in a 1.2-ounce cylindrical container with a red label, with a prominently displayed logo of a goose head wearing glasses on top of a yellow circle. Super Jovy Chili Powder is packaged in a 1.2-ounce cylindrical container with a red label and red cap. These products can be found in small markets and flea markets throughout California.

Pregnant women and the parents of children who may have consumed any of these products and are concerned about their exposure to lead should consult with their physician or health care provider about the need for a blood lead test.

For more information about lead poisoning, parents and caretakers should contact their local childhood lead prevention program or local public health department. Additional information and a list of local childhood lead prevention programs are available at DHS' Web site at: http://www.dhs.ca.gov/childlead. The California Childhood Lead Poisoning Prevention Branch can also be reached at (510) 622-5000 for a list of these programs.

REF: California Department of Health Services Warnings Issued: August 4, 2004



EPA Has Released a List of Pesticides With the Agency's Evaluation of Their Potential to Cause Cancer

Carcinogenicity is difficult to predict because many factors are involved, and animal data do not conclusively show what will happen in humans. Because of the uncertainties, pesticides are placed in groups, such as "carcinogenic to humans," "possible human carcinogen," "not likely to be carcinogenic," and "insufficient data." The EPA is still in the process of standardizing the language, so you may notice some variety in the specific terminology.

Here are the categories for some commonly used pesticides.

Captan (fungicide) – probable human carcinogen Carbaryl (insecticide) – likely to be carcinogenic to humans Chlorpyrifos (insecticide) – evidence of non-carcinogenicity for humans DEET (insect repellent) – not classifiable as to human carcinogenicity Glyphosate (herbicide) - evidence of non-carcinogenicity for humans

You will find the whole list here http://www.pestmanagement.rutgers.edu/

REF: Georgia Pest Management Newsletter, August 2004/Volume 27, No. 8



National Pesticide Medical Monitoring Report

The 2003 Annual Report from the National Pesticide Medical Monitoring Program (NPMMP) states that the majority of inquires (68%) related to residential use of pesticides. They received 318 inquiries and 51% were for information purposes only. Seventy-five percent of the inquires dealt with exposure to adults. The majority of exposure routes were inhalation and dermal. When a certainty index was used only 3% of the actual pesticide exposures were deemed probable with 52% possible and 41% classified as unlikely.

The majority of inquires resulted from pyrethroid (47%) and organophosphate (33%) insecticides. Insecticides represented about 55% of the inquires, herbicides 16%, repellents 7.5% and wood preservatives 7%. DEET and chlorpyrifos were the two most reported inquires with permethrin the third most inquired pesticide.

Seventy percent of the inquires had a Severity Index of "Low Severity" with 24% "Moderate Severity" and 5% High Severity involved early entry into a tobacco storage that was under fumigation with magnesium phosphide. Another involved a

female applying a concentrated formulation of chlorpyrifos to a basement. The product was reportedly given to her by an acquaintance (landscaper). The product was reportedly labeled for outdoor use and the woman applied the product in her bare feet.

Of the herbicide inquires, the majority occurred in the residential environment (lawn & garden applications). Eighty percent of the inquires involved adults. 2,4-D and Glyphosate were the most inquired about.

To read the entire report link to: NPMMP 2003 Annual Report

REF: Pesticide Reports (Oklahoma State University), July 2004





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EPA has released the "Supplemental Guidance on Interpretation of Revised Chromated Copper Arsenate (CCA) Wood Preservative Label." This document clarifies allowed and not allowed uses of CCA. It also provides a reference table with the American Wood Preservers Association Commodity Standards related to CCA, with examples of some of the uses that are permitted and disallowed since the December 31, 2003, voluntary cancellation date.

EPA has a Fact Sheet on the disposal of CCA-treated wood. According to EPA, CCA-treated wood can be disposed of with regular municipal trash (i.e., municipal solid waste, not yard waste). Do not burn it or use it as a mulch or in compost. EPA does not believe there is any reason to remove or replace CCA-treated structures, including decks or playground equipment.

The entire guidance on CCA-treated wood is provided to stakeholders, regions, consumers, public interest groups, wood treaters, and registrants with a reference tool that supplements the product labeling to better identify the specific uses of CCA-treated lumber are permitted or disallowed. It also references enforcement and compliance strategies drafted by the Office of Enforcement and Compliance so that all affected parties will be aware of the Agency's position regarding compliance monitoring, targeting inspections, and reporting tips and compliants. (Source: EPA Program Update 6/18/04 and web site)

REF: The Label, 16(8), August, 2004.



Pet reptiles pose salmonella risk

A University of Michigan study published in the Sept. 1 issue of Clinical Infectious Diseases was cited as finding that young children have a greater risk than older children of contracting salmonella from pet reptiles and of developing serious -- and potentially fatal -- complications from the infection.

The study noted reptiles caught in the wild and bought at a pet store often carry salmonella bacteria, which can cause diarrhea.

The story explains that the researchers studied salmonella reports received by the Michigan Department of Community Health between January 2001 and June 2003, and found that nearly 12 percent of salmonella cases in children up to age 5 were reptile-related.

Diet, susceptibility and the lower amount of bacteria required to infect these young children may explain why they are more likely to contract salmonella when they handle turtles, lizards and snakes.

Study author Dr. Eden Wells was cited as saying in a prepared statement that parents with pet reptiles at home need to make sure they wash their hands thoroughly after handling the reptiles to avoid transferring salmonella bacteria to their children and that if the children handle the reptiles, they need to be taught to wash their hands thoroughly.

Reptile pets should not be allowed to roam freely in the house and their enclosures should be kept clean.

The U.S. Centers for Disease Control and Prevention recommends that reptiles not be kept in homes with children under age 5 or in homes with people who have impaired immune systems.

REF: FSnet, September 4, 2004.



Aspartame and Its Effects on Health

The European population of 375 million consumes about 2000 tonnes annually of aspartame (NutraSweet®) an artificial sweetener, which contains two amino acids -- aspartic acid and phenylalanine. It is 180-200 times sweeter than sucrose, and almost half a million extra tonnes of sugar would therefore be needed to generate the same sweetness. Was the world screaming for all this sweetness, and what has it done to us? Anyone searching the web on aspartame, launched in 1982 by Monsanto, the manufacutrer of NutraSweet®, will find a vast catalogue of frightening personal accounts attributing multiple health disasters to exposure to aspartame. Although no orchestrated public outcry about aspartame has taken place, much sensationalist journalism has been published mostly on websites. In contrast, aspartame marketing implies that it embodies a healthy way of life and avoids obesity. Are these claims of hazards and benefits supported by evidence?

To read this entire article link to: British Medical Journal

REF: BMJ 2004;329:755-756 (2 October).



FDA Warns Consumers About Risks Associated With Unpasteurized Juice

The Food and Drug Administration today reminded consumers of the dangers associated with drinking unpasteurized fruit and vegetable juices. This warning follows reports that the New York State Departments' of Health and Agriculture and Markets, and local health departments in northern New York are investigating a recent foodborne disease outbreak possibly linked to the consumption of unpasteurized apple cider.

Under FDA regulations, most juice processors are required to use Hazard Analysis and Critical Control Point (HACCP) principles to increase the protection of consumers from illness-causing microbes and other hazards in juices. But not all juice that consumers purchase comes from a facility for which HACCP is required.

In light of this outbreak, FDA would like to remind consumers that there are health risks associated with drinking juice or cider that has not been treated in any way to kill harmful bacteria. Such products may be sold in bottles or by the glass in supermarkets, at farmers markets, at roadside stands, or in some juice bars. Untreated products that are sold in bottles are generally displayed on ice or in refrigerated cases and are required to carry the following warning statement on their label:

WARNING: This product has not been pasteurized and therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

Untreated products that are fresh squeezed and sold by the glass are not required to carry the warning label statement.

FDA advises consumers that, when in doubt, look for this warning statement on bottled juice and ask if fresh squeezed juice has been treated in a way to kill bacteria.

Consumers who do not wish to risk illness from consumption of raw juices should not drink unpasteurized juices. If you cannot determine if a juice has been processed to destroy harmful bacteria, either don't drink it or bring it to a boil in an open container to kill any harmful bacteria that may be present.

For additional information visit, http://www.cfsan.fda.gov.







Antimicrobial Resistance of Escherichia coli

A recent study published in the Journal of the American Veterinary Medical Association titled: "Antimicrobial Resistance of Escherichia coli Strains Isolated from Urine of Women with Cystitis or Pyelonephritis and Feces of Dogs and Healthy Humans" had an interesting conclusion:

"Conclusions and Clinical Relevance: Results suggest that dogs are unlikely to be an important external reservoir of antimicrobial-resistant *E coli* strains causing infections in humans. On the contrary, the data suggest that dogs conceivably could acquire resistant *E coli* strains from humans."

REF: JAVMA, 225(3), August 1, 2004



Safeguards Strengthened Against Mad Cow Disease

The FDA and the U.S. Department of Agriculture (USDA) have taken three actions to strengthen existing safeguards that protect consumers against the agent that causes bovine spongiform encephalopathy (BSE), also known as "mad cow disease."

In July 2004, the FDA published an interim final rule (IFR) that prohibits the use of certain materials from cattle that could carry the BSE-infectious agent in human food, dietary supplements, and cosmetics. These high-risk materials, known as "specified risk materials" (SRMs), include the brain, skull, eyes, and spinal cord of cattle 30 months of age or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age. Also prohibited are materials from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef.

This IFR, in conjunction with IFRs issued by the USDA in January 2004, will minimize human exposure to materials that may put people at risk for a disease similar to BSE called variant Creutzfeldt-Jakob disease (vCJD). Scientific studies have demonstrated that SRMs could contain the BSE agent when derived from cattle that are harboring the BSE agent. Consumption of products contaminated with the agent that causes BSE is the likely cause of vCJD in people. This rule was effective immediately, but the FDA was accepting comments until Oct. 12, 2004, for consideration before publishing a final rule.

In a second action, the FDA published a proposed rule requiring manufacturers and processors of human food, dietary supplements, and cosmetics derived from certain cattle materials to maintain records showing that prohibited materials are not used in their products.

Finally, the USDA and the FDA jointly published an advance notice of proposed rulemaking (ANPR) requesting comments and scientific information on additional measures to help prevent the spread of BSE. In the ANPR, the FDA is requesting comments on potential new controls on animal feed, including:

- removing SRMs from all animal feed, including pet food, to control the risks of cross contamination throughout feed manufacture and distribution, as well as on the farm
- requiring dedicated equipment or facilities for handling and storing feed and ingredients that may contain prohibited material during manufacturing and transportation, to prevent cross contamination
- prohibiting the use of all mammalian and poultry protein in feed for ruminants (such as cows, sheep, and goats), to prevent cross contamination
- prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

The FDA's current animal feed rule, which became effective in 1997, helps prevent the establishment and spread of BSE through feed in the United States. FDA and state investigators inspect animal feed firms to ensure compliance with the rule. According to the inspection results of July 17, 2004, among companies handling material prohibited in feed for ruminants, compliance rates remain greater than 99 percent.

For more information, visit: www.fda.gov/oc/opacom/hottopics/bse.html or www.fsis.usda.gov/oa/topics/bse.htm.

REF: FDA Consumer September-October, 2004.



MUMS Legislation

The goal of "The Minor Use and Minor Species Animal Health Act of 2004" (MUMS) legislation is to provide incentives to pharmaceutical companies to develop drugs for limited uses and to provide some alternative approaches to the usual drug approval process for limited-use animal drugs, thus changing the economic outlook for the drug approval process. The new law provides some flexibility in getting limited-use drugs to market.

Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs and cats) that are needed for diseases that have limited geographic range or affect a small number of animals. Minor species includes all animals other than the major species, which includes zoo animals, ornamental fish, parrots, ferrets and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, catfish and honeybees.

The Center for Veterinary Medicine (CVM) was charged to develop policies, regulations or legislative options to facilitate drug availability for MUMS by a provision of "The Animal Drug Availability Act" of 1996.

Key provisions

The new law will modify provisions of the Federal Food, Drug and Cosmetic Act in three ways.

- Conditional Approval: An expensive part of the drug approval process for companies is demonstrating that a drug is effective. Drug companies typically collect data from various clinical trials. Under MUMS, the sponsor of a veterinary drug can ask CVM for "conditional approval," which allows the sponsor to make the drug available before collecting all necessary effectiveness data, but after proving the drug is safe. The drug sponsor can keep the product on the market for up to five years, through annual renewals, while collecting the required effectiveness data. The revenue the product generates during this period will help the company defray the cost of collecting the data. After the sponsor has completed the effectiveness component, the sponsor can present that component to CVM for full approval of the product. Under MUMS, FDA may refuse to renew the conditional approval if the company is not making sufficient progress toward collecting the effectiveness data.
- Indexing: In some cases, the potential market for a minor species drug is just too small to ever support the costs of the drug approval process, even under a conditional approval. The population may not be suitable for use in clinical studies because the animals are rare or valuable. In such cases, FDA now may add the drug to an index of legally marketed unapproved new animal drugs. After FDA determines that a drug could be eligible for listing on the index, the drug sponsor will use outside experts to review all of a drug's available safety and effectiveness information. The panel will provide a report to FDA/CVM of its findings so that the Agency may determine whether the drug should be placed on the index list. This provision will be especially helpful to veterinarians treating zoo or endangered animals or classes of animals that include several different species, such as ornamental fish. This provision will not be used for food animals with the exception of some early life stage uses, such as fish eggs. This provision would apply only to drugs for minor species, and not to minor uses of drugs in major species.
- Designation: This aspect of the legislation is similar to the "Orphan Drug Act" for humans, which helps pharmaceutical firms develop drugs for limited human uses. It provides incentives for approval. Grants to support safety and effectiveness testing will be available. Companies who gain approval for designated new animal drugs will be granted seven years of marketing exclusivity, which means the sponsor will face no competition in the marketplace for that use of the drug for that time.

Other provisions: The new law authorizes CVM to establish an office of Minor Use and Minor Species Animal Drug Development, which will be responsible for designating minor use and minor species animal drugs, administering grants, reviewing minor species drug index listing requests and serving as liaison to all parties involved with minor use or minor species drug development.

REF FDA Veterinarian, July/August 2004



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