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Carbon Monoxide Poisonings Resulting from Open Air Exposures to Operating Motorboats
Lake Havasu City, Arizona, 2003

During February 1997-August 2002, two fatal and six nonfatal cases of carbon monoxide (CO) poisoning occurred in vacationers who were wading in or boating near the Bridgewater Channel of Lake Havasu (Lake Havasu City [LHC], Arizona). The vacationers were near operating motorboats, primarily in the channel area, where large numbers of boaters congregate during holiday weekends. One person had a carboxyhemoglobin (%COHb) level of 40% on
autopsy. Follow-up environmental surveys were conducted during June-September 2003. This report summarizes the findings of these surveys, which documented excessive CO exposure and confirmed the health risk among vacationers and employees working in the channel near crowded motorboat gatherings.

Among 46 nonsmoking vacationers, the estimated %COHb increased from a mean of 1% in the morning to 11% in the afternoon. Among 16 smoking vacationers, the average estimated %COHb increased from 3% in the early afternoon to 13% in the late afternoon. The maximum estimated %COHb level among vacationers was 23% for nonsmokers and 26% for smokers.

Since the initial investigation in September 2002 (Labor Day weekend), one fatal and four nonfatal, hospital-treated CO poisonings involving loss of consciousness have occurred among channel vacationers, with %COHb levels ranging from 19% to 47%. One poisoning occurred on the back of a boat; the other four (including the fatality) occurred while persons were wading near boats in the channel.

**Ambient Air Monitoring**

During June 26-September 9, 2003, meteorologic conditions and CO concentrations were measured at fixed locations on the banks of the channel, on police and fire boats operating in and near the channel, and on police four-wheel, all-terrain vehicles patrolling the east and west banks of the channel. Concentrations in the channel and nearby onshore were higher (maximum 8-hour averages of 20-40 ppm at a typical onshore site) on the holiday weekends, when many boats were in the channel. Concentrations were highest when wind speeds were lower and temperatures were higher. Concentrations declined considerably with distance from the channel. The highest CO concentrations occurred in the late afternoon and early evening, usually during 5-9 p.m., when wind speeds typically decreased.

**Editorial Note:** The surveys described in this report document excessive CO exposures in employees and excessive and fatal CO exposures in vacationers amid large numbers of boats. The surveys also document substantial CO exposures in the late afternoon during crowded boating conditions, mirrored by elevations in expired CO concentrations among employees and vacationers. The majority of LHC employees had estimated %COHb levels indicating the potential for adverse health effects. Vacationers tested had higher %COHb levels than employees. These results indicate that elevated % COHb levels can occur among persons in open, outdoor settings. Previously described outdoor boat-related poisonings involved dangers to occupants of individual boats (e.g., houseboats and ski-boats).

Persons in communities with lakes and rivers where boats congregate in large numbers should be aware of the dangers of open air, boat-related CO poisoning and the need to evaluate CO exposures during high-traffic periods. Boat manufacturers should improve emission controls to reduce consumer CO exposure. The risk for boat-related CO poisonings should be reduced by considering measures such as limiting the number of boats in certain areas; enforcing a "no idle" policy when boats are stationary; and warning vacationers of 1) the signs and symptoms of CO poisoning; 2) the hazards related to occupying the back of the boat any time the motor is running; and 3) the risk for CO poisoning in areas of boat congestion, especially during calm weather conditions.
FDA Releases Acrylamide Data and Final Acrylamide Action Plan

The Food and Drug Administration (FDA) has released new data on acrylamide levels in more than 750 new food samples. These data expand the agency's ability to assess the extent to which this chemical is present in the food supply and its public health impact. In addition, the FDA has made available the final version of its action plan to evaluate the risk associated with acrylamide and examine ways to potentially reduce levels of acrylamide in food.

The chemical acrylamide was reported in food in April 2002 by Swedish scientists. Acrylamide is a natural byproduct in certain carbohydrate-rich foods that forms when these foods are fried, baked, or roasted at high temperatures. Although initial reports of acrylamide's presence in some foods raised concerns because of possible links with increased risk of cancer in some laboratory animals, it was largely unknown how pervasive it was in the food supply, and its true public health significance for humans.

To date, Acrylamide is known to cause cancer and reproductive problems in animals at high doses and is a neurotoxin in humans at high doses. Based on the current understanding of the science, FDA continues to advise consumers to eat a balanced diet, choosing a variety of foods that are low in trans and saturated fat and rich in high fiber grains, fruits and vegetables.

Since 2002, FDA has released an Action Plan to guide activities on acrylamide; performed research in the areas of methodology, toxicology, and acrylamide formation; and periodically released new data on acrylamide levels in food.
These new data results almost triple FDA's database of acrylamide levels in food. The new data are consistent with previous findings showing higher levels of acrylamide in potato-based and other carbohydrate-rich products processed at high temperatures and lower levels of acrylamide in dairy foods and infant formulas. The novel finding in the most recent sampling is the presence of acrylamide in black olives, prune juice and Postum, a powdered beverage.

"Acrylamide is an issue that FDA has followed very closely and has made rapid progress in understanding the science," said FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D. "The action plan and the new samples illustrate FDA's proactive stance with the issue of acrylamide in food, which until recently was relatively unknown in foods."

FDA is expanding its acrylamide testing program and plans to conduct tests on approximately 40 new infant formula samples. Although results from other infant formula samples tested by FDA indicated the products contain no acrylamide or trace amounts of acrylamide, the FDA will conduct further tests because of the importance of formula as a sole source food for many infants.

Most of the new data were taken from samples used as part of the FDA's FY03 Total Diet Study (TDS) survey. The TDS is an ongoing FDA program that determines levels of various contaminants and nutrients in more than 200 core foods (ready-to-eat) in the U.S. diet. Foods are collected from grocery stores and fast food restaurants and prepared table ready (i.e., cooked if required by TDS recipe) for analysis. Looking at the level of acrylamide in these foods will more accurately assess exposure to the U.S. consumer.

The final version of the Action Plan for Acrylamide in Food reflects the progress of research on acrylamide at FDA and the recommendations from a 2003 Food Advisory Committee meeting. In response to the committee's recommendations, the action plan contains more details about planned toxicology and epidemiology studies, risk communication activities, and coordination of acrylamide research. Specifically, the action plan addresses details on study timelines; the rationale for the use of brand-name data versus blinded data; and plans to incorporate factors such as ethnic and geographic groups into future exposure assessments.

FDA will share its expanded insights on acrylamide with the scientific community through the publication. In contribution to the acrylamide research community, the FDA is also citing publication of two recent research papers on FDA's methodology for measuring acrylamide and analytical issues associated with measuring acrylamide in coffee, a technically challenging food matrix. In addition, FDA's National Center for Toxicological Research (NCTR) has completed the first two of a series of studies, to support FDA's risk assessment, in its research initiative on acrylamide toxicology.

For More Information

The FDA's updated data on acrylamide in food based on the most recent Total Diet Study results [www.cfsan.fda.gov/~dms/acrydat2.html](http://www.cfsan.fda.gov/~dms/acrydat2.html)

A summary of the FDA's action plan on acrylamide [www.cfsan.fda.gov/~lrd/pestadd.html#acrylamide](http://www.cfsan.fda.gov/~lrd/pestadd.html#acrylamide)

None of the following cases resulted in death, although most victims required medical treatment. (State privacy law protects their identities.) Most cases occurred in 2001 and 2002 and were compiled by DPR's Pesticide Illness Surveillance Program. In no particular order, the "top 10" are:

1. A Contra Costa homeowner discovered sewer rats were entering his home through a toilet. He bought an incendiary device intended for gophers and other burrowing pests, and dropped it down a plumbing vent on his roof. The device melted a plastic elbow in the pipe and the roof caught fire, causing $80,000 in damage before firefighters could extinguish the blaze.

2. A Riverside County woman set off four foggers in her 1,000-square-foot apartment (about three cans more than the recommended application) and left the residence (as the label instructed), only to reenter several times to pick up things she had forgotten. She began to experience dizziness, nausea, and cramps, so she called 911. Upon arrival, a paramedic attempted to retrieve the fogger without wearing a respiratory protection device, and he too became ill.

3. In Stanislaus County, a 38-year-old woman found a home remedy for head lice on the Web. She then applied eight ounces of dog flea-and-tick shampoo and olive oil to her scalp, and wrapped her head in cellophane for five hours. Her scalp began to itch and burn. She felt shaky and also experienced nausea and drooling.

4. In San Joaquin County, a 23-year-old man spotted a fly on his beer can, and sprayed an insecticide on the can. Later, as he drank from the can, his lips began to tingle.

5. An 18-year-old Lassen County resident sprayed half a can of outdoor-use insecticide in his bedroom, then went to sleep. He awoke with nausea, vomiting, dizziness, sweating, abdominal cramps, diarrhea, and other symptoms. He denied his sister's allegation that he was sniffing the insecticide.

6. A Placer County man was spraying his yard with the insecticide diazinon when he stopped for a chew of tobacco, placing the wad into his mouth with an unwashed hand. He began vomiting, salivating, and experienced shortness of breath.

7. A Sonoma County apartment resident sprayed three aerosol cans of lice treatment on his bed, then went to sleep. He awoke the next morning with a headache, nausea, and vomiting. He did not read or follow the product label directions and told investigators he assumed the more he used, the more effective it would be.

8. In Los Angeles County, a woman diluted bleach in a cup to clean it, then forgot about it and went to bed. The next morning, she warmed the cup of liquid and took a sip before remembering the cup contained bleach. In a similar incident, a Sonoma homeowner left a cup of bleach solution that she had used for cleaning on her bathroom counter. She got up at midnight and drank from the cup. Her throat began to burn and she vomited.
9. A Tuolumne County homeowner tried to kill a spider in a cupboard by spraying it with insecticide. The woman then stuck her head in the cupboard to determine if the spider was dead. She began coughing and vomiting from the fumes. In a similar case, a San Joaquin County, a man stuck his head inside a cupboard to determine if the insecticide he had sprayed on ants was working. He developed a mild headache, dizziness, and respiratory symptoms.

10. A San Francisco physician over-treated his closet with mothballs. When he wore clothes from the closet, he began to feel dizzy, nauseated, and suffered loss of muscular coordination. The first time, he recovered in fresh air. The second time, he went to an emergency room and was hospitalized overnight to rule out a stroke before the problem was traced to excessive mothball fumes.

REF: DPR news release: April 5, 2004 (04-06)

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OEHHA Publishes Health Goal for Arsenic in Drinking Water

The California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment (OEHHA) announced the publication of a final Public Health Goal (PHG) for arsenic in drinking water.

The PHG identifies 4 parts per trillion as a level of arsenic in drinking water that would not be expected to pose a significant human health risk.

“Our public health goal establishes a long-term objective for the reduction of arsenic in California’s drinking water,” OEHHA Director Dr. Joan E. Denton said. “Arsenic is one of the most toxic substances commonly found in drinking water, and it occurs naturally in many parts of the world, including California.”

In developing the PHG, OEHHA conducted an exhaustive analysis of all available scientific studies on the health effects of arsenic. The PHG is based upon studies of hundreds of thousands of patients in Taiwan, Chile and Argentina with lung and bladder cancers associated with elevated levels of arsenic in drinking water. OEHHA estimates that a level of 4 parts per trillion of arsenic in drinking water would cause not more than one additional cancer case in a population of one million people drinking two liters of water daily for 70 years.

Arsenic is found naturally in air, water, soil, mineral deposits, and food. While arsenic in water typically is naturally occurring, the improper disposal of waste chemicals can also contaminate water supplies with arsenic. Long-term exposure to arsenic in drinking water can increase the risk of lung and bladder cancer and, to a lesser extent, increase the risk of skin, liver and kidney cancer.

State law requires OEHHA to develop PHGs for all regulated drinking water contaminants. A PHG is not a regulatory drinking water standard, and it is not a boundary between “safe” and “dangerous” levels of a chemical in drinking water. A PHG represents a health-protective level of a chemical in drinking water that can serve as a long-term goal for California’s drinking water providers and regulators. The Department of Health Services (DHS) will develop a
new state drinking-water standard for arsenic that, by law, must be as close to the PHG as is economically and technically feasible.

The existing state and federal drinking water standards for arsenic have been set at 50 parts per billion for many years. A new federal arsenic standard of 10 parts per billion will take effect in 2006. States may adopt a new standard that is equal to or more stringent than the federal standard. The U.S. Environmental Protection Agency has established a long-term Maximum Contaminant Level Goal (the federal counterpart to OEHHA’s PHG) of no arsenic in drinking water.

A legislative bill authored by Senator Don Perata and enacted into law in 2001 specifically requires OEHHA to develop a PHG for arsenic. The same bill also requires DHS to revise its drinking water standard for arsenic after the PHG is finalized.

The arsenic PHG document and an accompanying fact sheet can be viewed or downloaded from OEHHA’s Web site, www.oehha.ca.gov.


REF: California EPA/OEHHA News Release No. 04-02, April 23, 2004

2003 Residues in Fresh Produce

About California’s Pesticide Regulatory Program

California has the nation's most comprehensive program to regulate pesticide use. Under this program:

- A pesticide's safety and efficacy is evaluated before it is allowed to be used.
- All agricultural pesticide use must be reported.
- Pesticide specialists enforce restrictions intended to ensure the proper and safe use of pesticides.
- Domestic and imported produce is sampled and tested for pesticide residues.
- Annually, only a small fraction of the samples violated established standards.
- According to scientific experts, illegal residues rarely present a significant health risk.

Residue Monitoring

The Department of Pesticide Regulation’s (DPR) Residue Monitoring Program is the most extensive state residue-monitoring program in the nation. It is the final check in an integrated network of programs designed to ensure the safe use of pesticides in California. In 2003 this program analyzed 3,424 samples of fresh produce. (As a result of ongoing budgetary constraints, the number of samples collected in 2003 was reduced from previous years.) Samples were
collected throughout the channels of trade: at seaports and other points of entry into the State, packing sites, wholesale, and retail outlets.

The findings are consistent with those from previous years: there are few violative residues, and pesticide detections in produce are generally well below the allowable levels.

Our marketplace surveillance program is designed to monitor compliance with pesticide laws and to help ensure that any detected pesticide residues are within the established tolerance levels. This program is also designed to provide data on pesticide dietary exposure. This data helps make more realistic assessments of dietary pesticide risk.

In 2003 there were 3424 samples of more than 72 kinds of commodities. Domestic and imported produce were tested. All samples were tested with multi-residue screens capable of detecting more than 200 pesticides and breakdown products. No residues were detected in 68.3 percent of the samples. Residues within tolerance (the legal limits set by the U.S. Environmental Protection Agency [U.S.EPA]) were found in about 30.8 percent of the samples. The majority of these samples had residues at less than 10 percent of the tolerance level. Illegal residues were found in 0.88 percent of samples. Of these, 0.06 percent had residues that were over the tolerance level, and 0.82 percent had residues of a pesticide not authorized for use on the commodity.

DPR concentrates monitoring on commodities with:

- A history of violation (domestic and foreign).
- A significant percentage of detectable residues in previous years.
- A dietary significance based on consumption frequencies and quantities consumed taking into consideration the dietary patterns of adults, infants, children, and ethnic groups.

Findings and Significance

The validity of any sampling program lies in its design and in its ability to replicate the results. Over the past decade, even as the number of samples varied, the findings have been consistent from year to year. Most residues are below detectable limits. Residues that are found are usually at levels that are measured at a fraction of a part per million (ppm). Less than one percent of samples have residues over the tolerance levels. A tolerance is the highest residue level of the particular pesticide that is legally allowed on the particular commodity. A tolerance is set by U.S. EPA for regulatory purposes and is established at a level that incorporates a margin of safety, and usually assumes a lifetime of consumption of the commodity at the maximum allowable residue level.

While the goal of DPR's regulatory program is to ensure that all food is in compliance with pesticide safety standards, an occasional produce item slightly above tolerance should not automatically be considered a health hazard. The results from years of DPR residue monitoring document the safety of produce grown and consumed in California.

The data collected in 2003 are extensive and available for downloading.

REF: California Department of Pesticide Regulation website.
Regarding CDC Foodborne Illness Data

Dr. Elsa Murano, USDA Undersecretary for Food Safety
April 29, 2004

“The CDC, in its annual report on the incidence of infections from foodborne pathogens, noted significant declines from 1996 to 2003 in illnesses caused by E. coli O157:H7 (42%), Salmonella (17%), Campylobacter (28%) and Yersinia (49%). Illnesses caused by Salmonella Typhimurium (typically associated with meat and poultry) decreased by 38%. Most significantly, between 2002 and 2003, illnesses caused by E. coli O157:H7, typically associated with ground beef, dropped by 36%. The reduction in E. coli O157:H7 illnesses brings the U.S. very close to achieving the ’Healthy People 2010’ goal of 1.0 case per 100,000 people.

“The report adds to the body of evidence indicating real progress is being made toward our goals of preventing illness and protecting public health. The data, while inclusive of all foods, generally tracks the trends revealed through random regulatory testing of meat, poultry and egg products by the Food Safety and Inspection Service.

“In addition to testing results, recalls for Salmonella, E. coli O157:H7 and Listeria in FSIS regulated products also dropped from 65 in 2002 to 28 in 2003.

“In the past 18 months, FSIS has implemented a series of policies and directives to control E. coli O157:H7, Salmonella and Listeria. They include:

● Mandating that all slaughter and ground beef establishments reassess their HACCP plans. The reassessments led most establishments to either implement an intervention strategy at grinding or require their suppliers to do so;

● The first comprehensive audits of HACCP plans for scientific validity, carried out by an expanded, scientifically-trained force of FSIS HACCP experts and epidemiologists;

● Elimination of the E. coli O157:H7 testing exemption at slaughter plants that did their own carcass testing. All beef plants are now subject to FSIS ground-beef sampling;

● Creation of a new training program, Food Safety Regulatory Essentials, to improve training of inspectors in science-based regulations;

● Accelerating the scheduling of in-depth reviews of plants that have exceeded their Salmonella performance standards, so that potential sanitation problems can be identified and corrected promptly; and,

● Publishing a final rule to control Listeria monocytogenes, based on a quantitative risk assessment, to establish mitigation strategies that would result in risk reduction at ready-to-eat meat and poultry processing plants.

REF: USDA Website Release Release No. 0176.04
New Regulations to Prevent Ground Water Contamination

The California Department of Pesticide Regulation has adopted new regulations to prevent ground water contamination, advancing an environmental initiative that began nearly 20 years ago.

"These regulations demonstrate our commitment to making environmental rules more efficient and effective," said DPR Director Paul Helliker. "Our new ground water rules pro-actively protect a vital natural resource, while providing growers with a range of options to help keep California's agricultural economy strong."

Since 1986, efforts to protect ground water have been guided by the Pesticide Contamination Prevention Act (Assembly Bill 2021). Under the law, once pesticides were detected in ground water, they would be prohibited unless future contamination could be controlled. The regulatory program was based on limited mitigation measures and applied only to the one-square-mile "Pesticide Management Zones" around contaminated wells. Currently, those zones include about 313,000 acres statewide.

By comparison, the new regulations designate about 2.4 million acres across the state where soil conditions make shallow ground water most vulnerable to pesticide contamination from leaching and runoff. The regulations prescribe actions to prevent pesticides from reaching ground water in these "Ground Water Protection Areas" before contamination actually occurs.

PR scientists made new regulations possible when they developed computer modeling that identified vulnerable areas of the state. The model was constructed using almost 20 years of well monitoring data compiled in DPR's well inventory database, as well as soil data from the federal Natural Resources Conservation Service and climate information. DPR's computer modeling offers the capability to relate factors -- including farming practices and soil conditions -- to the use of soil-applied herbicides that most often threaten ground water.

Before a pesticide can be registered for use in California, DPR requires data on the active ingredient's potential to contaminate ground water. Only eight active ingredients in currently registered pesticides have been found in California ground water since the Pesticide Contamination Prevention Act was passed in 1986. DPR's new regulations will focus on preventing further contamination from seven of those pesticides. (Use of the eighth pesticide, aldicarb, is no longer allowed in areas where it may contaminate ground water.) Meanwhile, DPR will continue monitoring for other pesticides in ground water and act on detections as needed.

While the new regulations have been under development since the late 1990s, DPR has already launched other education and outreach efforts that will help protect ground water from pesticides.

Since the fall of 2001, DPR has held 64 training sessions in 27 counties as part of a "chemigation road show" to help the agricultural industry prevent ground water contamination. Chemigation is an effective method of applying pesticides and fertilizers through irrigation systems, but safeguards are needed to ensure that treated irrigation water does not back-flow into wells. The "chemigation road show" included a demonstration trailer with equipment that prevents back flow. Chemigation training sessions also were held for County Agricultural Commissioner employees.

DPR also has worked with industry to raise awareness of ground water concerns and prevention methods, including articles in the "CAPCA Adviser," a publication for pesticide professionals. In another cooperative effort, agricultural
publishing company Western Farm Press recently introduced an online course on the new ground water regulations for pest control professionals.

DPR also has held workshops to acquaint industry with specific features of the new regulations, which include the following:

-- Seven pesticides now listed as ground water contaminants (atrazine, simazine, bromacil, diuron, prometon, bentazon, and norflurazon) will require use permits within Ground Water Protection Areas (GWPAs).

-- A specific management practice will be required with any permits issued for application of those pesticides, but growers will have several options, so they can choose the practice that best fits their needs.

-- Protection areas may be designated as "runoff GWPAs" or "leaching GWPAs".

-- "Runoff GWPAs" require proper soil management practices. The goal is to prevent pesticides in surface water from making their way into ground water through drainage wells, poorly-sealed water wells, or similar conduits.

-- "Leaching GWPAs" require careful irrigation practices in coarse soil conditions to prevent pesticide residues from moving downward with percolating irrigation water.

-- Mixing, loading, storing, and other activities involving pesticides would be prohibited within 100 feet of water wells, unless they are sited or protected to prevent runoff contamination.

For the full text of the new regulations, go to www.cdpr.ca.gov/docs/legbills/rulepkgs/03-001gwp/03001final.pdf.

A fact sheet on DPR's Ground Water Protection Program and background on the new regulations may be found at www.cdpr.ca.gov/docs/gwp/index.htm.


TOXICOLOGY TIDBITS

~ ~ Final Rule Prohibiting Supplements With Ephedrine Alkaloids Goes into Effect

A final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra), published by FDA last Feb. 11, went into effect April 12. Ephedra supplements have been promoted to aid weight loss, enhance sports performance, and increase energy. FDA took the action because ephedra has been linked to significant adverse health effects, including heart attack and stroke. The agency determined that supplements containing ephedra present "an unreasonable risk of illness or injury."

~ ~ USDA Launches Consumer-Friendly Food Safety Web Site

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) launched its newly designed, customer-focused Website to help make finding information about food safety easier and faster.

"It is our goal to be more efficient and responsive to the needs of our customers," said USDA Under Secretary for Food Safety Dr. Elsa Murano. "This new Website certainly moves us in the right direction by providing continuous, uninterrupted global capabilities around the clock."

In January, Agriculture Secretary Ann M. Veneman announced an aggressive program to enhance USDA's electronic government capabilities as part of President Bush's Management agenda. The initiative began with a new design of the USDA home page as a first step to upgrade USDA's web presence and to be more responsive to its customers. The redesigned FSIS web site will help improve the USDA customer's access to vital information about food safety.

The revamped website provides the latest information about food safety with an innovative twist. Consumers can speak with the FSIS virtual hotline representative, "Karen." "Karen" can answer questions about safely storing, preparing and handling meat, poultry and egg products. "Karen" instantly can respond to questions originating from anywhere in the world. Consumers still can call the USDA Meat and Poultry Hotline, 1-888-MPHotline (1-888-674-6854) with questions.

"As a public health agency, it is our goal to empower consumers with knowledge as we continue to drive down the incidence of food-borne illness in America," said FSIS Acting Administrator Dr. Barbara Masters. "This website will give consumers immediate access to the information that will help them protect themselves and their families."

In just one click, consumers, scientists, businesses, consumer groups and USDA employees can find the information they need. Finding the latest updates such as FSIS recall releases, policies and regulations will be simple. The FSIS Website remains http://www.fsis.usda.gov.


~ ~ Lung Cancer Tops List of Cancer Deaths among Women
Breast cancer is the type of cancer most closely linked with women in the public consciousness, but lung cancer has now surpassed it as the leading cause of cancer deaths among women. According to a report published today in the *Journal of the American Medical Association*, fatalities for females suffering from the disease are up 600 percent since 1930, whereas the number of men who died of lung cancer over the same time period declined. The researchers suggest that future studies of the etiology of lung cancer need to include more women and take gender-related differences into account.

In 2003 80,100 women in the U.S. were diagnosed with lung cancer--a 60 percent increase from 1990--and 68,800 of them died. Over the same time period, the number of new cases among males was constant. Much of the discrepancy can be attributed to differences in smoking behavior, Mark G. Kris of Memorial Sloan-Kettering Cancer Center and his colleagues report. Since the 1960s, the number of male smokers has decreased by about half, whereas the number of female smokers declined by only 25 percent. In addition, the disease behaves differently in some female patients, leading to increased protein expression, decreased rates of DNA repair and increased incidence of mutation in specific genes. "Many of these women stopped smoking 20 years ago yet still get cancer," Kris says. "However, their response to some targeted therapies is more favorable than men and we are trying to figure out why."

In the U.S. lung cancer now kills as many women as breast cancer and all gynecological cancers combined. "The extraordinary increase in lung cancer rates seen among U.S. women in the 20th century will be repeated among women in developing countries during this century unless effective tobacco control measures are implemented," the team concludes. "Curtailing the increase in tobacco use among women in developing countries represents one of the greatest opportunities for disease prevention in the world today."


~ ~ FDA plans to increase enforcement (herbal and dietary supplements)

Acting FDA Commissioner Dr. Lester M. Crawford has announced plans to step up enforcement actions against improperly marketed herbal and dietary supplement products. In a recent talk, he stated that during the past six months, the FDA has inspected 180 domestic dietary supplement manufacturers; sent 119 warning letters to distributors; refused entry to 1,171 foreign shipments of supplements; and seized or supervised voluntary destruction of almost $18 million worth of mislabeled or adulterated products. In March the FDA ask 23 companies to stop distributing dietary supplements containing androstenedione, which are marketed to stimulate testosterone and muscle growth but have anabolic steroid effects in the body. To support its consumer protection actions, the agency is developing approaches to systematically review the evidence about the safety of individual dietary supplements. FDA expects to evaluate the available pharmacology, published literature and adverse event information, the approach that formed the scientific foundation for FDA’s recent ephedra ban. FDA's rulemaking on dietary supplements containing ephedrine alkaloids became effective on April 12th, shortly after a federal district court declined to issue a temporary restraining order sought by some sellers. [Acting FDA Commissioner Dr. Lester M. Crawford outlines science-based plan for dietary supplement enforcement. FDA news release, April 19, 2004]

~ ~ Permethrin Exposure

A risk assessment for the mosquito adulticide permethrin was conducted based upon data collected from ULV ground applications in Saginaw, MI during 1999. Samples of residue were collected from park surfaces after the applications had been made 12 hours earlier. The result of the analysis is that a child playing in the park would likely absorb only 0.007 percent of the acceptable daily intake (conversely, the exposure is 15,120 times less than the ADI). (Wing Beats, Winter 2003).

REF: Chemically Speaking, February 2004

~ ~ Fish Deformities

A three-year study at Oregon State has answered the question of fish deformities observed in a deep, slow-moving section of the Willamette River south of Portland. Preliminary analyses indicated that the level of pollutants was not greater in the area, but more than half of some fish species had skeletal deformities and lesions. Two parasites have been implicated (a fluke and a myxozoan), with most of the damage being caused by the fluke, *Apophallus donicus*, which at one stage in its life is a tiny worm the can penetrate into the fish bone and cause abnormal growth. (Chemical Regulation Reporter, 1/26/04).

REF: Chemically Speaking, February 2004

~ ~ Glyphosate Quickly Cleared by Humans

An exposure study of farm workers and their families showed that a substantial number of workers who applied glyphosate (Roundup®) had no detectable residues, even though the detection limit was one part per billion (ppb). The study, which was cooperatively conducted between Monsanto, Exponent Corporation, Emory University, and
University of Minnesota, examined urine samples of 48 South Carolina and Minnesota farmers, their spouses, and 78 children, aged four to 18. The samples were collected before application day, on the day after the application, and three days after the application. Farmers had applied glyphosate to a minimum of ten acres to over 100 acre

On the day of glyphosate application, 60 percent of the farmers had detectable residues, with a mean of three ppb. This yielded a theoretical dose of 0.004 mg/kg. Only four percent of spouses were found to have detectable residues on application day and none had residues in later monitoring. Twelve percent of the children had detectable residues the day of application, and all but one of the children who had detectable residues had helped with the application or been present during mixing, loading, or application. None of the theoretical doses approached EPA’s reference dose of two mg/kg/day. The results are in March’s edition of Environmental Health Perspectives. (Pesticide & Toxic Chemical News, 3/29/04).


~~Dangerous Flavorings

In mid-March, a married couple was awarded $20 million for lung damage that the husband claims was due to exposure to butter flavoring at a microwave-popcorn plant where he worked from 1997 to 1999. The man was diagnosed with bronchiolitis obliterans, which is characterized by inflammation and scarring in the smallest airways of the lungs, which leads to severe and disabling shortness of breath. The specific claim was that the manufacturer of the butter flavoring (International Flavors and Fragrances Inc.) failed to warn their customers about the dangers of chemicals contained in the butter flavor. The case was the first of 30 lawsuits filed against the company by plant workers.

A spokesperson for the plaintiff’s lawyer stated that the lung damage was probably caused by diacetyl, which is a component of the flavoring. An important part of the case was that International Flavors and Fragrances required all of its own workers to use respirators when working with butter flavoring, but did not warn its customers of the dangers of the butter flavoring or recommend that its customers afford their workers the same protections that it was using with its own workers.

The EPA has recently announced that it will investigate the safety of diacetyl when contained in products for consumers. The Agency hopes to complete the first phase of a study this fall identifying a wide range of volatile organic compounds that may be emitted when microwave popcorn is popped and opened. Work will then begin on quantifying the amounts of these indoor air pollutants. (Chemical Regulation Reporter, 3/22/04).

---California's Adult Smoking Declines to Historic Lows---

Smoking by California adults dropped to 16.2 percent last year, a record low, State Health Director Sandra Shewry announced today in observance of World No Tobacco Day, May 31. Adult smoking has dropped 12 percent since 1998, when the rate measured 18.4 percent.

"The continuing decline of smoking in California is one of the state's great public health achievements," Shewry said. "However, our success is tempered by the fact that those of lower socioeconomic status continue to smoke at rates that are substantially higher than other groups."

In California, the prevalence of smoking is 22.1 percent among those with low socioeconomic status. In contrast, the prevalence of smoking is 7.7 percent among those with high socioeconomic status. Men with low socioeconomic status have the highest smoking prevalence, 27.2 percent.

"The state’s comprehensive approach to tobacco education and cessation activities has proven highly effective," said Kimberly Belshé, secretary of the California Health and Human Services Agency. "By tackling tobacco cessation through many channels – policy development, outreach and education and offering cessation services – a more informed public has made the healthy choice of not smoking."

According to the World Health Organization, low-income individuals tend to use tobacco products more than people with higher levels of income and education. Tobacco use can also cause increased illnesses, making smokers less productive, and can kill individuals at the height of their productivity, depriving families of their breadwinners. Limited family resources spent on tobacco products and medical expenses also mean less money left for food and other basic needs.

"Tobacco addiction causes devastating emotional and medical consequences as well as serious financial hardships for lower socioeconomic groups," said Dian Kiser, director of RESPECT, a new statewide project to reduce smoking among individuals with low socioeconomic status.

This year alone, more than 43,000 people in California will prematurely die from a tobacco-related disease. In addition, the cost of smoking in California is nearly $16 billion annually, or $3,331 per smoker every year, according to a report released in 2002 by the Institute for Health and Aging at the University of California, San Francisco.

World No Tobacco Day is celebrated annually on May 31 in communities and countries throughout the world. It is designed to inform the public about the dangers of tobacco, the tobacco industry's business practices and what needs to be done to protect the health of future generations. This year’s theme is "Tobacco and Poverty – the Vicious Circle."

Californians who want more information on tobacco cessation and prevention can visit TobaccoFreeCA.com, an informational and interactive Web site that provides support and tools to help break the addiction to tobacco. For free and confidential telephone counseling, Californians can also call the California Smokers' Helpline at 1-800-NO-BUTTS.

REF: California Department of Health Services website.
~FDA, EPA Revise Guidelines on Mercury in Fish

One minute you hear that eating fish is good for your heart. The next, you find out that eating certain types of fish can be harmful.

Actually, there are benefits and risks to eating fish. Fish and shellfish are an important part of a healthy diet. They contain high-quality protein, other essential nutrients, and omega-3 fatty acids, and fish are low in saturated fat. A well-balanced diet that includes a variety of fish and shellfish can contribute to a healthy heart and to healthy, well-developed children.

However, nearly all fish and shellfish contain traces of methylmercury, a type of mercury found in water that can be harmful, especially to unborn babies and young children whose nervous systems are still developing. Some types of fish and shellfish contain higher levels of mercury. The risks depend on the amount of fish and shellfish eaten and the levels of mercury in the seafood.

The Food and Drug Administration and the Environmental Protection Agency (EPA), through a joint consumer advisory, warn that women who may become pregnant, pregnant women, nursing mothers, and young children should avoid the types of fish and shellfish with higher levels of mercury and eat only those that have lower levels.

For more information link to: mercury in fish and shellfish


~A Primer on Summer Safety

When it comes to summer, Olivia Kane, 36, mostly remembers the happy times: eating crabs on the beach, chasing flickering fireflies at night, and playing softball with friends. But there are other memories the Arlington, Va., resident wishes she could forget. Like the rash from poison ivy that broke out on her face, neck, and arms two days before she had to walk down the aisle in her sister's wedding. Or the time she went to the beach to get a tan before high school graduation. "What I got was a bright red sunburn," she says. "I had blistered cheeks, a blistered chest, and I was the graduation speaker."

But her worst summer memory was when she took a sip from a can of soda and gulped down a bee that had crawled into the can when she wasn't looking. "I knew I swallowed something," Kane says. "I got so hysterical that I threw up."

Out came the bee, and she went straight to the emergency room where she was treated for difficulty breathing.

Experts say there's a lot people can do to minimize the risks of health problems related to summertime activities. "While treatment with FDA-approved products is good, prevention is even better," says Jonathan Wilkin, M.D., director of the FDA's Division of Dermatologic and Dental Drug Products. So before you pack your swimsuit or hit the hiking trail this year, brush up on these summer hazards.

Topics covered in this report include:

- Sunburn
- Bites From Mosquitoes and Ticks
- Bee Stings
- Heat Illness
- Burns From Fireworks and Grills
- Foodborne Illness
- Poison Ivy, Poison Oak, and Poison Sumac
- Poisoning in Children
- Skin Reactions from Henna tattoos and depilatories

For more information link to: FDA Consumer


CVM Issues Guidance on the Unapproved Use of Hormone Implants in Veal Calves

On April 2, the Center for Veterinary Medicine announced that it was implementing special public safety measures in response to recent evidence of illegal use of growth-promoting hormone implants in veal calves.

Growth-promoting hormones are approved for use in ruminating cattle, but they have never been approved for use in non-ruminating veal calves. CVM believes there are differences between the way ruminating and nonruminating cattle process and eliminate such hormones.
On April 2, CVM issued a guidance that describes the four conditions veal producers must meet to be able to sell implanted calves for veal:

1. The veal calf cannot be slaughtered for at least 63 days after it was implanted.
2. The veal calf must be presented for slaughter before June 6, 2004.
3. The livestock producer must have implanted the veal calf “in accordance with labeled dose for beef, in accordance with the directions on the implant, and in the proper location,” which is under the skin of the ear.
4. The producer also must present appropriate certification outlined by a notice issued by the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

During an April 2 teleconference with reporters, CVM Director Dr. Stephen Sundlof explained, “We researched all the information we have and came up with a very conservative estimate of the time it would take for any residues of these drugs to fall below any concentration that we would consider to be of public health concern. That very conservative estimate is 63 days.”

CVM’s analysis was based on the best information available at the time and on the conditions outlined in the guidance, including that this is a one-time event and that illegal implants will not continue to occur.

The problem came to light earlier this year when USDA inspectors found indications of hormone treatment in veal calves brought to slaughter. The growth promoting hormones were implanted as small pellets in the ear of the calf. The hormones involved may include progesterone, testosterone, estradiol, zeranol, and trenbolone.

Information about the requirements and a copy of the guidance document are available on CVM’s website. (Search under “Guidances” for Guidance for Industry #172.)


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National Milk Drug Residue Database
Fiscal Year 2003 Annual Report

SUMMARY

This report presents summary data on samples and tests conducted during the Fiscal Year 2003, October 1, 2002 to September 30, 2003. Fifty States and Puerto Rico submitted data for this report.

The Pasteurized Milk Ordinance (PMO), the rules which State agencies use to implement their milk program, requires that all bulk milk tankers be sampled and analyzed for animal drug residues before the milk is processed. Any tanker found positive is rejected for human consumption.

During this period 4,382,974 samples were analyzed for animal drug residues. Of these samples 2,945 were positive.
for a residue. A total of \textbf{4,456,141} tests were reported on the samples for 11 different groups of families or individual drugs. \textbf{Thirty-four} testing methods were used to analyze the samples for residues. Details are presented in the tables in this report.

Sample Results

A \textbf{SAMPLE} is defined as representing a load or lot of milk sampled and analyzed, e.g. a bulk milk pick-up tanker, producer, or over-the-road tanker, a silo, etc.

Table 1 shows the results of the samples tested by source.

Data are reported by four \textbf{SOURCES OF SAMPLES}:

1. **Bulk Milk Pick-Up Tanker** - bulk raw milk from a dairy farm.
2. **Pasteurized Fluid Milk and Milk Products** - after pasteurization; finished product in package form or bulk. Includes milk products such as milk, cream, condensed milk and dry milk products, and condensed and dry whey products.
3. **Producer** - raw milk obtained from the bulk tank/silo on a dairy farm. Samples are reported by the permitting State, rather than by the analyzing State.
4. **Other** - milk from milk plant silos, over-the-road tankers, etc.

A \textbf{POSITIVE} result, as used in this report, means that the sample was found to be positive for a drug residue by a test acceptable for taking regulatory action in a certified laboratory by a certified analyst or the milk was rejected on the basis of an initial test by the milk processor.

The \textbf{DISPOSITION Per PMO} column represents the amount of milk contained in the tank or lot found to be positive and disposed of in accordance with the PMO and/or applicable State regulations.

### TABLE 1 -- Sample Results

\textbf{October 1, 2002 to September 30, 2003}

<table>
<thead>
<tr>
<th>Source of Sample</th>
<th>Total Samples</th>
<th>Number Positive</th>
<th>Percent Positive</th>
<th>Disposition per PMO (Pounds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulk Milk Pick-Up Tanker</td>
<td>3,571,834</td>
<td>1,899</td>
<td>0.053%</td>
<td>70,106,000</td>
</tr>
<tr>
<td>Pasteurized Fluid Milk and Milk Products</td>
<td>54,932</td>
<td>8</td>
<td>0.015%</td>
<td>64,000</td>
</tr>
<tr>
<td>Producer</td>
<td>665,627</td>
<td>1,009</td>
<td>0.152%</td>
<td>4,881,000</td>
</tr>
<tr>
<td>Other</td>
<td>90,581</td>
<td>29</td>
<td>0.032%</td>
<td>1,319,000</td>
</tr>
<tr>
<td>Totals</td>
<td>4,382,974</td>
<td>2,945</td>
<td>*</td>
<td>76,370,000</td>
</tr>
</tbody>
</table>

The asterisk (*) notes that a summary of the percent positive cannot be provided because there is no uniformity in terms of sampling in the four categories. For example, the PMO sets forth specific sampling requirements for Beta lactams testing as follows:

Table 5 shows the number of tests conducted by family and by individual drug.
### TABLE 5 -- Number of Tests Conducted by Family/Drug
**October 1, 2002 to September 30, 2003**

<table>
<thead>
<tr>
<th>Family/Drug</th>
<th>Total Tests</th>
<th>Total Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMINOGLYCOSIDES</td>
<td>1,290</td>
<td>1</td>
</tr>
<tr>
<td>Neomycin</td>
<td>1,858</td>
<td>2</td>
</tr>
<tr>
<td>AMPHENICOLS</td>
<td>201</td>
<td>0</td>
</tr>
<tr>
<td>BETA lactams</td>
<td>4,354,087</td>
<td>3,207</td>
</tr>
<tr>
<td>Cloxacillin</td>
<td>317</td>
<td>3</td>
</tr>
<tr>
<td>MACROLIDES</td>
<td>64</td>
<td>0</td>
</tr>
<tr>
<td>SULFONAMIDES</td>
<td>66,124</td>
<td>23</td>
</tr>
<tr>
<td>Sulfadimethoxine</td>
<td>4,478</td>
<td>3</td>
</tr>
<tr>
<td>Sulfamethazine</td>
<td>17,466</td>
<td>3</td>
</tr>
<tr>
<td>TETRACYCLINES</td>
<td>10,138</td>
<td>4</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>118</td>
<td>0</td>
</tr>
<tr>
<td>TOTALS</td>
<td>4,456,141</td>
<td>3,246</td>
</tr>
</tbody>
</table>

The full report is located at: [www.cfsan.fda.gov](http://www.cfsan.fda.gov)

REF: FDA Center for Food Safety and Applied Nutrition website.