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"IN THIS ISSUE"

Swimming Pools Put Rising Number of Americans at Risk for Diarrhea

The 'Poison Squad' and the Advent of Food and Drug Regulation
Swimming Pools Put Rising Number of Americans at Risk for Diarrhea

Two yet-to-be-released U.S. federal studies were cited as finding that swimming pools are giving people diarrhea and putting more Americans at risk of contracting the illness. The story says that the U.S. Centers for Disease Control and Prevention will announce Nov. 21 that the number of U.S. swimming-related outbreaks of illness caused by the parasite Cryptosporidium increased tenfold from 1990 to 2000.

Americans who swim in pools are 10.6 times more likely to contract the parasite than those who do not, according to preliminary results from another CDC study. While neither study has been published yet, epidemiologist Michael Beach let scientists peek at the data Wednesday at the American Society of Tropical Medicine and Hygiene convention in Denver. Beach was cited as saying that in the past two years more than 80 percent of the disease outbreaks from swimming pools have been due to the chlorine-resistant strain of crypto. The parasite is spread through feces.

The biggest culprits behind its presence in swimming pools are children who are not yet potty-trained. Beach was quoted as saying, "A single fecal accident in one of these major water parks is plenty to contaminate millions of gallons of water. You only have to swallow a mouthful of water or two to get contaminated."
But pool contamination is due to more than just diapers. Beach was further cited as saying that most people don't cleanse themselves sufficiently after bowel movements, which can add up to 2 to 3 pounds of feces a day in the average water park.

The latest statistics on the disease, for 1999 and 2000, will be published next week; they show "a very sharp increase over the past two years" in the number of Crypto outbreaks from recreational swimming, Beach said. Because 18 percent of the people who are ill with diarrhea continue to swim, the outbreak often resurfaces soon after swimming pools are drained and refilled, Beach said.

The story says that preliminary results of a risk analysis of swimming show that people who use kiddie pools have a 10.7 times higher risk of contracting Crypto than those who do not swim. The risk is 10.6 times higher for swimmers in regular pools, 2.4 times higher for ocean swimmers and 1.7 times higher for lake swimmers.

Better filtration and disinfectant technology geared for swimming pools is needed, Beach said. Until then, the key is public education -- telling people not to swim if they have diarrhea and trying to keep toddlers from soiling pools.

For more information, check out the CDC's Healthy Swimming Web site: [www.cdc.gov/healthyswimming](http://www.cdc.gov/healthyswimming)


### Outbreaks of Gastroenteritis Associated with Noroviruses on Cruise Ships --- United States, 2002

During January 1-December 2, 2002, CDC's Vessel Sanitation Program (VSP), which conducts surveillance for acute gastroenteritis (AGE) on cruise ships with foreign itineraries sailing into U.S. ports, received reports of 21 outbreaks of AGE on 17 cruise ships. Of the 21 outbreaks, nine were confirmed by laboratory analysis of stool specimens from affected persons to be associated with noroviruses, three were attributable to bacterial agents, and nine were of unknown etiology. Seven outbreaks were reported in 2001, and of these, four were confirmed to be associated with norovirus. This report describes five of the norovirus outbreaks that occurred during July 1-December 2, 2002, on cruise ships.

*Editorial Note:* Cruise-ship outbreaks demonstrate how easily noroviruses can be transmitted from person to person in a closed environment, resulting in large outbreaks. The continuation of these outbreaks on consecutive cruises with new passengers and the resurgence of outbreaks caused by the same virus strains during previous cruises on the same ship, or even on different ships of the same company, suggests that environmental contamination and infected crew members can serve as reservoirs of infection for passengers.
The increase in reported norovirus outbreaks on cruise ships in 2002 might reflect an actual increase in norovirus outbreaks or it might be attributable to improved surveillance with an electronic reporting format implemented January 1, 2001, and increased application of sensitive molecular assays. The surveillance system captures cases of illness reported to the ship's infirmary or to designated staff on board the ship. Other cases of AGE among passengers and crew members are not reported. In 2002, CDC has confirmed 26 land-based outbreaks of AGE attributable to norovirus; three were caused by strains closely related to the strain detected from cruise ships A, B, and E. Although several land-based outbreaks are linked to norovirus strains with unique sequence types, strains with identical sequence types are identified commonly in outbreaks with no obvious epidemiologic link. Further genetic characterization of common outbreak strains associated with epidemiologic data might help establish possible links among these outbreaks.

Noroviruses (i.e., Norwalk-like viruses or NLV) are members of the family Caliciviridae and are well-recognized etiologic agents of nonbacterial AGE (5). Noroviruses cause approximately 23 million cases of AGE each year and are the leading cause of outbreaks of gastroenteritis. Illness caused by norovirus infection lasts 12-60 hours and is characterized by sudden onset of nausea, vomiting, and watery diarrhea; the incubation period is 12-48 hours. The virus is transmitted by hands contaminated through the fecal-oral route, directly from person to person, through contaminated food or water, or by contact with contaminated surfaces or fomites. Aerosolized vomitus also has been implicated as a transmission mode. Because of high infectivity and persistence in the environment, transmission of noroviruses is difficult to control through routine sanitary measures. Although norovirus causes a self-limited AGE, elderly passengers, children, and those with severe underlying medical conditions might be at increased risk for complications because of volume depletion and electrolyte disturbances. Hospitalization of adults with norovirus who are otherwise healthy is rare. Neither specific antiviral treatment nor a vaccine has been developed for noroviruses.

In addition to emphasizing basic food and water sanitation measures, control efforts should include thorough and prompt disinfection of ships during cruises, and isolation of ill crew members and, if possible, passengers for 72 hours after clinical recovery. Suitable disinfectants include freshly prepared chlorine solutions at concentrations of >1,000 ppm, phenol-based compounds, and accelerated hydrogenperoxide products. Cruise ships also should promote frequent, rigorous hand washing with soap and water by passengers and crew members.

For the entire article link to: MMWR

A century ago, 12 men sat down to a plate of food laced with poison and came back for more. Blessed by Congress, the dinner was the first in a series of meals containing steadily increasing doses of suspected toxic chemicals. What better animal to test toxicity in humans, than a human?

The infamous five-year human feeding experiment took place in the basement of the Agriculture Department's former Bureau of Chemistry, located on what is now Independence Ave., in Washington, D.C.

Complete with kitchen and dining room and backed by a government laboratory, the project was the brainchild of scientists from the Bureau of Chemistry (now the Food and Drug Administration). Chief chemist Harvey W. Wiley, M.D., considered by many to be the founding father of the FDA, spearheaded the effort to separate scientific facts on food safety from the recurrent food safety scares that had fast become the subject of growing public mistrust, inflammatory publications, and Congressional hearings. Wiley's earliest concerns stemmed from the widespread use of borax as a food preservative. And, in fact, fraud was so widespread that even products labeled "pure" were often counterfeits, such as purported "pure Vermont maple syrup" that was little more than colored and flavored Iowa corn syrup.

At the same time, however, manufacturers argued that certain preservatives, such as sulfur, were indispensable in processing products such as wines and raisins. Nevertheless, the public was becoming increasingly concerned about all kinds of toxic substances reportedly found in foods.

Although Wiley believed the burden of proving the safety of preservatives should fall on the manufacturers of such additives, still, he boldly asked Congress during Senate hearings on food adulteration in 1899 for money to conduct such tests himself. Wiley hoped to learn "whether preservatives should ever be used or not, and if so, what preservatives and in what quantities." Ultimately, if Wiley could prove from his studies that food adulteration went beyond flagrant cheating to obvious harm, then both the public and Congress would likely support a national policy.

For the entire article, link to: www.fda.gov

REF: FDA Consumer Magazine, November-December 2002

Pesticides, Parasites, and Pollywogs
Hazards Versus Risks

(Dr. Allan S. Felsot, Environmental Toxicologist, WSU)

Public perception will forever link pesticides with Rachel Carson’s metaphor of a silent spring. Images of landscapes absent of birds will overshadow any benefits that pesticides have shown in stabilizing food production by protecting
yields against a myriad of pests. After the “bird killer” DDT was vanquished, raptorial and fish-eating bird populations rebounded surprisingly rapidly. Since then society has enjoyed the cacophony of birds only occasionally knocked cold by the neurotoxic insecticides still on the market.

Throughout the early history of modern pest control by synthetics, herbicides were untouched by the infamy assigned to insecticides. Today, however, Carson’s vernal silence has extended beyond the chirping of birds to include the croaking of frogs, and worldwide amphibian population declines have been associated with herbicides commonly used in field crop production. It seems that atrazine, especially, has been branded as the new DDT, with recent papers claiming it is hazardous to pollywogs.

A Tale of Two Maladies

Actually, there are two stories in the amphibian controversy, one involving death or population decline and one involving mutation or other sublethal effects. But the two issues have become intermingled and thus confused.

First, the population issue. Amphibian declines have been documented around the world. The laundry list of proposed factors precipitating the population crashes includes:

- increases in ultraviolet (UV) radiation due to ozone holes;
- increased predation due to the introduction of exotic predatory fish;
- competition with introduced amphibian species;
- habitat modification including removal of trees, drainage of wetlands, and changes in vegetation structure;
- changes in water quality (e.g., changes in pH, contamination by synthetic chemicals including pesticides);
- increased incidence of parasitism and disease;
- global climate change;
- synergistic interactions among any of these factors.

Ironically, the major amphibian population crashes have occurred in comparatively pristine habitats at higher elevations. Thus, human-associated factors such as pesticides or habitat modification are not good hypotheses. However, evidence has accumulated supporting the prevalence of a virulent pathogenic fungus (Batrachochytrium dendrobatidis) in diverse places like Australia and the mountains of Central America. The fungus attacks the toughened skin of juveniles and adults after metamorphosis, and the frogs seem to lack immunocompetence to fight the fast-developing infection.

The second issue involves mutation, malformation, and other sublethal effects. This issue is supported and exacerbated by compelling pictures of school kids holding multi-legged and eyeless frogs collected from agriculturally dominated habitats. Hypotheses of human-induced toxicosis have appeared faster than the flick of a frog’s tongue catching a fly. Concerns rose to a feverous pitch in Minnesota, the state where developmentally challenged frogs first made headlines, probably because University of Minnesota researchers had “linked” the incidence of birth defects with the use of pesticides.

To read this entire article, link to: Agrichemical and Environmental News.

Plastics and the Microwave

Stories about the dangers of chemicals leaching from plastic into microwaved food have circulated on the Internet for years. As a result, the Food and Drug Administration continues to receive inquiries from concerned consumers.

Consumers can be confident as they heat holiday meals or leftovers in the microwave that the FDA carefully reviews the substances used to make plastics designed for food use. These include microwave-safe plastic coverings that keep food from splattering and microwave-safe containers that hold frozen dinners. Even microwavable popcorn bags, which look like paper, actually contain a metalized plastic film that allows them to reach high temperatures so the corn can fully pop.

Under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, new substances used to make plastics for food use are classified as "food contact substances." They must be found safe for their intended use before they can be marketed.

"It's true that substances used to make plastics can leach into food," says Edward Machuga, Ph.D., a consumer safety officer in the FDA's Center for Food Safety and Applied Nutrition. "But as part of the approval process, the FDA considers the amount of a substance expected to migrate into food and the toxicological concerns about the particular chemical." The agency has assessed migration levels of substances added to regulated plastics and has found the levels to be well within the margin of safety based on information available to the agency. The FDA will revisit its safety evaluation if new scientific information raises concerns.

One chemical called diethylhexyl adipate (DEHA) has received a lot of media attention. DEHA is a plasticizer, a substance added to some plastics to make them flexible. DEHA exposure may occur when eating certain foods wrapped in plastics, especially fatty foods such as meat and cheese. But the levels are very low. The levels of the plasticizer that might be consumed as a result of plastic film use are well below the levels showing no toxic effect in animal studies.

Other claims have asserted that plastics contain dioxins, a group of contaminants labeled as a "likely human carcinogen" by the Environmental Protection Agency. "The FDA has seen no evidence that plastic containers or films contain dioxins and knows of no reason why they would," Machuga says.

Machuga says that consumers should be sure to use any plastics for their intended purpose and in accordance with directions. If you don't find instructions for microwave use, you should use a different plate or container that you know is microwave-safe. Such containers are made to withstand high temperatures.

For example, carryout containers from restaurants and margarine tubs should not be used in the microwave, according to the American Plastics Council. Inappropriate containers may melt or warp, which can increase the likelihood of spills and burns. Also, discard containers that hold prepared microwavable meals after you use them because they are meant for one-time use.

Microwave-safe plastic wrap should be placed loosely over food so that steam can escape, and should not directly touch your food. "Some plastic wraps have labels indicating that there should be a one-inch or greater space between the plastic and the food during microwave heating," Machuga says.

Always read directions, but generally, microwave-safe plastic wraps, wax paper, cooking bags, parchment paper, and
white microwave-safe paper towels are safe to use. Covering food helps protect against contamination, keeps moisture in, and allows food to cook evenly. Never use plastic storage bags, grocery bags, newspapers, or aluminum foil in the microwave.

REF: FDA Consumer magazine, November-December 2002

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Toxicology Tidbits

~~ The "Bad Bug Book"

This website includes all of the information in the U.S. Food & Drug Administration / Center for Food Safety & Applied Nutrition's handbook "Foodborne Pathogenic Microorganisms and Natural Toxins Handbook." This handbook provides basic facts regarding foodborne pathogenic microorganisms and natural toxins. It brings together in one place information from the Food & Drug Administration, the Centers for Disease Control & Prevention, the USDA Food Safety Inspection Service, and the National Institutes of Health.

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~~ What Does Mistletoe Have To Do With Christmas?

Want to know anything and/or everything about the Mistletoe plant? Mistletoe has been used, worshiped, and revered throughout history and across cultures. A full article on the history and biology of the parasitic Mistletoe plant is the subject of this month's feature story from the American Phytopathological Society (APS).


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~~ State Health Director Warns Consumers Against Eating Wild Mushrooms

SACRAMENTO - With the onset of the rainy season that promotes the growth of wild mushrooms, State Health
Director Diana M. Bontá, R.N., Dr.P.H., reminded consumers about the dangers of eating wild mushrooms.

"Wild mushrooms should not be eaten unless they have been carefully examined and determined edible by a recognized mushroom expert because some poisonous mushrooms look the same as non-poisonous mushrooms," said Bontá.

During the past decade, there have been at least two deaths, multiple hospitalizations and an unknown number of illnesses in California attributed to the consumption of wild mushrooms. During the winter of 1996-97, Northern California reported two deaths attributed to Amanita phalloides, also known as the "death-cap" mushrooms, that grow in some parts of California year-round, but most commonly are found in the rainy fall and winter months.

"Mushroom collectors often overestimate their ability to distinguish deadly mushrooms from edible mushrooms, with potentially tragic results," Bontá said. "Individuals who refer to mushroom guidebooks or have families who have collected mushrooms for many years in their native countries may mistakenly believe that they can distinguish the deadly mushroom found in the Western United States from edible varieties."

Eating poisonous "death cap" mushrooms can cause abdominal pain, cramping, vomiting, diarrhea, liver damage and death. Abdominal symptoms are usually delayed six to 12 hours, so victims may not initially connect their symptoms to wild mushrooms. As the initial gastrointestinal symptoms subside, evidence of liver damage appears and some victims may require a liver transplant to survive.

Individuals who develop any symptoms after eating wild mushrooms should immediately contact the California Poison Control System at 1-800-8-POISON (1-800-876-4766) and seek medical attention.


http://www.dhs.ca.gov

~~Sunning for Science: The Effects of Common Substances on Sun-Exposed Skin~~

Experts already know that exposure to ultraviolet radiation (UVR), either from sunlight or by artificial sources, contributes to the risk of developing skin cancer. Now, because of the public's increasing exposure to UVR through outdoor activities and more frequent use of artificial sources, the Food and Drug Administration's National Center for Toxicological Research (NCTR) in Jefferson, Ark., is studying whether the combination of sun and the ingredients found in cosmetics or the chemicals used in tattoo inks can be linked to toxic effects or cancer.

Testing the Safety of Chemicals

Today, more than 80,000 chemicals are registered for use in the United States in everyday items such as foods, drugs, and personal care products, according to the Department of Health and Human Services' National Toxicology Program (NTP). An estimated 2,000 new ones are introduced each year. The effects of many of these chemicals on health are unknown. For scientists in general and regulatory agencies in particular, the tasks of researching and regulating these
chemicals are daunting. Since the FDA is responsible for protecting the public health in regard to chemicals included in foods, drugs, and cosmetics, research at NCTR contributes to the FDA's ability to regulate and ensure the safe use of products containing these ingredients. NCTR studies investigate the toxicity of these chemicals, contributing to a database used by the FDA to make regulatory decisions.

**Ongoing Research**

Research is now being done for the FDA on alpha- and beta-hydroxy acids--two components common in a large number of skin-care creams and lotions used in the United States. Many of these lotions are marketed as aids to correct sun-damaged skin. The studies are being conducted to determine if there is a relationship between the appearance of sunlight-induced skin cancer and the continuous use of these topically applied acids. The FDA's Center for Food Safety and Applied Nutrition, which generally regulates cosmetics after they are on the market, nominated the alpha-hydroxy acids in 1998 because they are used by millions of people (mostly women) and have never been tested.

The FDA has particular concerns that, unlike traditional cosmetics, these acids might peel away layers of the skin to the point where sunlight can damage DNA in cells at the skin's deepest levels and promote skin cancer. And so, says Howard, "vanity may have a price." The question, he says, is "whether the use of these acids causes a change in skin cancer rates, and if so, whether glycolic acid (an alpha-hydroxy) and salicylic acid (the most widely used beta-hydroxy acid) work differently."

Aloe vera (marketed as a cosmetic ingredient among other skin-care uses), retinyl palmitate (used to correct unwanted skin lesions), and tattoo pigments are currently being studied simultaneously. Ongoing research may include dozens of chemicals at one time.

**Future Scientific Studies**

Many other compounds, including sunblock chemicals, tanning enhancers, skin colorants, and tattoo inks are candidates for future NCP studies to determine whether UVR or simulated solar light induce toxicity and cancer in laboratory animals.

For the entire article, link to:  [www.fda.gov](http://www.fda.gov)

REF:  *FDA Consumer magazine*, November-December 2002
In response to inquiries received by CVM concerning thalidomide, the following statements explain in detail the reasons why veterinarians are not able to prescribe thalidomide for use in their animal patients.

Thalidomide is approved as a drug for use in humans for the treatment of skin lesions associated with erythema nodosum leprosum. Because of thalidomide’s potential for causing birth defects, FDA invoked unprecedented authority to tightly control the marketing of thalidomide in the United States through the S.T.E.P.S.TM (System for Thalidomide Education and Prescribing Safety) program. Thalidomide was the first drug approved under the provisions of § 314.520 (approval with restrictions to assure safe use). Section 314.520 states that if FDA concludes that a drug product can be safely used only if distribution or use is restricted, FDA will require such post-marketing restrictions as are needed to assure safe use of the product. The restricted distribution program for thalidomide is specifically designed to ensure that no human fetus is exposed to the drug.

Due to the complexities of the S.T.E.P.S.TM program, which was specifically designed for human patients, and the need for careful assessment of all adverse reactions and possible fetal exposure, the manufacturer of the approved product will not knowingly register veterinarians as prescribers. Therefore, veterinarians are unable to prescribe the approved human drug.

FDA recognizes the need for veterinarians to have access to a variety of drug products that are not specifically approved for use in animals and provides several avenues for allowing such use under most circumstances.

Extra-label use of approved human drugs in nonfood producing animals is generally permitted under § 530.30(a), except when the public health is threatened. FDA has found that thalidomide poses a threat to public health unless access to the drug and its use are restricted. Thus, it is not available to veterinarians under this regulation because veterinarians cannot register as prescribers under the mandatory restricted distribution program.

For the entire article, link to: [www.fda.gov/cvm](http://www.fda.gov/cvm)

REF: FDA Veterinarian, XVII(VI), November-December, 2002.