



## Environmental Toxicology Newsletter

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# **Nosocomial Poisoning Associated With Emergency Department Treatment of Organophosphate Toxicity --- Georgia, 2000**

Emergency department (ED) staff caring for patients contaminated with toxic chemicals are at risk for developing toxicity from secondary contamination. This report describes three cases of occupational illnesses associated with organophosphate toxicity caused by exposure to a contaminated patient and underscores the importance of using personal protection equipment (PPE) and establishing and following decontamination procedures in EDs and other areas of acute care hospitals.

On April 11, a 40-year-old man intentionally ingested approximately 110 g of a veterinary insecticide concentrate. The insecticide contained 73% naphthalene, xylene, and surfactant, and 11.6% phosmet. On clinical examination at a local hospital ED approximately 20 minutes after the ingestion, the patient had profuse oral and bronchial secretions, vomiting, bronchospasm, and respiratory distress. The patient improved over a 9-day period and was transferred to a psychiatric facility.

The patient was brought to the ED by a friend, not by emergency medical services, and the friend developed symptoms that required treatment. ED personnel exposed to the patient had symptoms within an hour of his arrival. The

staff noted a chemical odor in the ED and contacted the regional poison center, which recommended decontaminating the patient's skin and placing gastric contents in a sealed container to minimize evaporation; however, no decontamination was performed.

One of the health-care workers who had contact with the patient's skin, respiratory secretions, and emesis, developed respiratory distress, profuse secretions, emesis, diaphoresis, and weakness. After medical management and serial doses of atropine and pralidoxime for 7 days, her respiratory function improved, and she was discharged after 9 days of hospitalization. The other two health-care workers who did not have skin contact with secretions or emesis (shared his breathing space) from the patient, developed diaphoresis, confusion, and abdominal cramps while caring for patient 1. After treatment with 10 mg of atropine and pralidoxime over the next 12 hours, their symptoms resolved.

**Editorial Note:** During the incident in this report, health-care workers were exposed to a patient contaminated with an organophosphate insecticide. These health-care workers were not wearing appropriate respiratory or skin protective equipment while caring for the patient. As a result, three health-care workers developed symptoms consistent with organophosphate intoxication and required treatment. This was the third episode reported during 2000 to the Georgia Poison Center of nosocomial poisoning of ED staff involved in the care of patients who had intentionally ingested a concentrated organophosphate mixed with xylene and other hydrocarbon solvents. Similar incidents have occurred elsewhere. During 1987-1998, the National Institute for Occupational Safety and Health identified 46 health-care workers who had acute pesticide-related illness after providing care to a pesticide-contaminated patient.

Depending on the extent of the contamination, health-care workers caring for chemically contaminated patients should use level C protection (i.e., full face mask and powered/nonpowered canister/cartridge filtration respirator) or level B protection (i.e., supplied air respirator or self-contained breathing apparatus). The type of canister/cartridge should be appropriate to the agent; if the agent cannot be identified, an organic vapor/HEPA filter is recommended. To prevent dermal absorption, chemical barrier protection appropriate to the contaminant is needed; latex medical gloves are of little protection against many chemicals. In addition to the need for surface decontamination of patients, body fluids also must be contained to prevent dermal and inhalational exposure. To limit distant spread of the contaminant, the EDs ventilation exhaust should be directed away from the hospital's main ventilation system.

EDs may have to care for persons contaminated with chemicals resulting from self-inflicted contamination, industrial incidents, and terrorist events. To protect health-care workers caring for these patients, EDs should adhere to existing guidelines and decontamination protocols, train staff in the use of PPE, and maintain adequate quantities of antidotes.

REF: *Morbidity and Mortality Weekly Report*, 49(51), January 05, 2001.



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## **FDA Announces Advisory on Methyl Mercury in Fish**

The Food and Drug Administration (FDA) is announcing its advice to pregnant women and women of childbearing age who may become pregnant on the hazard of consuming certain kinds of fish that may contain high levels of methyl mercury. The FDA is advising these women not to eat shark, swordfish, king mackerel, and tilefish. As a matter of prudent public health advice, the FDA is also recommending that nursing mothers and young children not eat these fish as well.

Fish such as shark, swordfish, king mackerel, and tilefish contain high levels of a form of mercury called methyl mercury that may harm an unborn baby's developing nervous system. These long-lived, larger fish that feed on smaller fish accumulate the highest levels of methyl mercury and therefore pose the greatest risk to the unborn child. Mercury can occur naturally in the environment and it can be released into the air through industrial pollution and can get into

both fresh and salt water.

The FDA advisory acknowledges that seafood can be an important part of a balanced diet for pregnant women and those of childbearing age who may become pregnant. FDA advises these women to select a variety of other kinds of fish -- including shellfish, canned fish, smaller ocean fish or farm-raised fish -- and that these women can safely eat 12 ounces per week of cooked fish. A typical serving size of fish is from 3 to 6 ounces.

The FDA's Center for Food Safety and Applied Nutrition will launch a comprehensive education program to reach pregnant women and women of childbearing age who may become pregnant and their health care providers concerning the hazard posed by methyl mercury to the unborn child. As one of its priorities for fiscal year 2001, the Center will also develop our overall public health strategy for future regulation of methyl mercury in commercial seafood.

EPA is also issuing advice on possible mercury contamination to women and children eating fish caught by family and friends (non-commercial fish). EPA particularly recommends that consumers check with their state or local health department for any additional advice on the safety of fish from nearby waters. Additional information is available on EPA's Web site at: <http://www.epa.gov/ost/fish>.

For more info on the consumer advisory link to: <http://www.fda.gov/bbs/topics/ANSWERS/2001/advisory.html>

REF: *FDA News*, January 12, 2001.



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## **FDA Mercury Advisory Criticized by Industry, Consumers**

FDA's recent revision of its consumer advisory on methyl mercury in fish is facing criticism from both consumer and industry groups.

The agency's Jan. 12 advisory tells pregnant women, women who may become pregnant, nursing mothers and young children not to eat swordfish, shark, king mackerel or tilefish. However, these women can eat 12 oz. per week of cooked fish. FDA specified the following fish as safe choices: shellfish, canned fish, smaller ocean fish and farm-raised fish.

The Center for Science in the Public Interest, a consumer group, is calling FDA's new advisory a half measure. While the group applauds the do-not-eat advice for swordfish and shark, it believes that large tuna should also be included among the types of fish pregnant women should not eat.

Meanwhile, the fishing industry also is attacking FDA's announcement. The National Fisheries Institute issued a statement questioning the timing of the revision and asking FDA to provide the scientific basis for its decision. "Protecting people who are especially sensitive to the potential effects of mercury is of paramount concern to the seafood industry," NFI said. "But when FDA tells some consumers not to eat a food, it should have adequate justification for doing so."

REF: *Food Chemical News Daily*, 3(137), January 17, 2001.



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## FDA Announces Report on Safety of Imported Foods

FDA announced the enactment of procedures to advance the Administration's food safety program by more effectively preventing unsafe imported food from entering the United States. These procedures have been developed in response to President Clinton's directive on July 3, 1999, to the Secretaries of Health and Human Services and Treasury to work together to address six specific issues, targeting unscrupulous importers who violate the rules and subvert the system by moving unsafe food into U.S. markets. FDA and U.S. Customs Service presented their joint plan in an October 27, 1999 report to the President, posted it for public comment, and held a series of public meetings to discuss the plan. FDA and Customs then worked together to develop procedures and new rules to initiate the plan.

FDA has now established a procedure to prevent distribution of unsafe imported food by requiring that shipments from "bad actor" importers be held in a secure storage facility at the importers' expense until released by FDA. FDA has also established procedures to enhance interagency coordination and efficiently use Customs' civil monetary penalties procedures against importers who attempt to enter food into the United States by means of a material false statement, act, or omission. Penalties can be issued in amounts up to the domestic value of merchandise so imported.

FDA has also published, for comment, a proposed rule that will require marking food shipments refused for safety reasons to indicate that the product was denied entry into the United States. This will help eliminate the practice of "port shopping" in which importers whose cargo is denied entry at one port try to re-introduce it at another port without bringing the food into compliance with U.S. laws and regulations.

In addition, FDA is developing a proposed rule that will establish standards for importers and other persons who use sample collection services and/or private laboratories to demonstrate compliance with FDA law, including standards for the collection and analysis of samples.

Although Americans enjoy the safest food supply in the world, the implementation of these procedures will increase the tools available to FDA and Customs to penalize unscrupulous importers and discourage those who import or attempt to import food that jeopardizes the public health. As a result, consumers will be still better protected against unsafe food.

In some cases, these activities can be accomplished through changes to internal operating procedures; in others, regulations are being proposed. FDA and Customs will continue to work with other government agencies and Congress to further ensure the safety of the U.S. food supply.

REF: *FDA Press Release*, January 19, 2001.



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## HHS and USDA Release Listeria Risk Assessment and Listeria Action Plan

The Department of Health and Human Services/Food and Drug Administration (HHS/FDA) and the U.S. Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) released a draft risk assessment of the potential relative risk of listeriosis from eating certain ready-to-eat foods -- as well as an action plan designed to reduce the risk of foodborne illness caused by *Listeria monocytogenes*.

*L. monocytogenes* is a bacterium that can cause a serious infection in humans called listeriosis, and causes an

estimated 2,500 serious illnesses and 500 deaths each year. Foodborne illness caused by *L. monocytogenes* in pregnant women can result in miscarriage, fetal death, and severe illness or death of a newborn infant. Others at risk for severe illness or death are older adults and those with weakened immune systems.

"Listeria is a serious public health concern because it can be life threatening," said Health and Human Services Secretary Donna E. Shalala. "Listeriosis, the disease caused by Listeria, primarily affects pregnant women, older adults and persons with weakened immune systems. The Listeria risk assessment and action plan are steps to help protect these individuals."

To ensure food safety and because ***Listeria monocytogenes* can grow at refrigerator temperatures**, FDA and FSIS advise all consumers to reduce the risk of illness by:

- Using perishable items that are precooked or ready-to-eat as soon as possible;
- Cleaning their refrigerators regularly; and
- Using a refrigerator thermometer to make sure that the refrigerator always stays at 40 degrees F or below.

Since pregnant women, older adults, and people with weakened immune systems are at higher risk for listeriosis, FDA and FSIS provide the following advice to those at-risk consumers of foods that have a greater likelihood of containing *Listeria monocytogenes*:

- Do not eat hot dogs and luncheon meats, unless they are reheated until steaming hot.
- Do not eat soft cheeses such as Feta, Brie and Camembert cheeses, blue-veined cheeses, and Mexican-style cheeses such as "queso blanco fresco."

Cheeses that may be eaten include hard cheeses; semi-soft cheeses such as mozzarella; pasteurized processed cheeses such as slices and spreads; cream cheese; and cottage cheese.

- Do not eat refrigerated pâtés or meat spreads. Canned or shelf-stable pâtés and meat spreads may be eaten.
- Do not eat refrigerated smoked seafood, unless it is contained in a cooked dish, such as a casserole. Refrigerated smoked seafood, such as salmon, trout, whitefish, cod, tuna or mackerel, is most often labeled as "nova-style," "lox," "kippered," "smoked," or "jerky." The fish is found in the refrigerator section or sold at deli counters of grocery stores and delicatessens.
- Canned or shelf-stable smoked seafood may be eaten.
- Do not drink raw (unpasteurized) milk or eat foods that contain unpasteurized milk.

To keep food safe from harmful bacteria, follow these four simple steps:

- **Clean:** Wash hands and surfaces often
- **Separate:** Don't cross-contaminate
- **Cook:** Cook to proper temperatures
- **Chill:** Refrigerate promptly

The risk assessment and the Action Plan are also available on the Web at <http://www.foodsafety.gov/>, the FDA Web site at <http://www.cfsan.fda.gov/> and the FSIS Web site, <http://www.fsis.usda.gov>.

REF: HHS/FDA Press Office Release, January 18, 2001.







## **Arsenic in Drinking Water: Final Rule**

**SUMMARY:** Today EPA is establishing a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero and an enforceable Maximum Contaminant Level (MCL) for arsenic of 0.01 mg/L (10 micrograms/L or 10 ppb). This regulation will apply to non-transient non-community water systems, which are not presently subject to standards on arsenic in drinking water, and to community water systems.

In addition, EPA is publishing clarifications for monitoring and demonstration of compliance for new systems or sources of drinking water. The Agency is also clarifying compliance for State-determined monitoring after exceedances for inorganic, volatile organic, and synthetic organic contaminants. Finally, EPA is recognizing the State-specified time period and sampling frequency for new public water systems and systems using a new source of water to demonstrate compliance with drinking water regulations. The requirement for new systems and new source monitoring will be effective for inorganic, volatile organic, and synthetic organic contaminants.

REF: *Federal Register*, 66(14), January 22, 2001.




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## **EPA Completes Risk Assessment and Announces Risk Reduction Agreement for the Pesticide Diazinon**

On December 5, 2000, EPA announced an agreement to phase-out diazinon, one of the most widely used pesticides in the United States, for indoor uses, beginning in March 2001, and for all lawn, garden and turf uses by December 2003.

Diazinon is the most widely used pesticide by homeowners on lawns, and is one of the most widely used pesticide ingredients for application around the home and in gardens. It is used to control insects and grub worms. The agreement reached today with the manufacturers, Syngenta and Makhteshim Agan, will eliminate 75 percent of the use which amounts to more than 11 million pounds of the pesticide used annually.

EPA is taking this action under the Food Quality Protection Act, which President Clinton signed into law in 1996 after the Administration helped lead the way for the new, tougher national pesticide law. Since then, EPA has targeted a large group of older, riskier pesticides called organophosphates for review because they pose the greatest potential risk to children. In August of 1999, for example, EPA announced action against methyl parathion and azinphos methyl to protect children from pesticide residues in food. The Agency reached an agreement to halt by December 2000 the manufacture of chlorpyrifos, or Dursban, for nearly all residential uses. Diazinon - used in homes, and on lawns and gardens - is the latest organophosphate to be phased out. Specifically, the terms of the agreement implement the following phase-out schedules:

- For the indoor household use, the registration will be canceled on March 2001, and all retail sales will stop by December 2002.

- For all lawn, garden and turf uses, manufacturing stops in June 2003; all sales and distribution to retailers ends in August 2003. Further, the company will implement a product recovery program in 2004 to complete the phase out of the product.
- Additionally, as part of the phase out, for all lawn, garden, and turf uses, the agreement ratchets down the manufacturing amounts. Specifically, for 2002, there will be a 25 percent decrease in production; and for 2003, there will be a 50 percent decrease in production.
- Also, the agreement begins the process to cancel around 20 different uses on food crops.

It is legal to purchase and use diazinon products according to label directions and precautions. Consumers should take special care to always read and follow the label directions and precautions. If consumers choose to discontinue use, they should contact their state or local hazardous waste disposal program or the local solid waste collection service for information on proper disposal.

Additional diazinon documents can be found at: <http://www.epa.gov/pesticides/op/diazinon.htm>

The Federal Register notice is available on EPA's web site at: <http://www.epa.gov/fedrgstr>

REF: *EPA Press Release*, December 5, 2000.



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## **America's Children and the Environment: A First View of Available Measures**

*America's Children and the Environment: A First View of Available Measures* is EPA's first report on trends in measures reflecting environmental factors that may affect the health and well-being of children in the United States. This report represents an initial step in the identification, development, and compilation of a set of measures that fully reflect environmental factors important for children.

Developed by EPA's Office of Children's Health Protection in collaboration with the National Center for Environmental Economics in the Office of Policy, Economics and Innovation, *America's Children and the Environment* presents measures that reflect trends in levels of environmental contaminants in air, water, food, and soil; concentrations of lead measured in children's bodies; and childhood diseases that may be influenced by environmental factors.

Some key findings in this report are:

### **Outdoor Air Pollution:**

Between 1990 and 1998, the percentage of children living in counties where one or more of the six criteria air pollutants (ground-level ozone, particulate matter, carbon monoxide, lead, sulfur dioxide, and nitrogen dioxide) exceeded national air quality standards decreased from 28 percent to 24 percent, although it fluctuated from a high of 32 percent to a low of 17 percent.

The percentage of children's days with unhealthy air quality decreased between 1990 and 1998, dropping from 4 percent in 1990 to less than 2 percent in 1998.

In 1990, 100 percent of America's children lived in counties in which a 1-in-100,000 benchmark for cancer risk was exceeded by at least one hazardous air pollutant. In the same year, 6 percent of children lived in counties in which a 1-in-10,000 cancer risk benchmark was exceeded by at least one hazardous air pollutant. Also in the same year, nearly 95 percent of children lived in counties in which a benchmark for non-cancer health effects was exceeded by at least one hazardous air pollutant.



**Indoor Air Pollution:**

The percentage of homes with children under 7 in which someone regularly smokes declined from 29% in 1994 to 19% in 1999.

**Drinking Water Contaminants:**

Between 1993 and 1998, the percentage of children living in areas served by public water systems in which a drinking water standard for chemicals, radiation, or microbial contaminants was exceeded, or treatment rules were violated, decreased from 19 to 8 percent.

Between 1993 and 1998, the number of children served by a public water system in which the nitrate or nitrite drinking water standard was exceeded decreased by close to 20 percent.

The percentage of children living in areas served by public water systems with at least one major monitoring or reporting violation dropped from 21 percent in 1993 to 10 percent in 1998.

**Pesticide Residues in Foods:**

Of the fruits, vegetables, grains, dairy, and processed foods tested by the U.S. Department of Agriculture's Pesticide Data Program, 62 percent showed detectable pesticide residues in 1994. This number decreased to 55 percent in 1998 but fluctuated in the interim years. *(These numbers do not appear to be correct. Due to advances in our ability to detect lower and lower concentrations of chemicals, the percentage of detectables has increased in all other surveys. This does not mean increased risk, it simply means better analytical capability. (Editor))*

**Concentrations of Lead in Blood:**

Average concentrations of lead in the blood of children aged 5 and under dropped 78 percent from 16.5 micrograms per deciliter in 1976-80 to 3.6 in 1992-94. The decrease is largely attributed to the elimination of leaded gasoline between 1973 and 1995.

Between 1992 and 1994, approximately 1.5 million children aged 17 and younger had elevated blood lead levels (higher than 10 micrograms per deciliter).

Race and poverty affect a child's likelihood of having elevated concentrations of lead in his or her blood. Children living in families with incomes below the poverty line are more likely to have elevated blood lead levels. Black children are more likely to have elevated levels than white non-Hispanic and Hispanic children.

The full report is available at [www.epa.gov/children/indicators](http://www.epa.gov/children/indicators).




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## **Website Offers Comprehensive List of Cost-Utility Ratios in Health and Medicine**

Understanding whether a treatment, a medical procedure, or a public health program is cost-effective is an important part of health policy decision making. But how can we compare the cost-effectiveness of various health interventions to determine which one will yield the greatest health effect within the constraints of limited resources?

Rankings of the cost-effectiveness of various health and medical interventions, often called "league tables" (after the tables used for British soccer standing), can facilitate those comparisons. The Harvard Center for Risk Analysis has recently compiled a comprehensive list of one form of cost-effectiveness analyses, known as cost-utility analyses, from the published literature. The Cost-Utility Analysis Database is now available on the Web at



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## Clarification on Chocolate and Flavonoids

Several recent research reports, including *California Agriculture's* September/October issue have suggested that naturally occurring flavonoids in cocoa and chocolate have antioxidant properties that may be good for the cardiovascular system. Flavonoids comprise about 10% to 12% by weight of cocoa beans, the starting material for chocolate products.

However, every step of chocolate manufacturing, from harvest to the shelf, has the potential to reduce flavonoid levels in the finished product, including:

- **Fermentation.** After harvesting, cocoa beans are fermented for varying amounts of time to imbue flavor.
- **Drying.** Cocoa beans are then dried, reducing water activity in order to stop fermentation and prevent mold.
- **Chocolate-making.** Beans are then roasted, milled into a paste and blended with other ingredients.
- **Final steps.** Dutching or alkalization may be undertaken to increase the product's pH.

The nutrient content of any plant-based food, including cocoa beans, depends upon cultivar type, growing region, farming practices, postharvest handling and finally, processing and storage.

At present, consumers who wish to know the flavonoid content of their chocolate must seek additional information from the manufacturer in question. Sheryl Lazarus and Harold Schmitz of Mars, Inc., authors of the previously mentioned article, note that Mars' products with higher flavonoid content carry a "Cocoapro" trademark. Mars collaborates with universities and research institutes globally, and has advanced research on the health benefits of cocoa and chocolate.



# ♦ Toxicology Tidbits ♦

## **Report Assesses Health Risk of Pesticide Exposure to U.S. Troops**

The Office of the Special Assistant for Gulf War Illnesses released an environmental exposure report examining the use, and potential long-term health effects, of pesticides during the Gulf War. Some Gulf War veterans have reported a wide array of unexplained illnesses that many suspect may be related to their use of and exposure to pesticides during the war. The results of the health-risk assessment conducted by investigators suggests that exposure to some pesticides may be a cause for some of the illnesses reported by some veterans.

To aid in determining the extent of health effects from pesticide exposure, investigators prepared a peer-reviewed health risk assessment. The purpose of the health risk assessment was to provide a hypothetical estimate of the likelihood and magnitude of health effects from pesticide exposure during deployment. Such effects would have been limited to the time of deployment and may not have implications for long-term health effects.

The report stressed that the results of the health risk assessment alone do not prove either that overexposures occurred during deployment, or that any connection exists between pesticide exposures and chronic health effects months or years after exposure. But investigators noted that some groups may have been exposed to concentrations of pesticides which exceeded conservatively derived, risk-based levels of concern, and that because of the overall lack of data, there is not enough evidence to rule out possible long-term effects resulting from exposures to pesticides during the Gulf War deployment.

For more info go to: <http://www.gulflink.osd.mil/news/>



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## **USDA Finalizes a Definition for the Term "Organic"**

The new national standards will apply to the production, handling and processing of organically grown agricultural products. The final rule along with detailed fact sheets and other background information, can be found at: <http://www.ams.usda.gov/nop>



## New FDA Article Offering Guidance To Safer Eating Out and Taking Out

You're probably already taking precautions against foodborne illness at home, but you need to be careful when you are away from home too. Here are four easy steps you can take to protect yourself and your loved ones when you are selecting foods that are ready to eat at a restaurant, delicatessen, take-out counter, or grocery store.

1. Be Aware of Raw or Undercooked Foods
2. Ask About Preparation
3. Request that Food be Thoroughly Cooked
4. Make a Different Choice

Also available, is a FDA model brochure chart of who's at risk, risky foods, and cause of illness.

<http://www.cfsan.fda.gov/~dms/fsrawhaz.html>



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## Herbicide Tolerant Genes, Part 4 Withering Wildlife?

A silent spring has become metaphor for ecological destruction by pesticides. Born forty years ago from the poetic pen of Rachel Carson, the idea grew and reached maturity with the banning of DDT in 1973. While there is no denying that Carson's book was a landmark event, the fact is that the spring never did go silent as she imagined. For example, the bald eagle (a putative tragic victim in DDT's heyday) seems to have made a comeback despite DDT's persistence.

Nonetheless, the idea of ecological destruction by pesticides has influenced public perception of crop protection technology, making every manmade chemical pest management tool out to be the twin sibling of DDT. DDT persists in the environment and accumulates in fatty body tissues. Pest management tools developed since the 1980s have neither of these traits. Glyphosate herbicide, for example, is a biodegradable non-accumulating synthetic amino acid. It has absolutely no chemical family relationship to DDT. Yet certain websites today assert that glyphosate poses enough ecological hazard and uncertainty to invoke the precautionary principle.

Further stoking the herbicide hysteria, news reports this fall highlighted a study that concluded herbicide tolerant crops held the potential to destroy avian wildlife as we know it (or at least would like it to be). Given the fact that the vast majority of herbicide tolerant crops are genetically engineered to resist the ravages of glyphosate, the world now has one more reason to despise Roundup Ready crops. Or does it?

For the entire article go to: <http://www.tricity.wsu.edu/aenews/>

REF: *Agrichemical and Environmental News*, Issue No. 178, February 2001.



## National Toxicology Program Finds Naphthalene Causes Cancer in Rodents

The U.S. National Toxicology Program (NTP) announced the results of its two-year study on naphthalene. The rat study found clear evidence that naphthalene causes cancer, a finding that scientists and regulators must wrestle with to determine if, as commonly used, it presents a risk to humans as well.

Naphthalene, the chemical that gives mothballs that strong, familiar scent, showed clear evidence of causing cancer in male and female laboratory rats in a two-year study by the National Toxicology Program headquartered at the National Institute of Environmental Health Sciences in Research Triangle Park, N.C. The rats in the study were exposed by inhalation, just as most people are, in doses comparable to some human consumer and workplace exposures.

The NTP said naphthalene was nominated for the study after some German workers exposed to the chemical developed a number of cancers, including laryngeal, gastric, nasal and colon cancer. A chemical can be nominated when there is evidence suggesting it causes cancer, or sometimes merely because large numbers of people are exposed to it.

The most widely known use of naphthalene is in mothballs and bathroom deodorizers, but it also has a number of chemical manufacturing uses, and is used in veterinary medicine to control lice and as a disinfectant for lesions and incisions. It enters the human food chain when used on livestock that then ingest or inhale it. Naphthalene manufacture and use goes back at least to the early part of the 20th Century.

An abstract of the study is available on request or at the web site listed below.

<http://ntp-server.niehs.nih.gov/htdocs/LT-studies/tr500.html>

REF: *National Institute of Environmental Health Sciences Press Release*, Jan. 25, 2001.



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## Methyl Parathion Tolerance Revocations To Take Effect

Under authority of The Food Quality Protection Act (FQPA), EPA published on Jan. 5 a notice in the [Federal Register](#) announcing the revocation (elimination) of 30 tolerances (maximum permissible residue levels) for the organophosphate pesticide methyl parathion. The tolerance revocation affects a variety of crops, including apples, broccoli, brussels sprouts, carrots, celery, cherries, grapes, nectarines, peaches, pears, and plums. This action follows up on the Aug. 1999 voluntary industry cancellation of these and certain other uses of methyl parathion. The uses were canceled based upon EPA's determination that acute dietary risks from methyl parathion in food did not meet current safety standards, especially for the protection of children. Under terms of the voluntary agreement between EPA and the companies that produce methyl parathion, this pesticide can not be used on these food crops after Dec. 31, 1999. The U.S. Food and Drug Administration is providing guidance for foods that have been legally treated with methyl parathion prior to Dec. 1999. FQPA ensures that legally treated foods are allowed to be marketed in commerce without any disruptions.



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## **New Web Page Features Tolerance Reassessment Status**

The EPA Office of Pesticide Programs has launched a new web page to provide status of the Agency's reassessment of pesticide tolerances (maximum residues in food). This web page includes several charts that show progress toward the goal of reassessing the 9721 tolerances that were in effect in August 1996 against the safety standard of the Food Quality Protection Act (FQPA). The reports available include a listing of all tolerances subject to reassessment and summaries of status of pesticides in several classes of interest, such as the organophosphate pesticides. The information on this web page will be updated periodically to reflect Agency decisions. In addition to the status reports, the page includes links to several background documents, such as a fact sheet on the reregistration program and information on how EPA sets pesticide tolerances. The URL for the web page is [www.epa.gov/pesticides/tolerance/index.html](http://www.epa.gov/pesticides/tolerance/index.html).



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## **Report Helps Clear Vitamin Confusion**

The new dietary reference intakes (DRI) report is the fifth in a series that updates and expands on the Recommended Dietary Allowances (RDAs) in the United States and Recommended Nutrient Intakes in Canada. Although DRIs are designed for use in the United States and Canada, they can provide guidance to researchers and policy-makers coping with malnutrition elsewhere in the world. For example, while iron deficiency, especially among pregnant women, is of concern in this country and Canada, it also is known to be prevalent -- along with vitamin A, zinc, and iodine deficiencies -- in developing countries.

The Institute of Medicine, a private science organization that sets the nation's RDAs for nutrients, spent four years reviewing the scientific research into vitamins and minerals.

For RDAs on all vitamins and minerals, search the institute website at <http://www.nas.edu>.

REF: *The National Academies Institute of Medicine Press Release*, January 9, 2001.





## California Department of Pesticide Regulation Updates

The California Department Pesticide Regulation (DPR) **Consumer Fact Sheets** have been revised and updated. The fact sheets include topics such as "Pull Welcome Mat In, Keep Pesky Guests Out" and "Emergency! What to Do When Accidents Happen". View or download them from <http://www.cdpr.ca.gov/docs/factshts/factmenu.htm>

DPR has launched a new **school IPM Web page** to help school districts comply with the requirements of the Healthy Schools Act of 2000 (Assembly Bill 2260). This law complements DPR's existing, voluntary school IPM program and adds some requirements for schools, such as parental notification of pesticide application, warning signs, and record keeping. To assist voluntary adoption of IPM (integrated pest management) in California schools, DPR's Web page provides sample signs and other instructional materials. Additional materials are under development at <http://www.cdpr.ca.gov/docs/schools/schlmenu.htm>

The Department has issued a **progress report** that summarizes major initiatives in 2000 and highlights regulatory goals for 2001. The report includes concise descriptions of a broad range of topics, including environmental monitoring, school IPM efforts, enforcement initiatives, and online projects. View or download the report from <http://www.cdpr.ca.gov/docs/pressrls/progressreport.htm>



## VETERINARY NOTES.....

### FDA's Regulation of Herbs & Botanicals Intended for Use In Animal Diets

#### *Background*

The use of herbal products is widespread and growing. The actual and perceived relative safety of natural products is a major reason for their popularity with the general public. In 1997, sixty million Americans spent 3.25 billion dollars on herbs as medical therapy. In 1999, United States herbal sales were expected to exceed five billion dollars. Unfortunately, the explosion in sales of such "supplements," has brought products to the marketplace that do not conform to the standards of safety and efficacy that we expect.

To better understand the concerns FDA has regarding the use of botanical and herbal substances in animal feeds, it is important to understand how these products are regulated.

FDA carries out the responsibility of regulation of animal feed products in cooperation with State and local partners through a variety of mechanisms: cooperative agreements, contracts, grants, memoranda of understanding and partnerships. For instance, FDA cooperates with the Association of American Feed Control Officials (AAFCO) and the States for the implementation of uniform policies for regulating the use of animal feed products. AAFCO helps to harmonize feed laws and regulations in the U.S. by establishment of model law and regulations, uniform feed ingredient definitions, and proper labeling rules to assure the safe use of animal feed products.

#### *Federal Food, Drug, and Cosmetic Act*

The use of food products is governed by the provisions of the Federal Food, Drug, and Cosmetic Act (the Act), and the regulations issued under it. The Act sets forth requirements for food products in the Sections 402 and 403. The Act requires that animal feeds, like human foods, be pure and wholesome, contain no harmful substances, and be truthfully labeled. Failure to meet these requirements can result in a product being deemed adulterated or misbranded. Adulteration includes, among other things, food packaged or held under unsanitary conditions, food or ingredients that are filthy or decomposed, food that contains any poisonous or deleterious substance, and food that contains unapproved food additives.

### ***Dietary Supplement Health and Education Act***

For decades, the FDA regulated "dietary supplements" as foods, to ensure that they were safe and wholesome, and that their labeling was truthful and not misleading. However, with passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994, Congress amended the Act to include several provisions that apply only to dietary supplements. As a result of these provisions, dietary ingredients used in dietary supplements are no longer subject to the premarket safety evaluations required of other "new" food ingredients or for "new uses" of old food ingredients. Through the DSHEA, Congress expanded the meaning of the term "dietary supplements" beyond essential nutrients to include such substances as ginseng, garlic, fish oils, psyllium, enzymes, and mixtures of these. In addition, the DSHEA permits certain limited claims to be made about dietary supplements without resulting in the supplement becoming a drug.

### ***Definition of Dietary Supplement***

The DSHEA established a formal definition of "dietary supplement" using several criteria. A dietary supplement is:

- a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- intended for ingestion in pill, capsule, tablet, or liquid form.
- not represented for use as a conventional food or as the sole item of a meal or diet.
- labeled as a "dietary supplement."

### ***Inapplicability of DSHEA to Animal Products***

On April 22, 1996, CVM published a notice in the Federal Register outlining why Congress did not intend DSHEA to apply to products for use in animals. Particularly, it was noted that under the food additive provisions of the Act, FDA must determine that the product will not leave harmful residues in food before FDA can approve a product for use in a food-producing animal. However, nowhere in its revision of the regulation of ingredients in dietary supplements does the DSHEA address how the effect of supplements on foodproducing animals and human food safety is to be assessed. Not only are there human food safety concerns, but when compared with human use of supplements, there is less information on the safe use of dietary supplements in animals.

In addition, many substances that fall under the definition of dietary supplements for human consumption, such as herbs and other botanicals, have a history of use in humans that can be used to establish reasonably safe levels. However, the same is not true for use of many of these same ingredients in animals. Moreover, each animal species requires different nutrients, absorbs and metabolizes nutrients differently, and can exhibit different toxic reactions to food and its components. The toxic reaction of dogs to chocolate is one example of species differences. The lack of information on the safe use of these kinds of substances in animals, and the fact that the animal population is not as homogenous as the human population are two more reasons why FDA has determined that the DSHEA should not apply to animal products.

Finally, many drugs intended to increase the production of meat, milk, egg, or fiber (so called production drugs) or otherwise affect animal performance could arguably be covered as dietary supplements under the DSHEA. Currently, products bearing such production claims are animal drugs under the Act, and as such, can only be marketed after approval by FDA after the manufacturer conducts extensive scientific studies to show that the drug is both safe (in

animals and humans) and effective.

In summary, there are significant complex scientific and regulatory issues relating to human and animal safety that would need to be resolved by Congress before a similar scheme for animal supplements could be put in place. Accordingly, FDA has concluded that animal dietary supplements are not covered by the DSHEA.

It is important to note that DSHEA defines the term "dietary supplement" to exclude products intended for use as conventional foods. For example, St. John's Wort would not be considered a dietary supplement if it were added to soup. Soup is a conventional food and any ingredient added to conventional foods must be used in accordance with its food additive regulation or be generally recognized as safe (GRAS) for its use in soup.

### ***Market Availability***

Nevertheless, many dietary supplements are being marketed for use in animal diets. Many of these products contain botanical and herbal ingredients. While the majority of these are intended for companion animals such as dogs, cats, and horses, there are products that are intended for food-producing animals. These products are often promoted as nutraceuticals, and may contain a number of herbal substances. Currently, none of these ingredients is accepted for use in animal feed.

### ***Safety Concerns***

Most of these herbal products contain substances possessing significant pharmacological activity and consequently potential adverse effects. The specific ingredients that determine the pharmacologic activity of the product are generally unknown.

California investigators in 1998 found that nearly one-third of 260 imported Asian herbal remedies were either spiked with drugs not listed on the label or contained potentially hazardous levels of lead, arsenic or mercury. The potential for diversion of such hazardous products or their byproducts, for use in food-producing animals is a matter of serious safety concern.

Use of herbal products in lieu of veterinary care is also a concern. For example, in one country, comfrey is purported as a drench for swine to treat "fevers." It also is recommended as a treatment for dogs after hip dysplasia surgery. Some other oral uses of comfrey in dogs include treating rickets, arthritis, and rheumatism. For livestock, it is recommended as a treatment for ulcers, arthritis, and rheumatism. In the U.S., comfrey has been marketed in horse products as an anti-inflammatory and to promote wound healing. No published studies could be found to support these medicinal claims.

Moreover, there are several dangers associated with the use of comfrey. Comfrey contains at least eight pyrrolizidine alkaloids (PA). PAs are hepatoxins and can cause irreversible liver damage. Since the alkaloid effects are cumulative, it may be difficult to associate the damage to the liver with alkaloids in comfrey. Sometimes toxicity signs will not be present until an animal is stressed by something that requires greater liver function (e.g., lactation). Also, the leaves and roots of comfrey have been shown to be carcinogenic. PAs from comfrey given to rats caused mortality. Liver pathology was characteristic of PA toxicosis. When rats were fed dietary levels of 0.5% roots and 8% leaves, they formed hepatomas.

Another concern of comfrey feeding would be the safety to humans consuming meat and milk. One study has shown that small amounts, (less than 0.5%) of PA can be transferred to the milk (Dickenson, 1976, JAVMA 169:1192). However, there appears to be no research regarding residue in meat. There are questions that need to be answered: what happens to PAs when animals consume them, how are they metabolized, and are PAs and their metabolites transferred to meat, milk, and eggs.

### ***Generally Recognized as Safe Herbs***

In the absence of drug claims, the use of herbal substances in animal feeds is regarded as a food use. This regulatory status determination is made by the Center for Veterinary Medicine (CVM) on a case-by-case basis. Botanical ingredients allowed in animal feeds, considered GRAS, are listed as flavoring agents under Part 582, Title 21 of the

CFR. These include common herbs such as oregano, thyme, rosemary, etc. These are acceptable for use in animal feeds as flavorings and the level of use should be in accordance with their use as a flavoring. Most flavorings are used in part-per-million levels.

### ***Product Claims***

With regard to claims, we emphasize that an animal food label must not state and/or imply that the introduction of the product in the animal's body results in a physiological or therapeutic effect. Under the Act, claims in or on animal feed products that establish the intended use to cure, treat, prevent or mitigate disease, identify the intent to offer the product as a "drug." For example, statements on promotional material associating the use of the product with prevention or treatment of diseases such as *E.Coli* and *Salmonella* infections could establish the use of the product as a drug. If the promotional material is documented as labeling, these statements are enough to establish the intended use of the product as a new animal drug. Unless the product has been shown to be safe and effective for its intended use via approval of a New Animal Drug Application, it could be subject to regulatory action as an adulterated drug.

In addition, claims that establish the intended use or affect the structure/function of the body in a manner other than food (nutrition, aroma, or taste), identify the intent to offer the product as a "drug." However, statements associating the nutrients in the product with their "known" functions may be acceptable provided they are truthful and not otherwise misleading. On a case-by-case basis, CVM has allowed references to "nutritional support" for specific organs or body functions. For example, we would not object to a claim that an animal food product contains vitamin E for prevention of fat oxidation in the feed or serves as an antioxidant in the body.

### ***Interaction with AAFCO***

To the current market situation, FDA and AAFCO are currently working to establish procedures to evaluate the use of "novel" ingredients in animal foods. In 1999, the AAFCO's Novel Ingredient Task Force was formed and charged to set forth a regulatory scheme for these novel ingredients. Botanicals and herbs are part of a group of substances recognized by AAFCO as "novel ingredients." The Novel Ingredient Task Force recommends that a standing committee be formed to specifically address botanical and herbal ingredients.

The Botanical and Herbs Committee met for the first time at the AAFCO's Midyear meeting in Phoenix, AZ, in January 25, 2000, and again in July 2000 in Charleston, WV. The committee decided that a survey would be taken of the animal feed industry to determine which ingredients are currently on the market or utilized by animal health care professionals. The results of the survey revealed that there are about 180 botanical species currently being marketed or used by animal health care professionals in the United States.

### ***Summary***

The FDA is charged with enforcement of the Act which requires that animal foods be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled. Although not covered by DSHEA, currently many dietary supplements, including herbal supplements, are being marketed for use in animal diets. Since most herbal products contain substances possessing significant pharmacological activity and consequently potential adverse effects including harmful residues, the use of these products in food-producing animals is a major safety concern.

REF: *FDA Veterinarian*, November/December 2000.



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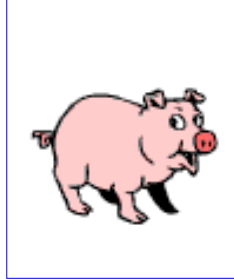
## **BSE ("Mad Cow Disease") Information**

FDA has posted a new page that assembles information on bovine spongiform encephalopathy (BSE) from several sources within the agency and elsewhere in the federal government.

Link to this site: <http://www.fda.gov/oc/opacom/hottopics/bse.html>

REF: *FDA News Digest* -- Feb. 5, 2001.

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