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INTRODUCTION:

PESTICIDE RESIDUES AND RISK

My colleague and friend Dr. Alan Felsot, Extension Toxicologist at Washington State University, has written an excellent article about pesticide residues and risk. I **highly** recommend that readers link to his site and read his article (*How Much Punch Does a Peach Pack? How EWG & CU Have Confused Risk Management with Hazard.*) which is an excellent explanation of the major flaw in virtually all of the recent "scares" regarding pesticide residues in foods. The problem is this; the DOSE, one of the two main factors in determining risk (potency being the other main factor); is ignored!

He has also posted a letter from the Society of Toxicology Executive Board, to the EPA administrator about the recent "scares" and their potential to influence the public. Enjoy Alan's article and be sure to include his newsletter in your list of favorites sites!

<http://www2.tricity.wsu.edu/aenews/April99AENews/Apr99AENews.htm>



ADVERSE EVENTS ASSOCIATED WITH INGESTION OF GAMMA-BUTYROLACTONE

Minnesota, New Mexico, and Texas, 1998-1999

Products containing gamma-butyrolactone (GBL) are marketed for many claimed purposes, including to induce sleep, release growth hormone, enhance sexual activity and athletic performance, relieve depression, and prolong life. GBL is converted by the body into gamma-hydroxybutyrate (GHB), a drug banned outside of clinical trials approved by the Food and Drug Administration (FDA). Recognized manifestations of GHB toxicity include bradycardia, hypothermia, central nervous system depression, and uncontrolled movements. This report describes seven cases of GBL toxicity involving the product "Revivartant," which is labeled as containing 1.82 g of GBL per fluid ounce, reported from two hospital emergency departments (EDs) in Minnesota during October-December 1998 and summarizes an additional 34 cases of GBL toxicity reported to poison centers in New Mexico and Texas during October 1998-January 1999.

Minnesota

Patient 1. On November 26, 1998, a 24-year-old man vomited and had seizures shortly after drinking 3-4 oz of Revivartant. His behavior became unusual, and he alternated between extreme agitation and profound calm. Paramedics noted that his skin was warm, flushed, and profusely diaphoretic, and he had bradycardia (pulse as low as 45 beats per minute {bpm}). During transport to an ED, he had periods of combativeness lasting 30 to 60 seconds followed by coma lasting 1-3 minutes. A urine toxicology screen and blood ethanol test were negative. He had no recollection of events except for having ingested Revivartant. He was discharged with normal mental status.

Patient 2. On December 12, 1998, a 46-year-old woman had a seizure and lost consciousness after drinking approximately 2.7 oz of Revivartant in conjunction with ethanol. Paramedics found her unconscious and in severe respiratory depression with a pulse of 54 bpm. A serum ethanol level was 0.11%. She was admitted to the ICU, mechanically ventilated through the night, and awoke in improved condition the next morning; she was discharged with no memory of the events.

Patient 3. On November 8, 1998, a 31-year-old man drank approximately 1 oz of Revivartant, four beers, and a large sip of wine. Shortly thereafter, he gradually lost consciousness and subsequently fell. He regained consciousness but had involuntary muscle movements and episodes of confusion. Paramedics noted that he was ambulatory but confused. On physical examination in the ED, he was agitated, anxious, and unable to recall the preceding events. His shoulders twitched, and he had a small abrasion below his left eye. He had a pulse of 64 bpm and hypothermia (oral temperature of 95.2 F {35.1 C}). Breath ethanol level was 0.08%. He denied previous GBL use or illicit drug use. He recovered completely and was discharged.

Patients 4 and 5. On October 31, 1998, a 24-year-old man (patient 4) and a 26-year-old man (patient 5) each drank 10-13 oz of Revivartant while drinking alcohol at a bar. On leaving the bar, witnesses observed them fall and become unresponsive. On arrival at the ED, they alternated between somnolence and confusion. When awake, neither patient could consistently follow commands. Patient 4 had fecal incontinence. Vital signs for both patients were within normal limits. Breath ethanol levels were 0.09% (patient 4) and 0.15% (patient 5). Neither patient had a history of using medications or illicit drugs. After 2 hours of observation, the patients recovered but were unable to recall most of the evening's events.

Patients 6 and 7. On December 12, 1998, a 19-year-old woman (patient 6) and a 22-year-old woman (patient 7) were

brought to an ED by friends because of vomiting and decreased levels of consciousness. These symptoms followed ingestion of Revivarant (2 oz by patient 6 and an unknown amount by patient 7). Patient 6 had drunk one beer; patient 7 had had no ethanol. Vital signs were normal except for respiratory depression. On physical examination, patient 6 was lethargic and disoriented. Patient 7 exhibited intermittent periods of extreme agitation, necessitating chemical treatment and physical restraint, punctuated by moments of calm during which her attention focused on minor details. Mental changes for both patients resolved, and they were discharged approximately 4 hours after arrival.

New Mexico

From October 3, 1998, through January 29, 1999, the New Mexico Poison Center identified 14 cases of adverse events resulting in an ED visit among persons who had ingested GBL-containing products. Ten (71%) of the cases were reported in January. Patients' ages ranged from 14 to 36 years; nine were male. Products used included "Firewater" (11 cases), "Blue Nitro Vitality" (two), and "RenewTrient" (one). The approximate amount ingested ranged from 1 to 10 oz (mean: 3 oz). Five (36%) persons also had ingested ethanol and/or other drugs. Most of the patients were discharged from the ED within 13 hours of arrival; three were hospitalized. The most common symptoms and signs were nausea/vomiting (ten {71%}), obtundation (*dullness*) (nine {64%}), bradycardia (*slow heart rate*) (seven {50%}), prolonged unconsciousness (six {43%}), syncope (*fainting*) (six {43%}), seizures (four {29%}), confusion (four {29%}), combativeness (four {29%}), respiratory depression (three {21%}), amnesia (two {14%}), and euphoria (two {14%}). One person had cardiac arrest, one had respiratory arrest, and one had a motor-vehicle crash associated with the effects resulting from use of a GBL-containing product. No deaths were reported.

Texas

From October 2, 1998, through January 24, 1999, Texas poison-control centers identified 20 adverse events resulting in ED visits among persons who had ingested GBL-containing products. Twelve (60%) of the cases were reported in January. Patients' ages ranged from 11 to 41 years; 13 were male. Products known to have been used included "RenewTrient" (six cases), "Revivarant" (four), "Revivarant-G" (two), and "Blue Nitro Vitality" (two). Ten persons also ingested ethanol and/or other drugs. Ten patients were admitted to the hospital from the ED. The most common symptoms and signs were obtundation (13 {65%}), prolonged unconsciousness (nine {45%}), respiratory depression (nine {45%}), anxiety/nervousness (seven {35%}), nausea/vomiting (six {30%}), confusion (six {30%}), tremors/twitching (four {20%}), tachycardia (three {15%}), and combativeness (three {15%}). One person had respiratory arrest; no deaths were reported.

Editorial Note: GBL is metabolized to GHB in the body, but because of better absorption GBL has greater bioavailability than GHB on an equimolar basis. Clinical effects of GHB appear to be dose-related and include reports of vomiting, hypotonia, tremors, seizures, aggression, impairment of judgment, coma, respiratory depression, hypothermia, and bradycardia. GHB mixed with ethanol acts synergistically to produce central nervous system and respiratory depression. Symptoms usually resolve with supportive care within 2-96 hours. Death occurring when GHB was the sole intoxicant also has been reported. Toxic effects of GBL would be expected to be similar or identical to those of GHB, but previous clinical experience is limited. There is no antidote for GHB; treatment consists of supportive therapy until symptoms of toxicity subside. A withdrawal syndrome, which can include insomnia, tremor, and anxiety, has been reported following discontinuance of GHB in chronic, high-dose users.

GBL is an industrial and household solvent of acrylate polymers, and unintentional poisonings have been reported. It also is marketed as a dietary supplement at health food stores and on the World-Wide Web under several trade names. Although labeled as dietary supplements, GBL-containing products are illegally marketed, unapproved new drugs that have been involved in at least 55 reports of adverse events, including one death. On January 21, 1999, FDA asked manufacturers to recall their GBL-containing products and warned consumers through press releases to avoid taking these products. Public education efforts should inform consumers that FDA review procedures for drugs are different than those used for dietary supplements. Consumers should be alert to the potential dangers of these products and understand that terms such as "natural" do not necessarily imply safety. Physicians should counsel patients about these products and be prepared to recognize and treat the toxic reactions that some might produce. Chronic GBL users should be monitored for withdrawal symptoms when discontinuing use of the product. Depending on the severity of the withdrawal symptoms, medical intervention may be required. Physicians are encouraged to report serious adverse events associated with these products to FDA's MedWatch program, telephone (800) 332-1088.

REF: *Morbidity and Mortality Weekly Report*, 48(07):137-140, February 26, 1999.



FARM WORKER ILLNESS FOLLOWING EXPOSURE TO CARBOFURAN AND OTHER PESTICIDES

Fresno County, California, 1998

In California, suspected pesticide-related illnesses and suspected work-related illnesses and injuries are reportable conditions. On July 31, 1998, the Occupational Health Branch of the California Department of Health Services (CDHS) received a report from the California Department of Pesticide Regulation (CDPR) of a pesticide exposure incident in Fresno County involving 34 farm workers. CDHS investigated this incident by reviewing medical records of the 34 workers and interviewing 29. *The findings indicated that the workers became ill after early reentry into a cotton field that had been sprayed with a cholinesterase-inhibiting carbamate pesticide.*

On July 31 at 4 a.m., a cotton field was sprayed aerially with a solution containing as active ingredients 0.26% carbofuran (n-methyl carbamate), 0.05% abamectin (macrolytic lactone), and 0.05% mepiquat chloride (growth regulator). Although carbofuran, when used on cotton, has a restricted entry interval (REI) of 48 hours and requires both posting of treated fields and oral notification of workers, neither warning was provided. At 6 a.m., the 34 workers (age range: 13-64 years; median: 31 years) entered the field to complete weeding begun the previous day. After weeding for approximately 4 hours, the workers were transported to a second field 2-1/2 miles away that had been sprayed 2 days earlier with a solution containing cyfluthrin (synthetic pyrethroid), diclofol (organochlorine), and mepiquat chloride. The REI for these pesticides is 12 hours. Within approximately 1/2 hour of entering the second field, the workers began feeling ill and stopped working.

Symptoms most commonly reported by the 34 farm workers were nausea (97%), headache (94%), eye irritation (85%), muscle weakness (82%), tearing (68%), vomiting (79%), and salivation (56%); the most commonly observed signs were bradycardia (*slow heart rate*) (21%), diaphoresis (*profuse perspiration*) (15%), and miosis (*pupillary constriction*) (12%).

Thirty (88%) workers were transported immediately to a medical clinic; the other four went home, showered, and sought medical care 3-17 days later. All workers evaluated at the clinic were decontaminated by clothing removal and showering and were sent to six area hospitals. Twenty-nine were evaluated and released the same day. One worker was hospitalized overnight for new-onset atrial fibrillation. All workers received hospital treatment for symptoms, and most (28 {82%}) lost at least 1 day of work.

Plasma and red blood cell (RBC) cholinesterase samples obtained from 29 workers on the day of the incident were within laboratory normal values (no workers had baseline levels available). However, these specimens were not placed on ice when obtained and were tested by an outside laboratory after several hours delay. In comparison, RBC (but not plasma) cholinesterase levels were lower than laboratory normal values in 10 workers who had second cholinesterase tests drawn at two local hospitals (3 hours after the original specimens were obtained); these samples were placed on ice and analyzed in hospital laboratories within 1 hour of collection. Urinary metabolites of carbofuran were detected by CDPR in 18 (58%) of 31 samples obtained up to 11 days following the exposure.

Foliage samples obtained in the first field by CDPR on July 31 showed carbofuran levels up to 0.77 $\mu\text{g}/\text{cm}^2$; these levels were consistent with application of pesticide early that morning. Information about pesticide levels to be expected on leaf samples at 48 hours was not available. Other pesticide residues found on leaves in the first field were abamectin (up to 0.009 $\mu\text{g}/\text{cm}^2$) and dicofol (up to 0.58 $\mu\text{g}/\text{cm}^2$). Workers clothing contained carbofuran residues (up to 91 mg per clothing item) and abamectin residues (up to 6000 μg per clothing item). CDHS is continuing follow-up on these workers to assess the subacute and chronic effects associated with carbofuran overexposure.

Editorial Note: Pesticide exposure can cause serious acute illness among farm workers. In the incident described in this

report, workers entered a field well before the end of a label-specified REI and incurred pesticide exposure that resulted in moderately severe illness (as defined by the American Association of Poison Control Centers). The incident demonstrates that 1) posted and oral warnings based on the REI are necessary to prevent illness among workers performing hand labor in fields recently treated with pesticides and 2) failure to adhere to an REI can result in substantial morbidity among exposed workers. Because this incident demonstrates that sole reliance on these control measures may be inadequate, the substitution of safer, less toxic alternative pesticides should be adopted when feasible.

Prompt, appropriate medical attention, including decontamination by clothing removal and showering, probably prevented more acute illness in this incident. However, some exposed workers went home before decontamination, increasing the potential for secondary contamination of children and other family members. Secondary contamination can be reduced by developing, in advance, appropriate procedures for decontaminating clothing, homes, and vehicles. Illnesses among family members exposed to the workers were not reported.

Although the incident involved exposure to several pesticides, the agent with the greatest acute systemic toxicity is the broad-spectrum insecticide/nematocide carbofuran. Carbofuran exposure was the probable cause of illness based on biologic evidence (foliage and clothing samples and urine metabolites), signs and symptoms of cholinergic excess (voluntary and involuntary muscle movement, exocrine gland overactivity, and central nervous system effects), and laboratory evidence of cholinesterase depression. Although atrial fibrillation has been reported with other cholinesterase-inhibiting pesticides, this is the first report following carbofuran exposure. In 1995, 248,000 lbs of cholinesterase-inhibiting carbamate pesticide were used in California, primarily on alfalfa, rice, table and wine grapes, and cotton. During 1995, carbamate pesticides composed 1.8%, by weight, of all pesticides used and alone caused 30 (1.9%) of pesticide-related illnesses reported to CDPR.

Clinical diagnosis of carbamate toxicity is based primarily on known or suspected history of carbamate use and presence of cholinergic symptoms and signs. Isolated cases may be less recognizable, resulting in delays in diagnosis and treatment. Because cholinesterase inhibition by carbamates is rapidly reversible, cholinesterase testing may be unreliable in diagnosing carbamate poisoning. The incident described in this report also illustrates the importance of limiting the time between cholinesterase collection and analysis, placing specimens on ice, and using the most appropriate analytic techniques to conduct cholinesterase assays. Measurement of urinary metabolites may be useful to confirm suspected carbamate-related illness, but because this assay is highly chemical-specific and is performed only by certain reference laboratories, it is not a practical tool for most clinicians. Treatment of carbamate poisoning includes decontamination, supportive care, and the use of atropine in severe exposures.

Some of the symptoms reported by these workers are consistent with effects reported for other pesticides involved in this incident. However, the residues for these pesticides were either not assayed or found to be low, and unlike the cholinesterase-inhibiting pesticides, methods to assess the biologic effects of other pesticides are not readily available to clinicians. Several of these pesticides have been associated with adverse effects in animals, but reliable data for humans are lacking. The toxicity related to combined exposures to pesticides remains unresolved and requires further research.

CDHS participates in two CDC-funded pesticide illness prevention projects that use case reports generated by these mandatory reporting requirements: the Sentinel Event Notification System for Occupational Risks and Community Partners for Health Farming. REI are established by the U.S. Environmental Protection Agency for pesticides used on agricultural crops to which workers have substantial contact with treated surfaces during hand labor. No worker without prescribed protective clothing should enter a treated area to perform a hand labor task until the REI expires. The length of the REI depends on the specific pesticide but generally can be no less than 12 hours.

REF: *Morbidity and Mortality Weekly Report*, 48(06):113-116, February 19, 1999.



USDA RELEASES PESTICIDE DATA PROGRAM REPORT FOR 1997 RESIDUES ON FRUITS AND VEGETABLES

Pesticide residues were detected on 57% of fruits and vegetables sampled throughout the United States as part of the U.S. Department of Agriculture's 1997 Pesticide Data Program (PDP), although nearly all residues fell below EPA tolerance levels for the commodities, according to a report by USDA's Agricultural Marketing Service.

There was a marked difference between fresh produce and processed foods in terms of the number of pesticide residue detections, with 70% of fresh produce, and 45% of processed products, containing at least one pesticide residue, USDA said in the report, "Pesticide Data Program: Annual Summary Calendar year 1997."

PDP found that 15% of the 732 whole milk samples, 80% of the 623 wheat samples, and 87% of the 159 soybean samples tested had at least one pesticide residue. In 1997, PDP collected and analyzed a total of 8,177 samples, originating in 43 states. Of the 6,321 fruit and vegetable samples, 13% were imported and 2% were of mixed national origin. Apple juice, orange juice, pears, tomatoes, and winter squash accounted for most of the imports.

Postharvest uses of pesticides, including fungicides to control mold and fungus, and growth regulators to prevent sprouting, accounted for 24% of residues detected. Compounds with approved postharvest applications include the fungicides dicloran, used on peaches and sweet potatoes; diphenylaine; imazalil for citrus; o-phenylphenol; and thiabendazole.

Thiabendazole was the most frequently found pesticide, occurring primarily in fruit. The fungicide accounted for 737 detections, or 10.7% of all residues detected. Wheat data indicated that the two pesticides chlorpyrifos methyl and malathion accounted for 85% of the residue detections in the 623 wheat samples tested. Soybean data showed that preharvest and postharvest uses of chlorpyrifos and malathion combined accounted for 93% of residue detections in the 159 samples tested.

In 1997, PDP found 455 "presumptive violations" in 412, or 5% of the samples. There were presumptive violations in 383, or 6%, of fruit and vegetable, 23, or 4% of wheat, and 6, or 0.8%, of milk samples. A tolerance is defined as the maximum quantity of a pesticide residue allowable on a raw agricultural commodity.

"A violation occurs when a residue is found which exceeds the tolerance level or when a residue is found for which there is no tolerance for that particular crop. Many presumptive violations, where there is no EPA tolerance, may be due to spray drift or crop rotations. Only four presumptive violations (about 1 in 100) were for pesticide residues where the EPA tolerance was exceeded, and 451 were violations with no established tolerance for the pesticide/commodity pair," USDA said.

In 1996, 71.8% of the fruits and vegetables tested by the PDP contained at least one pesticide residue, up from 65% of the fruits and vegetable samples in 1995. In 1996, there were 243 presumptive violations in 198 samples.

EPA seeks special review of aldicarb on potatoes

EPA uses PDP data for its dietary risk assessment and pesticide registration process, while FDA uses the data to refine sampling to more effectively enforce tolerances, USDA noted.

In response to a request by EPA to re-evaluate the tolerance for use of aldicarb on potatoes, the PDP initiated a single-serving size survey to assess dietary risk. Aldicarb is used only as a soil application; it readily metabolizes to a sulfoxide and sulfone metabolite. The survey design targeted potato samples originating from four states with a registered use for aldicarb (Florida, Idaho, Oregon and Washington).

A total of 342 potato sample composites were analyzed for residues of aldicarb and its metabolites. The highest combined residue detected was identified in a single-serving sample and was 0.373 ppm (0.330 ppm aldicarb sulfoxide plus 0.043 ppm aldicarb sulfone), just slightly over one-third the established tolerance of 1.0 ppm for this pesticide/commodity pair.

For additional information on the report, contact William Franks, deputy administrator, AMS Science and Technology, at (202)720-5231, or Robert Epstein, associate deputy administrator, at (202)720-2158.

REF: *Pesticide & Toxic Chemical News*, 27(13) January 21, 1999.



PESTICIDE APPLICATORS MAY EXPOSE OTHER FAMILY MEMBERS

Unlike many other occupations, family farms are different in that the workplace is often at the same location as the worker's home. Therefore, families of farmers have unusual opportunities for potential indirect exposure to occupational hazards, such as pesticides, regardless of whether they themselves are engaged in the daily operations. Additionally, family members may assist in farm duties and, thus, have the potential for direct pesticide exposure.

The National Cancer Institute and the National Institute of Environmental Sciences conducted an Agricultural Health Study in which all people applying for private pesticide applicator licenses in North Carolina and Iowa from 1994-96 participated. The study included an extensive questionnaire assessment of exposures and health. One questionnaire was administered at enrollment. Applicators were then given a supplemental questionnaire that queried many items relevant to indirect household exposure to complete and return. Applicators were also given a take-home questionnaire for their spouse to complete that included additional items on indirect exposures as well as items relating to farm work carried out by the spouse that might lead to direct exposure. The final take-home questionnaire included information about children. A total of nearly 26,800 applicators supplied completed surveys, and this included information on more than 18,800 children.

Results suggest that members of households of licensed private applicators have several types of potential opportunities for indirect exposure. Many homes (21%) and wells were located within 50 yards of pesticide mixing areas, and 48 percent of homes were within 100 yards of the nearest field or orchard where pesticides were applied. Proximity of homes to areas of pesticide use has been shown to be related to pesticide residue levels in household dust and yard soil. In addition, there was the opportunity for potential indirect exposure via pesticides inadvertently carried into the home on the applicators themselves and on their clothing.

Another route of potential exposure was the fact that 79 percent of applicators indicated that they usually washed up or showered in an in-house bathroom after mixing pesticides, whereas 5 percent used an outside shower and 16 percent used another area outside the home. The laundry is yet another mechanism of possible exposure. The most common practice, used by 81 percent of respondents, was to wash clothes worn when mixing or applying pesticides separately in the machine used for all laundry. Another 2 percent always wore disposable clothing, and 4 percent sent the work clothes out to be laundered or washed it in a machine used only for this purpose. The remaining 13 percent mixed clothes worn when mixing or applying pesticides in with the other wash.

Work boots were another route of bringing pesticides into the house. Typical habits show that 38 percent of respondents who had been working in the fields usually did NOT take their boots off before entering the house. A total of 93 percent reported that there was a wipe mat by the door used by family members working in the fields.

The data showed that spouses and children of licensed private applicators frequently engage in farming activities, thus potentially directly exposing themselves to pesticides. Approximately 50 percent of wives did some work in the fields, and 40 percent reported having mixed or applied pesticides (66 percent of these performed both duties, 3 percent only mixed, and 31 percent only applied). The vast majority of older boys and more than half of the older girls also participated in farm activities.

The consequences of families being exposed to pesticides in these manners are uncertain but could be potentially serious. The extent of these opportunities for family member exposure makes additional studies of their health important. The Agricultural Health Study includes follow-up plans for continuing formal contact with the applicators and their families. Passive follow-up is also planned through cancer registries and death certificates.

Somewhat conversely, however, was a study released in October 1998 suggesting that farmers have a lower standardized mortality rate, are healthier, and have a lower rate of accessing health care than other occupational groups and the general

population. The study assessed the health status of more than 1,200 male farmers matched against 1,100 nonfarmers from the national population. Results of the physician-administered examinations included:

- Farmers had significantly more lower back pain, hip pain, and numbness of the hands;
- Farmers had significantly less fatigue, dizziness, chest discomfort, and heartburn;
- Farmers had significantly less use of outpatient health care for psychiatric, neurologic, ear-nose-throat, ophthalmologic, gastrointestinal, and dermatological diseases;
- Farmers had significantly more use of outpatient health care of trauma;
- Farmers had lower rates for all causes of admission to the hospital;
- Farmers had a heavier workload, worked longer hours, had more sleeping hours, and consumed less alcohol.

Interpretation of these data shows that the differences between farmers and nonfarmers were independent of the urban-rural factor and could not be explained by traditional determinants of health and health care utilization. (From: *American Journal of Industrial Medicine*; December 1998 *Agromedicine Program Update*; Nov. 1998, via *Chemically Speaking*, University of Florida, Jan.1999)

REF: *Kansas Pesticide Newsletter*, 22(2), February 17, 1999.



NORWALK-LIKE VIRAL GASTROENTERITIS IN U.S. ARMY TRAINEES -- TEXAS, 1998

During August 27-September 1, 1998, 99 (12%) of 835 soldiers in one unit at a U.S. Army training center in El Paso, Texas, were hospitalized for acute gastroenteritis (AGE). Their symptoms included acute onset of vomiting, abdominal pain, diarrhea, and fever. Review of medical center admission records for AGE during the previous year indicated that fewer than five cases occurred each month. This report describes the outbreak investigation initiated on August 30 by a U.S. Army Epidemiologic Consultation Service (EPICON) team; the findings indicated the outbreak was caused by a Norwalk-Like Virus (NLV).

Interviews with foodhandlers in the base's two dining facilities (DF1 and DF2) revealed illness in a confection baker, who had become ill in DF1 while baking crumb cake, pie, and rolls on August 26. One other DF1 employee who was not a foodhandler also reported self-limited gastrointestinal illness during August 27-29. No worker in DF2 reported illness.

Cultures of food specimens from the ice cream dispenser in DF1 grew nonpathogenic coliform bacteria (*Citrobacter diversus* and *Serratia liquefaciens*); however, the sample was at room temperature before culture. *Enterobacter cloacae* coliform bacteria were cultured from the soda fountain in DF2. Water samples taken from multiple sites in the training compound and from elsewhere on post were all negative for coliform contamination.

A questionnaire about food preferences, based on the previous week's menu, was administered to 86 hospitalized soldiers (84 of whom had eaten in DF1 during the 10 days before answering the questionnaire) and to 237 randomly selected soldiers from the training unit. Of the 237 nonhospitalized soldiers, 41 (17%) did not eat at DF1 during the 10 days before answering the questionnaire; 40 (17%) had illnesses that met the case definition. Thus, cases of AGE were characterized in 126 soldiers.

To determine the point source of the outbreak, cases with onset during August 27-28 (n=98) were analyzed separately for odds ratios (ORs) of selected exposures. The univariate OR for illness associated with dining at DF1 during the week before the outbreak was 9.8 (95% confidence interval=2.8-40.2). Two soldiers who ate exclusively at DF2 became ill, and one ill soldier reported not eating at either facility. Food items (crumb cake, pie, cinnamon rolls, and ice cream) and soda fountain dispensers were associated with illness by univariate analysis. Using multivariate analysis, only DF1 and the carbonated

beverage dispensers remained strongly associated with illness.

Editorial Note: NLVs, previously known as small round-structured viruses, are the most common cause of nonbacterial gastroenteritis outbreaks in adults. Classified in the family Caliciviridae, NLVs are transmitted by the fecal-oral route and have been implicated in 42%-71% of viral outbreaks associated with contaminated water and food since the Norwalk virus was identified. NLV outbreaks have been caused by eating contaminated raw shellfish and by unsanitary food preparation practices by foodhandlers. NLVs are hardy, ubiquitous, and extremely persistent in the environment, resisting disinfection and chlorination, and have caused serial gastroenteritis outbreaks.

The epidemiologic evidence described in this report indicates that the outbreak was a point-source, propagated, foodborne viral illness. Although cases occurred before the onset of acute illness in the confection baker, he could have been the point source because he probably shed virus before the onset of clinical symptoms. The strong association with drinking carbonated beverages is not easily explained and may represent increased thirst among ill persons. The use of the Army hospital as a quarantine bay probably decreased secondary propagation of the illness.

Prevention of future outbreaks of NLVs in U.S. military dining facilities or any food service establishment depends on vigilance and rigorous enforcement of simple measures to prevent food contamination. These measures include handwashing, exclusion of ill foodhandlers from the workplace, and basic hygiene and sanitation measures.

REF: *Morbidity and Mortality Weekly Report*, 48(11):225-227, March 26, 1999.



MASS TREATMENT OF HUMANS WHO DRANK UNPASTEURIZED MILK FROM RABID COWS -- MASSACHUSETTS, 1996-1998

Rabies is a viral zoonosis that is usually transmitted by the bite of an infected mammal. However, in Massachusetts, two incidents have been reported since 1996 of potential mass exposures to rabies through drinking unpasteurized milk. This report presents the investigations of these two incidents.

Incident 1

On November 12, 1998, the Virology Laboratory of the Massachusetts Department of Public Health (VLMDPH) diagnosed rabies in a 6-year-old Holstein dairy cow from a farm in Worcester County. Further analysis of the cow's brain tissue with monoclonal antibodies revealed the cow was infected with a variant of the rabies virus associated with raccoons in the eastern United States.

The cow had loss of appetite beginning November 4 and hypersalivation beginning November 6. An intestinal obstruction was suspected initially as the cause of illness. However, the cow became ataxic and aggressive and died on November 8.

The cow had been milked 12 times during the week before death. Milk from the cow had been pooled with milk collected from other cows, and an unpasteurized portion was distributed for human consumption. Public health investigations identified 66 persons who drank unpasteurized milk collected from this dairy during October 23-November 8. All 66 received rabies postexposure prophylaxis (PEP). In addition, five persons received PEP because of exposure to the cow's saliva during the 15 days preceding her death. Neither milk nor mammary tissue from the rabid cow was available for examination for the presence of rabies virus.

Incident 2

On November 12, 1996, the VLMDPH diagnosed rabies in a 14-year-old Jersey dairy cow from a different farm in

Worcester County. Analysis with monoclonal antibodies revealed the cow was infected with a variant of the rabies virus associated with raccoons in the eastern United States.

The cow developed tenesmus and depression on November 6 and was euthanized on November 10. The cow had been milked during October 26-November 2. An investigation identified 14 persons who drank unpasteurized milk collected from this cow during this period. All 14 persons received rabies PEP. In addition, four persons received PEP because of exposure to the rabid cow's saliva during the 15 days preceding her death.

Editorial Note: Management of mass human exposures to rabid animals requires public health officials to balance knowledge of rabies epidemiology, risk for transmission, and pathogenesis with the perceived risk for death among exposed persons. Because of the nearly 100% case-fatality ratio of human rabies and the virtually complete effectiveness of PEP, many mass exposure incidents prompt administration of rabies immune globulin and vaccine, even if the circumstances do not meet the criteria for exposure.

An average of 150 rabid cattle have been reported to CDC in the United States each year since 1990. In addition to concerns about rabies transmission from animals to humans through bites, rabid livestock raise the potential for foodborne transmission. The National Association of State Public Health Veterinarians recommends against consuming tissues and milk from rabid animals. However, **because rabies virus is inactivated by temperatures below those used for cooking and pasteurization, eating cooked meat or drinking pasteurized milk from a rabid animal is not an indication for PEP.**

Rabies virus can be transmitted by direct contact with infected material, such as saliva from an animal infected with rabies, and mucous membranes, including the oral and gastric mucosae. In addition to saliva and neural tissue, rabies virus also has been detected in the kidney, prostate, pancreas, and other tissues and body fluids. However, saliva and neural tissue are the primary proven vehicles for rabies virus in naturally occurring cases. Anecdotal reports exist of rabies transmission by ingestion of milk from rabid animals (e.g., from a rabid sheep to a nursing lamb). In these reports, the more conventional routes (e.g., bite or mucous membrane exposure) could not be completely excluded.

Transmission of rabies virus in unpasteurized milk is theoretically possible. The risk could be defined better if samples of milk and mammary tissue were collected from rabid livestock and assayed for the presence, viability, and infectivity of rabies virus. Regardless of the amount of viable rabies virus that may be shed in cows' milk, the theoretical risk for transmission of rabies from this route can be eliminated if all dairy products are pasteurized before consumption.

REF: *Morbidity and Mortality Weekly Report*, 48(11):228-229, March 26, 1999.



HERBAL REMEDIES MAY HURT FERTILITY

Many women trying to become pregnant are careful to avoid ingesting any substance that might impair their fertility or damage a developing embryo. According to a new study, several popular herbal remedies should be added to the list of substances that could have detrimental effects on men as well as women and could interfere with conception or a healthy pregnancy. Despite the widespread belief, often fostered by advertising copy, that herbal preparations are "natural" and "drug-free," those that have drug-like effects in the body do in fact contain potent chemicals that act like drugs. **Like many prescription and over-the-counter drugs that are known to be unsafe before or during pregnancy, some herbal remedies may also be expected to interfere with normal reproductive function.** This expectation prompted researchers at California's Loma Linda University School of Medicine to explore the effects of four popular herbs on eggs and sperm. Their findings were published in the current issue of *Fertility and Sterility*, the journal of the American Society for Reproductive Medicine.

Three of the herbs, St. John's wort, *Echinacea purpurea* and *Ginkgo biloba*, had ill effects on either eggs or sperm or both. The damage, the researchers said, included a reduced ability of sperm to penetrate an egg, changes to the genetic material in sperm, poor sperm viability and, in the case of St. John's wort, mutation of the tumor suppressor gene, BRCA1, a change that can increase the risk of breast and ovarian cancers in women who inherit the mutated gene.

Of the herbs tested, only saw palmetto, which is commonly taken by men to relieve the symptoms of an enlarged prostate, did not damage eggs or sperm in the doses tested. But even saw palmetto reduced the viability of sperm that were exposed to the herbal preparation for seven days.

The researchers emphasized that their study, which was conducted in the laboratory on both human sperm and hamster eggs, indicated only a potential risk to those who take the herbs in question. They said it was possible that no untoward effects would occur in people who used the herbs in the usual recommended doses. "To our knowledge, no data exist on concentrations of these herbs in semen or serum," the team, headed by Dr. Richard R. Ondrizek, noted. Thus, it is not possible to say whether the herbal doses tested represented an amount that may actually reach the eggs or sperm in people who use these preparations. Also, **the remedies, which are sold over-the-counter as dietary supplements, are not required to undergo premarket tests for safety or accuracy of dosage.**

Two types of studies were conducted. In one, hamster eggs that were prepared for fertilization were exposed to various concentrations of the herbs and then inseminated with sperm. Sperm were unable to penetrate the eggs exposed to higher doses of St. John's wort and penetration was impaired by the higher doses of both echinacea and ginkgo. In the second study, human sperm were exposed for seven days to different herbal concentrations. This long-term exposure to St. John's wort and echinacea resulted in significant changes to the sperm and reduced their viability.

REF: *San Francisco Chronicle*, March 25, 1999.

Editorial Note: I obtained a copy of this paper to better understand exactly what the authors did in this research. They prepared concentrated solutions of each of the herbs in a buffered synthetic human tubal fluid and filtered the solutions. They tested these as follows: saw palmetto = 0.9 and 9 mg/ml; ginkgo biloba = 0.1 and 1 mg/ml; echinacea pupura = 0.8 and 8 mg/ml, and St. John's wort = 0.06 and 0.6 mg/ml. The low doses represented a thousandth of the daily dose dissolved in 1 ml, except for the St. John's wort, which was one millionth of a daily dose. These results should be interpreted with caution because extracts of these plants were placed directly into the nutrient media. One limitation of such studies is that the processes of absorption, distribution and metabolism are circumvented, thus the results may not reflect what is actually going on in the whole animal system. While the results are interesting, this study was only a pilot study, and should not be used for making any decisions about the risks of herbal remedies on reproduction. Whole animal studies will be needed to establish whether or not these substances indeed can exert reproductive toxicity. Perhaps the most important aspect of this research and the popular press reporting of it, is the fact that herbal products sold as nutritional supplements no longer must be tested for effectiveness or safety. Natural does not mean non-toxic.



ARS RESEARCHERS LINK DIOXIN IN BEEF TO PCP-TREATED WOOD ON FARMS

Cattle readily pick up dioxin from treated wood in barns, enclosures and fence posts on the farm, a USDA researcher told an American Chemical Society meeting, March 23, 1999.

Individual animals have different dioxin exposures, depending on how accessible and weathered the treated wood is and how likely the animal is to lick and chew it, said Vern Feil of the Agricultural Research Service's (ARS) Biosciences Research Laboratory in Fargo, ND. In a research summary, Feil said ARS studies have "established another source of

dioxins in food from animal sources, namely the exposure of animals to wood in feeding facilities that were treated with pentachlorophenol (PCP)." An effective fungicide, herbicide, and algicide, PCP was used for treating fence posts and barns during the 1950s and 1960s. Its use was curtailed in the early 1980s and is still used to treat utility poles.

The ARS researchers made their discovery in a roundabout way. To study the impact of dioxin and furan compounds on cattle, they conducted a feeding study in which small amounts were fed to animals. But some of the control animals had higher levels of dioxin than the test animals, suggesting an unknown source of contamination. The contamination source was subsequently traced to PCP-treated wood in the feeding facility. While the feeding-study animals had serum dioxin levels mostly below detection limits at the start of the experiment, the dioxins detected in back and kidney fat afterward were similar to those found in treated walls and supporting posts in the barn where the study was conducted. Since then, Feil and his colleagues have found high concentrations of dioxin in animals living with PCP-treated wood at 13 production facilities at state and federal research sites around the U.S.

Dioxin and dioxin-like compounds (there are hundreds) are persistent environmental contaminants that bioaccumulate in fat and breakdown very slowly. Some have been linked to increased risks of cancer, diabetes, endometriosis, and other health problems. ARS found international toxic equivalent levels of 0.27 parts per trillion (ppt) to 30.8 ppt dioxin in fat from 11 bulls, and 0.33 ppt to 7.8 ppt in fat from nine beef cows. Likewise, a national survey conducted by FSIS and EPA detected 2.52 ppt and 4.1 ppt in two bulls and 0.52 ppt to 2.0 ppt in six beef cows. Another study of four university-based cattle production facilities found parts per million levels of octachlorodibenzo-*p*-dioxin (OCDD) in treated wood at two sites where animals with high dioxin levels were raised; likewise, PCP-treated components were not found at the sites where animals with low dioxin levels were raised.

Tests on wild elk in North Dakota revealed dioxin levels of 0.09 ppt to 10.79 ppt. The researchers determined that the elk inhabited areas where local Wildlife Clubs had constructed feeding stations from old utility poles containing up to 89 ppm OCDD and other PCP-treated wood. The feeding facilities were used to support animal survival during severe winter weather. The regulatory implications of Feil's findings are unclear because PCP-treated wood is such a diffuse source. Most large, modern, feedlots are constructed of concrete and metal and analyses of feed hay and grain have shown dioxins at below detection limits. But cattle can still pick up dioxins on smaller ranches where they are raised.

REF: *Food Chemical News*, 41(8), April 12, 1999.



ALDICARB AS A CAUSE OF FOOD POISONING -- LOUISIANA, 1998

Cholinesterase-inhibiting pesticides (i.e., organic phosphates and carbamates), widely used in agriculture, can cause illness if they contaminate food or drinking water. Aldicarb, a regulated carbamate pesticide, is highly toxic, and the U.S. Environmental Protection Agency (EPA) requires applicators to be trained and certified. This report describes a foodborne outbreak of aldicarb poisoning that occurred when improperly stored and labeled aldicarb was used mistakenly in food preparation.

On July 19, 1998, 20 employees attended a company lunch prepared from homemade foods. Shortly after eating, several persons developed neurologic and gastrointestinal symptoms. Ten visited a hospital emergency department, and two were hospitalized. On July 20, a hospital infection-control nurse reported the incident to the Louisiana Office of Public Health, which then investigated the outbreak.

Investigators interviewed all 20 lunch participants about illness and foods eaten during the meal; 14 (70%) reported gastrointestinal or neurologic symptoms. The most common gastrointestinal symptoms were abdominal cramps (13 {93%}), nausea (13 {93%}), and diarrhea (12 {86%}). Neurologic symptoms included dizziness (13 {93%}), sweating (12 {86%}), muscle fasciculations (12 {86%}), eye twitching (eight {57%}), and blurred vision (six {43%}). Illness lasted a median of 4

hours (range: 1-8 hours). Median time between ingestion of food and onset of symptoms was 45 minutes (range: 40 minutes-3 hours). The heart rate of one of the two persons hospitalized was 20 beats per minute on arrival at the emergency department, but his heart rate increased after treatment with atropine. The second person was hospitalized for an increased and irregular heart beat that responded to treatment with digitalis.

The lunch consisted of pork roast, boiled rice, cabbage salad, biscuits, and soft drinks. Only the cabbage salad was associated with illness. Of the 16 persons who ate the cabbage salad, 14 became ill (attack rate: 88%); the four persons who had not eaten the cabbage salad did not develop symptoms (attack rate: 0%, $p=0.003$, Fisher's exact test).

The employee who prepared the cabbage salad reported mixing two 1-lb bags of precut, prepackaged cabbage in a bowl with vinegar and ground black pepper. The black pepper came from a can labeled "**black pepper**" that he had found 6 weeks before the lunch in the truck of a deceased relative. This black pepper had not been used by the employee for food preparation before the company lunch. The cabbage salad was prepared the night before the lunch and stored in the refrigerator until it was brought to work and served at approximately 11 a.m.

The **contents of the black pepper container** were tested for organophosphate and carbamate pesticides. High-performance liquid chromatography identified the granules in the container as 13.7% **aldicarb**, the pesticide TEMIK{Registered}15G. A 6-g portion of cabbage salad contained 272.6 parts per million (ppm) of aldicarb.

The deceased owner of the pepper can had been a crawfish farmer. After its investigation, the Louisiana Department of Agriculture and Forestry believed the crawfish farmer had used aldicarb on bait to prevent destruction of his crawfish nets, ponds, and levees by wild dogs and raccoons. The source of the TEMIK{Registered}15G could not be determined despite the department's extensive traceback effort.

Editorial Note: Aldicarb (2-methyl-2-{methylthio} propionaldehyde O-{methylcarbamoyl} oxime) is one of the most potent pesticides used in the United States. It is absorbed rapidly through the gut and, in liquid form, through intact skin. As a cholinesterase inhibitor, it increases parasympathetic nervous system activity. Common symptoms of poisoning include malaise, dizziness, sweating, nausea, diarrhea, and muscle weakness; blurred vision and muscle spasms also can occur. EPA has placed aldicarb in its highest acute toxicity category.

Aldicarb is classified as a **restricted-use pesticide** and can be sold to and applied by **trained certified applicators only**. Applicators are required to wear personal protective equipment (i.e., coveralls, waterproof gloves, chemical-resistant footwear and headgear, and protective eyewear). In cases of aldicarb poisoning, atropine sulfate is the antidote of choice and can be supplemented by treatment of symptoms and rapid removal of the toxicant (e.g., by induced vomiting).

The 272.6 ppm of aldicarb found in a 6-g cabbage salad sample was enough to be toxic to humans. Each person who had eaten the salad would have consumed approximately 17 mg of aldicarb if equal amounts of salad had been eaten. A 150-lb (70-kg) adult would have ingested 0.2 mg of aldicarb per kg of body weight, nearly 10 times the lowest observed effect level for subclinical blood cholinesterase depression (0.025 mg per kg body weight). Blood levels as low as 0.0011 mg per kg body weight have been associated with poisoning in humans. In addition, cabbage and vinegar, both acidic substances, are less effective than alkaline substances at breaking down aldicarb to less toxic chemical compounds.

In addition to occupational exposures, aldicarb poisoning has resulted from unintentional or suicidal ingestion of aldicarb illegally used as a rodenticide and from eating contaminated watermelons and cucumbers. **The largest pesticide-related foodborne outbreak in the United States occurred in 1985 when 1373 persons reported becoming ill after eating watermelons grown in soil treated with aldicarb**; 78% of these persons had probable or possible pesticide-related illnesses. The median amount of aldicarb sulfoxide eaten per person in that outbreak was approximately 0.027 mg per kg body weight. Aldicarb residues have been detected in ground water and drinking water wells, but studies of the clinical implications of these exposures have been inconclusive. EPA has developed **tolerance levels** for aldicarb residues on food or animal feed and a maximum contaminant level for aldicarb in **drinking water (0.003 mg/L)**.

Nonprofessional pesticide users and certified applicators should be alert to the adverse effects of pesticides on human health and to the risks involved in distributing pesticides to noncertified persons. In addition, the public should be reminded to **store pesticides and other hazardous chemicals exclusively in containers that are clearly and correctly labeled and secured by safety caps**. Finally, health-care providers and public health officials should keep in mind that food poisoning might result from pesticide or other chemical contamination as well as from infectious organisms.

REF: *Morbidity and Mortality Weekly Report*, April 09, 1999 / 48(13);269-271.



♣ Toxicology Tidbits ♣

Don't withhold herbal information ...

Despite the growth in annual sales of herbal supplements to an estimated \$27 billion, consumers are not telling their doctors that they use the products, says a study sponsored by the Beth Israel Deaconess Medical Center. The effects, say researchers, can be dangerous. Patients who have abruptly ended alternative medicines when hospital treatments are necessary have suffered devastating consequences such as delirium and racing heart, resulting in intensive care. If the patients had disclosed their self-treatments, many of the complications could have been prevented. (*Journal of the American Medical Association*, November 1998).

REF: *FDA Consumer magazine*, March-April 1999.



No cancer from hair dye ...

There is little convincing evidence of increased cancer risk with normal use of hair-color products, says an eight-year study. Researchers at the University of California in San Francisco found that though rising worldwide rates of cancer of the immune system have suggested a link to dye use, hair color products were not a factor. (*American Journal of Public Health*, November 1998).

REF: *FDA Consumer magazine*, March-April 1999.



Health Information-en Español ...

Healthfinder, a 2-year-old consumer health Website, now has a special site that presents 200 health information resources in Spanish. At www.healthfinder.gov/justforyou/espanol/, you'll find sections on cancer, diabetes, and infant mortality. The site also offers Spanish materials on pregnancy, children's health, and healthy lifestyles, along with special information for handicapped people, residents of rural and agricultural areas, and professionals. The Healthfinder site is managed by the

Department of Health and Human Services.

FDA's Website also has a lengthy list of health publications available on-line in Spanish. Included at www.fda.gov/opacom/catalog/spanlist.html are materials on the importance of fiber, stroke, lead poisoning, arthritis, eating for a healthy heart, and using medicines properly.

REF: *FDA Consumer magazine*, March-April 1999.



Pesticide-related accidents ...

Many pesticide-related accidents happen because of simple human error brought on by fatigue or stress. Anyone looking to reduce the chances of this happening to them may want to visit Minnesota's Stress-Ticide site <http://www.bae.umn.edu/~fs/stress2.html>. This educational theatrical presentation follows several weeks in the life of a typical pesticide applicator, his co-workers, and his family.

REF: *Chemically Speaking*, February 1999.



Safe food website ...

The National Food Processors Association has launched a new Web site. The site is located at <http://www.safefood.org> and offers information on food safety facts and tips, how processed foods are made, frequently asked questions, and fact sheets on juice, food safety, irradiation, biotechnology, and other topics.

REF: *Chemically Speaking*, March 1999.



Candles as a source of indoor-air pollution?...

A woman from Texas is suing Gap Inc., owner of Banana Republic, alleging that the decorative candles she bought at her local Banana Republic store "gave off excessive soot and noxious fumes." Explanations given for the soot problem from some candles include low-quality wax, an improper mix of dyes and scents, and failure to trim the wick. In the past, some manufacturers used wicks with lead cores to help keep the wick standing in the wax, but most companies discontinued that practice in the 1970s.

REF: *Wall Street Journal*, 31 March 99, A1, A8.



Top shelf pesticides ...

Following an incident in which a 2½ year-old girl sprayed a pesticide into her eyes at a retail store, EPA Regional Offices have proposed a policy that would require stores to keep pesticides more than four feet from the floor unless children could not open the package. After all, every pesticide label must carry the warning "Keep out of the reach of children," so retail outlet stores need to comply as well. (*Georgia Pest Mgt. Newsletter*; December 1999.)

REF: *Chemically Speaking*, March 1999.



Annual Report to the Nation on the Status of Cancer, 1973-1996...

On the 25th anniversary of the National Cancer Act in 1996, the American Cancer Society (ACS), the Centers for Disease Control and Prevention (CDC), which includes the National Center for Health Statistics (NCHS), and the National Cancer Institute (NCI) reported the first sustained decline in cancer mortality since national record-keeping was instituted in the 1930s.

This second report **updates and confirms the continuing declines in cancer incidence and death rates** in the United States and presents detailed information on the occurrence of lung cancer, the leading cause of cancer death, and on tobacco smoking in adults and youth.

Among the 10 leading cancer incidence sites, statistically significant decreases in incidence rates were seen in males for leukemia and cancers of the lung, colon/rectum, urinary bladder, and oral cavity and pharynx. Except for lung cancer, incidence rates for these cancers also declined in females. Among the 10 leading cancer mortality sites, statistically significant decreases in cancer death rates were seen for cancers of the male lung, female breast, the prostate, male pancreas, and male brain and, for both sexes, cancers of the colon/rectum and stomach.

REF: *Journal of the National Cancer Institute*, 91(8), April 21, 1999.



Parkinson's disease is caused primarily by environmental factors, not genetics: JAMA...

Environmental factors, not genetics, probably cause most cases of Parkinson's disease diagnosed after age 50, according to a landmark study published in the January 27 *Journal of the American Medical Association (JAMA)*. The study is based on complete data on more than 17,000 male twins enrolled in a World War II-era registry. Analyses focused on 161 twin pairs (both identical and fraternal) in which at least one brother had Parkinson's and suggests that likelier triggers of the disease are diet and environmental exposure to chemicals and tobacco smoke. (Parkinson's is a degenerative disease of the brain and nerves, causing such symptoms as tremors, shuffling gait and increasing muscular weakness.)

REF: *Pesticide & Toxic Chemical News*, 27(14), 01/28/99.



Polio Vaccines and Cancer: Headlines and reality...

"Polio Shots in 50s, 60s Are Linked to Cancer. Tainted Vaccine Given to Millions." Washington Times, 17 February 99.

This headline appeared in February in a number of newspapers across the country, and reported a finding that polio shots in the 1950's and 1960's which may have been contaminated with a simian virus (SV40) were linked to cancer. We investigated this by going to the *Journal of the National Cancer Institute's* (JNCI) website and searching for this link. What we found was an article titled: SV40 Bugaboo: Spinning the News, by Bob Kuska. In this article, Kuska describes how a previous article published in the JNCI on the prevalence of the SV40 virus in humans, (Cell and Molecular Biology of Simian Virus 40: Implications for Human Infections and Disease, *Journal of the National Cancer Institute*, 91(2):119-134, January 20, 1999) was reported in the popular press. The authors in the last sentence of their abstract state: "*Critical assessment of virologic and epidemiologic data suggests a probable causative role for SV40 in certain human cancers, but additional studies are necessary to prove etiology.*"

The focus of the popular press articles was the possible link with the polio vaccinations, whereas the focus of the scientific paper was to examine the relationship between human infection with SV40 and disease.

The primary author of the original paper has stated that she does not think that the main issue is how the human population has become infected with this virus, but "the virus now infects humans, and we need to understand those infections."

REF: *Journal of the National Cancer Institute*, 91(8): 662-664, 1999.



Pregnancy Outcome and Organic Solvent Exposure...

A recent report in the *Journal of the American Medical Association* found an elevated relative risk of birth defects for pregnant women exposed to organic solvents compared to those who were not. The study was performed in Canada between 1987 and 1996, and looked at 125 pregnant women who were exposed to organic solvents during the first trimester. Each subject was matched with a control subject based on age, gravidity, smoking and drinking status. The results showed a significantly elevated risk of major birth defects in the organic solvent exposed women. The results support a recommendation that exposure to organic solvents should be minimized or avoided during pregnancy.



DPR Proposes Reduced-Risk Pesticide Exemptions...

SACRAMENTO -- Cal/EPA's Department of Pesticide Regulation has proposed regulations that would exempt certain kinds of minimum-risk pesticides from registration requirements. (See list, [below](#))

DPR's registration process requires payment of fees and submission of specific studies before products can be advertised and sold for pest control in California. Among the substances proposed for exemption are many common household and food products that currently must be registered in California as pesticides when labeled and sold for pest-controlling purposes. They include substances such as garlic, peppermint, rosemary, corn oil, cedar chips, and castor oil.

The proposed regulations were authorized by 1997 legislation (SB 445, Monteith). This bill allowed DPR to exempt certain chemicals from registration after the U.S. Environmental Protection Agency had done so.

The major category of exempt chemicals are low-risk substances that have a wide range of other, nonpesticidal uses as foods, medicines, or household items. All are on U.S. EPA's exempt list and were evaluated by DPR scientific staff for potential hazards.

The Department is proposing to divide 40 federally exempted, minimum-risk substances into two lists. The first includes several spices and herbs (such as cinnamon, cloves, garlic, mint, and rosemary), sodium chloride (common table salt), several oils (including corn oil, cottonseed oil, and linseed oil), and zinc metal strips. Because of their widespread and long-standing use, and the fact they pose minimum risk to users, products containing these 22 substances will be exempted without further restrictions.

The 18 chemicals that DPR proposes to place on the second list have the potential to cause eye or skin irritation, although they also include many food or household substances, such as citric acid, clove oil, mint oil, white pepper, and corn gluten meal. Pesticide products that contain more than 8.5 percent of a chemical on this list must have label language requiring use of eyewear and gloves.

For substances on both lists, the label will have to identify the name and percentage of each active ingredient and the name of each inert ingredient. Moreover, all ingredients in a formulation must qualify for exemption. Only inert ingredients that the U.S. EPA has classified as minimum-risk would be allowed. Among these approximately 160 inerts are beeswax, dextrose, eggs, gelatin, honey, lanolin, milk, sawdust, and yeast.

To qualify for exemption, products containing these 40 chemicals cannot make claims to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease-transmitting bacteria or viruses. Claims that specify possible control for disease carried by insects or rodents would also be prohibited. In addition, the product must not include any false or misleading statements.

Besides the low-risk compounds on the two lists, DPR also proposes to exempt from registration four other categories of substances: certain natural cedar products; pheromones labeled for use in traps or the pheromone traps themselves (as defined in the regulation); certain preservatives (including embalming fluids and products used to preserve laboratory animal specimens); and foods used as pest attractants that contain no chemical or biological toxicants.

Products exempted from registration will remain under DPR oversight. The Department will require manufacturers to submit reports of any adverse effects from the use of the exempted products so that DPR can reassess exemptions if necessary.

Copies of the proposed regulations are available on DPR's Web site www.cdpr.ca.gov, or by calling Ann Prichard at (916) 324-3931. Comments may be submitted until 5:00 p.m. on May 12, 1999. E-mail comments may be sent to dpr99001@cdpr.ca.gov. Address written comments to: Ann Prichard, Department of Pesticide Regulation, 830 K Street, Sacramento 95814. (The Department of Pesticide Regulation is one of six boards and departments within the California Environmental Protection Agency.)

***Products containing these minimum-risk substances are proposed for exemption from registration,
with requirements that labels list active and inert ingredients:***

Castor oil	Linseed oil
Cinnamon	Mint
Citronella	Peppermint
Citronella oil	Putrescent whole egg solids
Cloves	Rosemary
Corn oil	Sesame (ground plant)
Cottonseed oil	Sesame oil
Dried blood	Sodium chloride (common salt)
Garlic	Soybean oil
Geraniol	Thyme
Geranium oil	Zinc metal strips

The pesticides listed below are proposed for exemption with requirements that labels list ingredients and have language requiring the use of eye and skin protection if the product has more than 8.5 percent active ingredient:

Cedar oil	Malic acid
Cinnamon oil	Mint oil
Citric acid	Peppermint oil
Clove oil	2-Phenethyl propionate
Corn gluten meal	Potassium sorbate
Eugenol	Rosemary oil
Garlic Oil	Sodium lauryl sulfate
Lauryl sulfate	Thyme oil
Lemongrass oil	White pepper

The four categories of substances below would be exempted, some with labeling or other requirements:

Natural cedar products
Certain pheromones labeled for use in traps
Pheromone traps (as defined in the regulations)
Certain preservatives, including embalming fluid
Foods intended to attract pests that contain no chemical or biological toxicants



Food Quality Protection Act...

On April 7, EPA announced the availability of two draft policy papers relating to the Food Quality Protection Act and the Tolerance Reassessment Advisory Committee.

The first paper, "Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern," addresses EPA's Office of Pesticide Program's interim policy on comparing this percentile to the Population Adjusted Dose, a value that reflects an amount of a pesticide to which a person may safely be exposed in one day.

The second document, "Data for Refining Anticipated Residue Estimates Used in Dietary Risk Assessments for Organophosphate Pesticides," discusses the types of data that may be used to refine residue estimates; the basic characteristics of useful data; how residue data and usage data are linked and how EPA will use these data in its dietary exposure assessments.

Comments on both policy papers should be submitted by June 7. <http://www.epa.gov/oppfead1/trac/science/index.htm>



"CERTIFIED ORGANIC BY" LABELING ON MEAT AND POULTRY PRODUCTS

The Food Safety and Inspection Service (FSIS) is announcing the availability of guidance concerning the use of the claim "certified organic by (a certifying entity)" on the labeling of meat and poultry products. The claim "certified organic by (a certifying entity)" will be permitted on the labeling of meat and poultry products if the labeling is submitted to FSIS for approval, the labeling meets certain criteria, and the labeling submitted is accompanied by specified certification documentation that has been provided by the certifying entity to the meat or poultry producer seeking labeling approval.

The United States Congress passed the Organic Foods Protection Act of 1990 (1) to establish national standards governing the marketing of certain agricultural products as organically produced, (2) to assure consumers that organically produced products meet a defined, consistent standard, and (3) to facilitate commerce in organically produced fresh and processed food. The Agricultural Marketing Service (AMS), United States Department of Agriculture (USDA), published a proposed rule in the Federal Register (62 FR 65850) on December 16, 1997, to permit the use of the term "organic" on the labeling of certain agricultural products. AMS received approximately 280,000 public comments in response to the proposal, which raised many complex issues. AMS has decided to publish a revised proposed rule that will address those issues and to seek further input and comment from interested parties.

A number of meat and poultry producers asked FSIS to permit the marketing of meat and poultry products bearing the claim "certified organic by (a certifying entity)" during the pendency of the rulemaking and before AMS issues its final rule. Because AMS's decision to issue a revised proposal and to seek further public comment before finalizing the organic standards rule will likely take some time, FSIS has decided in the interim to permit the use of the claim "certified organic by (a certifying entity)" on the labeling of meat and poultry products under certain conditions.

As indicated in FSIS's guidance documents, to use the claim "certified organic by (a certifying entity)" on the labeling of a meat or poultry product, processors will have to submit the labeling they want to use to FSIS for approval. Processors will also have to submit to FSIS, simultaneously with the labeling for which they are seeking approval, specified certification documentation provided to them by the certifying entity, including documentation that demonstrates that the certifying entity has standards for what constitutes an organic product, and that the certifying entity has a system for ensuring that that the product it certifies as organic meets the standards it has established. The specific certification documentation that must be submitted to FSIS includes: (1) the name of the certified meat or poultry product and/or certified ingredient used in the meat or poultry product; (2) the certifying entity's name and address; (3) the name and signature of the responsible official of the certifying entity; (4) the date of certification, and (5) documentation from the certifying entity that (a) its criteria, i.e., standards, for what constitutes an organic product have been met by the product or ingredient for which labeling approval is being sought and (b) that the certifying entity employs a system for evaluating ongoing compliance with the criteria, i.e., standards, it has established.

As also indicated in FSIS's guidance document regarding this policy, the statement "certified organic by (a certifying entity)" must be followed by the name of the certifying entity on the labeling of a meat or poultry product. Upon approval, the claim "certified organic by (a certifying entity)" may appear anywhere on the labeling of a meat or poultry product in regard to the meat or poultry product portion certified and in regard to any nonmeat ingredients so certified. All words in the claim are to be contiguous and of the same size, style, and type. Further, as indicated in FSIS's guidance document, FSIS will also continue to permit the use of approved animal production claims and an approved claim of "natural" on the labeling of meat and poultry products.

In allowing the claim "certified organic by (a certifying entity)" to appear on the labeling of a meat or poultry product, FSIS is not defining the term "organic." AMS, supported by the National Organic Standards Board, is responsible for carrying out the Department's program under the Organic Foods Protection Act to define the term "organic" and to establish the circumstances in which it can be applied to agricultural products, including meat and poultry products.

Applications for approval of labeling bearing the claim "certified organic by (a certifying entity)" should be sent to the Labeling and Additives Policy Division, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, USDA, Room 602, Cotton Annex, Washington, DC 20250-3700. Inquiries regarding labeling claims, including the labeling claim "certified organic by (a certifying entity)" or animal production claims, may be directed to Dr. Robert Post, Director, Labeling and Additives Policy Division. Staff of the Labeling and Additives Policy Division may be reached by telephone, at (202) 205-0279, for consultation.

REF: *Federal Register*, 64(69), April 12, 1999.



ANTIMICROBIAL RESISTANCE AND ANTIMICROBIAL USE IN ANIMALS

There has been a lot of activity in relation to antimicrobials and antimicrobial resistance during the last year. In response, the FDA Center for Veterinary Medicine has published a document describing a way in which this issue might be addressed. The document is titled:

"A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New

Animal Drugs Intended for Use in Food-Producing Animals."

This document can be found on the FDA/CVM website at the following address:

<http://www.fda.gov/cvm/fda/infores/vmac/antim18.htm>

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