



Western Association of Food & Drug Officials

# THE FLASH!

Alaska, Alberta, Arizona, British Columbia, California, Colorado, Guam  
Hawaii, Idaho, Mexico, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming

[www.wafdo.org](http://www.wafdo.org)

## WAFDO Board of Directors

### President

Claudia Coles, Food Safety Program Mgr  
Washington Dept. of Agriculture  
111 Washington Street  
Olympia, WA 98504-2560  
Phone: (360) 902-1905 Fax: (360) 902-2087  
Email: [ccoles@agr.wa.gov](mailto:ccoles@agr.wa.gov)

### President Elect

Barbara Cassens, Director, State Cooperative Programs  
US FDA Pacific Region  
1301 Clay Street, Ste. 1180N  
Oakland, CA 94612  
Phone: (510) 637-3960 Ext. 140 Fax: (510) 637-3976  
Email: [bcassens@ora.fda.gov](mailto:bcassens@ora.fda.gov)

### Past President

Mike Govro, Assistant Administrator  
Oregon Dept. of Agriculture, Food Safety Division  
635 Capitol St. NE  
Salem, OR 97301-2532  
Phone: (503) 986-4720 Fax: (503) 986-4729  
E.mail: [mgovro@oda.state.or.us](mailto:mgovro@oda.state.or.us)

### Secretary – Treasurer

Susan Parachini, Program Mgr.  
Wholesale Food Manufacturing & Storage  
Colorado Dept of Public Health & Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530  
Phone: (303) 692-3646 Fax: 303-753-6809  
Email: [Susan.parachini@state.co.us](mailto:Susan.parachini@state.co.us)

### Liaison to AFDO

Barbara Hruska, Director  
Consumer Protection Division  
Colorado Dept. of Public Health & Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530  
Phone: (303) 692-3639 Fax: (303) 753-6809  
Email: [barbara.hruska@state.co.us](mailto:barbara.hruska@state.co.us)

### Regional Board Members

Stuart Wilson, Regional Director  
Canadian Food Inspection Agency  
#101-620 Royal Ave  
New Westminster, BC, V3M 1J2  
Phone: (604) 666-2847 Fax: (604) 666-9814  
Email: [wilsons@inspection.gc.ca](mailto:wilsons@inspection.gc.ca)

Inge Small, Unit Chief  
California Dept. of Health Services  
Food & Drug Branch, P.O. Box 94273  
Sacramento, CA 94234-7320  
Phone: (916) 322-8443 Fax: (916) 322-6272  
E.mail: [ismall@dhs.ca.gov](mailto:ismall@dhs.ca.gov)

### FLASH! Editor

Sue Hutchcroft, Public Affairs Specialist  
US FDA - Seattle District  
22201 - 23rd Drive SE  
Bothell, WA 98021-4421  
Phone: (425) 483-4953 Fax: (425) 483-4996  
E.mail: [shutchcr@ora.fda.gov](mailto:shutchcr@ora.fda.gov)

## Message From the Board

Fall 2002

Greetings WAFDO Members! The arrival of our Fall FLASH reminds us of another year coming to a close. Reflecting on the events of the past year, as we do during waning December days, it is our hope the year 2002 brought professional and personal triumphs to each of you. Looking forward expectantly to the year to come, we wish you new and exciting challenges and achievements. As we take the next few weeks to be with our family and friends, let us think on the individual freedoms and prosperity we all share, and remember in prayer and deed those in our world who are less fortunate. Our thoughts are with our colleagues of the Pacific Islands, their friends and family, as they struggle to recover from the aftermath of yet another tropical storm, Typhoon Pongsona.

In closing, the WAFDO Board wishes Happy Holidays to each of you and your families - Good Health, Prosperity, and most importantly, Peace for all on Earth.



Each month the WAFDO board members meet to discuss issues of interest and make decisions that impact each of you. In each issue of the FLASH we will be now be including a new column keep you informed of key decisions made on behalf of the our WAFDO members. Should you have any questions for the Board on these topics or any other areas, please contact WAFDO President Claudia Coles at [ccoles@agr.wa.gov](mailto:ccoles@agr.wa.gov).

### November 12, 2002 Board Meeting:

- **MEMBERSHIP:** We decided to set a cutoff date for renewing annual membership at October 31. Dues received after that time would be applied to the upcoming calendar year. We also agreed to accept only U.S. funds for payment of dues to avoid significant bank charges for handling other funds.
- **ANNUAL MEETING:** This meeting will be held September 20 -24, 2003 at the Silver Legacy in Reno, Nevada. Mike Govro is chairing the planning committee for this meeting. If you have any ideas for agenda topics, speakers, or would like to help in any way, please contact Mike by phone at 503-986-4720 or electronically at [mgovro@oda.state.or.us](mailto:mgovro@oda.state.or.us).

## Fall 2002 FLASH! Highlights

Orlen Weimann Remembered.....	2
Where's the Beef.....	3
Encephalitis Surveillance.....	4
AFDO Seeks Nominees for Awards.....	5
Dr Crnich Joins Utah.....	6
Dr Osorio Joins FDA's Pacific Region.....	7
FDA's Bioterrorism Act Website.....	9

## Orlen J. Wiemann Remembered

*Submitted by Barbara Hruska, Director Consumer Protection Division, Colorado Dept of Public Health and Environment*

Orlen J. Wiemann passed away September 12, 2002. Mr. Wiemann was head of the Milk, Food, and Drug Section of the Colorado Department of Health until he retired in May of 1979. This section is currently the Consumer Protection Division of the Colorado Department of Public Health and Environment. Orlen Wiemann provided a key leadership role for the drafting, adoption, and implementation of the *Colorado Pure Food and Drug Law*, *Colorado Restaurant Law*, and the *Colorado Hazardous Substances Act*. Mr. Wiemann served twice as president of the Western Association of Food and Drug Officials (WAFDO) and the highest award given by WAFDO is named after the first recipient of the award, Orlen J. Wiemann. He was president of the Association of Food and Drug Officials (AFDO) in 1967 and was the recipient of AFDO's Harvey W. Wiley Award in 1987. Mr. Wiemann served as Editor of the AFDO Journal from 1970 until 1987 and was active on numerous AFDO committees. Orlen Wiemann's past contributions to public health protection continue to provide a structure for core regulatory responsibilities and are greatly valued.

## Mark McClellan to be Commissioner of the Food and Drug Administration

Mark B. McClellan was confirmed as Commissioner of the Food and Drug Administration on October 17. Dr. McClellan is currently a member of the President's Council on Economic Advisors, and he also serves as a senior policy director for health care and related economic issues for the White House.

When he nominated Dr. McClellan, President Bush said "As a doctor and researcher, Mark McClellan is uniquely qualified to serve as Commissioner of the Food and Drug Administration. His experience will be very valuable as the FDA faces new challenges in the coming year, including the implementation of legislation I recently signed to help protect the nation from bioterrorism threats, to help speed access to breakthrough medical treatments,

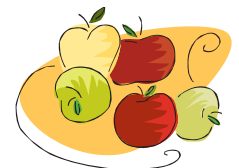
and to make medical treatments safer. As head of the FDA, Mark will focus on empowering consumers and ensuring rapid access to products that are safe and effective."

Dr. McClellan was confirmed as a Member of the Council of Economic Advisers by the Senate on July 19, 2001. Before joining the CEA, he was Associate Professor of Economics at Stanford University, Associate Professor of Medicine at Stanford Medical School, a practicing internist, and Director of the Program on Health Outcomes Research at Stanford University. He was also a Research Associate of the National Bureau of Economic Research and a Visiting Scholar at the American Enterprise Institute. Additionally, he was a Member of the National Cancer Policy Board of the National Academy of Sciences, Associate Editor of the *Journal of Health Economics*, and co-Principal Investigator of the Health and Retirement Study (HRS), a longitudinal study of the health and economic well-being of older Americans. From 1998-99, he was Deputy Assistant Secretary of the Treasury for Economic Policy, where he supervised economic analysis and policy development on a wide range of domestic policy issues.

His research studies have addressed measuring and improving the quality of health care, the economic and policy factors influencing medical treatment decisions, technological change in health care and its consequences for health and medical expenditures, uninsurance, and the relationship between health and economic well-being. He has twice received the Arrow Award for Outstanding Research in Health Economics. He earned his MD degree from the Harvard-MIT Division of Health Sciences and Technology and his PhD in Economics from MIT. He completed his residency training in internal medicine at Brigham and Women's Hospital, and he is board-certified in Internal Medicine.

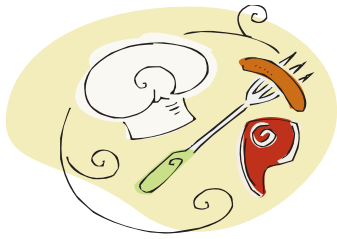
## Juice HACCP Training

*Jim Waddell, Chief Food Safety Section  
California Dept of Health Services*



Federal regulations developed to make fruit and vegetable juices safer for consumers are now mandated for large juice processors, and all other juice processors will be required to comply by January 22, 2004. The regulations mandate manufacture under a Hazard Analysis and Critical Control Point program (HACCP). HACCP has been mandated for all seafood processors since 1997. Juice HACCP is intended to ensure that all commercial juice is free of pathogens such as Salmonella, Listeria, E. coli O157:H7 and Cyclospora. Recent California illness outbreaks have been caused by contaminated carrot juice, orange juice, and apple juice. To implement these new regulations, California's Food and Drug Branch (FDB) worked with the National Juice HACCP Alliance, U.S. food and Drug Administration (FDA) and the Association of Food and Drug Officials to develop a training curriculum. FDB then developed courses for regulators and industry. FDB completed its initial Train-the-Trainer program and trainer training on October 3, 2002 developing six trainers (4 FDB and 2 FDA). Training for FDB and FDA has now been conducted on October 9-10 (Sacramento) and October 23-24 (Irvine). The number of investigators estimated to have attended is 150. This training will

be followed up with a half-day of compliance training via satellite by FDA on October 30, 2002. This training will facilitate implementation of the regulations and safer juice production in California.



## Where's The Beef? More Importantly, Cook Your Ground Beef! An Investigation of Foodborne Illness Related to ConAgra Ground Beef

*Article submitted by: Karen Gieseke, Ph.D, Disease Control and Environmental Epidemiology Division; James Beebe, Ph.D., Laboratory and Radiation Services Division; Patricia Klocker, Consumer Protection Division.*

During July and August of this year, Disease Control and Environmental Epidemiology (DCEED), Consumer Protection (CPD) and Laboratory and Radiation Services (LARS) Divisions participated in the investigation of a foodborne illness outbreak associated with the consumption of ground beef contaminated with *E. coli* 0157:H7. *E. coli* 0157:H7 is a bacterial illness causing non-bloody diarrhea that progresses to diarrhea with visible blood. Other symptoms include abdominal cramps, fever, fatigue, and vomiting. Hemolytic uremic syndrome (HUS) is a severe complication of *E. coli* 0157:H7. Transmission is most often through ingestion of contaminated foods and incubation ranges from 1-8 days, with an average of 3-5 days.

In response to two national ground beef recalls and evidence of an increase in cases of *E. coli* 0157:H7, a news release entitled "Thoroughly Cooked Hamburgers Important to Safe Holiday," was distributed on July 2, 2002, by CDPHE to remind Coloradans of the importance of thoroughly cooking hamburger to prevent illnesses caused by the *E. coli* bacteria. At the same time, epidemiologic investigations of *E. coli* 0157:H7 cases began to show an association of illness to ground beef purchased at Safeway Stores. Additionally, it was discovered by CPD that the ground beef purchased at the Safeway Stores originated from the ConAgra Beef Company who had recalled 354,200 pounds of ground beef on June 30, 2002. ConAgra supplied a list of distributors who were then contacted by CPD to ensure that the contaminated meat was being removed from distribution. By July 8th, LARS had identified 12 matching cases of *E. coli* 0157:H7 by using pulse field gel electrophoresis (PFGE) a method of DNA fingerprinting.

Based on information from all three divisions, DCEED, CPD and LARS, a press release was issued noting that ground beef sold in Colorado was the focus of an *E. coli* 0157:H7 outbreak. This press release resulted in front page coverage by the Denver Post indicating that 12 cases of *E. coli* 017:H7 from nine counties had been identified, and warning consumers to check their freezers,

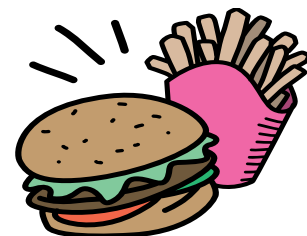
dispose of any suspect product, and when preparing ground beef to wash their hands, sanitize all surfaces that come in contact with raw ground beef, and to thoroughly cook all ground beef to a minimum temperature of 160 °F.

The following week, as case counts continued to increase, the Centers for Disease Control and Prevention, (CDC) confirmed that the PFGE pattern from a hamburger sample obtained by the USDA, from the ConAgra Beef Company in Greeley, matched the PFGE pattern of the cases in Colorado. Additionally, ground beef from the freezer of one of the initial cases also matched the outbreak PFGE pattern. At the same time, more cases of *E. coli* 0157:H7 linked to ConAgra ground beef were being identified in other states, which prompted ConAgra to expand their ground beef recall to 18.6 million pounds on July 19, 2002. This was the second largest recall of ground beef in US history.

After ConAgra expanded their initial recall, CPD made continuous efforts to obtain lists of distributors and wholesalers from ConAgra. Once received, every distributor and wholesaler in Colorado that had any meat implicated in this recall was contacted. Contacts made resulted in determining that very little of the product was returned to ConAgra. The majority of the contaminated ground beef was cooked and served in several restaurants throughout Colorado and sold directly to customers in seven different grocery stores, one of which was a national grocery chain. All reported illnesses in Colorado were the result of ground beef prepared at home. None of the reported illnesses were implicated as a result of consuming contaminated ground beef from a restaurant.

DCEED reported that a total of 22 cases of *E. coli* 0157:H7 from 10 counties were associated with this outbreak. The average age was 22 years with a range from 1 – 72 years. Onset dates of illness were from June 12<sup>th</sup> to July 22<sup>nd</sup>, 2002. Colorado had 12 hospitalizations, 4 cases of HUS, and no deaths associated with this outbreak. Nationally, the CDC reported 38 cases from 11 states, 17 hospitalizations, 6 cases of HUS, and one death associated with this outbreak.

Lessons learned include: (1) that communication between local, state, and national entities is essential in identifying and investigating a multi-state outbreak associated with ground beef contamination; (2) that PFGE is an important laboratory method in identifying outbreak cases and potential vehicles of contamination; (3) that collaboration between health agencies, the public, and private industry is vital in protecting the health of the public and in preventing additional illnesses in such an outbreak; (4) and that teamwork between DCEED, CPD and LARS is fundamental in the identification, investigation and prevention of this public health threat.



---

## Encephalitis Surveillance Program

*Submitted by: John Pape, Disease Control & Environmental Epidemiology Division, CDPHE; Dale Tanda, Consumer Protection Division, CDPHE*

The Colorado Department of Public Health and Environment has participated in encephalitis surveillance since 1969 when the Department and CDC set up sentinel chicken flocks in Sterling, San Luis Valley, Lamar, Grand Junction, and Durango. Cooperative surveillance activities with CDC continued until 1972. Following the 1977 Big Thompson flood, sentinel chicken flocks were again set-up as a precaution to monitor for encephalitis activity.

Following the 1987 encephalitis outbreak that resulted in thirty (30) human cases and 1 death in Colorado, local health departments and CDPHE established a surveillance system to monitor for Western equine and St. Louis encephalitis. Over the past 14 years, the program has expanded to include sixteen (16) local health departments, private firms, mosquito abatement districts, CDC and members of the public.

In anticipation of the arrival of the West Nile Virus (WNV) into Colorado, the surveillance program was expanded beyond its traditional sentinel chicken flocks to include dead birds and mosquitoes. Because St. Louis (SLE) and Western equine encephalitis (WEE) are bird viruses that occasionally infect humans and horses, chickens are used to provide an early warning system to public health officials that virus is circulating in the local bird population. Although WNV is also essentially a bird virus, the disease has created new problems and challenges for the surveillance program. It is hoped that sentinel chicken flocks supplemented with dead bird surveillance and increased mosquito trapping and testing will provide the program with a detection system that will enable CDPHE to provide timely public announcements as well as guidance to local health authorities relative to response and control strategies.

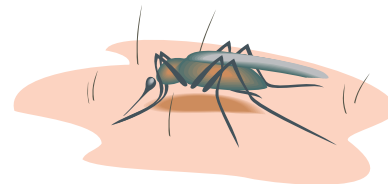
Next year, it is anticipated that mosquito trapping and testing will increase as a component of encephalitis surveillance since they are the insect vector in the transmission cycle of the disease, can be tested for all three viruses and because the portability of the traps allows trapping to be done nearly anywhere mosquito activity is suspected.

In regard to mosquito control issues, monitoring mosquito breeding areas and trapping adult mosquitoes are key to determining whether control efforts are necessary. To maximize the use of limited resources, monitoring the presence of mosquitoes is paramount before instituting control measures. Dipping for mosquito larvae provides information on breeding habitat, species, and relative numbers. Adult mosquito trapping provides information on the species of mosquito present, historical comparison of population density, and specimens to test for the presence of virus.

This year, the lab began testing mosquitoes for the presence of WNV, SLE, and WEE. The Colorado Dept. of Public Health and Environment Laboratory and Radiation Services (CDPHE/LARS) performed a molecular test (i.e., RT-PCR) to determine the presence of virus. In addition, the dept. also purchased portable field test kits that could detect the presence of virus in mosquitoes in a 30 minute test. Although these portable test kits are only half as sensitive as the molecular test being used by the lab, the field test kits can provide real time results for local health depts.

*Culex pipiens* is suspected of being the primary mosquito species that circulates WNV, SLE, and WEE among birds. *Culex tarsalis* is thought to be a very good mosquito species for transmitting the viruses to humans and other mammals.

Controlling mosquito populations by eliminating breeding sites is the key to breaking the transmission cycle of WNV, WEE, SLE, and other mosquito borne diseases. The process is not simple nor is it cheap; however, domestic actions as simple as eliminating/draining or frequently changing water filled containers (e.g., bird baths, fountains, unused tires, cans, leaking sprinkler heads, wading pools, livestock tanks, etc.) collectively can dramatically reduce the number of mosquitoes and subsequently reduce the risk of exposure to these diseases.



## Training Brought to Guam after Typhoon Chata'an

In response to a request for assistance from Guam's Department of Health, Richard Runyon, Interstate Sanitation Specialist (Seattle District FDA) and Dr. Chang-Rae Lee, Scientist (California State DHS) held four days of safe water training in Guam, Sept. 26 through Oct. 1, 2002. During the typhoon, the island's municipal water sources were contaminated, putting a higher demand on bottled and vending water supplies that are recovered from the same source. The training consisted of classroom lectures and field tours for regulators to apply the classroom training that included safe and sanitary operations for water transport, vending, and bottling operations. Seventy individuals attended, including representatives of the Guam Department of Health, Guam EPA, industry and hotel operators. The training was well received and additional training avenues will be explored.

On his return trip Richard Runyon had an opportunity to meet with Saipan Health Officials to review their drinking water situation. Saipan has many of the same issues as Guam with regards to providing potable water for its people.

---

---

## AFDO Seeks Award Nominees



AFDO has put out another call for nominees for the honor awards to be given at the next conference in Chicago. Please take some time to consider the following awards and nominate one of your colleagues, associates or a worth student.

### **ACHIEVEMENT AWARD**

Nominations are being sought for the AFDO achievement Award for exceptional accomplishments, during calendar year 2002.

Eligible candidates must be in their first five years of service as a sanitarian, food specialist, radiological health inspector, consumer product safety inspector, or similar regulatory position.

The individual must be a field person, who has displayed one or more specific achievements, or has documented sustained high levels of performance.

Examples that would be considered are:

Developing evidence in a specific case that results in an indictment, conviction or administrative action.

Bring about a measurable improvement in general conditions such as raising test scores on dairy farms or average scores in food service establishments.

Candidates must be employed by a federal, state, county, or municipal regulatory agency, that has at least one employee who is a member of AFDO. The candidate does not have to be a member of AFDO.

### **ASSOCIATE AWARD**

Nominations are being sought for the AFDO Associate Award, which will be presented at the 2003 Annual Conference, in Chicago, Illinois. The award is presented to an Associate Member, based on the following.

Long term active membership in the Association:

Active involvement in committee work:

Development of model codes:

Promoting the objectives of AFDO:

### **SCHOLARSHIP AWARD**

Applications are being sought for the AFDO Scholarship Award. The George M Burditt Scholarship and the Betsy B Woodward Scholarship both in the amount of \$1500.00 are awarded annually to two worthy recipients, who are in their third or fourth year of college.

The following qualifications have been established for the award recipients:

The recipients should have demonstrated a desire to serve in a career of research, regulatory work, quality control, or teaching in an area related to some aspect of foods, drugs, or consumer product safety:

The recipients should have demonstrated leadership capabilities and must have at least a 2.5 grade average during the first two years of undergraduate study:

It is necessary to use the official AFDO form to nominate your candidate.

Forms are available from Gene Blake, Awards Chair, at 37 Green St Concord NH 03301 or by e-mail [eblake@ci.concord.nh.us](mailto:eblake@ci.concord.nh.us)

Nominations must be returned to the Awards Chair by Feb 1 2003 to be considered.

---

## Oregon Report

*Submitted by Mike Govro, Asst. Administrator, Oregon Dept of Agriculture*

### **E. coli Outbreak**

The Lane County Fair was the site of E. coli 0157:H7 outbreak last August. Epidemiologists considered food as a possible vehicle of transmission but changed their minds when they discovered that the fair's animal exposition was the common link among those who had become ill. About 65 people became ill, and 12 were hospitalized with hemolytic uremic syndrome. One person was hospitalized for over a month and will suffer serious long-term effects and several others will suffer less serious long-term effects from the illness.

Epidemiologists from Oregon Health Services Division were unable to identify a specific source of the contamination common to visitors of the animal barn. There were no common links such as contact with animals, equipment or structures; handwashing practices; specific areas of the barn visited; or time spent in the barn among those that became ill. After the outbreak, state epidemiologists and county health officials swabbed surfaces in the barn and found a matching strain of E. coli on upper surfaces such as roof beams and light fixtures. While it appears that E. coli was airborne in the barn, epidemiologists are not ready to conclude that the illnesses were caused by airborne transmission, although they believe it was possible.

### **Food Code Adoption**

The Oregon Department of Agriculture is nearly finished with its adoption of the Food Code. The Food Safety Division conducted staff training on the new code the week of October 21 and held public hearings on the adoption in three cities the week of October 28. Only testimony in favor of the adoption was received. If the code is signed into rule as expected, it will become effective January 1, 2003. ODA will complete revision of its computerized inspection program to accommodate the new code before implementation. The new inspection form will document incidence or absence of risk factors on the cover page with "yes", "no", "not applicable" and "not observed" categories.

Oregon Health Services, which adopted the code last year for use in food service facilities, will undertake a code revision in the near future to clean up minor problems and also adopt a prohibition against the use of latex gloves.

### **Labeling of genetically engineered food**

On November 6, Oregon voters rejected a citizens' initiative that would have required that all food sold or distributed in or from Oregon that contained genetically engineered (GE) ingredients in excess of one tenth of one percent bear a label that claimed it was genetically engineered.

The measure's definition of GE foods was considerably broader than the definition used in the National Organic Program or other countries that require the labeling of GE foods. It included meat and milk that came from animals that had been fed GE feed or had been given GE antibiotics, hormones or other inputs, regardless of whether the final product contained GE material. It also applied

to crops grown using GE agricultural inputs, and foods manufactured using GE enzymes or processing aids, regardless of whether GE ingredients were present in the final product. While the initiative's filers claimed that they didn't intend for the measure to include restaurant food, the language in the measure did not exclude it.

The measure was opposed by a well-funded coalition of agriculture, food industry and biotechnology interests that argued that the measure would harm Oregon businesses and be costly to Oregonians. Opponents estimated that the measure would cost a family of four about \$550 per year, while proponents estimated the cost at 71 cents per year. Proponents claimed a fundamental right to know how their food is produced and claimed that GE food is or could be unsafe.

FDA Deputy commissioner Lester Crawford wrote a letter to Oregon's governor, stating that GE food is as safe as conventional food, and that the measure would "impermissibly interfere with manufacturers' ability to market their products on a nationwide basis." The measure was rejected by about 75% of the voters.

## **Dr. Chris Crnich Named Regulatory Services Director**

*Submitted by Kyle Stevens, Director Division of Regulatory Services, Utah Dept of Agriculture and Food*

Utah Commissioner of Agriculture and Food, Cary G. Peterson, today announced the appointment of Dr. Chris Crnich as Director of the Division of Regulatory Services. Dr. Crnich, a Doctor of Veterinary Medicine, is currently the Manager of the Division of Animal Industry's Meat and Poultry Inspection program.

"Dr. Crnich has distinguished himself as a highly organized and motivated leader in our department," said Commissioner Peterson. "As the new director of Regulatory Services, he brings those skills that earned him one of the Governor's "Manager of the Year" awards for the State of Utah," Peterson added. Dr. Crnich's appointment takes affect immediately.

Regulatory Services is responsible for several important consumer-oriented programs such as Food Compliance; Meat, Egg and Poultry Compliance; Dairy Compliance; Weights and Measures; and Labeling and Product Compliance.

"I am extremely honored and thrilled to have been selected for this new and challenging assignment," said Dr. Crnich. "I look forward to working with the many dedicated and professional individuals in Regulatory Services," he added.

Dr. Crnich manages the department's meat and poultry inspection program that has earned the rare U.S. Department of Agriculture Category I status. This program serves as a model for other states.

Since 1982 Dr. Crnich has been the U.S. Air Force's Chief of Military Public Health for the 419<sup>th</sup> Medical Squadron at Hill Air Force Base. As such, he has gained much experience and knowledge in

---

the field of medical intelligence and disaster preparedness, and participates directly in the department's homeland security and public safety responsibilities. This military/public safety background contributed greatly to the department's successful food safety program during the 2002 Winter Olympics.

He has improved his staff's computer literacy, as well as internal communications that add to the program's efficiency.

His management style focuses on the well being of his employees. Dr. Crnich went out of his way to locate a training tutor to assist an employee who had a reading impairment. As a result, this employee has significantly increased his oral reading skills as well as his self-confidence.

Dr. Crnich graduated from the University of Utah with a B.A. degree in Biology. He earned a D.V.M. in General Veterinary Medicine and Surgery from Colorado State University. He was the Air Force Reserve's Public Health Officer from 1999 to March of 2002, and has been the manager of the department's Meat and Poultry Inspection Program since 1999.

Dr. Crnich fills the vacancy created in April of 2002 when former Regulatory Services Director, Kyle Stephens, was named department Deputy Commissioner.

## **New Retail Food Specialists**

*Submitted by Carolyn Swanson,*

Welcome Sharon Smith and Brad Tufto to the Pacific Region of FDA and the Cooperative Programs Staff, also known as CPOG! They will be joining Katey Kennedy, John Marcello, Richard Ramirez, and Lisa Whitlock as retail food specialists. Sharon, who began her work with FDA on October 21, 2002, will work out of the Puget Sound Resident Post in Seattle (206-553-7001, ext. 12). Brad, beginning on November 4, will be located in the Spokane Resident Post (509-353-2470).

Together, they bring to FDA 33 years of environmental health experience!

Sharon Smith is a registered sanitarian in food safety and environmental health and comes to us from Seattle-King County Health Department. Brad Tufto, an environmental health officer/program supervisor, joins us from the Alaska Department of Conservation.

We are hoping Spokane winters will bring back good Alaska memories for Brad, who enjoys hunting and fishing, and generally being outdoors. He also knows how to make an excellent barbecue sauce. Sharon, already living north of Seattle, is an animal lover, or, as she puts it, a "critter" lover. She has been known to volunteer at animal shelters and sometimes as a foster parent for the animals.

We wish them both well in their new positions with FDA. FDA is pleased to have them.

## **Regional Medical Officer Joins FDA Pacific Region**

Commander Anna Maria Osorio, MD, MPH, recently began her work at FDA Pacific Region, Oakland, California. Dr. Osorio provides medical assistance for Pacific Region field investigations for all FDA regulated products, develops training on food safety counter-terrorism, creates training curricula on the evaluation of disease outbreaks and related epidemiological concepts, and assists the regional headquarters staff on medical and epidemiological projects, as needed. Prior to coming to FDA, Dr. Osorio served within the California Department of Health Services as Chief of the Occupational Health Branch, then as Chief of the Division of Environmental and Occupational Disease Control, and, subsequently, acted as the Chief Medical Officer for the Office of Pesticide Programs at the U.S. Environmental Protection Agency.

Dr. Osorio comes to FDA with an impressive background in public health. She is board-certified in Occupational Medicine and has an MPH in Epidemiology. Her training includes serving as an Epidemic Intelligence Service Officer at the National Institute for Occupational Safety and Health (NIOSH) and Centers for Disease Control and Prevention (CDC). Dr. Osorio is the author of numerous book chapters and journal articles dealing with various aspects of environmental and occupational medicine and has lectured in Latin America, Europe, Asia, and Africa. Her research topics include agricultural worker health, pesticide-related health conditions, reproductive hazards in the environment, ergonomic risk factors, environmental pulmonary hazards, tribal medicine, cancer workplace risks, adult and child lead intoxication, public health disease monitoring systems, and international public health issues.

***We sincerely welcome Dr. Osorio to FDA and the Pacific Region!***

## **Pacific Region's Milk Seminar**

Each November the Annual Pacific Region's Milk Seminar brings together a variety of people to provide a meaningful dairy forum: State Milk Rating and Sanitation Officers; State Dairy Program Directors; FDA Regional Milk Specialists; FDA Regional Management; FDA Headquarters folks from the Division of Federal/State Relations, State Training Branch, Milk Safety Branch, Laboratory Quality Assurance Branch; a Staff Fellow; industry leaders; and academia personnel! All are welcome.

**The Dates:** November 19-21  
**The Location:** The Atlantis Hotel in Reno, Nevada.

The agenda makers seek to make the Seminar heavily programmed with information on the topics that have become the concern of today. These topics include the dairy import issues, food allergens, new juice HACCP requirements, dairy food safety, and food borne illness outbreaks.

---

Besides sharing and receiving information, each state brings an item of food or drink especially connected with that area. Together they provide a hospitable table of good things from our western states.

## **An International Event**

In a spirit of true cooperation by many agency and industry personnel, Chilean visitors, Dr. Claudio Poblete and Dr. Oscar Vedela, were welcomed to the United States. This important event, held in Oakland, California, was designed to explain the U.S. regulatory system regarding dairy products. Working cooperatively, and within a short time frame, the U.S. Food and Drug Administration, U.S. Department of Agriculture, California Department of Food and Agriculture, Land O' Lakes Western Region, and Cheese and Protein International, LLC put together a successful program. Both Drs. Poblete and Vedela were thoroughly impressed by the nature of the United States dairy industry and regulatory structure, the technical expertise of the various staff members, and the hospitality and open communication demonstrated between industry and regulatory members. It is hoped the exchange will facilitate resolution of the U.S. Free Trade Agreement with Chile.

## **It Really Is Happening in Retail Food!**

*Seventy-two (72) jurisdictions have enrolled in the FDA Program Standards nationwide and 30 of them are right here in the Pacific Region!*

What is the "Nine-Step" Program Standards Program?

It's voluntary. Its input comes from 1997 grassroots meetings and many weeks/years of workshops of federal, state, and local regulatory officials, trade and professional associations, academia, and consumers. Nine (9) National Retail Food Program Standards are in place. The Conference for Food Protection has charged FDA to work with selected State and local regulatory jurisdictions in the use of these standards.

The Standards apply to the operation and management of a regulatory retail food program focused on the reduction of risk factors known to cause food borne illness and on the promotion of active managerial control of these risk factors. They provide a foundation for regulatory agencies to conduct their own retail food program self-assessments against the Standards, identify gaps, and develop a strategic plan for enhancing program effectiveness. The nine standards ask the following questions:

What is your Regulatory Foundation?

How do you train your Regulatory Staff?

Is your inspection program based on HACCP principles?

Does your Inspection Program have uniformity?

What do you do for Food Borne Illness Surveillance?

Is it sufficient?

Are you in compliance and, if not, how do you handle enforcement?

Are your Industry & Community Relations good?

What are you doing to enhance those relations?

What are your Program Resources?

Overall, what is your Program Assessment of these factors?

The Program is ongoing, not stagnant, as evidenced in a Follow-Up Workshop for the 30 enrollees (and those interested in enrolling) August 15-16, 2002, in Stateline, Nevada. It included participants from State, Federal, and Local regulatory as well as industry who shared from their various perspectives experiences in conducting food program self-assessments against the Standards criteria, the challenges, discoveries, and benefits.

Thanks to the leadership from Pacific Region's Retail Food Specialists, John Marcello, Katey Kennedy, Lisa Whitlock, and Richard Ramirez for their hard work.

You can view the complete Program Standards at the web site [www.fda.gov](http://www.fda.gov).

## **Consent Decree Filed in Conjac Candy Case**

*Submitted by Tom Sawyer, FDA Los Angeles District*

On May 22<sup>nd</sup>, 2002, a Compliant for Forfeiture was filed in the Central District Court in Los Angeles, to seize thousands of mini-cup gel candies in possession of New Choice Food Inc., Irwindale, Ca. These mini-cup gel candies consisted of a flavored center, or in some instances a piece of fruit enclosed in a small shell of konjac jelly (also called conjac, konnyaku, or glucomannan). The candies were packaged as individual, mouth size servings in small cup-like plastic containers which are similar in size and shape to individual coffee creamer servings, except that the containers have a rounded bottom which gives the product a bullet shape. The principal charge was that the product is unfit for food because the articles pose a serious choking hazard [Section 402(a)(3) of the Food, Drug and Cosmetic Act]. The case was brought after FDA became aware that the mini-cup jelly products were associated with a series of suffocation deaths and near-deaths due to suffocation among children and elderly persons who consumed the product. Mini-cup gel candies have caused at least six choking deaths in children within the U.S. Both FDA and experts at the U.S. Consumer Product Safety Commission concluded that the packaging, size, slipperiness and consistency of the products contribute to their inherent choking potential. In October of 2002, after a contested seizure case unfolded through the Court, the claimant, New Choice Food Inc., entered into a Consent Decree of Condemnation and Destruction, which also has a provision for withdrawing any remaining stocks from distribution channels. FDA will witness the destruction of the seized and withdrawn products. In the summer of 2002, a number of other firms recalled similar mini-cup gel candies. The State of California, Food and Drug Branch, was instrumental in placing embargoes on several locations where the mini-cup gel candies

---

were found, and was of great assistance in this effort to remove this dangerous product from the marketplace.

## FDA Bioterrorism Act in on Line

FDA has added a new page to its existing bioterrorism website to provide information on the agency's efforts, related to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

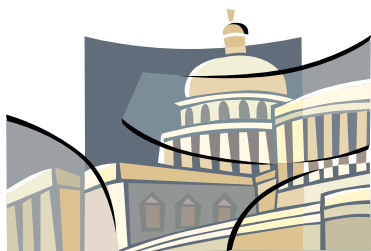
Signed into law by President Bush on June 12, 2002, this semiannual legislation authorizes the Department of Health and Human Services (HHS) to take specific measures to protect the nation's food and drug supplies against bioterrorist threats. FDA, as the primary regulatory arm of HHS for these products, is responsible for implementing those measures.

The new page on the Bioterrorism Act provides easy access to the Act, the provisions of the law related to FDA, and the Agency's activities to implement these provisions.

Among the website's features are:

- An overview of the Bioterrorism Act, including those aspects that most involve FDA such as protecting the nation's food, drug and biologic supplies.
- FDA's plans for implementing the Act, including four proposed rules for protecting the food supply. These rules include Registration of Food Facilities; Establishment and Maintenance of Records for Food Facilities; Prior Notice of Imported Food Shipments; and Administrative Detention Authority.
- Summaries of the provisions related to FDA as well as links to guidance documents, Federal Register notices, and dockets associated with the respective provisions.
- Links for directly submitting electronic comments to the dockets established for registration of food facilities; establishments and maintenance of records for food facilities; prior notice of imported food shipments; and administrative detention authority.
- Links to other sources of information related to the Bioterrorism Act at websites for the White House, the U.S. Centers for Disease Control and Prevention, and individual FDA centers.
- Access to FDA updates on its activities related to the Bioterrorism Act through a free subscription to a directed E-mail list.

The new FDA Bioterrorism Act site is at,  
<http://www.fda.gov/oc/bioterrorism/bioact.html>.  
FDA's main bioterrorism site is  
<http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html>.



## FDA Strengthens Controls, Issues Consumer Alert on Importing Certain Prescription Drugs

As part of its ongoing efforts to reduce preventable adverse events from the products it regulates, the Food and Drug Administration (FDA) today announced that it is strengthening the controls designed to protect patients by restricting imports of certain prescription drugs that can be used safely only with specified controls in place.

FDA's action involves adding the drugs to an existing FDA Import Alert, which alerts FDA field personnel to the possible importation of these drugs, provides guidance as to their detention and refusal of admission into the United States, and also advises United States Customs personnel to refer any attempted importation to the local FDA field office.

The drugs added to the Import Alert are as follows:

- Accutane (isotretinoin) - indicated for the treatment of severe recalcitrant nodular acne
- Actiq (fentanyl citrate) – indicated for the management of severe cancer pain in patients who are tolerant to opioid therapy
- Clozaril (clozapine) – indicated for the management of severe schizophrenia in patients who fail to respond to standard drug treatments for schizophrenia
- Lotronex (alosetron hydrochloride) – indicated for the treatment of severe irritable bowel syndrome in women
- Mifiprex (mifepristone or RU-486) – indicated for the medical termination of early intrauterine pregnancy
- Thalomid (thalidomide) – indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum
- Tikosyn (dofetilide) - indicated for the maintenance of normal sinus rhythm in patients with certain cardiac arrhythmias
- Tracleer (bosentan)- indicated for the treatment of severe pulmonary arterial hypertension
- Trovan (trovafloxacin mesylate or alatrofloxacin mesylate injection) - an antibiotic administered in in-patient health care settings for the treatment of severe, life-threatening infections
- Xyrem (sodium oxybate)- indicated for the treatment of cataplexy in patients with narcolepsy

In a related action, FDA today alerted consumers not to buy these drugs over the internet, because drugs obtained via websites usually are not accompanied by these safety controls. FDA is concerned about the safety risks posed by use of any of these products without the specified controls in place.

The revised Import Alert and the consumer advisory are available online at [http://www.fda.gov/ora/fiars/ora\\_import\\_ia6641.html](http://www.fda.gov/ora/fiars/ora_import_ia6641.html) and <http://www.fda.gov/oc/buyonline/consumeralert120902.html> respectively.

Although these drugs have important benefits for many patients, they have serious known risks and so are available in the U.S.

---

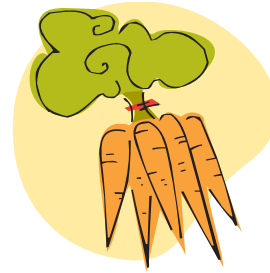
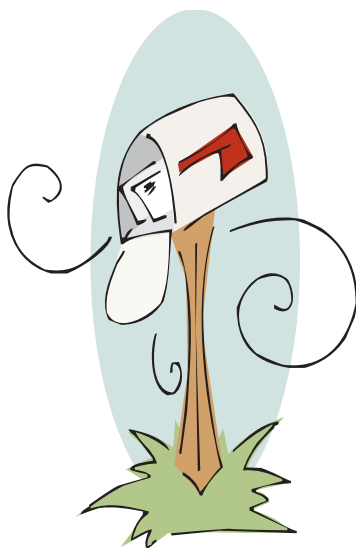
only under specially created safety controls. These safety controls are bypassed when these drugs are purchased from foreign sources, placing patients who use these imported drugs at higher risk. Therefore, because of this higher risk to patients, FDA took action to further curtail the products' availability from foreign sources. The drugs purchased from foreign sources are generally not FDA-approved.

Controls on these prescription drugs include limiting their distribution to specific facilities (such as hospitals); limiting their distribution to physicians with special training or expertise; or requiring certain medical procedures (such as pregnancy testing or blood testing) with their use.

Commissioner of Food and Drugs Mark B. McClellan, M.D., has set as a major FDA priority the reduction of preventable adverse events. "The FDA is committed to taking action, through educational activities and other means where necessary, to improve patient safety," said Dr. McClellan. "Use of these FDA-approved products without adequate controls or monitoring, and using versions of these products not approved by FDA, increases the risk of serious adverse events for patients who might otherwise benefit from the drugs' use."

According to a 1999 report by the Institute of Medicine, medical errors in hospitals alone cause annually 40,000-98,000 deaths. The IOM has estimated that preventable adverse events cost the United States economy \$17 billion a year.

Detailed information for consumers and patients who would like to learn more about how to buy prescription drugs safely may be found in FDA's guide, "Buying prescription Medicines Online: A Consumer Safety Guide," available online at <http://www.fda.gov/cder/drug/consumer/buyonline/guide.htm>



### **Note from AFDO about Organic Certification Cost-Share Program**

Dear AFDO Member:

We have just received information that funds are available to states to assist organic producers or organic handlers certified to the National Organic Program.

States interested in obtaining cost-share funds for their organic producers or handlers will have to submit an application for Federal Assistance, and will have to enter into a cooperative agreement with AMS for the allocation of such funds.

Completed applications for federal assistance along with signed cooperative agreements must be received by December 31, 2002 in order to participate in the program.

Individual producer/handler payments for certification are limited to 75% of the costs incurred by the producer or handler in obtaining certification under the National Organic Program as certified to and approved by the Secretary, up to a maximum of \$500 per year.

For additional information, interested producers and handlers should contact their state agency (Department of Agriculture) contact person. A state contact list can be found at [www.ams.usda.gov/nop](http://www.ams.usda.gov/nop). The state agencies will be collecting applications and making the decisions on reimbursement.

Tiffany Wimmer  
Administrative/Special Projects Assistant  
717-757-2888  
[www.afdo.org](http://www.afdo.org)



## MEMBERSHIP

### Classifications

### Dues

Regulatory	Member is engaged in official regulatory activities	\$15.00
Retired	Member held an active membership in the Association during employment	\$15.00
Scholastic	Member is engaged in research, teaching or studying issues involving food, drug, cosmetics, devices, biotechnology or environmental control	\$15.00
Associate	Member is engaged in activities other than regulatory activities	\$50.00

**Please complete the bottom portion of this form and return with your dues to:**

**Western Association of Food and Drug Officials (WAFDO)**

P.O. Box 460725

Glendale, Colorado 80246

**Make Checks Payable to Western Association of Food and Drug Officials**

IRS-EIN 91-1149139

### The Western Association of Food and Drug Officials Membership Invoice

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Agency: \_\_\_\_\_ Firm: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Email Address: \_\_\_\_\_

Member type:

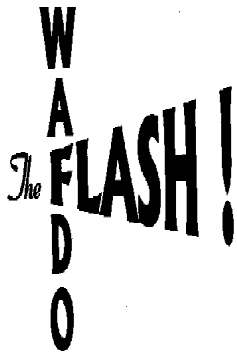
Regular (\$15.00)     Retired (\$15.00)     Scholastic (\$15.00)     Associate (\$50.00)

WAFDO Scholarship Fund donation \$ \_\_\_\_\_

Is this a New Membership  or Renewal?  Has your address changed?  Yes  No

Check here if you do NOT want your contact information published on WAFDO's Internet site ([www.wafdo.org](http://www.wafdo.org)) within the WAFDO Membership Directory.

Renewal membership dues must be received by December 31<sup>st</sup> of each year to remain in good standing for the coming year. Prices are in U.S. funds.



*Published by*  
**Western Association of  
Food and Drug Officials**  
c/o Food and Drug Administration  
22201 23rd Drive SE  
Bothell, Washington  
98021-4421



**Mark Your Calendars**  
**WAFDO Education Conference**  
**September 20-24, 2003**  
**at**  
**The Silver Legacy, Reno, Nevada**