S. A. I. L.

STATE ACTION INFORMATION LETTER

Published by the Division of Federal-State Relations
Office of Regulatory Affairs
Food and Drug Administration

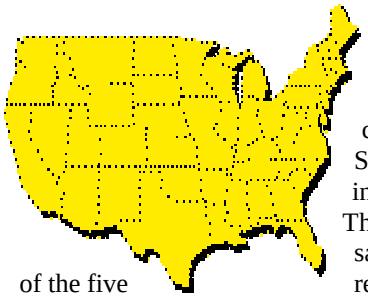
Editor: Cynthia C. Leggett
Design: Ada Y. Nelson
Winter 2001

Report from the Director

Richard H. Barnes

Happy New Year! The **State Action Information Letter** was started some years ago to serve as a mechanism for sharing information on consumer protection activities that the states engage in and as a means for letting local regulators know what's up with FDA. Are we accomplishing that goal? We want to know what you think about **S.A.I.L.** Do you find it useful and informative? Do you have ideas for additions – or deletions! - that would make it more valuable to you? We need to hear from you to assure that **S.A.I.L**. is providing a valuable service to its customers. You will notice, we have already changed the format for **S.A.I.L.** based on comments received earlier. Please complete the attached questionnaire and return to us by e-mail. In the meantime, here's to a productive New Year working together!

Report from the States



NEBRASKA - Ag Lab Samples Fast Food

In late October, the Nebraska Department of Agriculture food sanitarians collected foods from fast food restaurants to compare with the Nutrition Facts those restaurants provide to consumers. Samples were taken at five "fast-food" restaurants of sandwiches or French-fries. Since this was a special project and not done on a routine basis, all results were reported as indicators and no action was taken.

The results showed that the sandwiches often exceeded the declared fat, calories from fat, and saturated fat. The French fries often exceeded the sodium declaration. As a general rule, three of the five restaurants sampled met their nutrition statement declaration. Results were sent to the national corporate offices for their information. Two of the corporate offices were concerned enough to respond to the Department. For more information on the sampling and results, contact the Nebraska Department of Agriculture, (402) 471-2536.

WISCONSIN - *E., coli* 0157:H7 Detection Success Story!

FDA, USDA and the State of Wisconsin have a real success story to share. In September of 1999, the National Food Safety System's (NFSS) Laboratory Operations and Coordination Workgroup provided training for eight local, state, and federal laboratories participating in the *E. coli* 0157:H7 Pilot Program. In an effort to establish an integrated food safety system, the *E. coli* 0157:H7 Pilot Program was created to achieve the following goals: (1) Develop national standards for the analysis of *E. coli O157: H7*; (2) Obtain laboratory accreditation by International Organization for Standardization (ISO)-ISO Standard 17025, and (3) Effectively demonstrate electronic data exchange between local, state and federal laboratories. The City of Milwaukee Health Department (CMHD), one of the pilot laboratories, received training in the USDA method for meat samples and the FDA method for non-meat samples. By January/February, 2000, the *E. coli* 0157:H7 Pilot Program was ready to begin with all the pilot labs proficient in both the USDA and FDA methods.

Between July 12 – 22, 2000, a Milwaukee Sizzler Restaurant served ground beef that was ultimately implicated in an *E. coli* 0157:H7 foodborne outbreak. By July 18, eight people were reporting diarrheal symptoms. Ultimately, 63 people were culture positive, 20 were hospitalized and one child died. All persons had eaten at the restaurant over during a 10-day period. CMHD was notified on July 24th when the Lab received several cultures for stereotyping and a Children's Hospital nurse reported several children with apparent *E. coli*-related diarrhea. The next day, food histories implicated the restaurant, and within the next few hours of the first special inspection of the restaurant, CMHD was generating results using the newly acquired USDA/FDA methods.

A total of 92 food samples were obtained by CMHD. Of the 34 samples tested, one was positive for *E. coli* 0157:H7, two were inconclusive. Uncooked ground beef-contaminated salad bar items were implicated. The laboratory worked closely with the Wisconsin State Lab of Hygiene (WSLH), that performed the PFGE analysis as well as several Federal laboratories/agencies, sharing samples and communicating by email, faxes and conference calls on a regular basis throughout the investigation. Daily press conferences were held to keep the media as well as the general public informed of any new developments of the outbreak, which helped minimize community alarm and to decrease congestion within the system of true non-related cases.

All Microbiological work was under the direction of CMHD's Chief Microbiologist, Dr. Ajaib Singh who had attended several of the NFSS's *E. coli* 0157:H7 Pilot Program training sessions and was therefore able to respond quickly with the new technology. Prior to his adoption of this new technology, the State would have been unable to respond to the outbreak in such a timely manner. The Electronic Laboratory Exchange Network (eLEXNET) is being updated with the findings to share with other labs. eLEXNET is the nation's first internet-based food safety system that consolidates a repository of pathogenic findings in the food supply by federal, state, and local food laboratories.

To quote Wisconsin's Health Commissioner, Dr. Seth Foldy, "A second feature that sped recognition of the outbreak was the local capacity of the Milwaukee Health Department lab to confirm suspected cases using technology lacked by typical clinical labs. Having advanced lab knowledge and technology gives us the edge of time in battling an outbreak." For further information, contact Steve Gradus, CMHD, at Telephone (414) 286-3526 or sgradu@ci.mil.wi.us or visit the CMHD website at www.ci.mil.wi.us/citygov/health/lab/mainpage.htm

WASHINGTON – Dental X-Ray Film Boxes Pose A Problem

In Washington State, as in most other states, the Department of Health or similar agency inspects dental offices for radiation safety. State regulations establish standards for safe performance and operation of X-ray machines to ensure that patients and operators are not unnecessarily exposed to either primary beam or scatter radiation. Recently a dental hygienist reported finding a white powder in the lead-lined film boxes in a dental office in which she worked. These boxes are commonly found in dental offices and are used to hold fresh dental intra-oral film used for periapical and bitewing X-rays, protecting them from scatter radiation when X-rays are taken in that room. She wondered what the powder was since the films are put into patients' mouths. She sent in a sample, it was analyzed at the state lab and it came back as lead oxide. This alerted DOH of a possible toxicological problem of introducing lead directly into peoples' mouths because of contamination of the films with lead oxide. The State Dental Society and the CRCPD were alerted. They found this phenomenon in at least half a dozen dental offices, indicating that it is quite common. Current questions and concerns include:

> "Is this an issue or problem?"
> "Is it widespread?"
> "Is the lead oxide formed naturally over time, or is it happening because the facility personnel are cleaning the lead surfaces with some agent?"
> "Is there a significant introduction of lead into a person's body by this avenue?"
> "In light of the focus over the years with reducing lead in automobile exhaust and eliminating lead from paint, in order to reduce people's exposure and intake, what does this phenomenon in the dental office mean?"

Obviously, the States, ADA, FDA and state toxicological experts need to work together to solve the problem. Pictures are available of some of these powdery boxes. Dentists who have become aware of the problem have been quick to replace the box, line it with plastic, or clean it once again. For more information, contact Mike Odlaug, X-ray Manager, Department of Health at (360) 236-3237.

COLORADO – Sampling Reveals a Problem

The Consumer Protection Division of the Colorado Department of Public Health and Environment recently initiated a routine sampling program of ready to eat foods. To date 96 samples of ready to eat foods was collected and analyzed for Listeria, Salmonella and E. coli. Samples included a wide variety of ready to eat foods including cut fruits, various vegetables (including those from salad bars), focaccia and chop block breads, sushi, sandwiches, cream cheese pastries, cheese, tofu, crab salad, macaroni salad etc. A sample of garbanzo beans collected from a salad bar revealed a positive test for Listeria monocytogenes. The particular garbanzo bean sample was a canned product, thus raising the question of whether or not the

beans were contaminated before opening the can. Initial presumption is that due to the type of processing required for low acid canned foods, including garbanzo beans, it was felt that the contamination occurred after opening the can.

An extensive re-sampling of many products from this salad bar and numerous environmental swabs from the area of this facility, where the salad bar products are prepared, handled and stored were collected and tested for Listeria monocytogenes. Preliminary results from this follow-up sampling indicated a strong possibility of positive results on four foods and one environmental sample. However, confirmation tests resulted in positive Listeria on only two foods, garbanzo beans and sliced radishes. The firm, in total cooperation with this Department, voluntarily shut down the salad bar and it's associated preparation area and began an extensive cleaning and sanitization of all areas in question. They also decided to dispose of all foods currently on hand that were intended for use in the salad bar, thus hopefully eliminating potential sources of the contaminant. Environmental swabs of the area in question and some deli meats were collected following the firm's cleaning/sanitization program for Listeria analysis. The meats were collected on advice of an epidemiologist as well as some swabs from the deli meat processing area in a further attempt to locate the source of the contaminant. In that the garbanzo beans and radishes were received from the same source but were temporarily not available at the firm, a sample of these items were collected from the source for analysis even though a lot or code for these items was not available. The last sampling from the salad bar in question revealed all negative results and the salad bar is now back in full service. The firm is maintaining an extensive cleaning and sanitization program. For more information, contact Roberta Boitano at Roberta.Boitano@state.co.us or telephone at (303) 692-3659.

Colorado Retail Food Risk Communication:

When Colorado adopted the 1997 version of the Food Code for the regulation of retail food establishments, a point system for "rating" sanitation was no longer in place. During the implementation phase of the new regulation, the news media and public were requesting a rating system based on the inspection reports from several local health agencies. The laws, rules and regulations for retail food establishments in Colorado does not address the scoring or rating of retail food establishments and several different scoring or rating systems were being used to satisfy the news media and public requests. A Communicating Risk Task Work Group was convened to develop a rating system that could be used by all health jurisdictions throughout Colorado to communicate risk in a uniform fashion. This work group generated the Colorado Retail Food Establishment Guideline for Communicating Sanitation Rating. This document has been finalized, and is only a guideline. It is not required that every inspection of a retail food establishment be rated. This guideline can be used to communicate risk of retail food establishments when media or consumer inquiries are received. If you would like more information regarding this guideline, you can contact, Patti Klocker at the Consumer Protection Division at (303) 692-3637 or patricia.klocker@state.co.us.

Colorado and CDC, EHS-net: Colorado is happy to be participating with California, Georgia, Minnesota, New York, Oregon and Tennessee in a CDC Environmental Health Specialist Network project. The vision of this project will be to have food safety systems pro-actively anticipate, identify, and respond to the system failures or combination of failures that contribute to food borne illness and food borne disease outbreaks. This project will involve Environmental Health Specialists working with and strengthening food protection efforts with epidemiology and laboratory personnel in existing FoodNet sites. As a result, the ability to develop efficient and effective food borne disease prevention strategies will be enhanced and opportunities for training future Environmental Health Specialists can be identified. For more information, contact Patti Klocker at (303) 692-3637 or patricia.klocker@state.co.us.

Hruska Named CPD Director

Barbara Hruska has been named the new Director of the Consumer Protection Division. Barbara started with the Division in 1985. In 1992 she was promoted to manager of the Drugs, Medical Devices and Health Fraud Program. Barbara was one of the founders of the Colorado AIDS Fraud Task Force, which is dedicated to leveraging the resources necessary to ensure that all communities and individuals that have been impacted by this disease have the most reliable treatment information available. Prior to her arrival at CDPHE, Barbara worked for Coors as a Quality Control Inspector and Laboratory Technician, and at National Jewish Hospital where she was an Immunology Research Technician. She has also owned and operated a restaurant. For more information, contact Roberta Boitano at Roberta.Boitano@state.co.us or telephone at (303) 692-3659.

Colorado's Holbrook Retiring

On January 5, 2001, Roger Holbrook retired from his position as the Director of Food Safety in the Consumer Protection Division. Roger joined the Colorado Department of Public Health and Environment in 1974 as an inspector in the Food Processing and Storage Program in the Division. He later became manager of that program before assuming responsibility as the Division's Food Section Chief. Roger plans on spending more time raising llamas on his property near Elizabeth and less time commuting to work. Best wishes to Roger!

KENTUCKY - Kentucky Food Safety Branch Grants Leadership Award

Guy F. Delius, Manager of Kentucky's Food Safety Branch, received top honors recently from Public Health Commissioner Rice C. Leach. During a November 2000 awards ceremony in Frankfort, Kentucky, Delius was named the recipient of the

Commissioner's Award for "*Excellence in Supervision of Kentucky's Food Safety Program/ Increasing Food Safety Awareness through Video Training Packages.*" The award honors individuals in leadership positions within Kentucky's Department for Public Health whose efforts have made an outstanding contribution to the public's health, safety, and welfare. It also honors those individuals who demonstrate exemplary leadership skills and a commitment to advancing Kentucky Public Health. Delius earned his BS degree from Eastern Kentucky University. Following graduation he worked several years as a Health Environmentalist for the Madison County Health Department in Richmond, Kentucky. He later accepted a position as a Health Inspection Program Evaluator for Kentucky's Food Safety Branch. In 1999, following the retirement of John Draper, Delius was named Branch Manager.

As manager of the Food Safety Branch, Delius has direct supervision of fifteen employees and indirect supervision of some 350-food safety professionals employed at local health departments across the state. These individuals conduct 334,700 inspectional and regulatory activities per year in the retail food, food storage and manufacturing, vending machine, frozen food locker, and food salvage programs.

During his relatively brief tenure as branch manger, Mr. Delius has demonstrated a commitment to enhancing food safety awareness across the state. Under his leadership, the Food Safety Branch produced and implemented both a video-training program for inspectors, industry, and consumers in general, as well as a video training program to certify high school students as food-service workers. Both video-training packages have been provided to regulatory agencies in sister states for use in training of inspectors and industry. Funding for both projects was obtained, in part, through grants and partnerships with the FDA.

FLORIDA - Association for Food Protection Promotes Safe Foods Education

This year, the Florida Association for Food Protection has placed a concentrated effort in promoting safe foods in Florida through Education. Our Annual Conference this past October 2000, had one of the most powerful line-ups of Food Safety Professionals and Educators, addressing attendees, sharing their knowledge and views about the future of food safety. The membership of the Association is made up for individuals in the food industry, at all levels of manufacturing, retailing, and more. Membership includes representatives of Government, Industry and Academia, all working together to enhance a safe food supply in Florida and ultimately, worldwide. Currently there are 250 members in Florida and over 3000 members from over 50 Countries, in a parent organization; The International Association for Food Protection (http://www.foodprotection.org/) and the organization is growing steadily. Emphasis has been placed on raising the standards of sanitation and safety with wholesalers, processors and retailers throughout Florida. Through education and membership, FAFP hopes to make a major impact on the Food Industry, ultimately providing a better forum for information sharing and providing a safer way of doing things for all industries in Florida. Information on membership can be obtained by sending a request for a membership application to FAFP, c/o Zeb E Blanton, Jr., P. O. Box 160032, Altamonte Springs, FL 32716-0032, Telephone (407) 682-4720 or FAX (407) 682-2165 or by e-mail to blantoz@doacs.state.fl.us.

FDA News

***Vibrio parahaemolyticus* Draft Risk Assessment Available:** FDA recently announced the availability of a draft risk assessment report on the estimated public health risks associated with raw oysters containing pathogenic *Vibrio parahaemolyticus*. *V. parahaemolyticus* is a bacterial species that occurs naturally in oysters and occasionally causes illness in humans following the consumption of raw oysters. Most often the illness occurs as sporadic cases of self-limiting gastroenteritis, with symptoms such as diarrhea, vomiting and abdominal cramps. In recent years, however, several outbreaks have occurred involving dozens to hundreds of consumers. In addition, though rare, the organism can produce a life-threatening septicemia, especially in people having underlying medical conditions such as liver disease or immune disorders. FDA began this risk assessment in 1999 and has held public meetings seeking scientific information and suggestions regarding the risk assessment. Having completed the draft, the Agency is now seeking comments on the technical aspects of this draft report in the following areas: 1) assumptions incorporated, 2) modeling approach, 3) data sets employed, and 4) transparency of the project and report. FDA will review and evaluate all comments and make modifications as appropriate.

The draft risk assessment is available on FDA's website at www.foodsafety.gov/~dms/fs-toc.html. It may also be reviewed in FDA's Dockets Management Branch. Written comments should be submitted by March 20, 2001 to the Dockets Management Branch (HFA-305), FDA, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Participation in Voluntary National Retail Food Regulatory Program Standards Project Needed: A letter issued December 29 from the Division of Federal-State Relations soliciting participation by at least 100 jurisdictions across the nation to perform a self-assessment against the Voluntary National Retail Food Regulatory Program Standards. The purpose is to help FDA further define the usability of the measurements and reporting documents. The Standards were

designed to serve as a guide to regulatory managers in the design and management of a retail food program, to help identify program gaps and improvement strategies, and to provide a means of recognition for those programs that meet the standards.

If you are interested in participating, a FDA Regional Food Specialist will make arrangements to meet with you to discuss the project and provide technical support as the project proceeds. To find a list of the Regional Food Specialists, check out our website at http://www.fda.gov/ora/fed_state/default.htm and to view the latest draft of the standards, go to http://vm.cfsan.fda.gov/~dms/ret-toc.html.

FDA Publishes Final Regulation on Tissue Registration: FDA has just published a final regulation requiring all establishments that manufacture human cells, tissues, and cellular and tissue-based products to register and list their products with the agency. When this regulation is fully implemented, it will provide, for the first time, a complete base of information on the tissue bank industry, including certain cells and tissues that were not previously regulated. The action is part of FDA's implementation of a new comprehensive regulatory framework, announced in 1997, designed to help ensure the safety and quality of products, including new technologies, without imposing unnecessary regulatory requirements. It establishes a tiered system of regulation, under which certain tissues and cells will be subject only to regulations aimed at preventing the spread of communicable disease. Other tissue-related products will be required to obtain premarket approval in addition to following the communicable disease requirements.

The new tissue rule covers a broad array of cells and tissues, such as skin, tendons, bone, heart valves, and corneas, which have long been used to repair or replace damaged or diseased tissues. It also applies to novel uses under development for human cells and tissues, such as the use of manipulated human cells to treat viral infections, Parkinson's disease and diabetes. It covers tissues that have not been regulated before, including reproductive tissues and stem cells derived from umbilical cord blood and other blood sources. Tissue establishments already regulated by FDA have 105 days to comply with the new rule, whereas establishments of newly regulated human cells and tissues will have two years to put its provisions into effect.

FDA is not requiring registration and listing by establishments that:

*Use cells and tissues solely for nonclinical scientific or educational purposes;
*Remove cells and tissues and transplant them into the same person in a single surgical procedure;
*Deliver cells or tissues in the usual course of business;
*Recover reproductive cells or tissue and immediately transfer them into a sexually intimate partner of the donor;
*Receive or store cells or tissues solely for use within a single facility.

FDA earlier proposed two other related rules to implement the 1997 regulatory approach. One ("Suitability Determination for Donors of Human Cellular and Tissue-Based Products") was issued on Sept. 30, 1999, and focuses on donor screening and testing measures to prevent the unwitting use of contaminated tissues with the potential to transmit infectious diseases. The other one ("Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement") was issued Jan. 8, and would establish good tissue practice standards for the methods, facilities and controls used to manufacture these products.

FDA's current regulations addressing tissues were promulgated in December 1993 as an interim final rule that required the screening and testing of tissue donors for certain transmissible diseases such as HIV infection and hepatitis. The interim final rule was made final with minor changes on July 29, 1997, and took effect on Jan. 26, 1998. The two proposed rules, once they are made final, and today's rule on registration and listing will provide a more comprehensive, risk-based regulatory approach and include provisions for the regulation of innovative products. It is expected that all three rules of the 1997 regulatory approach will be finalized within the next two years. For further information, contact Jill Warner, at (301) 827-0372, or warnerj@cber.fda.gov.

AFDO News

AFDO and FDA are collaborating with the industry in sponsoring a 3-day seminar for the drug and medical device industry on **Industrial Sterilization**. The program will be held at the Adam's Mark Hotel in San Antonio, TX, from April 10 – 12, 2001. The agenda addresses the principles of sterilization, Steam, Ethylene Oxide and Radiation Sterilization, Water Systems, Laboratory Inspections, Lyophilization and special issues for sterilization. The program is aimed at R&D Staff, regulatory affairs personnel, consultants, QC Specialists, Sterilization Technicians, Quality Auditors, Manufacturing Personnel, Contract Manufacturers and Managers. Registration fees include continental breakfast, breaks, all training materials and AFDO training certificate. AFDO Member Rate Industry $695 Government $495. Non-Member Rate: Industry $795 and Government $595.

Hotel Reservations and Room Rates: Adams Mark Hotel San Antonio Riverwalk, 111 Pecan St., East, San Antonio, TX. For reservations, call 1-800-444-2326 and ask for the **INDUSTRIAL STERILIZATION WORKSHOP GROUP RATE**. Standard/Double Rate per night: Industry - $149, Government - $91. Cut off for this rate is March 2, 2001.

To register, call AFDO at (f717) 757-2888 or FAX at (717) 755-8089, or visit their website at www.afdo.org.

Other Meetings Coming Up:

NASDA, February 23 – 27, 2001, Washington, DC
MCAFDO, February 27 – March 1, 2001, Springfield, MO
NERO, March 11 – 14, 2001, Myrtle Beach, SC
NEFDOA, April 18 – 20, 2001, Newport, RI
CRCPD, April 27 – May 3, 2001, Anchorage, AK

For information on State and National meetings visit the following website:
http://www.fda.gov/ora/fed_state/DFSR_Activities/State_Meetings.htm

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Please complete the following:

WE WANT TO HEAR FROM YOU! Tell us what you think about the State Action Information Letter.

Yes, I find S.A.I.L. to be useful.

Never_____ Always _____ Sometimes _____

The Report from the Director gives me something new in the way of information.

Never_____ Always _____ Sometimes _____

The Reports from the States of use to me.

Never_____ Always _____ Sometimes _____

I find it helpful to know who to contact for more information about the various activities.

Never_____ Always _____ Sometimes _____

Do you have ideas for additions to S.A.I.L?

Never_____ Always _____ Sometimes _____

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Name_____

Agency/State_____

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E-mail/FAX_____

Please complete and e-mail to Cynthia Leggett, Editor, **S.A.I.L.**, at cleggett@ora.fda.gov, or FAX to (301) 443-2143. Thanks for your help!