



Annual Report 2005-2006

**The Joint Institute for Food Safety and
Applied Nutrition (JIFSAN)**

**0220 Symons Hall
University of Maryland
College Park, Maryland 20742**

Jianghong Meng, Acting Director
(prepared by Paul Mazzocchi, Associate Director)

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EXECUTIVE SUMMARY

This Annual Report covers the ninth year of operation for the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) – the fourth year of the five-year renewal (September 2002 through September 2007). The non-competitive base funding for the ninth year was \$607,100; plus \$1,538,086 in carry forward funds.

The Advisory Council met on October 27-28, 2005. These meetings involved brief presentations with updates on selected research and education/outreach programs, from JIFSAN, CFSAN and CVM. Discussions were held on potential industry needs that could influence future JIFSAN programs. The meeting was well attended with representatives from the University, FDA and the Advisory Council membership.

Although research has played an important role in JIFSAN's programs and has assisted in strengthening the knowledge base for public health policy, JIFSAN's Internal Competitive Grants Program was phased out due to lack of funding. No new grants were made in this grant year and only one research project remains active.

As a result of an accumulation of a significant amount of carry-forward funds over a period in excess of six years, it was possible for JIFSAN to fund a significant amount of short-term (one or two years) research projects. In collaboration with the Food Industry Alliance (an informal designation for food companies that have contributed funding for research) and the International Life Sciences Institute (ILSI) North America (NA), JIFSAN provided funding for five projects dealing with issues raised from finding acrylamide in foods and five additional projects were funded in areas addressing needs identified by CFSAN in 2004. Those projects are now complete. One new project was funded to support the JIFSAN portion of a collaborative research effort being developed with the Department of Natural Resources and Environment, Victoria, Australia, with whom JIFSAN has a cooperative agreement. These projects are all completed or are working on short budget extensions.

A senior research scientist, split-funded with the Department of Chemistry and Biochemistry, continued a highly productive research program in carotenoids. The individual has established an international reputation for work in this area.

Development of the Risk Analysis Clearinghouse continued under the guidance of the Steering Committee. A new IT Manager has been hired to continue the development and coordination of Clearinghouse activities. A major emphasis is being placed on acquisition of data and material beyond those sought initially from microbiological risk assessments. The Clearinghouse has begun a process of modernization and improvement to design structure and presentation of content. Operation of the Acrylamide Infonet (the FAO/WHO Acrylamide in Food Research Network) continued. The establishment of education and outreach programs, in areas within JIFSAN's responsibilities, is of vital importance. These programs are both domestic and international in scope. JIFSAN was

involved as sponsor or co-sponsor of a number of different meetings (workshops, conferences, etc) this past year.

The Food Safety Risk Analysis Professional Development Program continued to develop and offer face-to-face and distance learning courses. Technical support of the distance learning program is no longer provided by the AGNR group, but is now provided by the JIFSAN technology group. The three-week Summer Integrated Program (SIP) was offered in July 2006 with a change in location to Washington DC. This change in venue reduced operational costs significantly. SIP was well received, attracting 51 participants from 6 countries. It will be offered again in July 2007. Four on-line risk analysis courses were also offered to a total of 67 students. JIFSAN also offered a “boutique” risk analysis training program for the Thai Ministry of Science and Technology and is offering a similar program to COEPRIS in Mexico in December 2006. A distance learning course on risk analysis will be offered to a group of students in Croatia in December as well.

A strong program of international cooperation and training is being developed and offered. One of JIFSAN’s major programs is the Good Agricultural Practices (GAPs) international training program and the new Advanced Good Agricultural Practices Program for the production of fresh produce with reduced microbiological contamination. These five-day programs were offered in Guadalajara, Mexico, San Salvador, El Salvador, and Beijing, China. Approximately 50 individuals participated in each training program. During this grant period JIFSAN developed the Good Aquacultural Practices Training program and is offering a pilot program in Viet Nam in November 2006 and China in March 2007. This program was supported by a grant from JohnsonDiversey.

As part of a cooperative agreement with the Central Science Laboratory (CSL) in the U.K the Seventh Joint CSL/JIFSAN Symposium on Food Safety and Nutrition was held at the Central Science Laboratory, York, UK on June 6-7, 2006. The topic was Quality Assurance in Food Safety -- Networking of Laboratories.

JIFSAN renewed its designation as JIFSAN-PAHO/WHO Collaborating Center for Food Safety Risk Analysis.

Development of the Center for Risk Communication Research (CRCR), led by the Department of Communication (UM), is continuing with seed money being furnished by JIFSAN for a three-year period. The CRCR will serve as a focal point for scholarly activity and discussion related to risk communication.

The JIFSAN Student Internship Program continues to increase in importance and participation. UM undergraduate students are offered an opportunity to work with FDA scientists in their laboratories on specific projects identified by the FDA scientist involved. During 2005-2006, 48 different UM students participated for a total of 84 semesters in FDA laboratories. Since its inception, the internship program has had 213 individual student participants. UM Students were co-authors on 9 posters presented at the FDA Science Forum. The titles of the poster presentations appear later in this report.

BACKGROUND

In 1996, the Commissioner of the Food and Drug Administration, Dr. David Kessler, and the President of the University of Maryland, Dr. William Kirwan, met to discuss opportunities for cooperative interactions that would be productive for both institutions. The result of this and a number of subsequent meetings was the April 15, 1996 signing of a Memorandum of Understanding (MOU) that established a cooperative venture, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). Initial partners in the cooperation were the University and the FDA Center for Food Safety and Applied Nutrition (CFSAN). Later, the MOU was amended to include the FDA Center for Veterinary Medicine (CVM). The actual operation of JIFSAN began with its initial funding on September 30, 1997. Dr. Paul Mazzocchi, Dean of the College of Life Sciences, as Principal Investigator on the FDA-JIFSAN cooperative agreement, served as Acting Director of JIFSAN while the search for a permanent Director was conducted. Dr. David Lineback became Director in November 1998. He retired on September 30, 2005. Dr. Maureen Storey was appointed Interim Director on October 1, 2005. Dr. Storey was replaced on September 1, 2006 and Professor Jianghong Meng was appointed as Acting Director of JIFSAN.

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) is a multidisciplinary research, education and outreach program. Dr. Jianghong Meng (University of Maryland) is the Acting Director; Dr. Paul Mazzocchi (University of Maryland) is Associate Director, and Dr. Elizabeth Calvey is Acting Associate Director, representing CFSAN/ FDA. Dr. David Batson is the CVM representative.

FDA's broad goals within the collaboration are to expand food safety, human nutrition, and animal health sciences research and education programs that are necessary to provide the Agency with expertise and knowledge needed to recognize and effectively deal with emerging food safety issues. Collaborative activities involve research, education, and outreach, with both domestic and international emphases, in microbial pathogens and toxins, food constituents and applied nutrition, animal health sciences: animal health and food safety, food safety risk analysis, and economics.

JIFSAN provides a neutral environment in which experts from industry, consumer and trade groups, international organizations, government agencies, and academia pool their resources and ideas to contribute to the scientific base for the development of sound public health policy. Members of the JIFSAN Advisory Council provide advice, vision, and support critical to advancing the Institute's mission of cooperative research and education/outreach. Visiting scientists are encouraged from all sectors. The interactions of FDA, the University, and visiting scientists will help ensure that federal regulatory and scientific personnel remain in the forefront of food safety issues. This will also provide visiting scientists, faculty and staff insight into regulatory processes. Opportunities for undergraduate and graduate students to work with FDA scientists as interns enhance students' understanding of regulatory processes and provide them with valuable practical experience. Collaborative research projects contribute to the science undergirding current and future regulatory issues and activities that impact on public health policies.

Risk analysis (risk assessment, management, and communication) is one focus of JIFSAN programs. This effort promotes the development of risk-based, scientifically supportable safety standards. These standards can deliver the intended degree of measurable public health protection and can be used to identify priorities to effectively apply available resources. JIFSAN is developing new approaches to information management related to risk analysis through operation of a web-based Food Safety Risk Analysis Clearinghouse. This provides a mechanism to collect and disseminate available data and methodologies from government, academia, and industry. The intent of the Clearinghouse is to provide a centralized information source in areas of risk analysis related to food safety. The unique feature of this Clearinghouse model resides in the examination and documentation of state-of-the-art methods, data sources, and current results of on-going risk assessments so that a more complete and up-to-date picture of risk assessment is assembled.

An internal competitive research grant program provided seed funding to University of Maryland faculty to support research projects that are closely aligned with FDA's research needs. FDA collaborators on each project helped provide additional scientific expertise and insight into public health impacts of the research. This program has been discontinued due to lack of funds.

Trade initiatives have put food safety high on the international agenda. JIFSAN is actively involved in developing collaborations with international organizations to facilitate cooperative research and education programs and the exchange of scientists.

The Harvey W. Wiley Federal Building, CFSAN's office and laboratory facility, is located adjacent to the University of Maryland in College Park, enabling FDA and the University to share many resources. Programs initiated by JIFSAN have demonstrated that the benefits to be achieved by this partnership are substantial. The MOU established a set of relationships that closely link the University with CFSAN and CVM by committing to the sharing of facilities, personnel, and intellectual resources when appropriate. Thus, FDA personnel have access to University facilities such as libraries and may be appointed as adjunct or research faculty in recognition of their involvement in cooperative programs in research, teaching, mentoring, and direction at the graduate and undergraduate levels. FDA supports and utilizes major instrumentation facilities (electron microscopy and nuclear magnetic resonance spectroscopy) on the campus and those facilities house University of Maryland and FDA personnel. These and other synergistic relationships outlined in the MOU allow both institutions to remain state of the art in a number of areas where duplicative efforts would be less than successful.

Subsequent to the signing of the MOU, FDA and University personnel developed an Umbrella Cooperative Research and Development Agreement (CRADA) and a multi-party CRADA template. These tools were designed to facilitate the development of collaborative research beyond the internal competitive research program and to provide a mechanism to address issues related to sharing of resources.

FDA and the University provided financial support for the operation of JIFSAN. FDA provided a cooperative agreement for \$6.5M for five years starting on September 30, 1997, subsequently supplemented to a total amount of \$11,450,053. The cooperative agreement was renewed for an additional five-year period (September 2002 through September 2007) for up to \$3,000,000 per year. The University provided support in several ways including the return of 100% of the Designated Research Initiative Fund (DRIF) funds from the cooperative agreement to JIFSAN, providing space and administrative support to the program in the form of personnel, and providing space for instrumentation facilities.

PROGRESS REPORT

During the ninth year of operation for JIFSAN, several education and outreach programs were continued, developed and/or initiated; research programs were continued; and contacts were developed to build partnerships/strategic alliances to plan and initiate additional research, education, and outreach programs. Progress in these areas will be outlined with specific examples included.

The non-competitive base funding for the ninth year was \$607,100, plus \$1,538,086 in carry forward funds.

ADMINISTRATIVE STRUCTURE

A unique administrative structure is needed for JIFSAN to allow it to most effectively use resources while planning, organizing, and accomplishing multidisciplinary, multi-institutional programs in research, education, and outreach. An effective way to do this is to utilize, to the greatest extent possible, the administrative structures available in the University of Maryland as one of the major partners in JIFSAN. The structure and policies of a major land-grant university offer the flexibility needed to enable JIFSAN to create and operate strategic alliances involving multiple partners and multiple funding sources.

Events related to JIFSAN's administrative structure and function include:

- Dr. Jianghong Meng was appointed Acting Director of JIFSAN on September 1, 2006 replacing Dr. Maureen Storey
- Mr. Jonathan Velasquez was appointed as IT Manager for JIFSAN and has responsibility for the Food Safety Risk Analysis Clearinghouse
- The fifth meeting of the JIFSAN Advisory Council was held October 27-28, 2005. The Advisory Council is composed of representatives from 13 private sector corporations, four academic institutions, two from the consumer community, and one from a federal (UK) laboratory and two independent scientists.
- A Steering Committee continues to oversee and guide activities of the Food Safety Risk Analysis Clearinghouse

The JIFSAN Advisory Council

Central to the operation of JIFSAN is the Advisory Council composed of members from private sector business, government agencies, academia, and representatives of consumers' interests. This group provides guidance to JIFSAN in developing research, education, and outreach programs to address problems in food safety, nutrition, animal health sciences, and risk analysis.

The Advisory Council met on October 27-28, 2005. These meetings involved updates from JIFSAN, CFSAN and CVM and brief presentations on selected research and education/outreach programs. Discussions are held concerning potential industry needs that could influence future programs of JIFSAN.

The Acting Director maintains contact with Advisory Council representatives throughout the year.

Members of the Advisory Council include:

- Private sector industry

- Cargill, Inc (Dr. Jeanne McCaherty)
- Coca-Cola Company (Dr. Henry Chin)
- Campbell Soup Company (Dr. George Evancho)
- Frito-Lay (Dr. Steve Saunders)
- General Mills (Dr. Thomas Trautman)
- Gerber Products Company (Dr. Richard Jarman)
- Kellogg Company (Dr. Mark Moorman)
- Kraft Foods (Dr. William Sveum)
- McCormick and Company (Dr. Hamed Faridi)
- Masterfoods USA (Dr. Steven Rizk)
- Mead Johnson Nutritionals (Dr. Craig Hadley)
- Monsanto Company (Dr. Jerry Hjelle)
- Unilever Bestfoods NA (Dr. Richard Lane)

- Representatives of Consumers' Interests

- Ms. Mary Heersink (Safe Tables Our Priority)
- Ms. Darlene Adkins (National Consumers League)

- Academia

- Dr. Michael Doyle (University of Georgia)
- Dr. Julie Miller Jones (College of St. Catherine's)
- Dr. Sanford Miller (Center for Food Nutrition and Agriculture Policy, University of Maryland)
- Dr. Michael Pariza (University of Wisconsin)

- Government

- Dr. Michael Roberts (Central Science Laboratory, Department of Environment, Food and Rural Affairs, UK)

- Individuals

Dr. David Lineback (Director-Retired, JIFSAN)

Dr. Gilbert Leveille (Consultant)

RESEARCH INITIATIVES

Research has been a major focus of JIFSAN. Collaborative research supports the goal to develop a strong science base to address ongoing and increasingly complex public food safety issues.

JIFSAN Internal Competitive Research Program:

First initiated in 1998, each project required collaboration between at least one University of Maryland faculty member as Principal Investigator (PI) and one or more FDA collaborators. The latter help provide additional scientific expertise and insight into public health impacts of the research. Additional collaborators may be from other institutions, if the PI so desires. These projects contribute to the science for current and future regulatory issues and activities that impact on public health policies.

Effective July 2002, projects were funded at \$30,000 per year to be used for partial support of either a graduate research assistant or a postdoctoral associate and some operational support. Proposals were for as many as three years, but were funded for only one year at a time with continuation contingent upon a satisfactory annual progress report, a request for continuation of the research, and availability of funding.

On the basis of satisfactory progress towards meeting objectives and annual reports, four projects in July 2003 were continued for a third year. One project funded in July 2004 was continued for a second year. Unfortunately, the JIFSAN Internal Competitive Research Program is being discontinued due to lack of funding. Only one project remains and is described in more detail in Appendix A.

Third-year project (funded July 2004):

- Predicting exposure estimates: Experimental food additive partitioning studies and model development, Robert Walker (UM), Timothy Begley and William Limm (FDA).

Collaborative/Cooperative Research Projects:

An important function of JIFSAN is establishing research efforts involving collaboration/cooperation with other organizations addressing current issues of mutual interest. The extent of this effort is dependent upon the availability of funds. The availability of carry-forward funds has enabled JIFSAN to participate in developing several projects. Most of these projects are of one-year's duration and some have

involved additional funds from external sources. Research projects have been funded to address issues involved with the finding of acrylamide in foods, to initiate collaborative research with a partner in Victoria, Australia, and to address issues of specific interest to CFSAN. Those continuing in the period covered by this report, include the following which are described in more detail in Appendix B:

1. In collaboration with the Industry Acrylamide Alliance, an informal designation for food industries that have donated financial support for research, JIFSAN funded the following research projects. Financial support from JIFSAN involved the use of carry-forward funds.
 - Effects of consumer food preparation on acrylamide formation, George Sadler/Lauren Jackson, Illinois Institute of Technology (IIT)/National Center for Food Safety and Technology (NCFST, completed, final report in preparation)
 - Acrylamide content of home-prepared surface-browned foods, George Sadler/Lauren Jackson, IIT/NCFST (completed, final report appears in Appendix B)

2. As the JIFSAN portion of a cooperative research program being developed with the Department of Natural Resources and Environment, Melbourne, Victoria, Australia, with whom JIFSAN has a Memorandum of Cooperation, the following three-year research project is in progress.
 - Rapid assay for detecting human enteric viruses and viral survival dynamics on fresh fruits and vegetables, Jianghong Meng, Department of Nutrition and Food Science, University of Maryland. (Completed, final report in Appendix B)

Additional Research Projects Funded

These projects are funded from JIFSAN carry-forward funds and address issues of specific interest to CFSAN/FDA.

- Analysis of sera from previous Norwalk-like virus human exposure study, Mark Sobsey, Department of Environmental Sciences and Engineering, University of North Carolina. (Project extended until 4/30/07, description in Appendix B)
- Development of molecularly-imprinted polymers (MIPs) for selective detection of marine biotoxins, Kenneth J. Shea, Department of Chemistry, University of California, Irvine. (Completed 10/06, awaiting final report)
- Enzymatic Degradation of Prion Surrogate Proteins, Jason C. H. Shih, Department of Poultry Science, North Carolina State University. (Continued through 9/30/07)

- Public perceptions of conflicting information about safety guidelines for consumption of fish, Linda Aldoory, Department of Communications (CRCR), University of Maryland. Collaborator: Marjorie Davidson, CFSAN, FDA (funded with JIFSAN DRIF. Final report in Appendix B)

JIFSAN Postdoctoral Research Associate Program:

This program strengthened the science base for public health policy by providing short-term research scientists to work in FDA laboratories. Originally, six postdoctoral research associates were recruited to work in FDA laboratories in areas in which significant knowledge gaps or the lack of appropriate scientific data, methods, or models exist.

Not only did this program generate significant amounts of new knowledge, applicable to needs of FDA, it allowed the postdoctoral research associates the opportunity to work in a regulatory environment. FDA has the important opportunity of evaluating the potential of these individuals to become productive staff members when vacancies exist. This program is now terminated. Only one postdoctoral fellow remains active with the appointment ending 4/30/07 (Kwang-Young Song, below). A summary of the fellowships ending in 2005-2006 appears in Appendix C.

Development of a Real-time PCR assay for the detection and identification of *Shigella* spp. from foods Keith A. Lampel (FDA) Kwang-Young Song (JIFSAN Research Associate) (ends 4/30/07)

Senior Research Scientist (split funded with Department of Chemistry and Biochemistry):

Dr. Frederick Khachik is a senior research scientist and adjunct professor with an appointment in the Department of Chemistry and Biochemistry. He has been partially supported by JIFSAN since it began operation. Dr. Khachik has established an international reputation for his research in the area of carotenoids. Additional information on progress in this research program is in Appendix E.

Leveraging:

One of the basic tenets for operation of JIFSAN is the leveraging of resources. This includes the development of research partnerships and core facilities.

- Development of Core Facilities: The development of core facilities that will benefit FDA and University scientists and their collaborators is a cornerstone of JIFSAN's cooperative programs and objective to leverage resources. The effective use of the arrangements for shared facilities (electron microscopy and nuclear magnetic resonance) is increasing since CFSAN has relocated to its facilities in College Park.

- Cooperative and alternative funding for training programs. Over the past year we have initiated a negotiating process that has resulted in significant savings to the JIFSAN core grant. In effect we have required cost sharing with the recipients for all training programs. Those shares have amounted to a minimum of in country costs to full costs including administrative expenses.

EDUCATION AND OUTREACH PROGRAMS

The establishment of education and outreach programs, with both domestic and international emphases, is of vital importance to JIFSAN. These programs involve aspects of food safety, applied nutrition, animal health sciences, and risk analysis that have been identified as areas of need within the purview of JIFSAN's responsibilities. Identification of these areas is done in collaboration with the JIFSAN Advisory Council. The following efforts were initiated or continued during the reporting period.

JIFSAN Student Internship Program:

The JIFSAN Student Internship program is designed to provide University of Maryland undergraduate students with an opportunity to collaborate with FDA scientists on specific projects related to the JIFSAN mission. This program was implemented as part of the agreement between the University and FDA to cooperate in educational efforts. These opportunities for students enhance their knowledge of and experience in science, particularly in a regulatory environment, and familiarize them with career opportunities in the regulatory sector of public service.

Students' participation in the program requires that they have completed two college semesters, be willing to commit to volunteering 100 hours during the first term as an intern, and submit a completed application form, current transcript and resume. The positions may be part-time during the semester and full-time during the summer. Undergraduate students volunteer to work on a project, listed by an FDA staff member. Upon successful completion of the initial 100-hour period, students can be converted to paid internships. During all phases of the internship, the students have a variety of ways to obtain academic credit for their internship experience.

During 2005-2006, 48 different University of Maryland students participated for a total of 84 semesters in FDA laboratories. Efforts are being made to extend opportunities for internships beyond laboratory experiences. UM Students were co-authors on 17 posters presented at FDA Science Forum and one at Bioscience Day (UM). (See below)

Participation in the JIFSAN Internship Program continues to grow. Dr. Kaci Thompson of the UM Information Resource Center (College of Life Sciences) has worked to increase student, faculty, and staff awareness of the Program through literature, seminar series, and the annual Internship Day, which the Center sponsors. JIFSAN has actively and regularly participated in the Internship Day. One of the strongest features of the Program is the continuing collaborative spirit among the participants. Details of the student posters appear in Appendix D.

JIFSAN Student Posters

- 1. Automation for Isomer Specific Determination of Polychlorinated dibenzo-p-dioxins/furans, Polychlorinated biphenyls and Polybrominated diphenyl ethers in Foods and Feeds**
D. G. Hayward¹, T. S. Pisano², ¹CFSAN, FDA, College Park, MD, ²JIFSAN, University of Maryland, College Park, MD
- 2. Investigation of Flour Tortillas Implicated in Episodes of Illnesses Associated with School Lunches**
C. R. Warner¹, G. O. Noonan¹, N. Sugimoto², A. Beisaw³, W. Hsu³, G. A. Perfetti¹, T. H. Begley¹, G. W. Diachenko¹, ¹FDA, College Park, MD, ²National Institutes of Health Sciences, Tokyo, ³JIFSAN, University of Maryland, College Park, MD
- 3. Increasing Confidence Level in DNA Microarray Chip Hybridization Data of 71 Genes with PCR Amplification of 10 genes in Salmonella Typhimurium**
S. F. Al-Khaldi¹, S. Courtney², M. E. Mossoba¹, T. S. Hammack¹, C. E. Keys¹, ¹CFSAN, FDA, College Park, MD, ²JIFSAN, FDA, College Park, MD
- 4. The Creation of Consolidated FDA Databases and the Development of Real-Time Data Entry to Support Structure Activity Relationship Approaches in Hazard Identification and Risk Assessment**
K. B. Arvidson¹, R. D. Benz², E. J. Matthews³, J. Mayer¹, E. Lee², M. L. Twaroski¹, C. Yang⁴, ¹CFSAN/OFAS, ²JIFSAN, University of Maryland ³CDER/OPS/ICSAS, ⁴Leadscope, Inc.
- 5. Distribution coefficients for alpha-Amanitin, Ricin and T-2 toxin in milk and salad dressings**
H. Njapau¹, F. S. Thomas¹, A. Chowdhury², S. Trujillo¹, B. J. Cañas¹, D. L. Park¹, ¹CFSAN, FDA, College Park, MD, ²JIFSAN/University of Maryland, College Park, MD
- 6. Effects of Food Preparation and Lactose on the Detection and Lectin Binding Ability of Ricin B-Chain**
G. M. Orłowski¹, G. C. Ziobro², E. A. Garber², ¹JIFSAN, University of Maryland, College Park, MD, ²CFSAN, FDA, College Park, MD
- 7. CFSAN Outbreak Surveillance Database: Outbreaks and illnesses reported for 2004 and 2005**
K. Vierk¹, E. Elliot¹, J. J. Guzewich¹, G. Henderson¹, T. Hill¹, K. C. Klontz¹, P. McCarthy¹, S. McGarry¹, C. Purdy³, M. Ross¹, J. Sanders¹, F. K. Shakir², D. Street¹, B. Timbo¹, ¹CFSAN, FDA, College Park, MD, ²JIFSAN, University of Maryland, ³CFSAN, FDA, Atlanta, GA

8. Contributing Factors (CFs) Identified in Produce-Associated Outbreaks from CDC's National Electronic Foodborne Outbreak Reporting System (eFORS), FoodNet Sites, 1999-2002

F. K. Shakir², P. V. McCarthy¹, J. J. Guzewich¹, C. R. Braden³, K. C. Klontz¹, C. W. Hedberg⁴, K. E. Fullerton⁵, A. Bogard⁶, M. Dreyfuss⁷, K. Larson⁸, D. Vugia⁹, D. C. Nichols¹⁰, V. J. Radke², T. F. Jones¹¹, ¹FDA, Center for Food Safety and Applied Nutrition, Washington, DC, ²CDC, Atlanta, GA, ³JIFSAN, University of Maryland, College Park, MD ⁴University of Minnesota, Minneapolis, MN, ⁵CDC, Atlanta, GA, Atlanta Research and Education Foundation, Atlanta, GA, ⁶Minnesota Department of Health, Minneapolis, MN, ⁷USDA, Food Safety and Inspection Service, Washington, DC, ⁸Maryland Department of Health and Mental Hygiene, Baltimore, MD, ⁹California Emerging Infections Program, Oakland, CA, ¹⁰New York State Department of Health, Albany, NY, ¹¹Tennessee Department of Health, Nashville, TN

9. Single Laboratory Validation of Commercially available kits for the detection of Aflatoxin M1

S. Trujillo¹, N. J. Fico², H. Njapau¹, B. J. Cañas¹, D. L. Park¹, ¹CFSAN, FDA, College Park, MD, ²JIFSAN, University of Maryland, College Park, MD

Bio-Science Research & Technology Review Day, November 16, 2006

Poster Presentation:

"A risk assessment of *Listeria monocytogenes* contamination in soft-ripened cheeses" Presented by: Ms. Elizabeth Yanik, Biology, College of Chemical and Life Sciences

FOOD SAFETY RISK ANALYSIS CLEARINGHOUSE

The Food Safety Risk Analysis Clearinghouse was established to collect and disseminate available data and methodologies from government, academic, and industry sectors domestically and internationally. The Clearinghouse provides a centralized information source for risk analysis related to food safety.

Development of the Risk Analysis Clearinghouse continued under the guidance of the Steering Committee. A new IT Manager has been hired to continue the development and coordination of the Clearinghouse activities. A major emphasis is being placed on acquisition of data and material beyond those sought initially from microbiological risk assessments. The Clearinghouse has begun a process of modernization and improvement to design structure and presentation of content.

Progress for the Food Safety Risk Analysis Clearinghouse includes:

- By unanimous decision the Steering Committee has approved a new name and description to represent the Clearinghouse website: FoodRisk.org “*The Online Resource for Food Safety Risk Analysis*”
- Information structure updates include division of content heavy pages into easy-to-navigate smaller subsections.
- A shorter and easy to remember domain address, <http://www.FoodRisk.org>, has been acquired and is being advertised in our marketing program.
- Several new sections have been added to the Clearinghouse to keep pace with recent trends, such as sections on food allergy, bioterrorism, and perchlorate. In addition, some of the existing sections have been significantly expanded, such as risk profiles, weight management, and acrylamide.
- Digitization of 1993 Federal Register, Volume 58, Part IV is near completion. This volume, which is not available on the U.S. GPO website, provides information on nutrition and labeling requirements.
- Development of a discussion forum with the aim of providing an open platform to discuss food safety-related issues. This was initiated with a QRA-Analytica listserv to discuss quantitative risk assessment issues related with the use of Analytica software.
- Several additions to its exclusive holdings.
- The Clearinghouse continues to host the Interagency Risk Assessment Consortium and the Acrylamide Infonet

The Clearinghouse website received an average of 85,000 hits per month from over 120 countries.

Issues related to the Clearinghouse include:

- Funding- there is no funding in the JIFSAN Cooperative agreement beyond September 2005. Efforts are being made to obtain replacement funding.

Acrylamide Infonet:

At the request of the United Nations’ World Health Organization and Food and Agricultural Organization, JIFSAN is operating the *Acrylamide Infonet* (www.acrylamide-food.org), the WHO/FAO Acrylamide in Food Network, through the Risk Analysis Clearinghouse. This Network was established as a result of the June 2002 FAO/WHO Consultation on the Health Implications of Acrylamide in Food. The consultation recommended that an international network on acrylamide in food be established, inviting all interested parties to share relevant data as well as ongoing investigations.

The focal point for the network is the website www.acrylamide-food.org which contains a database of researchers/data providers; references for research published elsewhere; studies in development database; listing of acrylamide websites; acrylamide documentation (general information); events and activities; Infonet updates; and call for data (a call by WHO for analytical data for use in the 2005 JECFA risk assessment of acrylamide in food and subsequent risk assessments).

This network functions as a global resource and inventory of ongoing research on acrylamide in food. It includes formal research, surveillance/monitoring and industry investigations, etc. Any interested party may submit information, and it is hoped that government agencies, research institutions, industry and others will share information via the network.

Coordination is occurring with the European Food Standards Agency (EFSA Parma, Italy) to ensure that pertinent entries into their databases are included in the Infonet. The Infonet is intended to be a worldwide resource for the issues of acrylamide in food. Approximately 200 projects have been entered.

INTERNATIONAL TRAINING PROGRAMS

International Training in Minimizing Food Safety Hazards for Fresh Fruits and Vegetables:

- Good Agricultural Practices (GAPs) Train-the Trainer International Training Programs were offered in Guadalajara, Mexico, May 22 – 24, 2006; San Salvador, El Salvador, June 5 – 9, 2006; and Beijing, China, September 25 – 29, 2006. The Training in Guadalajara, Mexico piloted the new Advanced GAPs training, bringing together over 50 participants who previously received basic GAPs training and shared information regarding the impact of the training and their progress to date. Approximately 50 individuals attended the basic GAPs courses held in El Salvador and China. These courses had been revised on the basis of recommendations from the GAPs Training Program Review Team. JIFSAN continues to make an effort to have the host countries share more of the cost of these training sessions, so training can continue at a reduced cost to JIFSAN.
- The instructional team for the training programs is composed of faculty/staff from Clemson University, Mississippi State University, University of Maryland, Cornell University, JohnsonDiversey and FDA. A core group of instructors are used for each of the training programs that are offered in English or Spanish with text materials in either language; China cosponsor translated the course material into Chinese.

World Trade Organization Sanitary/Phytosanitary (WTO SPS) Leadership Development Program:

JIFSAN was instrumental in offering the World Trade Organization Sanitary/Phytosanitary (WTO SPS) Leadership Development Program for the People's Republic of China in cooperation with the UM's Institute for Global Chinese Affairs (IGCA). JIFSAN linked the program with the IGCA, which handled logistics. The Foreign Agricultural Service (FAS) of the USDA organized the program with assistance from FDA, USTR, FSIS, APHIS, GIPSA, and EPA. Two programs have been delivered for groups of 15 China food safety officials. The first program was from September 6 through November 20, 2004 and the second was from March 6 through April 28, 2006. Each group was engaged in training at UM with site visits in the Washington DC area, as well as in agriculture areas of the U.S. Funding for the first group was provided through the American Soybean Association and the second group through U.S. Wheat Associates. JIFSAN was awarded \$300,000 for the first group and \$295,000 for the second.

The JohnsonDiversey International Training Initiative:

JIFSAN was successful in finalizing the JohnsonDiversey International Training Initiative in late 2005. Once approved the JohnsonDiversey Initiative immediately became involved in supporting the JIFSAN GAPs and WTO-SPS efforts with personnel and funding.

The first major effort in the initiative was the development of the Good Aquacultural Practices training program. Additional programs in meat and poultry are being considered - SPS efforts with personnel and funding.

The Good Aquacultural Practices Training Program:

A team, with representatives from the University of Maryland, Virginia Polytechnic Institute, FDA and JohnsonDiversey, developed the program and offered a very successful pilot in Can Tho City, Viet Nam on November 13-17 2006. The program is now being revised based on findings from its initial offering and a formal training manual is being developed. It will next be offered in China in March 2007 and again next fall in a location yet to be determined.

FOOD SAFETY RISK ANALYSIS PROFESSIONAL DEVELOPMENT TRAINING PROGRAM

The Professional Development Training Program in Food Safety Risk Analysis provides training in the key components of risk analysis. The program is developed and taught by FDA staff, UM faculty, and private consultants. Courses in the program are available in face-to-face (scheduled on demand, as a summer integrated program and as individual "boutique" programs tailored for specific audiences) and distance delivery formats. The

third offering of the Summer Integrated Program, offered in July - August 2006, placed courses back-to-back in a three-week format. There was a major and very successful change in location from College Park to Washington DC. The change resulted in significant decreases in facility costs and other expenses, as well as providing participants all of the advantages of an urban location for non-class times. Four courses are currently available and being scheduled in on-line format. Boutique training programs will be offered in Thailand and Mexico December 2006. An on-line program will be offered to a group of students in Croatia in December, as well.

JIFSAN Food Safety Risk Analysis Distance Learning:

Four JIFSAN Food Safety Risk Analysis courses were offered in distance learning mode: *Overview of Risk Analysis; Food Safety Risk Management; Food Safety Risk Assessment; and Food Safety Risk Communication.*

Sixty seven individuals enrolled in these courses, for a total of 83 class seats. Of these 67 individuals, 48 were international participants. Countries represented included Australia, Canada, China, Croatia, Hong Kong, Japan, Kenya, Norway, Spain, UK, and South Korea.

Summer Integrated Program 2006:

Four Core courses including *Overview of Risk Analysis; Food Safety Risk Management; Food Safety Risk Assessment;* and *Food Safety Risk Communication* and two Intermediate courses in *Quantitative Risk Assessment Methods: Model Building* and *Quantitative Risk Assessment Methods: Probabilistic Methods* were taught in the Summer Integrated Program. Core courses were held at Food Products Association (FPA) in Washington, D.C., while the Quantitative courses took place on the UMD campus.

Fifty one individuals enrolled in the courses, for a total of 113 class seats. Of these 51 individuals, approximately 20% were international government individuals representing 8 countries including Australia, China, Italy, Malaysia, Malaysia, Norway, South Korea, and Taiwan. Thirty-five percent represented the U.S. Food and Drug Administration (FDA), 15% represented other U.S. government agencies, and 15% were from U.S. industry.

In Thailand from July 17-22, 2006, 20 individuals from BIOTEC in Bangkok, Thailand took part in a customized risk analysis training program incorporating three of JIFSAN's Food Safety Risk Analysis courses: *Introduction to Risk Assessment, Quantitative Risk Methods: Model Building and Quantitative Risk Assessment Methods: Probabilistic Methods.*

Other International Training Opportunities

- JIFSAN signed an MOU with the Korean Food and Drug Administration (KFDA) in August 2005. Expectations are that JIFSAN will participate by delivering training programs and facilitating scientist exchanges with KFDA.
- JIFSAN signed an MOU with the Ministry of Science and Technology (MOST) of Thailand to offer risk analysis training in Thailand. A “boutique” program was designed to meet the needs of MOST and offered July 17-22, 2006 in Bangkok. The training was offered with full support from the Thai government.

OTHER ACTIVITIES

Establishment of a Center for Risk Communication Research

JIFSAN furnished “seed money” to initiate establishment of a Center for Risk Communication Research (CRCR) led by the Department of Communication, University of Maryland. JIFSAN has pledged support for three years. The Center’s mission is to advance understanding about how communication helps control risk; the public perceives risk communication; and the political, economic and social contexts for risk communication. The Center’s goals include helping to establish public and scholarly agendas for risk communication research, collaborating with other institutions and individuals to secure funding for research projects, and providing support for research and fellowships.

The Center for Risk Communication Research has had a productive term. Some of the accomplishments include working on an evaluation of past CDC campaign materials, aid in the development of more effective future interventions, and team with organ procurement agencies in the region. Dr. Monique Turner and affiliate researchers in the Center are continually working toward building networks outside of the university. Center researchers aim to use their knowledge and research to help practitioners develop effective messages. In 2006, Dr. Turner was awarded a University Technology Apprentice (UTAP) who was given the task of implementing the new design of the CR2 website (<http://www.comm.riskcenter.umd.edu>). The website has been re-designed to effectively achieve the goal of acting as a way to be the center of risk communication dialogue; specifically, the site has added features such as the spotlight study, focus on CR2 research, a risk research archive, a risk researcher’s forum, and other risk resources. Dr. Turner has focused on the Center being viewed as the hub of the most up-to-date and rigorous risk research. In addition, the CR2 continues to broaden its network of researchers which allows for a broader understanding of risk and health risks; and improves the ability to engage a wide range of risk topics. Dr. Turner and other Center researchers also continue to examine research gaps and submit major grant proposals to study these topics. The Center will participate in the Center of Excellence for Behavioral and Social Research on Terrorism and Counter-Terrorism, recently awarded to the University of Maryland by the Department of Homeland Security. Finally, Center

researchers continue to collaborate with JIFSAN to offer classes in risk communication. The full report of CRCR appears in Appendix F.

JIFSAN Participation in Exhibitions

- JIFSAN featured a booth display at the 12th Annual FDA Science Forum in Washington, D.C., April 18 - 20, 2006.

Joint CSL/JIFSAN Symposium on Food Safety and Nutrition: Bioactive Substances

As part of a cooperative agreement with the Central Science Laboratory (CSL), Department for Environment, Food and Rural Affairs (UK), an annual symposium is held on themes relating to food safety and nutrition. The symposia alternate between York, UK and College Park, MD. The Seventh Joint CSL/JIFSAN Symposium on Food Safety and Nutrition: Quality Assurance in Food Safety – Networking of Laboratories, was held June 6-7, 2006 at the Central Science Laboratory, York, UK. Speakers from Europe and the U.S. were involved. Material presented at the Symposium is posted on the CSL website (<http://www.csl.gov.uk/prodserv/ana/jifsan06.cfm>). The Eighth Joint CSL/JIFSAN Symposium on Food Safety and Nutrition: Nanotechnology in Foods and Cosmetics will be held in College Park on June 26-28 2007.

Future Plans (2006-2007)

Due to severe budget reductions by the FDA, the budget allocated for this year will require the use of carry-forward funds. Reductions/eliminations in several JIFSAN programs are necessitated. Efforts will continue to obtain external funding for program support.

1. Administrative

- On September 1, 2006 Dr. Jianghong Meng was appointed Acting Director of JIFSAN and will continue in this position until a search is completed for the Director.
- JIFSAN now reports administratively to the Dean of the College of Agriculture and Natural Resources (AGNR). AGNR has a major initiative in progress, the Center for Food Systems Security and Safety (CFS3). JIFSAN will likely become a key component of this university wide initiative.
- A meeting of the JIFSAN Advisory Committee will be held on April 11-12, 2007. This meeting will concentrate on comprehensive strategic planning.
- Development of the Center for Risk Communications Research (CRCR) will continue.
- The JIFSAN newsletter, IMPACT, will continue to be published electronically.
- JIFSAN plans to exhibit at the Society for Risk Analysis Annual Meeting, San Antonio, TX, December 9-12, 2007; the 13th Annual FDA Science Forum, Washington, D.C.; and the International Association for Food Protection (IAFP) Annual Meeting in Lake Buena Vista, FL, July 8-11, 2007. The Risk Analysis Clearinghouse will participate in these exhibitions.

2. Research Initiatives

- The last project in the discontinued JIFSAN Competitive Grants program will be funded until July 2007.
- The Collaborative/Cooperative research projects that have been extended will be monitored and completed.
- Funding will continue for one postdoctoral research associate in the JIFSAN Postdoctoral Research Associate Program until April 2007; then the program will be discontinued.

3. Education and Outreach Efforts

- Operation of the Risk Analysis Clearinghouse will be further developed under the guidance of the recently appointed Steering Committee, the new IT Manager and Dr. Steven Gendel from the FDA. The Clearinghouse website and data warehouse are undergoing a complete redesign and update. A major emphasis will be acquisition of data beyond those sought from microbiological risk assessments. Operation of the Acrylamide Infonet, including acquisition of data on the occurrence of acrylamide in foods in countries around the world for later use in risk assessments, will continue. A critical issue for the Clearinghouse is funding. There will be no Clearinghouse support from the cooperative agreement in the coming year.
- Operation of the JIFSAN Internship Program will continue.
- Present plans are to offer the train-the-trainer programs in minimizing food safety hazards in production of fresh fruits and vegetables (GAPs Training Programs) in Guatemala, China and Peru in the 2006-2007. JIFSAN will also consider offering the very successful Advanced GAPs course.
- The GAPs team will hold a two-day retreat in February 2007 to discuss the present status of GAPs and plans for the future.
- JIFSAN will continue the JohnsonDiversey Training Initiative program in seafood aquaculture. A formal manual will be developed and published based on results from the pilot program in Viet Nam. A second training program will be offered in China and a third will be considered for the fall.

A second JohnsonDiversey program in poultry or meat is under consideration.

- An effort will be made to raise funds to develop and offer a program in Low Acid Canned Foods.
- The 2006-2007 schedules of courses in the Risk Analysis Professional Development Program are completed and can be accessed at: <http://www.jifsan.umd.edu/pd2006/schedule.cfm>. This will include the Summer Integrated Program and offerings of the courses available in distance learning format. Offerings of face-to-face courses will occur only if the demand warrants. The special effort that was made to reduce operating costs to put the program on a pay-as-you-go basis by offering the program in a commercial location in Washington D.C. was very successful and will be continued. Administrative changes will be made; in view of a key person in the CFSAN-JIFSAN group being reassigned and will no longer assist in the program.

Conversion of the Food Safety Risk Analysis Courses into on-line distance learning modules has been completed. The College of Agriculture and Natural Resources has approved an on-line masters program in risk analysis and will utilize much of the material developed in the professional development program.

- JIFSAN was instrumental in offering the World Trade Organization Sanitary/Phytosanitary (WTO SPS) Leadership Development Program for the People's Republic of China in 2005 on behalf of the Foreign Agricultural Service (FAS) of the USDA; with assistance from the FDA, USTR, FSIS, APHIS, GIPSA, and EPA. Funding was provided through the American Soybean Association. JIFSAN has been awarded \$275,000 from the FAS, through the Wheat Association, to offer the second World Trade Organization Sanitary/Phytosanitary (WTO SPS) Leadership Development Program in 2006. JIFSAN is currently negotiating for the 2007 program.
- Support and development of the Center for Risk Communication Research will continue in collaboration with the Department of Communications (UM).
- One of the best means for obtaining visibility for JIFSAN and its education/outreach programs is through co-sponsorship of symposia, workshops, conferences and other types of meetings. This will continue in areas appropriate to JIFSAN's responsibilities. The extent will depend upon the availability of funding.
- JIFSAN is organizing the workshop: *Tools for Prioritizing Food Safety Concerns* to be held in April 2007 (tentative dates 9-11). The purpose of the workshop is to bring together different organizations who are working on risk ranking models to discuss approaches and develop recommendations for criteria for a process to prioritize risks associated with foodborne hazards (chemical and microbial). The specific objectives are: (1) To develop criteria needed with respect to chemical contaminants in the context of foodborne hazards (chemical and microbial) to determine when to expend resources to address potential food safety risks; and (2) To develop recommendations on next steps, including knowledge gaps and research needs.

4. International Collaboration

- Planning is in progress for the Eighth Joint CSL/JIFSAN Symposium on *Food Safety and Nutrition: Nanotechnology in Foods and Cosmetics*. It will be held in College Park, June 26-28 2007.
- JIFSAN will continue to develop its education/outreach with Korea, China, Thailand, Afghanistan, and other selected countries.