

CELEBRATING 15 YEARS OF EXCELLENCE



JIFSAN

ADVISORY COUNCIL ANNUAL SYMPOSIUM

April 27-28, 2011

Greenbelt Marriott Hotel
Greenbelt, Maryland

Sponsored by



JIFSAN

Celebrating 15 Years

Spanning the Globe



In

Food Safety Training and Partnerships

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Welcome from the Chair and Vice-Chair JIFSAN Advisory Council

We are delighted to welcome you to JIFSAN's 2011 Advisory Council Annual Spring Symposium. This will celebrate JIFSAN's 15th Anniversary of fostering the missions of the Food & Drug Administration and the University of Maryland to provide the scientific basis for advancing the food safety agenda through multidisciplinary research, outreach and educational programs.

JIFSAN also provides valuable opportunities for collaborative efforts with other federal and state agencies, industry, consumer and trade groups, and international organizations that promote food safety throughout the supply chain.

To commemorate this milestone event, we will review JIFSAN's achievements over the past 15 years and feature a program that we hope is both engaging and informative. We also want to celebrate several pioneers who were involved in the inception and launching of this 15 year effort especially the first two directors of JIFSAN, Dr. David Lineback and Dr. Jianghong Meng and a pioneering founder, Dr. Paul Mazzocchi.

The theme of the symposium is: "Mitigating Consequences of an Outbreak /Adverse Event." It will cover an overview of lessons learned from past events; the use of risk analysis tools to focus resources on preventing future occurrences; and understanding how the consumer interprets and reacts to information.

This symposium could not happen without the help of many dedicated people and generous donations from our sponsors. We want to acknowledge industry's participation and financial support as a vital part of the continued success of JIFSAN. We would also like to express our sincere thanks to the Organizing Committee for defining the topics of this symposium, and our distinguished speakers for sharing their knowledge and insights. We especially like to thank you for participating, enriching the discussions and sharing in this occasion.

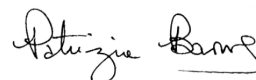
Please let us know if there is anything we can do to maximize your symposium experience. We wish you a pleasant and productive two days and hope that you will gain valuable insights from our expert speakers, establish new connections and enhance relationships.

Thank you for attending and making the 2011 Spring Symposium a success!

Sincerely,



Julie Jones
Chair



Patrizia Barone
Vice-chair



November 2010 Advisory Council Meeting Attendees

(First row) DeAnn Benesh, Donna Rosenbaum, Julie Jones, Elizabeth Calvey

(Second row) Daniel March, Patrizia Barone, Henry Chin, Michael Doyle, James Willis, Courtney Brein, Paul Mazzocchi

(Third row) Mark Empie, Craig Llewellyn, Bradd Eldridge, Kenneth Falci, Thomas Trautman, Gordon Smith, (VP ConAgra, Inc.) Jianghong Meng, (JIFSAN Director) David Lineback, Joseph Scimeca, John Vicini, James Rushing (JIFSAN, Manager International Programs), Steven Robbs (Program Liaison, FDA), George Evancho (JIFSAN, Senior Fellow)

Advisory Council Members not pictured:



Steven Hermansky



Sanford Miller



Gilbert Leveille



Deirdre Schlunegger



Alejandro Mazzota

From the Desk of the Director

As we are celebrating the 15th Anniversary of JIFSAN, we recall that JIFSAN was established to advance sound strategies that improve public health, food safety, applied nutrition and animal health using risk analysis principles through cooperative research, education and outreach programs. Today JIFSAN has made great progress in these areas.

JIFSAN plays an exemplary role in building partnerships with the federal government, the industry and international community. We have developed and will continue to conduct applied research that focuses on risk analysis, and to offer professional development courses and training programs that are delivered in a variety of modes to improve the expertise of government, academia and industry personnel in risk analysis and to train food safety professionals from all over the world.

This is an exciting time with challenges and opportunities. JIFSAN is well positioned to assist in improving the safety of national and global food supply, especially in light of new requirements arising from the recent passage of the Food Safety Modernization Act. With internationally recognized strength and expertise in food safety training JIFSAN will collaborate with its partners in developing food safety training centers in countries/regions to build capacity of both foreign regulators and manufacturers in the use of international best practices in food safety management to better assure the safety of the food supply chain.

Jianghong Meng

JIFSAN Directors

Dr. Paul Mazzocchi, 1996-1998 (Seated)

Dr. David Lineback, 1998-2005 (Standing – Left)

Dr. Jianghong Meng, 2006- Present (Standing – Right)



JIFSAN - 15 Years Building Partnerships

1996-2011

In the mid 1990s it was clear that concerns surrounding a safe food supply were becoming an emerging issue in the US and that more creative ways were needed to address these concerns. Recognizing the need to reach beyond the traditional roles of a government regulatory body and an academic institution, FDA and the University of Maryland, College Park, a leading land-grant institution, forged a partnership to leverage resources and provide additional mechanisms to address these increasing concerns with food safety. Thus, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a cooperative venture of the University of Maryland and the US FDA, was established in 1996.

Since its inception JIFSAN has been a key partner in FDA's food safety program and has developed additional partnership with other U.S. government agencies including USDA-FAS; USDA-FSIS and USAID; various commodity groups; foreign governments and the food industry. JIFSAN's programs and activities have impacted the safety of the global food supply by actively contributing to the 1997 Food Safety Initiative; FDA's 2007 Food Protection Plan; and FDA's ability to implement the current Food Safety Modernization Act. As a part of the 1997 National Food Safety Initiative, JIFSAN was instrumental in developing the framework for the Food Safety Risk Assessment Clearinghouse that has evolved into the

"The FDA Food Safety Modernization Act only heightens the imperative that we in the United States work in partnership with the global food safety community to meet the public's high expectations for the safety of food, no matter its origin."

From: Remarks by M. Taylor;
17Feb11: Global Food Safety
Conference

<http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofFoods/ucm243591.htm>

JIFSAN as part of a leading land-grant institution developed its programs around the three core concepts of the land-grant philosophy: teaching, research, and extension/outreach. JIFSAN has the flexibility to recruit and utilize the very best expertise from around the world to address important problems in food

The Food and Drug Administration, on behalf of the Center for Food Safety and Applied Nutrition has joined with the University of Maryland at College Park to create and intellectual partnership to increase the quality of research and public health policy... to be named the Joint Institute for Food Safety and Applied Nutrition. The terms of this arrangement are established in the Memorandum of Understanding between FDA and the University, signed on April 15, 1996.

From joint press release,
April 15, 1996.

internationally recognized FoodRisk.org – the only on-line resource specializing in food safety risk analysis. JIFSAN's globally recognized training programs including Food Safety Risk Analysis, Good Agricultural Practices (GAP) and Good Aquacultural Practices (GAqP), have contributed to increased understanding of those principles which underpin prevention of food-borne illness and contamination within the food supply chain. As the regulatory framework for global food safety is transformed, JIFSAN will continue to contribute by building on its past efforts.

safety. Most of these efforts are partnerships with other units in this and other universities, foreign and US government agencies, NGOs and industry, an approach that leverages JIFSAN's limited resources and magnifies its impact.

JIFSAN has many active programs in research, education and outreach. JIFSAN's research efforts are extensive and varied, and include not only traditional laboratory and field research, but also educational, behavioral or social research, focused on defining the behavioral determinants that promote sound food safety practices. JIFSAN has also developed and implemented innovative education and training programs. It reaches a broad community by sponsoring/co-sponsoring and participating in workshops, conferences and seminars, promoting debate and dialogue on emerging issues in food safety and applied nutrition. JIFSAN's goal is to become an internationally recognized source of scientific information and trainings on food safety, applied nutrition and animal health that will enable the development of sound public health policy, the improvement of human nutrition, and the reduction of the burden of food-borne illness.

JIFSAN
ADVISORY COUNCIL
Membership



Henry B. Chin
The Coca Cola Company

Dr. Henry B. Chin is the Senior Director for Food Safety, Scientific and Regulatory Affairs at The Coca-Cola Company. At The Coca-Cola Company he is responsible for scientific and regulatory policy on food safety issues, including ingredients, and standards. He has made numerous presentations on food safety and on managing food safety risks.

Prior to joining Coca-Cola, he was with the National Food Processors Association (NFPA) for nearly 30 years, providing scientific and technical advice to most of the major food companies in the United States. At NFPA, Henry held positions as Vice President of the Laboratory Centers, with responsibility for analytical chemistry, food microbiology and process development, and as Vice President of Toxicology and Food Science, with responsibility for food safety programs related to food composition, and chemical contaminants.

Henry is a past President of AOAC International (the Association of Official Analytical Chemists), and has been a member of numerous government and academic advisory panels on various aspects of food safety including food additives and pesticide residues. He currently serves on the Board of Trustees of the Health and Environmental Sciences Institute (HESI) and the International Life Sciences Institute (ILSI) and chairs the Chemicals Management Committee of GMA, co-chairs the Food Safety Committee of the International Food Information Council, is a member of the Food Ingredients Intentional Adulterants Expert Panel at the Food Chemicals Codex/USP, one of the leaders of a task force on food safety policy at the Institute of Food Technologists (IFT), and a member other professional and trade organizations. For the past 3 years, Henry has been head of the delegation representing the International Council of Beverage Associations (ICBA) at the Codex Committee on Contaminants in Food.

He received his doctorate in chemistry from the University of Southern California, and Bachelors degree from the University of California, Berkeley. After completing his doctoral studies, Dr. Chin returned to Berkeley as a post-doctoral research associate in Chemistry.



Alejandro Mazzotta
Campbell Soup Company

Dr. Alejandro Mazzotta is Senior Director of Global Food Safety with Campbell Soup Company, where he leads the Global Microbiology and Thermal Processing functions.

Prior to Campbell's, he worked as Director of Food Safety & Quality Systems for McDonald's Corporation, Microbiology Safety Manager for The Pillsbury Company/General Mills and as Scientist with the National Food Products Association.

Alejandro received his M.S. in Biology from the University of Buenos Aires, Argentina in 1985 and obtained his doctoral degree in Food Science from Rutgers, The State University of New Jersey in 1997.

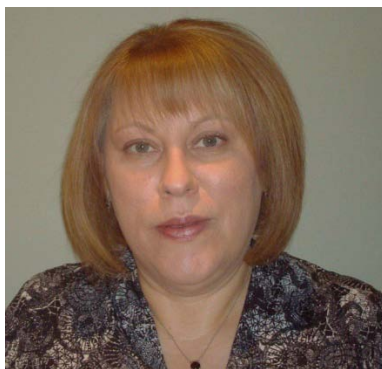
Alejandro has more than 20 publications in peer reviewed scientific journals and has spoken at numerous international meetings and symposia. He has been appointed to the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), served in the Editorial Boards of the American Society for Microbiology (ASM) and the International Association for Food Protection (IAFP). He currently chairs the IAFP Program Committee, and he serves to the advisory boards for the Center for Food Safety at the University of Georgia (CFS), the Institute of Food Safety and Health (IFSH) and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN).



Thomas D. Trautman
General Mills

Dr. Thomas D. Trautman is Fellow, Toxicology and Regulatory Affairs, for General Mills, where he has been employed for more than thirty- two years. Dr. Trautman received a Ph.D. degree in Comparative Pharmacology and Toxicology from the University of California at Davis and a B.A. in chemistry from North Park College in Chicago. He is a Diplomat of the American Board of Toxicology (Class of 1981).

Dr. Trautman has been actively involved in food industry efforts to address numerous food safety and regulatory issues, including the safety of food and color additives, pesticide residues, mycotoxins, food allergens, contaminants, and various aspects of current and emerging risk assessment methodologies. He is a member of the Society of Toxicology, the International Life Sciences Institute, and the Institute of Food Technologists. He has served as chairman of the food toxicology divisions of each of these professional organizations. Additionally, Dr. Trautman is a former member of the National Academy of Sciences' Board on Agriculture and has served on various other NAS/NRC committees that study food safety, risk assessment, and regulation.



Laurie S. Post
MARs Snackfood US, LLC

Dr. Laurie S. Post has spent over 25 years in the food industry as a Food Microbiologist and Food Safety professional. She is an expert in pathogen control programs for low moisture foods and processes. Dr. Post earned her B.S. and Master's Degrees in Microbiology from the University of Maryland and her PhD in Food Microbiology from the University of Tennessee. Following a post-doctorate fellowship in the Department of Food Science, Rutgers University and a three-year period as an Assistant Professor of Food Microbiology, Dr. Post joined Mars Inc. as a Senior Research Scientist. She is currently the Food Safety Program Manager for Mars Chocolate North America. Dr. Post is the author of numerous publications and has chaired the microbiological food safety committees of the International Life Sciences Institute and GMA.



G. Craig Llewellyn
Kraft Foods, Inc.

Dr. G. Craig Llewellyn is currently a Research Principal in the Global Toxicology Group at Kraft Foods. His global responsibilities include the science and management policies of food allergens, addressing toxicological food safety issues, and food ingredient safety assessments. In North America, Dr Llewellyn also represents Kraft Foods in numerous external organizations including the National Coffee Association, the International Life Science Institute, the Grocery Manufacturers Association, the International Food Information Council, the International Chewing Gum Association, and the Flavors and Extracts Manufacturers Association. He also serves on advisory boards for the Joint Institute of Food Safety and Applied Nutrition at the University of Maryland and the Food Allergy Research and Resource Program at the University of Nebraska. Dr. Llewellyn is a member of the Society of Toxicology (past President of the Food Safety Specialty Section), the Institute of Food Technologists and the American College of Toxicology. He began his food industry career at Kraft Foods in 2000 as a Research Scientist in the Scientific Affairs Group.

In 2006, Dr. Llewellyn joined the Wm. Wrigley Jr. Company as a Principle Scientist in the Scientific and Regulatory Affairs Group, and in 2008 he returned to Kraft Foods. Prior to completing his Ph.D., he was an Analytical Food Chemist in the Department of Consolidated Laboratory Services for the Commonwealth of Virginia. Dr Llewellyn received his B.S. degree in Biology from Virginia Commonwealth University, his Ph.D. in Pharmacology and Toxicology from the Medical College of Virginia, Virginia Commonwealth University, and he completed a postdoctoral fellowship at Eli Lilly and Company.



Kenneth J. Falci
W.K. Kellogg Institute

Dr. Kenneth J. Falci is currently the Senior Director, Scientific Regulatory Operations since September 2007. In this position Dr. Falci is responsible for external influence in the company for Grocery Manufacturers Association (GMA), International Institute of life Sciences (ILSI), CODEX, FDA, USDA, U.S. and the Customs and Border Protection. Dr. Falci is involved in nutrition GRAS labeling and he continues to provide expertise for crisis management, food and chemical safety, domestic and international ingredients and GRAS food determinations.

Before coming to Kellogg Company, Dr. Falci was the director of the Office of Scientific Analysis and Support at the Food and Drug Administration's Center of Food Safety and Applied Nutrition (CFSAN), College Park, Maryland. Dr. Falci's department was responsible for CFSAN's chemical instrumentation, epidemiology, mathematics, economics, consumer nutrition food labeling and claim research, pathology, medical doctors and the creation of the national food adverse event reporting system. He additionally has expertise in food contact packaging. Dr. Falci is a member of the Board of the International Life Sciences Institute (ILSI, North America) and the Food Allergy and Anaphylactic Network (FAAN). He is also a member of several associations to advance nutrition science, food safety and quality, including the Institute of Food Technology and the Strategic Issues Group of the International Life Sciences Institute. He additionally serves on the technical Committee on Food and Chemical Safety, ILSI NA.

Dr. Falci received a Ph.D. degree in organic chemistry drug synthesis from Fordham University in New York City. He, and his wife, Barbara, reside in Battle Creek, Michigan. They have three children.



PATRIZIA BARONE
Unilever

Dr. Patrizia Barone is the Regional Regulatory Affairs Director at Unilever, leading the strategic regulatory activities for the North American region. Before joining Unilever, Patrizia held positions at Reckitt Benckiser, initially as Vice President of R&D for North America. She moved to Australia to head the Asia Pacific & South Asia R&D Laboratory, and upon her return held positions culminating as Global R&D Category Group Director - Regulatory Affairs & R&D Systems, responsible for product safety and regulatory strategies for all products globally. Earlier, Patrizia worked with Colgate-Palmolive and Miles, Inc. Household Products Division, a division of Bayer AG.

Patrizia has a Bachelor of Science in Chemistry from the University of Maryland College Park and a Ph.D. in Inorganic Chemistry from Georgetown University, Washington, D.C.



John L. Vicini
Monsanto

Dr. John L. Vicini is a Senior Research Fellow and the Lead of the Nutrition and Composition Team in Monsanto's Product Safety Center. Dr. Vicini grew up in Maryland and received his B.S. in Animal Sciences from the University of Maryland, his M.S. in Animal Sciences from West Virginia University, and his Ph.D. in Dairy Science from the University of Illinois. The American Dairy Science Association recognized his research at the University of Illinois by awarding him the R. M. Hoyt Award in 1987. Dr. Vicini joined Monsanto in 1987 where he conducted numerous studies with POSILAC® brand of bST. In 1994 he worked with the Monsanto Technical Services group in Syracuse, NY. In 1998 he moved back to the Technology Group in St. Louis. He is currently responsible for conduct of regulatory studies that demonstrate safety of crops bred by advanced breeding techniques or developed through biotechnology. He is also responsible for development of products for human or animal nutrition. Dr. Vicini has held numerous offices within the American Dairy Science Association and is an ad-hoc reviewer for several journals.



Joseph A. Scimeca
Cargill, Inc.

Dr. Joseph A. Scimeca currently holds the position of Senior Director of Global Regulatory & Scientific Affairs, in the Corporate Food Safety and Regulatory Affairs organization at Cargill, where he provides leadership for ensuring that company food and feed products and processes are safe, included being protected against intentional acts of adulteration and bioterrorism, and are in compliance with the appropriate national regulations. Before joining Cargill in February 2004, Dr. Scimeca was a Senior Manager for Quality & Regulatory Operations, at General Mills, Inc. Previously he held the position of Director, Food Safety and Regulatory Affairs with The Pillsbury Company, where he was employed since June 1999. Prior to joining Pillsbury, he was employed with Kraft, Inc. where for nearly twelve years he held various positions in toxicology and nutrition. Prior to Pillsbury, he received his Ph.D. in Pharmacology and Toxicology from the Medical College of Virginia, Virginia Commonwealth University, in 1987. He has and continues to serve on technical committees for several scientific organizations and trade associations, such as Grocery Manufacturers Association, Food Allergy Resource and Resource Program, Joint Institute for Food Safety and Nutrition, and the International Life Sciences Institute. For the latter organization, he has served as chairman of the Technical Committee on Food Toxicology and Safety Assessment. At the request of the National Academy of Sciences, he has served on a subcommittee involved in the development of a framework for evaluating the safety of dietary supplements. Similarly, he served on an expert panel for the Institute of Food Technologists in developing a report on evaluating food chemical safety. He has actively participated in the Society of Toxicology Food Safety Section since its inception, where he has held several positions, including president. Joe is currently serving as the co-chair of the Industry Working Group of the National Center for Food Protection and Defense, based at the University of Minnesota. He also chairs the Minnesota Food Safety and Defense Task Force, held under the auspices of the Minnesota Departments of Agriculture and Health. He has authored over thirty peer-reviewed scientific publications and four book chapters.



James N. Willis
Waters Corporation

Dr. James N. Willis is the Senior Director for Global Market Development. In 2000, he joined Waters Corporation as the Director of Field Marketing for Industrial Products in the North American Field Organization and in 2002 became Managing Director of Waters' Chemical Analysis Business Group. The areas of business that this role encompasses are fine and specialty chemicals, polymers, food and beverages including food safety, and the environmental arena. In 2009, he moved into a corporate role supporting key business and worldwide marketing opportunities for Waters. He is based in Milford, MA.

He entered the analytical instrument business in 1970 when he joined Cary Instruments as a Senior Applications Chemist. Over the last 40+ years, he has worked in product management and senior marketing management roles with a number of companies involved in analytical instrumentation.

Jim earned his MS and Ph.D. degrees at the University of South Carolina in 1964 and 1970, respectively, with an intervening three-year tour of duty with the United States Air Force between 1964 and 1967. His field of study was molecular spectroscopy.



Mark W. Empie
Archer Daniels Midland Company

Dr. Mark W. Empie, Vice President, Regulatory & Scientific Affairs heads the clinical, nutritional and regulatory affairs programs within the Office of Compliance and Ethics. Since joining ADM in 1997, he has been involved with new product identification, development and approvals; GRAS, color additive and feed ingredient submissions; health claim initiatives; GMO issues; supplement labeling; clinical and scientific substantiation for claims and advertising; various patent matters; industry organization contacts; and EU regulatory issues.

Mark draws upon over 25 years of R & D, project management and government interaction work. His industrial experience includes nine years with Stauffer and Dow Chemical companies discovering and developing new food ingredients and chemical intermediates produced through biochemical means for the agrochemical and pharmaceutical industries. An additional nine years were spent with the enzyme-fermentation company, Gist-brocades, initially in a development and research coordination role and the latter four years as a regulatory affairs manager. He currently serves as a Board of Directors member for International Life Sciences institute (ILSI) and has over 40 published papers, book chapters and patents. Mark has a B.S. degree in Chemistry from Syracuse University and a Ph.D. degree in Chemistry from Purdue University, concentrating in protein physical chemistry.



Bradd P. Eldridge
Abbott Nutrition

Bradd P. Eldridge is the Director of Quality Compliance, Food Safety and Strategy with Abbott Nutrition. He started with Abbott in 1990 and held a variety of roles with increasing responsibilities in quality and manufacturing across various levels of the organization starting at the manufacturing plant level, moving to the Abbott Corporate location in Chicago, Illinois and then to his current Director position within the Abbott Nutrition division. His current responsibilities include understanding global regulations, and developing and implementing programs to assure successful product quality and compliance across the Abbott Nutrition division.

Before joining Abbott 21 years ago, Bradd worked for the U.S. government in Washington, D.C., and for another U.S. healthcare company.

His professional affiliations include the International Association for Food Protection, the Institute of Food Technologists, the Joint Institute of Food Safety and Applied Nutrition, and the Association of Food and Drug Officials. Bradd is also active with the Asia Pacific Economic Cooperation and the Partnership Training Institute Network.

Bradd holds a Bachelor of Arts Degree with major studies in Chemistry and Computer Science and minor studies in Business Administration, Economics and Mathematics from Catawba College in Salisbury, North Carolina, and a Masters of Business Administration from Indiana University. Bradd and his wife are the parents of three children.



DeAnn L. Benesh
3M

DeAnn L. Benesh is a Global Regulatory Affairs Manager in 3M Food Safety, where she provides leadership to teams engaging in strategic local and regional regulatory activities to help drive recognition and acceptance of methods, and to actively partner with government and non-government organizations to participate in development of ideas, technologies, and processes to address food safety challenges and requirements within the food industry. She has worked in the food industry for 20 years, and at 3M for the past 30 years in a variety of businesses and capacities including: research in 3M Pharmaceuticals, new product development within 3M Health Care, and more recently as International Technical Services Manager within 3M Microbiology.

DeAnn has a Bachelor of Science in Medical Technology from the College of Pathology, University of Minnesota, Minneapolis, MN, and a Mini-Masters in International Business from the University of St. Thomas, St. Paul, MN.



Steven J. Hermansky
ConAgra Foods, Inc.

Dr. Steven J. Hermansky is the Vice President and Fellow in Scientific and Regulatory Affairs and Toxicology at ConAgra Foods. Steve joined ConAgra Foods in May 2007 to direct & oversee the corporation's toxicology & product safety risk assessment programs and now heads the Scientific and Regulatory Affairs department. He has over 20 years of post-doctoral toxicology experience in the chemical and pharmaceutical industries and has worked in a variety of product development and safety positions. Prior to coming to ConAgra, Steve was the Director of Product Safety and Performance for Schering-Plough HealthCare Products. In that capacity, he was responsible for pre-clinical toxicology, human clinical safety testing, claims substantiation, post-marketing safety surveillance (adverse event monitoring and reporting), and consumer relations.

Steve has a Doctor of Pharmacy degree as well as Master of Science and Doctor of Philosophy degrees in toxicology. He is a Diplomate of the American Board of Toxicology and has published over 40 textbook chapters, peer reviewed publications and scientific abstracts.



Michael P. Doyle
Center for Food Safety
University of Georgia

Dr. Michael P. Doyle is a Regents Professor of Food Microbiology and Director of the Center for Food Safety at the University of Georgia. He is an active researcher in the area of food safety and security and works closely with the food industry, government agencies, and consumer groups on issues related to the microbiological safety of foods. He serves on food safety committees of many scientific organizations and has served as a scientific advisor to many groups, including the World Health Organization, the Institute of Medicine, the National Academy of Science-National Research Council, the International Life Sciences Institute-North America, the Food and Drug Administration, the U.S. Department of Agriculture, the U.S. Department of Defense, and the U.S. Environmental Protection Agency. He is a Fellow of the American Academy of Microbiology, the International Association for Food Protection and the Institute of Food Technologists, and is a member of the National Academies Institute of Medicine.



Sanford A. Miller
JIFSAN

Dr. Sanford A. Miller is currently an Affiliate Professor in the Nutrition and Food Science Department and Senior Fellow at the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland, College Park, Maryland. He was named Professor and Dean Emeritus of The Graduate School of Biomedical Sciences at The University of Texas Health Science Center at San Antonio (UTHSCSA) in December 2000. From 1987-2000, Dr. Miller was the Dean of the Graduate School of Biomedical Sciences and Professor in the Departments of Biochemistry and Medicine at the UTHSCSA. He is the former Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. Previously, he was a Professor of Nutritional Biochemistry at the Massachusetts Institute of Technology.

Dr. Miller has served on many national and international government and professional society advisory committees. He is a recipient of the Outstanding Teacher of the Year Award from M.I.T. and has received many other honors including The Conrad A. Elvehjem Award of the American Institute of Nutrition, The Esther Peterson Consumer Service Award from the Food Marketing Institute, The Sterling B. Hendricks Award (given before the American Chemical Society) established by the Agricultural Research Service of the U.S. Department of Agriculture, the Babcock-Hart Award from the International Life Sciences Institute - Nutrition Foundation and the Institute of Food Technologists, and in June 1997, received the Atwater Memorial Lectureship Award from the USDA Agricultural Research Service and the Institute of Food Technologists. In 1998, Dr. Miller was elected a Fellow of The American Society for Nutritional Sciences. He was also a member of the Institute of Medicine and National Research Council's Committee to Ensure Safe Food from Production to Consumption, the Committee on Agricultural Biotechnology, Health and the Environment of the National Research Council, and the Roundtable on Environmental Health Sciences, Research, and Medicine. He served as Chair of the Food Advisory Committee of the Food and Drug Administration. In June 2000, he became the recipient of the Food and Drug Administration's Distinguished Alumni Award. In February, 2002 he was named a National Associate of the National Academies. He is author or co-author of more than 200 original scientific publications. Dr. Miller received a B.S. in Chemistry from the City College of New York, and a M.S. and Ph.D. from Rutgers University in Physiology and Biochemistry.



Courtney Brein
National Consumer League

Courtney Brein is the Linda Golodner Food Safety and Nutrition Fellow at the National Consumers League (NCL), where she works on a range of food safety, nutrition, and truth-in-advertising issues. Courtney joined NCL in August 2009 to establish the League's Food Safety and Nutrition Division.

Previously, she worked in the Division of Health Policy at the New York Academy of Medicine, where she focused on disease prevention and health promotion policies and initiatives. Courtney earned a bachelor's degree in Anthropology from Princeton University, where she conducted award-winning, independent research on the experience of overweight American children and the medicalization of the obesity epidemic in the contemporary United States.



Julie Miller Jones
St. Catherine University

Dr. Julie Miller Jones, a board Certified Nutrition Specialist and Licensed Nutritionist, received her B.S. degree from Iowa State University and her Ph.D. Food Science and Nutrition from the University of Minnesota. Currently, she is an Emeritus Professor and Distinguished Scholar of Food and Nutrition at St. Catherine University in St. Paul. She has twice been named the outstanding professor, was awarded the Myser Award as a professor ‘who made a difference in people’s lives’.

She regularly communicates about whole grains and dietary fiber, carbohydrates, sugars, the glycemic index, fat, antioxidants, gluten free, food safety and diets. She authored Food Safety (Eagan Press) and edited Dietary Fibre: Food and Feed and Bio-active Ingredients. She has appeared on radio and TV shows in many cities and has answered hundreds of consumer letters in the FIXIT column of the *Minneapolis Star and Tribune*. A frequent speaker for many professional and consumer organizations, locally, nationally and internationally.

As part of her many activities in many professional organizations, she has served as President and Board Chair of the American Association of Cereal Chemists_ International. In 2004 she received their highest award, the Geddes Award. She is a scientific advisor for the Joint Institute of Food Safety and Nutrition of the US Food and Drug Administration and the University of Maryland, the International Life Sciences Institute, and the Grains Food Foundation.



Donna Rosenbaum
Food Safety Partners, Ltd.

Donna Rosenbaum is the CEO and lead consultant for Food Safety Partners, Ltd. of Northbrook, Illinois. Food Safety Partners is a national food safety consulting firm that specializes in consumer-based projects. She earned her degree in Neurobiology from Northwestern University and was working in healthcare management when *E. coli* disease claimed the life of her daughter's best friend as the first victim in the Jack in the Box outbreak in 1992. Donna then became a committed food safety advocate and now has over 18 years of expertise in working on consumer food safety issues. She has personally worked with thousands of foodborne illness victims and consumers concerned with the safety of our food supply. She is a long-time member of IAFP, has recently spoken at the APHL conference on "The Impact of Emerging Foodborne Pathogens", at a joint meeting of the USDA, FDA, & CDC on "Measuring Progress on Food Safety", and has been an invited participant to the WHO/FERG stakeholder event in Geneva, Switzerland. Endeavors include consultation on various foodborne illness cases, development of material for management of recalls and outbreaks for a food industry insurance group, and media and social media outreach platforms on food safety for interested corporations.



Gilbert A. Leveille
Leveille Associates

Dr. Gilbert A. Leveille is currently the Emeritus Director of the Wrigley Science Institute and is also President of Leveille Associates, a company providing consultation in the areas of Nutrition, Food Science and Regulatory Affairs.

Dr. Leveille started his career in academia as Professor of Nutritional Biochemistry at the University of Illinois (1965-1971) then was Professor and Chairman of the Department of Food Science and Human Nutrition at Michigan State University from 1971 to 1980. In 1980 he moved to the private sector where he has been employed by a number of food firms including General Foods, Nabisco, McNeil Nutritionals, and Cargill.

Dr. Leveille received his Ph.D. from Rutgers University and received his undergraduate degree from the University of Massachusetts at Amherst. He also has been awarded an honorary D.Sc. degree from Purdue University.

Dr. Leveille is a past president of the Institute of Food Technologists and of the American Society for Nutrition and is a Fellow of both organizations. He is a member of numerous other professional organizations. He lectures widely and has published more than 300 scientific papers and several books and patents. Dr. Leveille is the recipient of several awards including the Mead Johnson and the Conrad Elvehjem Awards from the American Society for Nutrition and the Carl Fellers, Industrial Scientist and Appert Awards from the Institute of Food Technologists. In 2010 an endowed lectureship was established, The Gilbert A Leveille Award and Lectureship, honoring Dr. Leveille's commitment to the disciplines of Food Science and Nutrition, the award will be jointly managed by the American Society for Nutrition and the Institute of Food Technologists



David R. Lineback
JIFSAN

Dr. David R. Lineback, Senior Fellow, Joint Institute for Food Safety and Applied Nutrition (JIFSAN), University of Maryland at College Park is a food/cereal scientist with extensive academic experience. He has been dean, College of Agriculture, University of Idaho and head of the Departments of Food Science at Pennsylvania State University and North Carolina State University. He has served on the faculty of the University of Nebraska and Kansas State University. He is active in AACC International (formerly the American Association of Cereal Chemists) and the Institute of Food Technologists, having been President of both. He has been active in the Council for Agricultural Science and Technology (CAST), serving on the Board of Directors, the Executive Committee, and as President. He has provided leadership in several public and private sector food-related organizations. He has been involved in international activities for many years. He currently serves as immediate Past President and a member of the Governing Council and the Board of Directors of the International Union of Food Science and Technology (IUFoST). He has a B.S. degree (chemistry) from Purdue University and a Ph.D. degree from Ohio State University (organic chemistry).



Deirdre Schlunegger
STOP Foodborne Illness

Deirdre Schlunegger, Chief Executive Officer for STOP has over twenty years of nonprofit experience. Before she joined STOP, she held the position of President & CEO with the Make A Wish Foundation in Oklahoma. Prior to Make A Wish, she was Vice-President of Affiliate Relations at Breast Cancer Network of Strength (formerly known as Y-Me National Breast Cancer Organization). She had oversight of all the organization's chapters around the country. She developed business plans and launched new chapters in new markets. She has served as the Executive Director of a Chicago nonprofit organization and a national foundation, has been the Director of Child Life Programs in a number of Children's Hospitals, served as an adjunct faculty member at the Medical College of Georgia Hospital and Clinics, developed a program at Cabrini Green and was the Director of a Chicago Head Start Program. Deirdre has also worked as a consultant for various organizations.

Deirdre graduated from Colorado State University with a Bachelors of Science degree in Human Development and Family Studies, completed a Child Life Internship at Johns Hopkins Children's Hospital and a program in Nonprofit Management at Kellogg School of Business and has attended numerous courses in leadership including one at the Wharton School of Business. She served on the Chicago Mayor's Office on Domestic Violence Advisory Committee, the Juvenile Court Domestic Violence Committee and was a Board Member of the Illinois Coalition of Domestic Violence.

Advisory Council
2011 Annual Symposium Program

Background

Outbreaks and adverse events appear to occur with alarming frequency resulting in a lack of, or decline in, confidence in the safety of foods. Preventing such events and restoring consumer confidence is the goal of the entire food industry and the Joint Institute for Food Safety and Applied Nutrition Advisory Council 2011 Symposium is designed to help facilitate that goal.

There are lessons to be learned from past outbreaks and adverse events, but learning from the past will only get you so far. Circumstances change, microorganisms adapt, analytical methods get refined and can detect infinitely smaller quantities, and our exposure to changing environments expands in a continuously shrinking world.

Using risk analysis tools in addition to past lessons-learned could help identify and quantify where we are most vulnerable, and allow us to focus our limited and increasingly valuable resources on prevention.

When the unexpected does happen, knowing how and what to communicate to the consumer could reduce damage to a brand's image and minimize loss of consumer confidence. And if lost, knowing how to regain consumer confidence can help rebuild your business.

The focus of the JIFSAN Advisory Council 2011 Symposium is mitigating consequences of an outbreak/adverse event. The symposium will provide an overview of lessons learning from past events; the use of risk analysis tools to focus resources on preventing future occurrences; and understanding how the consumer interprets and reacts to information.

Having the right tools and knowledge give you an advantage when facing the challenges of an outbreak/adverse event, and knowing how to communicate with consumers could help you remain competitive. Attend the JIFSAN AC 2011 Symposium on Mitigating Consequences of Outbreaks/Adverse Events and learn how to better understand and manage the issues.

Organizing Committee

(Front from left)

George Evancho, Chair
Patrizia Barone, Elizabeth Calvey
DeAnn Benesh

(Back from left)

Bradd Eldridge (back)
Thomas Trautman
David Lineback
Joseph Scimeca



University of Maryland
Joint Institute for Food Safety and Applied Nutrition
JIFSAN – Celebrating 15 Years of Success
Advisory Council 2011 Spring Symposium
Mitigating Consequences of an Outbreak/Adverse Event

Greenbelt Marriott Hotel

Greenbelt, Maryland

April 27, 2011

7:30 AM	Registration & Continental Breakfast Poster Session (10:00 am to 5:00 pm – Chesapeake Room)
9:00 AM	Welcome <i>Jianghong Meng, Director, JIFSAN</i> <i>George Evancho, Symposium Chair</i>
9:20 AM Past	Session 1: Making a Difference in the Future by Learning from the Past Session Chair & Moderator: <i>Dr. Patrizia Barone – Unilever</i>
9:30	Lessons from the Hydrolyzed Vegetable Protein Incident Speaker: <i>Jenny Scott, FDA, Center for Food Safety and Applied Nutrition, College Park, MD</i>
10:00	A Retrospective on the Multiagency Response to Seafood Safety Following the 2010 Deepwater Horizon Oil Spill Speaker: <i>Peter Koufopoulos, FDA, Center for Food Safety and Applied Nutrition, College Park, MD</i>
10:30	Break
10:45	Case Study – Managing through a Crisis: An Industry Perspective Speaker: <i>William Daniels, Earthbound Farms, San Juan Bautista, CA</i>

11:15 Lessons Learned from Salmonella in Eggs Outbreak
Speaker: *Donald Zink, FDA, Center for Food Safety and Applied Nutrition, College Park, MD*

11:45 Session Overview (15 Minutes)

12:00 Lunch (Annapolis Room)

1:30 PM Session 2: Risk Analysis Relevance and Applications

Session Co-Chair & Moderator: *Elizabeth Calvey – FDA*

1:40 Risk Assessment Tools for Decision Making
Speaker: *Greg Paoli, Risk Sciences International, Ottawa/Canada*

2:10 Rapid Risk Assessments to Make Informed Decisions on Emerging Issues
Speaker: *Sherri Dennis, FDA, Center for Food Safety and Applied Nutrition, College Park, MD*

2:40 **Break**

3:00 Communicating Uncertainty between Risk Managers and Risk Assessors
Speaker: *Sandrine Blanchemanche, INRA Met@risk, Paris, France*

3:30 Risk Analysis – Practical Examples of Where and When It Can be Applied: An Industry Perspective
Speaker: *Leon Gorris, Unilever, China*

4:00 Session & Day Overview (30 Minutes)

Evening Event

6:00 JIFSAN 15th Anniversary Reception (*Grand Ballroom*)

7:00 Anniversary Dinner (*Grand Ballroom*)

Keynote Speaker: Dr. William E. Kirwan
Chancellor, University System of Maryland

JIFSAN – Celebrating 15 Years of Success

Advisory Council 2011 Spring Symposium

Mitigating Consequences of an Outbreak/Adverse Event

Greenbelt Marriott Hotel

Greenbelt, Maryland

April 28, 2011

- | | |
|----------------|---|
| 7:30 AM | Registration & Continental Breakfast
Poster Session (9:00 am to 12:00 pm – Room TBD) |
| 9:00 AM | Welcome – Day Two
<i>Jianghong Meng, Director, JIFSAN</i>
<i>George Evancho, Symposium Chair</i> |
| 9:20 AM | Session 3: Communicating with the Consumer

Session Chair & Moderator: <i>George Evancho – JIFSAN</i> |
| 9:30 | Communicating to the Consumer: Managing Public Outrage
Speaker: <i>Stephen Sundlof, University of Maryland, College Park, MD</i> |
| 10:00 | Using Social Media to Communicate in Times of Crisis
Speaker: <i>Kimberly Reed, IFIC Foundation, Washington, DC</i> |
| 10:30 | Break |
| 10:45 | Consumers' Perceptions of Recalls
Speaker: <i>Donna Rosenbaum, Food Safety Partners, Ltd., Northbrook, IL</i> |
| 11:15 | Motivating Consumers to Respond Appropriately to Food Recalls
Speaker: <i>William Hallman, Food Policy Institute, Rutgers University, Camden, NJ</i> |
| 11:45 | Session Overview and Symposium Wrap-up |

SPEAKERS

AND

ABSTRACTS



Jenny Scott
Food and Drug Administration

Jenny Scott is Senior Advisor to the Director of the Office of Food Safety at the Food and Drug Administration's Center for Food Safety and Applied Nutrition. In that position she develops and implements policies, regulations and guidelines related to food safety and provides technical expertise in a variety of food safety areas. Prior to joining FDA in August 2009, Ms. Scott was Vice President of Science Policy, Food Protection, at the Grocery Manufacturers Association in Washington, DC, where she held various positions over a 29-year tenure. She received an A.B. degree in biology from Wellesley College, an M.S. in bacteriology from the University of Wisconsin, and an M.S. in food science from the University of Maryland. She has published widely in the areas of microbial food safety. She has been active in professional associations such as the American Society for Microbiology, the Institute of Food Technologists, and the International Association for Food Protection, of which she was President in 2000-2001. She is a fellow of both IAFP and IFT. Ms. Scott served 3 terms on the US National Advisory Committee on Microbiological Criteria for Foods and currently serves as the US delegate to the Codex Committee on Food Hygiene.

Lessons Learned from the Hydrolyzed Vegetable Protein Incident

Jenny Scott

Senior Advisor

Food and Drug Administration

CFSAN Office of Foods

College Park, MD

ABSTRACT

In early February, 2010, FDA received submissions from two companies to the Reportable Food Registry (RFR) related to the presence of *Salmonella* Tennessee in hydrolyzed vegetable protein (HVP). In February and March 2010 there were 177 products recalled from commerce as a result of this incident. However, the number of recalls could potentially have been much larger. HVP is a flavor enhancer used in a wide variety of processed food products, such as soups, sauces, chilis, stews, hot dogs, gravies, seasoned snack foods, dips, and dressings. It is often blended with other spices to make seasonings that are used in or on foods. The HVP recall by the supplier was responsible for 1001 RFR entries involving at least 11 different commodity categories. This incident emphasized the complexity of contamination events involving ingredients. It demonstrated the benefits to FDA of the RFR portal in making the agency aware of contamination events and documenting the distribution of contaminated ingredients. The event showed (1) the utility of finished product testing in uncovering contamination events; (2) the importance of root cause analysis in identifying the source; (3) the benefits of a good environmental testing program in identifying environmental contamination that could potentially lead to product contamination; (4) the importance of good supplier control programs; (5) the importance of firms knowing the impact of pathogen inactivation steps for their products (validation), including those to be delivered by the customer or consumer. The lessons learned from this incident have broad implications for the entire food industry, but food safety will be enhanced if appropriate actions are implemented as a result.



Peter Koufopoulos
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Peter Koufopoulos is a graduate of the University of South Carolina, obtaining his BS in Marine Biology in 1992. After graduating, he joined the SC Department of Health and Environmental Control working in the state's Superfund assessment group. Here he completed impact assessments and evaluated hazardous waste transmission routes (air, surface water and groundwater) to sensitive environments. Peter worked as project manager on several hazardous waste clean-up projects overseeing remediation efforts, budget, personnel, worker safety and contracts.

In September 1997, Peter left Superfund work and joined the agency's (molluscan) shellfish sanitation program. Over the next four years, he supervised the local shellfish program office in Charleston, SC. Peter was responsible for ensuring compliance with the standards found in the National Shellfish Sanitation Program (NSSP). The NSSP provides an outline of the minimum standards necessary to ensure wholesome shellfish; such as water quality thresholds, pollution source identification and abatement, processing plant standards, and laboratory and analysis guidelines.

A Retrospective on the Multiagency Response to Seafood Safety Following the 2010 Deepwater Horizon Oil Spill

*Peter Koufopoulos,
Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD*

ABSTRACT

During the period of April 20 through July 15, 2010 approximately 210 million gallons of crude petroleum spilled into the Gulf of Mexico (GOM) following the explosion and sinking of the Deepwater Horizon (MC 252) drilling platform. The explosion resulted in the loss of human life and the release of crude petroleum impacting approximately 88,000 square miles of Federal and State territorial waters. Among the significant human and environmental impacts of the spill, fisheries resources and supporting marine and estuarine ecosystems were subjected to contamination by crude petroleum, which compromised the health of the GOM and the safety of seafood resources. The FDA operates a mandatory safety program for all fish and fishery products under the provisions of the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and related regulations. The FDA and other Federal and State Agencies responded to the MC 252 petroleum spill in a coordinated manner to institute a unified seafood safety protocol for the testing and re-opening of GOM fisheries. To date, the unified protocol has resulted in the reopening of fisheries in approximately 98% of the state and federal waters of the GOM.



William Daniels
Earthbound Farm

William Daniels is the Senior Vice President of Operations and Organic Integrity and has been with Earthbound Farm since 1999. He has helped the company grow from a small, regional salad producer to the nation's largest grower, packer and shipper of organic produce. As Earthbound Farm's Senior Vice President of Operations and Organic Integrity, Daniels is responsible for operations (manufacturing, distribution, facilities), food safety, food quality and the company's organic integrity program.

As the leader of Earthbound Farm's industry-leading food safety program, Will is a sought-after speaker and has addressed key issues in food safety in the produce industry at meetings of the National Academy of Sciences, the National Restaurant Association, the Institute of Food Technologists, and the International Association for Food Protection. He has also been featured in a variety of national news stories on food safety with media such as *The New York Times*, and ABC News's *Good Morning America*; and is the author of a chapter, "Effectively Managing through a Crisis," in the book *Microbial Safety of Fresh Produce*, published by Wiley in 2009.

An active leader in the organic industry, Will serves on a variety of boards and technical committees. He currently serves on: The Board of Directors of the California Certified Organic Farmers, recently as President; the board of directors for the California Leafy Greens Marketing Agreement; the editorial advisory board for the *Organic Processing* magazine; numerous technical committees with California and Arizona Leafy Greens Marketing Agreement; the United Fresh Produce Association; the UC Davis Center for Produce Safety and the Organic Trade Association.

Prior to working with Earthbound Farm, Will had his own food service consulting company where he worked on projects in menu revision, nutrition and food safety. He graduated from California Polytechnic State University, San Luis Obispo with a bachelor of science in nutrition. In his free time, Daniels likes to cook — he makes a mean barbecue sauce — and enjoys spending time with his wife and daughters.

Managing through a Crisis: An Industry Perspective

*William Daniels
Earthbound Farms
San Juan Bautista, CA*

ABSTRACT

The summer of 2006 was an inflection point for the produce industry. The FDA had issued its second warning letter concerning outbreaks of foodborne illness caused by produce. FDA officials had arranged a special meeting with growers in the Salinas Valley to deliver the message that in the interest of public health; the next produce-linked outbreak would be dealt with swiftly and sternly. Unfortunately, for Natural Selection Foods, their spinach was linked to the subsequent produce-related outbreak.

In the following weeks and months, investigators for the company and the government combed diligently through paperwork, facilities, and fields. Despite the countless man-hours invested in an attempt to pinpoint the cause of the contamination that was responsible for 200 sicknesses and three deaths, none was ever identified. The closest they came was a sample taken about a mile from one spinach field that matched a case sample. For purposes of the investigation, it was solidified that EBF was involved.

In this presentation, Will Daniels takes you through his personal experience before, during and after the outbreak. What was the company doing before the outbreak? What happened during the outbreak that would help to shape the food safety program moving forward? What was developed as a result of the investigation? You will learn more about what it takes to be prepared for an incident, how to manage through the crisis and what Natural Selection Food is doing today, which is now regarded as one of the most aggressive multi-hurdle food safety programs in industry.



Donald L. Zink
Food and Drug Administration

Dr. Donald L. Zink received a Bachelor of Science degree from Abilene Christian University. He earned an M.S. degree in Microbiology and a Ph.D. in Biochemistry and Biophysics from Texas A&M University. Between 1978 and 1983, he held faculty positions at Texas A&M University's College of Veterinary Medicine and at the University of Arizona in the Department of Microbiology and the Department of Food Science. He joined Campbell Soup Company in 1983 as Manager of Process Microbiology where he worked in the area of refrigerated food safety and aseptic processing. In 1990, he joined Nestle, where he held various positions in Quality Assurance for the Carnation Company and later served as Director of Food Safety for Nestle USA. In 2000, he joined a new beef processing venture company, Future Beef Operations, as Vice President of Research and Development and Product Safety. In 2002, he joined the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition where he served as a Senior Food Scientist in the Office of Food Safety and is currently serving as Senior Science Advisor for CFSAN in the Office of the Center Director.

Dr. Zink has served as a member of several advisory committees including the Committee on Program and technical Review of the U.S. Army Natick RDEC for the National Research Council and the National Advisory Committee on Microbiological Criteria for Foods.

Lessons Learned from *Salmonella* in Eggs Outbreaks

Donald Zink, Ph.D.
Senior Science Advisor
Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD

ABSTRACT

Beginning in May 2010, CDC identified a nationwide outbreak of *Salmonella* Enteritidis (SE) through PulseNet. An epidemiologic investigation identified that eggs were the likely source of the infections. FDA, CDC, and state partners conducted traceback investigations and found that many cases were linked to eggs from a single firm, Wright County Egg, in Galt, Iowa. On August 13, 2010, this firm conducted a nationwide voluntary recall of shell eggs that it had shipped since May 19, 2010. The firm sold shell eggs to distributors and wholesalers in 22 states and Mexico, who then distributed the shell eggs further throughout the country. In all, more than 500 million eggs were recalled. According to CDC, approximately 1,939 reported illnesses are likely to be associated with this outbreak.

The FDA regulates the safety of shell eggs under the Federal Food Drug and Cosmetic Act and also has authority to take actions under the Public Health Service Act. When foods are a source of communicable diseases. The USDA regulates processed egg products under the Egg Products Inspection Act. The USDA Food Safety Inspection Service inspects egg product processors and the USDA Agricultural Marketing Service conducts surveillance to prevent the distribution of adulterated or misbranded egg products and provides grading and certification services on a voluntary basis. The USDA Animal and Plant Health Inspection Service is responsible for the health of layer flocks, including SE control programs.

This outbreak underscored the food safety implications for food producers that supply large segments of the US food supply. When there are numerous intermediate suppliers, traceback investigations can be time-consuming and complex. The eradication of SE from very large production operations is challenging and can impact the egg supply for many weeks or even months. The FDA Egg Safety Rule published in final form in July of 2009 and is expected to prevent approximately 79,000 cases of foodborne illness and 30 deaths each year caused by consumption of eggs contaminated with SE. The regulation requires preventive measures during the production of eggs in poultry houses and requires subsequent refrigeration during storage and transportation. Also, the rule requires that measures designed to prevent SE be adopted by virtually all egg producers with 3,000 or more laying hens whose shell eggs are not processed with a treatment, such as pasteurization, to ensure their safety.



Greg Paoli
Risk Sciences International

Greg Paoli serves as Principal Risk Scientist at Risk Sciences International. He has experience in diverse risk domains including toxicological, microbiological, and nutritional hazards. This experience has included exposures through a variety of environmental media, including air, water, dermal, and agricultural uptake of chemicals. Additional experience includes risk assessment projects in the areas of climate change impacts, medical and engineering devices, and consumer products. He specializes in probabilistic risk assessment methods, the development of risk-based decision-support tools and comparative risk assessment.

Greg has served on a number of expert committees devoted to the risk sciences. He was a member of the U.S. National Research Council committee that issued the 2009 report, *Science and Decisions: Advancing Risk Assessment*. He serves on the Canadian Standards Association Technical Committee on Risk Management, advisory committees of the National Roundtable on the Environment and the Economy, a US NRC Standing Committee on the Use of Public Health Data at the U.S. Food Safety and Inspection Service, and has served on several expert committees convened by the World Health Organization.

Greg completed a term as Councilor of the Society for Risk Analysis (SRA) and is a member of the Editorial Board of *Risk Analysis*. He has provided training in risk assessment methods around the world, including the continuing education programs of the Harvard School of Public Health and the University of Maryland. Greg holds a Bachelors Degree in Electrical and Computer Engineering and a Master's Degree in Systems Design Engineering from the University of Waterloo.

Risk Assessment Tools for Decision Making

Greg Paoli
Risk Sciences International
Ottawa, Canada

ABSTRACT

The provision of software-enabled risk assessment and decision support tools is increasingly recognized as a critical part of food safety infrastructure.

This presentation will focus on some potential roles for tools in the future of food safety, with examples of some tools in development and some imagined.

Sherri Dennis
Food and Drug Administration

Dr. Sherri Dennis serves as the Director for Center For Food Safety and Applied Nutrition's Risk Assessment Coordination Team (RACT), in the Office of Food Defense, Communication and Emergency Response, at FDA. RACT is responsible for strategic planning, management, and coordination of major risk assessments conducted within the Center. This team creatively facilitates improvements in risk assessment research, to support science-based risk management decisions. Dr. Dennis has been invited to serve on numerous agency, interagency, and international workgroups addressing a wide range of scientific and technical topics, including information quality, peer review, risk-informed decision making, *Listeria*, *Vibrio*, avian influenza, and thresholds for allergens and gluten in food. She earned her BS in Animal Bioscience from Pennsylvania State University and her MS and doctorate in Agronomy from Virginia Tech. Prior to joining FDA in 1999 she worked for an environmental consulting firm. Currently she co-chairs the Interagency Risk Assessment Consortium (IRAC) Policy Council.

Rapid Risk Assessment to Make Informed Decisions on Emerging Issues

Sherri Dennis

Food and Drug Administration

Center for Food Safety and Applied Nutrition

College Park, MD

ABSTRACT

The Food and Drug Administration is responding to the need for more rapid risk-assessment capability by developing new tools for the global food-risk analysis community. Typically, microbial risk assessments conducted by FDA are designed to provide scientific support for strategic regulatory and policy needs. The process of commissioning, conducting, reviewing, and validating these risk assessment models and reports typically is not particularly rapid and, from start to finish, can encompass several years. However, the timeframe needed for developing a risk assessment to support decision-making in an emergency or crisis is considerably shorter - hours or days. FDA has initiated several projects to develop tools for conducting risk assessments in a shorter timeframe. These tools include qualitative approaches (e.g., decision trees) and quantitative approaches (e.g., scenario analysis). The comparative risk assessment tool iRISK, into which users may enter their own data specific to their issues, will facilitate more rapid assessments. It allows assessors to share data and models and to conduct scenario analysis within a structured environment. This tool will be made widely available in the food-safety community via an on-line portal, to enable real-time collaborations. Templates, a library of information on food-supply chains, dose-response functions, and information from previously conducted risk assessments of specific food-hazard pairs are among iRISK's features.



Sandrine Blanchemanche
INRA Met@risk

Dr. Sandrine Blanchemanche is Director of Met@risk Unit (Food Risk Analysis Methodologies), a multidisciplinary Unit (statistics, computer sciences, nutrition, toxicology, social sciences) of the French Institute of Agricultural Research (INRA) and a collaborating center of the World Health Organization (WHO). She is a social scientist and highly interested in scientific uncertainty, consumer behavior change and risk communication. These last years, she directed several projects on decision making under uncertainty and developed experimental methods (survey, field and lab experiments). She analyzed the governmental communication on risk and benefits of fish consumption and showed the strong limitations of such a campaign: the consumption advice based on a scientific risk assessment resulted in ambiguity and complexity for people who decided not to change their behavior and relied on their consumption habits (2006-2008). She also explored a more controversial and uncertain topic with the direction of the project “Risk, Uncertainty and Regulation: NanoFoods in France and Germany” (2008-2010). The project team investigated the impact of information related to different implications of nanosciences (environment, human health and society) on risk perception and acceptance of NanoFoods. More recently, she focused her work on the dissemination of health information within social networks. She studied, through an experimental survey of 6000 individuals, how a message used to prevent foodborne diseases spreads among people and what are the patterns of information transfer (2009-2010). Currently, she is the director of HolyRisk Project (2009-2013) together with Pr Akos Rona-Tas (UCSD) and with a strong collaboration of the Joint Institute for Food Safety and Applied Nutrition (Jifsan). This project is interdisciplinary, involving scientists from sociology, economics, risk assessment and computer science. It is a comparative study of the EU and the US that investigates the ways different forms of uncertainty are expressed throughout the food risk analysis process (assessment, management and communication). It will provide an international database and a case-based reasoning system for Risk Managers as a tool for decision -making.

Communicating Uncertainty between Risk Managers and Risk Assessors

*Sandrine Blanchemanche
INRAMet@risk
Paris, France*

ABSTRACT

Scientific knowledge became one of the most important prerequisites for making regulatory decisions. Food risk policies are based on the framework of risk analysis which has been an effort to apply universal and formal methods of science to risk assessment and to place societal response to hazards on a scientific footing. As scientific knowledge is never complete, risk assessors are expected to present policy makers with not just what is known but also what is uncertain about a particular risk. For policy decisions the nature and level of the incompleteness of the evidence is of great importance and policy action will always be influenced not just by what seems firmly established but also by what is considered uncertain. One of the FAO General Principles of food safety risk management is “Risk management decisions should take into account the uncertainty in the output of the risk assessment: The risk estimate should, wherever possible, include a numerical expression of uncertainty, and this must be conveyed to risk managers in a readily understandable form so that the full implications of the range of uncertainty can be included in decision-making. For example, if the risk estimate is highly uncertain the risk management decision might be more conservative.” Despite the shared willingness to express, take into account and better communicate uncertainty in the framework of risk analysis, it does not exist standardized way to do it and finally uncertainties are expressed more or less explicitly all along risk assessment reports. With the objective to better understand the types of uncertainty are expressed, we built a hierarchical ontology composed by 29 uncertainty variables and used it to code food risk assessments reports (for chemical and biological agents). We also analyze the specificity of the language used in those reports especially the different forms of judgment expressed by the expert panels. The judgments are described through 5 variables (Hedging, Precaution, Assumption, Confidence and Disagreement). Because the role scientific uncertainty plays in policy making is also strongly influenced by institutional and regulatory conditions that vary from country to country, we compare risk assessments from the US and Europe. For instance, this comparison shows clearly that the European reports are more willing to express precaution and confidence than the American reports while these latter express more disagreement.

The clear expression of uncertainties in a harmonized way is of crucial interest to improve communication between risk assessors and risk managers. It is a key point for a better risk communication to the public.



Leon Gorris
Unilever

Dr. Leon Gorris is from The Netherlands. He graduated in Biology and holds a PhD degree in Microbiology from the University of Nijmegen. After a post-doc period there, he worked at the Agrotechnological Research Institute (part of the then Ministry of Agriculture, Nature Management and Fisheries of The Netherlands), where he established and headed the Department of "Food Safety & Applied Microbiology". Some of the main foods related research areas in this department were mild food preservation systems, hurdle technology applications and novel processing methods. Since 1998 he is with Unilever. He first headed the "Microbiology & Preservation" department at Unilever's Food R&D facility in Vlaardingen, The Netherlands. He then moved to Unilever's corporate safety centre in the UK to establish a new multi-disciplinary department with senior experts in toxicology, microbiology, occupational safety, and environmental care.

Leon has been engaged with international organisations, such as Codex Alimentarius, FAO and WHO, as a risk assessment specialist for about 12 years in many different roles (e.g. expert in consultations, organising meetings and workshops, capacity building projects). He is a member of the International Commission on Microbiological Specifications for Foods (ICMSF), past ICMSF secretary and current head of the ICMSF delegation to Codex. He is a member of the Industry Council for Development (ICD), which works with FAO and WHO on regional capacity building (focusing on Asia and Africa). He has been actively involved in the International Life Sciences Institute (ILSI), in Europe, North-America, India and South East Asia. He holds a part-time professorship position (the European Chair in Food Safety Microbiology) at the University of Wageningen, The Netherlands, with responsibility for the University's curriculum, post graduate education, distance learning education, and MSc and PhD research.

Risk Analysis – Practical Examples of Where and When It Can be Applied An Industry Perspective

*Leon Gorris
Regulatory Affairs
Unilever, Shanghai, China.*

ABSTRACT

Chemical contaminants such as pesticides and physical hazards such as glass much more often than not can be considered artificial and avoidable regarding food safety. However, the situation with respect to microbiological pathogens is more complex as generally they are naturally occurring on raw materials and in environments that foods pass through at different stages of the farm to fork continuum. Nevertheless, food safety relies on adequate control of all relevant hazards, chemical, physical or biological. Current best practice systems for food safety management (GAP-GMP-GHP, HACCP) can achieve a very high level of food safety assurance when they are deployed faithfully and consistently, and are based on a sound product concept. It is a misconception that testing alone or even HACCP alone can deliver safe food. Rather, the combination of a good product and process design, good deployment using best practice systems and selective use of testing (for validation and verification) is the overall “package” that is needed for reliable food safety assurance. Whilst this is not at all a radically new insight, current practices around the world do not always reflect this thinking and views of societies’ about what constitutes a safe food product is a dynamic aspect both in time and in place. Food safety standards and other “metrics” reflecting safe foods vary tremendously between countries and/or regions, and the rationale for this is not always evident or scientifically supported. Notably, food safety management in the international context is constantly evolving since it started to become more and more harmonized globally over the last 100 years. Whilst originally “hazard-based decision-making” has been (and often still is) the norm, governments around the world (lead by *Codex Alimentarius*, FAO and WHO) are adopting Risk Analysis (RA) as the framework for risk-based decision-making. This framework provides a structured and systematic foundation for modern food safety management as it supports a responsible move away from mere hazard-based to more risk-based food safety control at the governmental level. As part of the framework, and in the area of food safety microbiology, several new risk metrics have been designed to link country public health policy with operational control of the food present on the market. Unilever has adopted this governmental model to risk-based decision-making and the science/technologies involved in it into our food safety assurance approach to innovating and marketing food products. This approach consists of establishing a safe design based on pertinent knowledge/data, informed selection of processes and control measures to prevent, eliminate or adequately control significant hazards, and validation and verification by useful testing during the product innovation and product manufacturing, respectively. Examples will be given in the presentation.



Stephen F. Sundlof
Food and Drug Administration

Dr. Stephen F. Sundlof, an executive with the U.S. Food and Drug Administration (FDA), is serving a two-year assignment with the Center for Public and Corporate Veterinary Medicine (CPCVM) to expand its programs related to food safety and security. Under an agreement between the FDA and the CPCVM, Sundlof will work to enhance the public and corporate veterinary medicine curriculum for veterinary students with a focus on food safety and security, and to develop career transition training for veterinarians interested in public service. He will develop a new training and development program in regulatory science designed for government employees, which will be done in partnership with the University of Minnesota and the Ohio State University. The expectation of this collaborative effort is to provide a continuum of training in public practice from the veterinary school level through the mid-career level.

Sundlof has served as director of the FDA's Center for Food Safety and Applied Nutrition from 2008 to 2010, and spent the previous 14 years as director of the FDA's Center for Veterinary Medicine. He began his career in 1980 on the faculty of the University of Florida's College of Veterinary Medicine.

Sundlof has published numerous articles in scientific journals on drug residues and food safety. From 1994 to 2008, he served as chairman of the World Health Organization/Food and Agriculture Organization of the United Nations Codex Alimentarius Committee on Residues of Veterinary Drugs in Foods. He is a diplomate of the American Board of Veterinary Toxicology and a former president of the American Academy of Veterinary Pharmacology and Therapeutics.

Communicating to the Consumer: Managing Public Outrage

*Stephen F. Sundlof
Visiting Professor
University of Maryland
College Park, MD*

ABSTRACT

Communicating risk to consumers is challenging, but communicating negligible or absence of risk can be even more difficult, especially when the subject of the communication elicits strong emotional responses such as fear, anger, or moral outrage. Examples of such food-related issues include genetically modified plants and animals, cloning of livestock, and food irradiation. In an emotionally charged environment, messages intended to inform and calm consumers often have the opposite effect and cause damage to the credibility of the agency. In these situations, the focus of attention should be directed toward managing public outrage long before a regulatory decision is announced. Once the level of outrage has been reduced, the public is much more likely to be receptive to risk communication messages and ultimately make informed and rational decisions.



Kimberly A. Reed
International Food Information Council Foundation

Kimberly A. Reed is Executive Director of the International Food Information Council Foundation. She also serves as Senior Vice President for Membership, Communications, and Strategic Initiatives at the International Food Information Council (IFIC) and oversees IFIC's Media Relations, International Relations, and Trends and Consumer Insights Programs. Ms. Reed has more than fifteen years of experience at senior levels in both the public and private sectors. Most recently, she was Vice President for Financial Markets Policy Relations at Lehman Brothers in New York, NY.

Originally from Buckhannon, West Virginia, Ms. Reed earned a law degree from West Virginia University College of Law and a dual undergraduate degree in biology and government and a minor in chemistry from West Virginia Wesleyan College. She currently serves on the National Board of Directors of the Alzheimer's Association, Board of Trustees of West Virginia Wesleyan College, and Board of Governors of the Republican National Lawyers Association. She also teaches democracy-building courses to political parties in emerging nations in order to advance freedom and women's rights around the world.

Ms. Reed was honored with the U.S. Department of the Treasury Meritorious Service Award and Secretary's Honor Award, and the West Virginia Wesleyan College Young Alumni Achievement Award. She has been recognized as a "Young Professional Leader" by the American Swiss Foundation, American Council on Germany, and American Council of Young Political Leaders.

Using Social Media to Communicate in Times of Crisis

Kimberly Reed

Executive Director

International Food Information Council Foundation

Washington, DC

ABSTRACT

Social media is changing our world. No longer considered a “new” communication tool, social media is an initial and primary way that more and more consumers are obtaining their information, especially during a time of crisis. The world recently witnessed the power of social media during the earthquake and tsunami in Japan and the political protests that toppled governments in Tunisia and Egypt. The public used blogs, Facebook, Twitter, and YouTube to be news generators, instantly share information, including text, images, and videos, and attract large, global followings.

Today’s food safety and nutrition messages, when transmitted virally, can quickly and successfully reach, inform, engage, and influence target audiences. As such, the public has a growing expectation that those in positions of responsibility must connect with them using these tools. The IFIC Foundation *2010 Food and Health Survey* noted that close to half of Americans (47%) rated themselves as confident in the safety of the U.S. food supply. When asked who they believe is responsible for food safety in the U.S., 74% believe that the government is responsible, followed by food manufacturers (70%), farmers/producers (56%), retailers/food services (49%), and consumers/individuals (41%). Social media can help those in positions of responsibility maintain/increase this level of trust in the food supply, build relationships, and leverage and empower others to share important, accurate information during a crisis.

In just one year after being launched, the IFIC Foundation’s social media tools, including those found on www.foodinsight.org, connected stakeholders to the Foundation’s messages one million times. This presentation will share insights on how authorities, experts, and other stakeholders can share knowledge and understanding about potential risk, outbreaks, and adverse events through social media to help the public make well-informed decisions and restore confidence. It will cover the main social networking tools, “rules of engagement,” best practices, and a food safety case study. The discussion also will highlight the importance of using social media tools to monitor on-line conversations and identify trends which can serve as a warning sign for when action is required to help the public react appropriately.



Donna Rosenbaum
Food Safety Partners, Ltd.

Donna Rosenbaum is the CEO and lead consultant for Food Safety Partners, Ltd. of Northbrook, Illinois. Food Safety Partners is a national food safety consulting firm that specializes in consumer-based projects. She earned her degree in Neurobiology from Northwestern University and was working in healthcare management when *E. coli* disease claimed the life of her daughter's best friend as the first victim in the Jack in the Box outbreak in 1992. Donna then became a committed food safety advocate and now has over 18 years of expertise in working on consumer food safety issues. She has personally worked with thousands of foodborne illness victims and consumers concerned with the safety of our food supply. She is a long-time member of IAFP, has recently spoken at the APHL conference on "The Impact of Emerging Foodborne Pathogens", at a joint meeting of the USDA, FDA, & CDC on "Measuring Progress on Food Safety", and has been an invited participant to the WHO/FERG stakeholder event in Geneva, Switzerland. Endeavors include consultation on various foodborne illness cases, development of material for management of recalls and outbreaks for a food industry insurance group, and media and social media outreach platforms on food safety for interested corporations.

Consumers' Perceptions of Recalls

*Donna Rosenbaum
Food Safety Partners, Ltd., Northbrook, IL*

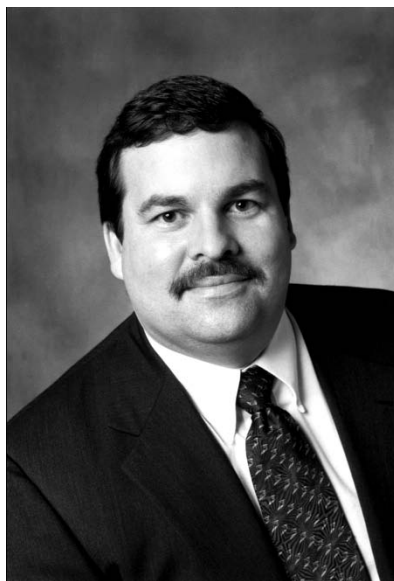
ABSTRACT

Every American consumer's perception of a particular food recall from the marketplace is drawn from their personal food safety belief system and is based on many subjective inputs over a period of time. Getting consumers to tune in to food recall information and take the recommended action(s) is a high priority for public health, yet the scientific study of human behavior regarding recalls and the best communication strategies is a relatively new area of inquiry and published data is scarce. In an attempt to understand how consumers react to recalls, where they go for information, and when and whether they return to purchasing and consuming the recalled product, this presentation will take two different approaches.

The first approach will be to review of a series of consumer perception studies on food safety and quality done in Canada in 2004, 2006 & 2010.* The most interesting Canadian data is quantitative information tracked on reactions to a recall and information sources used by consumers in food recall situations. The Canadian studies use a novel approach; results are defined for the following six consumer segments- Concerned Natural Food Buyers, Cautious Information Seekers, Prudent Family Shoppers, Unengaged Nutrition Focused Followers, Self-assured Habitualists, and Uninvolved Blind Trusters. Each of these consumer groups have unique characteristics and attitudes that shed light on how best to communicate specifically to them about recalls. Canadian consumers were found to be either active information gatherers or passive information absorbers. Those who actively seek information about food quality and safety were found to further influence other consumer segments. The concluding 2010 study has two additional compelling findings. More than one third of Canadians have avoided purchasing either a specific brand or type of food in the last year. For two thirds of all participants, their confidence in these products would be restored by a government investigation report clearing all of the problems. The questionnaire protocols for all three Canadian studies used many open-ended questions or when a list of answers was presented, it often included an "other" category for personally relevant responses.

The second approach will be more anecdotal in nature. The consultants at Food Safety Partners have spent a significant amount of time with thousands of consumers who have been adversely affected by failures in the U.S. food recall system. Included in this group are foodborne illness victims and their families, as well as consumers seeking important recall information who could not find what they needed in order to make informed decisions. The biggest obstacle to discuss is the nature of "voluntary" recall which has a variety of negative impacts on the entire recall system, including how quickly the recall is made public. In addition, company press releases are infrequently updated after the initial recall announcement, leading to outdated information on government websites that misleads consumers. Different government agencies relate and display recall information in different manners, often confusing consumers. Many of the common factors and concerns that have been raised by these consumers could help inform recall communication efforts in the future.

Note that the Canadian studies are being reviewed to inform the panel discussion on consumer confidence in the food supply and are not research projects of Food Safety Partners, Ltd.



William Hallman
Food Policy Institute
Rutgers University

Dr. William K. Hallman is a professor and Chair of the Department of Human Ecology and a member of the graduate faculties of Psychology, Nutritional Sciences, and Planning and Public Policy at Rutgers, the State University of New Jersey. Dr. Hallman also serves as the Director of the Food Policy Institute (FPI) at Rutgers. He earned a B.S. in Behavioral Analysis from Juniata College in 1983, and a PhD. in Experimental Psychology from the University of South Carolina in 1989. His research explores public perceptions of controversial issues concerning food, health, and the environment. Recent projects have examined consumer perceptions and behaviors concerning agricultural biotechnology, animal cloning, avian influenza, accidental and intentional food contamination incidents, and food recalls. His current research projects include studies of public perceptions and responses to food safety risks, the use of nanotechnology in food, public understanding of health claims made for food products, and food safety and security among older adults.

Dr. Hallman serves on the Executive Committee of Rutgers Against Hunger (RAH), and helped to found the New Brunswick Community Farmers Market, which offers food insecure residents access to fresh, locally grown, affordable, nutritious, and culturally appropriate produce and other food products.

Motivating Consumers to Respond Appropriately to Food Recalls

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ABSTRACT

Research suggests that simply telling people about a food recall is often not enough to motivate them to look for and discard recalled products. Instead, getting people to take action requires that they are aware of the recall, believe it applies to them, believe that the consequences are serious enough to warrant action, can identify the affected products, and believe that discarding (or returning) the product is both necessary and sufficient to resolve the problem. Moreover, getting people motivated to take action is only the first responsibility of food recall communications. Once the problem that led to the recall has been properly solved, consumers must also receive the message that the products are safe again to eat. This paper presents ways to improve awareness, increase relevance, convey consequences, accentuate identifying information, compel appropriate actions, and to reestablish consumer confidence. By providing the guidance in this paper, we hope to help communicators maximize the number of people who get their messages about food recalls, and increase the likelihood that the public will take appropriate precautionary behaviors without losing confidence in the food supply.

POSTER ABSTRACTS

Phylogenetic and Comparative analysis of Salmonella Newport from Different Sources by Whole Genome Sequencing

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Authors: Guojie Cao, Charles Wang, Errol Strain, Shaohua Zhao, Eric Brown, Jianghong Meng, Marc Allard

ABSTRACT

Salmonella Newport is the third most frequent Salmonella serotype to cause salmonellosis in America. It is polyphyletic with high amounts of variation and it is resistant to multiple- drugs. Whole genome sequencing provides a lot of information that is needed to understand microorganisms. Whole-genome-scale discovery of SNPs, which are evolutionary stable, enable us to differentiate strains for outbreak investigation. 454 Roche shotgun whole genome sequencing was employed for 24 isolates, analyzed together with 7 reference strains (including S. Paratyphi C, S. Choleraesuis, S. Virchow strain SL491, S. Newport strain Levine15, S. Newport strain Levine1, S. Newport strain SL317 and S. Newport strain SL254), which were selected from different sources to provide informative SNPs from major lineages of S. Newport. 101,474 SNPs were utilized to produce phylogenetic trees by GARLI and parsimony methods. MAUVE was utilized for comparative genomics and alignments. Unique genes and SNPs profiles of each group were analyzed. There are total 28,256 SNPs found in the gene cluster alignments of all isolates, which could help to determine SNP profiles that are unique to different sources in outbreak investigations. Phylogenetic relationships were shown on GARLI and parsimony trees. From these phylogenetic trees, isolates of seafood from Asia (Vietnam, India and Hong Kong) form a distinct cluster separated from other geographic locations (Mexico and America). Furthermore, Salmonella Pathogenicity Islands (SPIs) were investigated from these draft genomes. Five out of 24 samples that are multiple drug resistance isolates were compared with strain SNSL254. Whole genome sequencing enables us to further explore the genetic information found in these pathogenic microorganisms. Comparative genomic analysis helps us to a better understanding of the evolution and pathogenesis of Salmonella Newport, which play a significant role in foodborne outbreak investigations.

FSIS Actions During and After the 2010 Pepper Coated Salami Outbreak Investigation

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ABSTRACT

Abstract The Food Safety and Inspection Service (FSIS) works with federal, state, and local public health agencies to investigate foodborne outbreaks. During many outbreak investigations, food products available in commerce are tested for pathogens by partner organizations, referred to as non-FSIS laboratories. FSIS policy, published in 2007, provided a clear process and criteria to evaluate testing results by a non-FSIS laboratory. FSIS regulated meat and poultry establishments must identify and consider all food safety hazards throughout the manufacture of ready to eat (RTE) meat and poultry products to prevent adulterated products from entering commerce. After the 2010 Pepper Coated Salami Outbreak Investigation, FSIS developed a notice to all inspection program personnel regarding the addition of ingredients after processing steps. FSIS inspectors were asked to ensure that each establishment is appropriately addressing controls for these steps.

Background Between December 2009 and April 2010, FSIS collaborated with state public health officials, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) to investigate a multistate outbreak of Salmonella Montevideo infections. The investigation detected 272 case-patients from 44 states and the District of Columbia. A case-control study identified consumption of Italian-style deli meat as a possible source of illness. Investigators used purchase records obtained with permission from case-patients, to identify the retailer and subsequently a single, federally-regulated establishment located in Rhode Island. FSIS recommended and evaluated the effectiveness of three product recalls. The scope of each recall was determined by the evaluation of production records, on-site observations, and product testing. Two recalls were initiated after a non-FSIS laboratory detected Salmonella in products obtained from consumer homes and retail facilities. The third recall was triggered by FSIS sampling and testing of retail product available at retail. In total, the establishment recalled approximately 1.3 million pounds of RTE Italian sausage products. Following the first recall on January 23, 2010, FSIS withheld inspection services from the company, which immediately ceased all production at two establishments. Production at a third establishment was similarly interrupted after the third recall on February 16, 2010. Production resumed when federal and RI regulatory authority concerns uncovered during the investigation were addressed by the company. In January 2011, FSIS issued a Notice to all inspection program personnel regarding the addition of ingredients after processing steps. Inspectors were asked to verify that establishments are appropriately addressing controls for potential hazards at these steps.

Conclusions FSIS Policies allowed the Agency to take proactive steps during and after the outbreak investigation. An existing policy allowed FSIS to respond decisively to non-FSIS laboratory results. FSIS recommended two product recalls based on findings by non-FSIS labs. After the outbreak investigation, FSIS issued a policy to identify other establishments which add spice or other ingredients after the major processing steps. FSIS inspection personnel were asked to ensure that all establishments identify and mitigate hazards associated with the addition of ingredients after major processing steps.

Development of a Key Events Dose-Response Framework for Folate

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ABSTRACT

Fortification of food with folic acid has led to a decrease in neural tube defects (NTDs) by 30%. There is a call to increase fortification of food to further decrease the risk of NTDs. However, there is a concern that increasing folic acid intake will lead to neurological impairment caused by masking of vitamin B12 deficiency among older adults and increase the risk of colorectal cancers. Therefore, it is crucial to explore ways to find the minimum effective dose of folate intake to prevent NTDs without posing risk among vulnerable population. Nutrient risk assessment model may be a way to develop risk and benefit curves of folate to find a healthy range of intake. This study is the first step in developing a risk assessment framework following the Key Events Dose-Response Framework (KEDRF) developed by the International Life Science Institute's Global Threshold Project. Key events and control points in the metabolic pathway of folate have been identified by critically reviewing the literature. Four control points were identified along the metabolic pathway. Of these, one is a determining point which suggests that high doses of folic acid intake will overwhelm the key event of the conversion of folic acid to tetrahydrofolate (THF) by dihydrofolate reductase (DHFR) in the liver and lead to the appearance of unmetabolized folic acid (UMFA) in serum. UMFA is hypothesized as a contributing risk factor of concern in folic acid fortification. Further review of the literature will identify folic acid doses that may overwhelm the determining point. The data will contribute to the construction of risk and benefit curves for determination of optimal folate intake.

Comparative Analysis and Expression Patterns of Two Thermostable Nuclease Genes in *Staphylococcus Aureus*

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Authors: Yu Hu^{1,2}, Yanping Xie¹, Xianming Shi ^{*}and Jianghong Meng^{2*}

ABSTRACT

Thermonuclease is known as a specific virulence factor in *Staphylococcus aureus*. Previous studies have revealed the existence of two functional thermostable nucleases encoded by two different genes (nuc1 and nuc2) in *S. aureus*. To understand how these two thermonuclease genes are regulated, knowledge at the mRNA transcript level is required. Quantitative real-time PCR was used for comparative mRNA analysis of nuc1 and nuc2. Distinct expression patterns of nuc1 and nuc2 were observed at different growth stages and under the control of the sae regulatory system. nuc1 transcripts were at a maximum level at the post-exponential growth phase, while nuc2 transcript levels declined after the early exponential phase. The nuc1 gene was significantly down-regulated at the late-exponential phase in a sae mutant while the nuc2 gene was slightly up-regulated by the sae deletion compared to the wild-type RN4220. Combined with the increasing thermonuclease activity during growth and the diminished activity of thermonuclease in the sae mutant, nuc1 was found to play a primary role in producing thermonuclease. In addition, unlike the expression of nuc1 that varied in three different *S. aureus* clinical strains, the transcription of nuc2 remained relatively constant. Taken together, distinct expression results for nuc1 and nuc2 in different *S. aureus* strains indicated that nuc1 and nuc2 are under different regulatory systems and express independently with each other. This information will be useful for understanding the regulation and function of each thermonuclease in *S. aureus*.

Prevalence and Characterization of Shiga Toxin-Producing Escherichia coli in Retail Meat

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ABSTRACT

Background: Shiga toxin-producing Escherichia coli (STEC) are major foodborne pathogens, causing diseases ranging from self-limiting diarrhea to life-threatening hemolytic uremic syndrome (HUS). The aim of this study was to determine the prevalence of STEC in retail ground beef and ground pork and to characterize the STEC isolates.

Methods: A total of 480 ground pork (n=231) and ground beef (n=249) samples were collected from March 2009 to March 2010 in Washington DC area. STEC were identified using PCR screen followed by colony hybridization. The STEC isolates were serogrouped and characterized for the presence of virulence genes (stx 1, stx 2, eae and hly A) by multiplex PCR. Antibiotic resistance of isolates were determined by microdilution method. Molecular subtyping was performed by pulse field gel electrophoresis (PFGE). Also, the cytotoxic effect of STEC isolates was determined by the vero cell assay.

Results: STEC were identified in 12 (5.19%) of 231 ground pork and 13 (5.22%) of 249 ground beef samples. Two or more different STEC strains were isolated from three ground pork and two ground beef samples. Of the 32 STEC isolates, 8 (50.00%) from ground pork and 15 (93.75%) from ground beef harbored stx 2, whereas 8 (50.00%) from ground pork and only 1 (6.25%) from ground beef harbored stx1. hly A was detected in 3 (18.75%) of 16 ground pork and 4 (25.00%) of 16 ground beef isolates. eae was not detected in any STEC isolates. None of STEC isolates were O157, but 8 STEC isolates from ground pork and 1 from ground beef belonged to serogroups O91, which has been associated with diarrhea and HUS. Cytotoxicity to vero cell was detected in 13 (81.25%) STEC from ground pork and 13 (81.25%) from ground beef. Of the 33 STEC isolates, PFGE showed 27 distinct restriction patterns, suggesting a significant diversity of STEC from retail ground pork and ground beef. Of the antibiotic resistance, seventeen (53.13%) of the 33 STEC strains were resistant to Tetracycline, followed by 14 (39.4%) to Streptomycin, 13 (42.42%) to Sulfisoxazole, 4 (12.50%) to Nalidixic acid and 3 (9.38%) to Kanamycin.

Conclusion: This study showed that retail ground meat was contaminated by heterogeneous STEC. Some of STEC isolates were potential human pathogens.

Risk Information Integration: Facilitating Effective Mitigation Strategy Decision-Making

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ABSTRACT

Facilitating and capturing decision-critical risk information that is customized the needs of several levels of decision-makers throughout and across multiple organizations and sources of risk alert information systems is critical to a successful implementation of “mission”- critical food safety risk management (RM) and risk-informed decision management (RIDM). There are two major challenges in making time-critical and cost-conscious decisions related to mitigation options for reducing specific food safety risks – both systems-wide or within specific organizations.

A big challenge is timely incorporation and integration of information related to identified food safety risks from a complex array of sources. These sources may include complicated scenarios like statistical, event-based failure modes models of a food transport or supply chain systemic risks, or deterministic scenarios that account for microbial hazards and projections of outbreak adverse events in play, or it may include more anecdotal and qualitative risk data that relies on public knowledge-sharing and associated projected safety risks. This challenge may be addressed by using a combination of customized and facilitated risk management process deployment with an effective, easy-to-use risk communication, documentation, and information management methodology. Application of a “mission” or “enterprise” level approach, where the mission centers on successfully implementing a timely and cost-effective mitigation decision-making approach that is mapped to an identified high-priority food safety risk is a key strategy. Once this structured approach is in place, the criteria to streamline information, prioritize risks and make rapid mitigation decision is established, and responsible organizations may then apply resources to reduce, or even eliminate, adverse consequences.

This presentation will discuss a step-by-step, field-tested set of processes and methodologies to successfully deploy a risk-informed decision-making strategy that may be used for food safety mitigation scenarios. With information integration, a crucial success criterion is that the software application engages and adequately risk-informs all levels of personnel that are need to successfully mitigate food safety risks: from the compliance “field” inspector teams to business executive decision-makers to food safety toxicologists/scientists to policy/regulatory personnel to public health risk communications personnel. One of the challenging issues with this is deploying a tool that efficiently and easily communicates a structured approach to risk identification and information capture for users of all training levels – risk management (RM) novices to experts.

To address the information integration challenge for tracking, evaluation, and communication of risks over a broad audience with variable needs, we have deployed and successfully used a proprietary Integrated Risk Management Application (IRMA) that manages a risk through its life

cycle of identification, evaluation, mitigation, pre-decisional and decision metrics development. Additionally we designed a survey-based application, the Risk Scorecard Generator approach that is easy-to-use, easy-to-understand, and helps guide people who are new to implementing RM as a day-to-day exercise. Another critical element of the tool centers on providing an introduction to the benefits of a risk-informed approach in making tough management and technical choices and decisions.

This presentation will also discuss the tool and its potential applications in capturing and evaluating risk and decision information scenarios that are applicable to product, project/program, mission, corporate, or enterprise levels.

Mitigating Food Safety Risks of Packaged Leafy Greens via Temperature Control in Supply Chain

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ABSTRACT

Specific information regarding the effect of packaged fresh-cut leafy green storage temperature on pathogen growth is needed to develop science-based food safety guidelines and practices by the regulatory agencies and produce industry. Temperature control is commonly thought to promote quality of leafy greens, not safety, based at least partially on a theory that product quality deterioration precedes pathogen growth at elevated temperatures. This prevalent attitude results in temperature abuse incidents being frequently overlooked in the supply chain. This study investigated the effect of storage temperature and duration on the survival and growth of *Escherichia coli* O157:H7, the growth of indigenous microorganisms, and the changes in product quality of packaged baby spinach and lettuce salads. Within 2 days of processing, commercial packages of fresh-cut products were cut at one end, sprayed with fine mists of *E. coli* O157:H7 inoculum, re-sealed, and stored at 1, 5, 8 and 12 °C for 12 days until their labeled “Best If Used By” dates. Microbial enumeration and product quality evaluation were conducted on days 0, 3, 6, 9 and 12 post-inoculation. Spinach held at 12 °C supported significant *E. coli* O157:H7 growth ($P < 0.001$), with a 1.0 log cfu/g increase within 3 days post-inoculation, followed by additional growth during continued storage. *E. coli* O157:H7 grew slowly when held at 8 °C, with a significant level ($P < 0.01$) of growth reached after 6 days of storage. However, *E. coli* O157:H7 populations declined significantly on products held at 1 and 5 °C ($P < 0.01$ and $P < 0.001$, respectively) within 3 days of storage. Aerobic mesophilic bacteria, psychrotrophic bacteria, and yeast and mold populations increased significantly at all storage temperatures, with more growth on products held at elevated temperatures. Product quality scores remained high within the first 6 days of storage, with a sharp decline noted on samples held at 12 °C on day 9. Results suggest that *E. coli* O157:H7 can grow significantly on commercially packaged leafy green vegetables held at 8 °C or above before significant product quality deterioration occurs. Packaged fresh-cut salads are marketed as “ready-to-eat” while lacking an effective pathogen kill step during their preparation. Thus, maintaining storage temperature at 5 °C or below is critical to prevent pathogen proliferation and mitigate food safety risks should pathogen contamination inadvertently occur during crop growth or post-harvest fresh-cut processing.

Rapid and Reliable Targeted ToF Screening for Pesticides in Food

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ABSTRACT

Pesticides are used to generate improved crop yields, as the demands on global food production increase. Recently, European legislators updated the guidance for pesticide residue analysis in food and feed, which now recognizes that accurate mass data may be used as part of the evidence for the presence or absence of analytes. Consequently, data acquired on a Time of Flight (ToF) MS can be used when reporting findings from pesticide screening analyses of food crops.

The use of Time-of-Flight (ToF) screening approaches has steadily increased in both food safety and environmental monitoring laboratories. ToF screening can either be used for targeted screening activities – where an extensive database is used to target key compounds of interest after the screening acquisition stage, or it can be used in a non-targeted way – using deconvolution software to identify all peaks present in a sample after non-targeted data acquisition.

Typically, a ToF screening approach might be used to help reduce the number of suspected positive compounds, prior to sample analysis using a targeted MRM method on tandem quadrupole MS. However, reducing the number of false positives is key in ensuring that this approach is both robust and reliable. ToF screening also provides the ability to re-interrogate historical data for compounds not previously targeted.

A Xevo QToF with ACQUITY UPLC was used to screen extracted green beans for pesticide residues. A residue of thiabendazole was detected at a concentration below that of the MRL but well above the limit of detection of the instrument. Use of the MSE functionality of the Xevo QToF enabled the acquisition of exact mass data for both precursor and fragment ions in one screening run, with a high level of reproducibility. This provides extra confidence when identifying incurred residues and reduces false positives.

Comments

Presenting Author Rosnack K. Should you have any questions, please feel free to contact me anytime.

Samples provided by SASA, Roddinglaw Road, Edinburgh, Scotland EH12 9FJ.

Strains of the Escherichia coli O157:H7 Stepwise Evolutionary Model Exhibit Different IS629 Transposition Frequencies

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ABSTRACT

Insertion elements (IS) are known to play an important role in the evolution and genomic diversification of Escherichia coli O157:H7 lineages. In particular, IS629 has been found in multiple copies in the E. coli O157:H7 genome, and is one of the most prevalent IS elements in this serotype. Analysis of strains selected from various clonal groups on the E. coli O157:H7 stepwise evolutionary model showed that ancestral O55:H7 strains carry two IS629 copies whereby sorbitol fermenting O157 (SFO157) strains are IS629-deficient. SFO157 are on a divergent pathway in the emergence of O157:H7 suggesting that IS629 loss occurred in these strains during or after the divergence of this lineage. We determine that although O157:H- are IS629-deficient, this element is able to actively transpose in these strains with an excision frequency higher than in ancestral O55:H7 strains but lower than in highly pathogenic O157:H7 strains.

Antimicrobial Resistance of Salmonella Isolates from Retail Meats

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and

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Authors: Jinling Shen, Baowei Yang, Meili Xi, Shenghui Cui, Xiuli Zhang, Pengfei Yang, Shuai Zhi, Xin Wang and Jianghong Meng*

ABSTRACT

Salmonella isolates (n=220) representing 14 different serotypes recovered from retail meat samples in Shaanxi Province, China in 2007 and 2008 were examined for antimicrobial susceptibility. Selected isolates were further characterized for the presence of class 1 integrons, for molecular subtypes using pulse-field gel electrophoresis (PFGE) and plasmid profiles. Antimicrobial resistance transfer through conjugation was also analyzed. Antibiotic resistance was most often observed among chicken isolates. Approximately 47% of the chicken isolates were resistant to sulfamethoxazole, 40% to kanamycin, 36% to tetracycline, and 29% to amoxicillin and to ampicillin, respectively. Chicken isolates from free markets exhibited lower resistance than those isolated from supermarkets. Fifty four chicken isolates (29.83%) were resistant to three or more antibiotics, with 37 (20.44%) resistant to 10 or more antibiotics and 27 (14.92%) resistant to 13 antibiotics. Most of multidrug resistant chicken isolates belonged to serotypes Shubra and Indiana.

Ten of 63 (15%) of the isolates contained class 1 integrons, which carried dhfrXII-orf-aadA2 (2 Kb integrons) or blaPSE-1 (1.2 Kb integrons). Resistance to ampicillin, amoxicillin, chloramphenicol, tetracycline and sulfamethoxazole was most frequently transferred through conjugation, and plasmids and class 1 integrons in several donor strains were also transferred to recipients. PFGE based on different origins and antibiotic resistance profiles showed that these strains were diversified. Multidrug-resistant Shubra and Indiana isolates were common, whereas Enteritidis isolates were sensitive to or only resistant to a limited number of antibiotics.

Development of a Label Free Biosensor System for Detection of E. coli in Food Samples based on Carbon Nanotube Field Effect Transistor Arrays

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ABSTRACT

We are developing an electronic gene detection system that by-passes PCR and other time intensive steps required for food sample testing. Conventional fluorescence-based gene tests require labor-intensive laboratory procedures using proprietary reagents over a period of about 5 days to a week. Our approach, based on label-free detection of nucleic acids via carbon nanotubes, is amenable to integration into a “lab-on-a-chip” that would enable low-cost screening in the field with same-day results.

We designed a prototype biosensing platform and established a supply of microfabricated biosensor chips. In collaboration with the Food Science department at the University of Maryland, we sensitized the chips to E. coli using Deoxyribo - nucleic acid and developed accompanying protocols for the detection of shigatoxin producing E. coli from genomic DNA. We demonstrated successful recognition of E. coli strain using synthetic DNA targets. This versatile platform was originally engineered to target HER2 as a model oncogene but as shown it can easily be adapted to detect other genes. Our results lower the technological barrier towards commercialization of a rapid, low-cost gene detection system suitable for lab-on-a-chip integration

An Interactive Online Database for Reported Cases of Botulism

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ABSTRACT

Each year, there are more than 100 cases of botulism in the United States that are reported to the National Botulism Surveillance System (Centers for Disease Control and Prevention, Council of State and Territorial Epidemiologists). A small number of these cases resulted in death. In recent years, the most common cause for botulism in the United States is infant botulism, followed by foodborne and wound botulism, respectively. For this report, we have compiled a list of cases of either confirmed or suspected botulism from various locations around the world since 1974, from sources including PubMed(National Center for Biotechnology Information), ProMED-mail(International Society for Infectious Diseases), and Morbidity and Mortality Weekly Reports(CDC). A brief description of the circumstances surrounding each case is given, along with geographical information, when that information was available from publicly accessible sources. This compilation of data is part of a larger study to create an interactive internet database cataloging date, geological location, outcome, and other descriptive information about botulism cases in the United States and worldwide.

Bacterial Community Diversity and Variation in Spray Water Sources and the Tomato Fruit Surface

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ABSTRACT

Tomato consumption has been one of the most common causes of produce-associated salmonellosis in the United States. Contamination may originate from animal waste, insects, soil or water. Current guidelines for fresh tomato production recommend the use of potable water for applications coming in direct contact with the fruit, but due to high demand, water from other sources is frequently used. We sought to describe the overall bacterial diversity on the surface of tomato fruit and the effect of two different water sources (ground and surface water) when used for direct crop applications by generating a 454-pyrosequencing 16S Rna dataset of these different environments. This study represents the first in depth characterization of bacterial communities in the tomato fruit surface and the water sources commonly used in commercial vegetable production. The two water sources tested had a significantly different bacterial composition. Proteobacteria was predominant in groundwater samples, whereas in the significantly more diverse surface water, abundant phyla also included Firmicutes, Actinobacteria and Verrucomicrobia. The fruit surface bacterial communities on tomatoes sprayed with both water sources could not be differentiated using various statistical methods. Both fruit surface environments had a high representation of Gammaproteobacteria, and within this class the genera Pantoea and Enterobacter were the most abundant. Despite the major differences observed in the bacterial composition of ground and surface water, the season long use of these very different water sources did not have a significant impact on the bacterial composition of the tomato fruit surface. This study has provided the first next-generation sequencing database describing the bacterial communities living in the fruit surface of a tomato crop under two different spray water regimes, and therefore represents an important step forward towards the development of science-based metrics for Good Agricultural Practices.

Molecular Serogrouping for Shiga Toxin-producing *E. coli* Using the Luminex ® Technology

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ABSTRACT

Shiga toxin-producing *E. coli* (STEC) is one of the main causes of bacterial foodborne diseases in the US. Although *E. coli* O157:H7 has been the dominant serotype of STEC, other serotypes have caused several outbreaks and many sporadic cases of STEC infections. The present work used the Luminex® technology to design a rapid and specific serogrouping panel for STEC. A multiplex PCR and specific probes were designed for seven of the most commonly associated serotypes to foodborne illness (O26, O45, O103, O111, O121, O145, and O157) using *wzx* or *wzy* genes. Also, probes detecting the presence of shiga toxin genes *stx1* and *stx2* were included. Three to seven different isolates were used for each serogroup to optimize the panel. Most of isolates were correctly identified by their specific probes. The ratios of specific to non specific signals ranged from 2.9 to more than 60.0. This is the first report of a serogrouping panel for STEC using the Luminex technology. Current work is carried out to optimize the panel.

Highlighting Food Safety Risk Analysis Programs -- USDA National Institute of Food and Agriculture Institute of Food Safety and Nutrition

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Highlighting Food Safety Risk Analysis Programs
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ABSTRACT

NIFA seeks to reduce the incidence of foodborne illness and provide a safer food supply by supporting research, education, and extension activities addressing current priority issues and multiple disciplines in food safety. NIFA currently provides competitive funding to projects in the area of food safety risk assessment, management, and communication through the National Integrated Food Safety Initiative, Agriculture Food and Research Initiative, Specialty Crops Programs, Water Quality, Animal Health and Higher Education Programs. The projects NIFA supports are extremely diverse and address pre- and post-harvest issues in meat, poultry, and fresh fruits and vegetables looking at a variety of pathogens including *E. coli*, *Salmonella*, and Norovirus in numerous environments, on-farm, packaging/processing facilities, retail outlets, consumer homes, schools, and daycare facilities.

From 2008-2010, NIFA has competitively awarded over \$17M for 31 projects in food safety risk analysis. These projects will result in the development of risk assessment, management and communication that can be utilized by academia, federal agencies, industry, and public health workers to increase the safety of the US and World food supply. The research is being performed at Federal and University laboratories throughout the country. The education component is being utilized to distribute the data and information to students in veterinary programs, public health programs, and food science programs. The consumers and industry members at the growing, packaging, processing, and retail levels are reached via the extension arm. In addition to research, education, and extension programs, there is also funding allotted to bring risk analysis and food safety professionals together to collaborate and network at conferences and meetings. Highlights from these projects include a conference on "Public and Private Roles on Food Import Safety: A Risk Assessment Approach", a research and extension program at University of Wisconsin looking at Modeling Persistence of Non-O157:H7 Shiga Toxin-Producing *E. coli* in Beef Slaughter and Validation of Interventions used in Processing, an international project looking at "Understanding and Mitigating Potential Food Safety Risks on Dairy Farms in Kosovo and the US", and also education programs such as "Development of a Bilingual Minor in Food Safety at Universidad Del Este".

Distribution of Internalized *Salmonella* Inside Tomatoes and the Effects of Post Harvest-Harvest Handling on *Salmonella* Internalization

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ABSTRACT

Tomatoes have been implicated in several Salmonellosis outbreaks possibly as a result of contamination through bacterial infiltration during dump tank water immersion. This study was designed to determine the distribution of internalized *Salmonella* Thompson within tomato fruit and investigate the effects of post-harvest handling on *Salmonella* internalization. Mature green tomatoes, held at 90 °F (32.2 °C), were immersed in water containing approximately 10⁶ cfu/ ml *S. Thompson*. Tomato vascular, blossom-end, locule and pericarp tissues were excised using sterile technique and assayed for *Salmonella* Thompson. The distribution of *Salmonella* within the vascular core tissues was then determined by segmenting the core and enumerating the *Salmonella* population found within each segment. Tomato varieties (Mountain Spring, Applause, BHN961), temperature differentials between tomato pulp and bacterial suspension (-10 °F, 0 °F, 10 °F), and the time between stem removal and immersion in bacterial suspension (0, 2h, 16h) were evaluated for their effects on *Salmonella* internalization. Frequency and cell density of internalized bacteria were determined by culture enrichment and most probable number methods, respectively. All internalized *Salmonella* were found within the core tissue segments beneath the stem-scars. Overall, variety and post-stem removal time significantly affected the frequency of *Salmonella* internalization ($P = 0.0001$), while temperature differential did not ($P = 0.36$). Mountain Spring was less susceptible to *Salmonella* internalization than Applause and BHN961. Increasing the time interval between stem removal and immersion greatly reduced *Salmonella* internalization in BHN961 and Applause, while it had no effect in Mountain Spring tomatoes. This study provides valuable information for tomato industries to better control *Salmonella* internalization, thereby reducing the risk of tomato-associated salmonellosis in humans.

Effects of Dietary Phenolics and Botanical Extracts on Hepatotoxicity-Related Endpoints in Human and Rat Hepatoma Cells and Statistical Models for Prediction of Hepatotoxicity

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ABSTRACT

Toxicity assessment of botanical materials is difficult because they are typically complex mixtures of phytochemicals. In the present study, sixteen phenolics were tested in both human (HepG2/C3A) and rat (MH1C1) hepatoma cells using a battery of eight toxicity endpoints. Cluster analysis was used to group the phenolics into four clusters for each cell type. Comparison of overall and individual liver activity of phenolics on both human and rat hepatoma cell lines showed significant differences for some endpoints. However, the cluster membership was similar across both cell types with the majority of phenolics clustering with the solvent control group (cluster 1). Each cell type produced a cluster of compounds with reported *in vivo* liver toxicity (cluster 2). Five herbal extracts were prepared and then tested as above. Using the cluster model developed with the phenolics, in the HepG2/C3A cells green tea was assigned to cluster 2 and the remaining four extracts to cluster 1. In the MH1C1 cells, green tea and thyme were assigned to cluster 2, cinnamon to cluster 4, and juniper berry and peppermint to cluster 1. The data suggest that this *in vitro* model may be useful for identifying hepatotoxic phenolics and botanical preparations rich in phenolics.

Keywords: hepatotoxicity, dietary phenolics, botanical extracts, cluster analysis

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