

Risk Assessment, Economic Analysis, and Foodborne Illness Regulations Conference

November 16, 2007

Economic Research Service, USDA
1800 M Street NW, Washington, DC

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**Interagency Risk
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A G E N D A



Risk Assessment, Economic Analysis, and Foodborne Illness Regulations Conference

While risk analysis traditionally separates risk assessment from benefit/cost analysis, incorporating economics into risk assessments can improve the selection of viable pathogen control options for policymakers in the public and private sectors. This conference explores how economists can make greater contributions to risk assessments, including new methods of valuing the public health protection benefits of pathogen control in the food supply-chain.

The objectives of the meeting are: To introduce the concept of integrating risk assessment and benefit/cost analysis; using this integration, to look at recent advances in valuation for food risks; to examine economic incentives in the public and private sectors and how they contribute to safer food; and to hear what policymakers and risk analysts in the public and private sectors think about economic incentives and the new economic valuation methodologies.

Friday, November 16		
7:30-8:30 am	Coffee, Registration, \$15 payment for sandwiches and beverages	
8:30-8:35 am	Welcome and Statement of Purpose Kerry Dearfield, Food Safety and Inspection Service	
	Session 1: Interface Between Risk Assessment and Economics Moderator: Kerry Dearfield, Food Safety and Inspection Service	
8:35-9:05 am	Integrating Risk Assessment and Economics Richard Williams, George Mason University	
9:05-9:35 am	Economic Valuation Methods: COI, VSL, WTP & QALY Al McGartland, Environmental Protection Agency	
9:35-9:50 am	Common Misperceptions of Cost/Benefit Analysis for Public and Private Decision Making Cristina McLaughlin, Food and Drug Administration	
	Q&A from attendees (10 min)	
10:00-10:15 pm	BREAK	
	Session 2: Food Safety Valuation Using the Willingness to Pay Method Moderator: Cristina McLaughlin, Food and Drug Administration	
10:15-10:45 am	New Willingness to Pay Estimates of the Demand for Food Safety James Hammitt, Harvard University	
11:00-11:20 am	Using COI and WTP Methods to Estimate the Societal Costs of Foodborne Illness Tanya Roberts, Economic Research Service	
11:20-11:30 am	Discussant: Joseph Cooper, Economic Research Service	
	Q&A from attendees (10 min)	

Friday, November 16—Afternoon Sessions

11:40-12:30 pm	LUNCH ERS will be providing mixed sandwiches and beverages at a cost of \$15 to attendees, due at the registration desk on the morning of the conference.
	Session 3: Food Safety Valuation Using the Quality Adjusted Life Years Method Moderator: Tanya Roberts, Economic Research Service
12:30-1:00 pm	WTP & QALY Methods at FDA to Estimate the Societal Costs of Foodborne Illness Angela Lasher, Food and Drug Administration
1:00-1:20 pm	Using QALYS to Evaluate Chronic Sequelae: Case of Arthritis David Zorn, Food and Drug Administration
1:20-1:35 pm	Discussant for all papers: Dom Mancini, Office of Management and Budget
	Q&A from attendees (10 min)
1:45-2:00 pm	BREAK
	Session 4: Private Economic Incentives for Pathogen Control Moderator: Robert McDowell, Animal and Plant Health Inspection Service
2:10-2:35 pm	Risk-Based Optimization of the Danish Swine Salmonella Control Program Scott Hurd, Iowa State University
2:35-2:55 pm	Economic Incentives in Mandatory vs. Voluntary Meat Food Safety Standards Gary Weber, Gary Weber and Associates
2:55-3:05 pm	Discussant for all papers: Mike Ollinger, Economic Research Service
	Q&A from attendees (10 min)
3:15-4:30 pm	Session 5: Roundtable: Role of Economics in Pathogen Control Regulations Moderator and Speaker: Jim Schaub, Office of Risk Assessment and Cost Benefit Analysis Daniel Engeljohn, Food Safety Inspection Service Robert Buchanan, Food and Drug Administration/CFSAN Al McGartland, Environmental Protection Agency
	Q&A from attendees (30 min)
4:30 pm	Wrap-up Remarks: Kerry Dearfield, Food Safety and Inspection Service

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Gary Weber received his B.S. and M.S. degrees in animal science from Purdue University and his Ph.D. in animal husbandry from Michigan State University. He has had a diverse array of work experiences in his career including serving as an Extension Specialist and Adjunct Assistant Professor with Michigan State University; National Program Leader for Animal Science with the USDA-Extension Service; Executive Director –Regulatory Affairs with the National Cattlemen's Beef Association; Chief Operating Officer for an ethanol project; and now President of a consulting firm, G.M. Weber and Associates. In his more than 20 years in Washington, D.C., Dr. Weber has worked on a wide range of issues including meat inspection reform and the Hazard Analysis and Critical Control Points approach to improving the safety of meat products. He has also served on the Secretary of Agriculture's National Advisory Committee for Meat and Poultry Inspection. From 2004-2006, he served as the Co-Chair of the Food of the Agriculture Sector Coordinating Council's (FASCC) Animal Production Sub-Council and also on its Executive Committee [FASCC is an advisory organization on food and agriculture security to the Department of Homeland Security]. From 1996 until 2006, he worked extensively on efforts to prevent the amplification and spread of Bovine Spongiform Encephalopathy (BSE). In 2006, he received the Commissioner of the FDA's Special Citation for his efforts to help the FDA address the threat of BSE. Dr. Weber is currently working with several companies in the area of pre-harvest interventions to address the risks posed by E. coli O157:H7.

Richard A. Williams is the Managing Director of the Regulatory Studies Program and the Government Accountability Project. He has just joined the Mercatus Center at George Mason University in the Summer of 2007. Prior to that, he served as the Director for Social Sciences at the Center for Food Safety and Applied Nutrition in the Food and Drug Administration for 27 years. Dr. Williams is an expert in benefit-cost analysis and risk analysis, particularly associated with food safety and nutrition. His work included saving the U.S. economy over \$1.5 billion by making changes in the law and implementation of the Nutrition Label and Education Act. He also started a series of food safety risk analysis classes that have trained thousands of people internationally, and he instituted a social science peer review system for the entire Executive Branch of the federal government. He has published in *Risk Analysis* and *Journal of Policy Analysis and Management* and has addressed numerous international governments including the governments of the United Kingdom, South Korea, Yugoslavia, and Australia. Dr. Williams received his Ph.D. and M.A. in economics from Virginia Tech in Blacksburg, Virginia, and his B.S. in business administration from Old Dominion University in Norfolk, Virginia.

David J. Zorn is the Lead Economist in FDA's Center for Food Safety & Applied Nutrition, Office of Regulations, Policy and Social Sciences. He supervises the development of economic and industrial information on products and corporations regulated by CFSAN, and gives advice on the economic impact of present and proposed CFSAN policies. Dr. Zorn earned his Bachelor of Arts degree from Trinity University in San Antonio, Texas, and his Doctor of Philosophy degree in economics from George Mason University in the fields of public choice, industrial organization, and law & economics. His doctoral dissertation combined principal-agent, team, and transaction costs theories of the firm to clarify the barriers and incentives to horizontal price fixing. He has published articles in *Agricultural Economic Review*; *the European Journal of Law and Economics*; *FoodReview*; and *Scientific and Technical Review, Office Internationale des Epizooties*. Dr. Zorn joined the FDA in 1992. Since then he has been involved in a number of the agency's most significant regulatory initiatives.

Robert L. Buchanan is a Senior Science Advisor for the Center for Food Safety and Applied Nutrition, DHHS Food and Drug Administration in College Park, Maryland. Dr. Buchanan received his B.S., M.S., M. Phil., and Ph.D. degrees in food science from Rutgers University, and post-doctoral training in mycotoxicology at the University of Georgia. Since then, he has gained 30 years of experience teaching and conducting research in food safety, first in academia, then with the USDA Agricultural Research Service, and most recently with the FDA. His scientific interests are diverse, and include extensive experience in predictive microbiology, quantitative microbial risk assessment, microbial physiology, mycotoxicology, and HACCP systems. Dr. Buchanan has published approximately 300 manuscripts, book chapters, and abstracts on a wide range of subjects related to food safety, and is one of the co-developers of the widely used USDA Pathogen Modeling Program. He also has an ongoing interest in the development of science-based public health policy. In addition to currently serving as the FDA CFSAN Senior Science Advisor, he has served as Deputy Administrator for Science with the USDA Food Safety and Inspection Service, and is the U.S. Delegate to the Codex Alimentarius Commission Committee on Food Hygiene. Dr. Buchanan serves on the editorial boards of several journals, and is a member of the International Commission on Microbiological Specification for Foods. He has also served as a member of the National Academy of Science's Institute of Medicine Committee on Emerging Microbial Threats and the National Advisory Committee on Microbiological Criteria for Foods.

Joseph Cooper is a Senior Economist in the Market and Trade Economics Division of ERS, where he is conducting research on farm policy issues. From July 2005 to July 2006, he served as the Senior Economist in charge of agriculture and natural resources issues on the White House's Council of Economic Advisors. Prior to that, he served as a Deputy Director in the Economics Division at ERS, and before that was an economist in the Resource and Environmental Policy Branch in the Resource Economics Division at ERS, where his research covered such topics as the economics of agri-environmental programs, non-market valuation, and the economics of the conservation of agricultural genetic resources. Dr. Cooper has also worked as an economist for the Food and Agricultural Organization of the United Nations. He received a Ph.D. and M.S. in agricultural economics from the University of California, Davis, and a B.S. from the University of California, Berkeley.

Kerry Dearfield is currently the Scientific Advisor for Risk Assessment in the USDA's Food Safety and Inspection Service (FSIS). There in the Office of Public Health Science, he develops policies, guidance, and directions for risk assessments and advises on environmental and microbial risk assessments for food safety. Dr. Dearfield has published extensively in numerous peer-reviewed publications on genetic toxicology of chemicals, genotoxicity in regulatory decisions and guidelines, peer review and risk assessment practices, and science policy issues. His scientific interests include the development of science policy and guidance; health risk assessments of environmental and microbial food contaminants; modes of action for toxicity (including mutational, physiological, and pharmacological mechanisms); use of genotoxicity data in regulatory decisions (heritable risk, carcinogenicity, general toxicity); health effects testing guidelines (e.g., carcinogenicity, mutagenicity); development and use of peer review; and risk assessment, risk management, and risk communication issues. Prior to his current position, Dr. Dearfield worked for over two decades at the Environmental Protection Agency as a risk assessor and Senior Scientist for Science Policy. He earned his B.S. in biology from the College of William and Mary, his M.S. degree in cell biology from the University of Pittsburgh, and his doctorate in pharmacology from the George Washington University Medical Center.

Daniel Engeljohn serves in the Senior Executive Service at the USDA's Food Safety and Inspection Service (FSIS) in the Office of Policy, Program and Employee Development. He oversees the risk management activities associated with meat, poultry, and processed egg products and leads the strategic planning efforts involving the development of food safety regulations. Dr. Engeljohn represents FSIS on the National Advisory Committee on Microbiological Criteria for Foods and is the FSIS spokesperson on food irradiation issues. In addition, he serves as an adjunct assistant professor of nutrition on the graduate faculty at Howard University and teaches both undergraduate and graduate courses on human nutrition. From 1979 to 2002, Dr. Engeljohn served as both a Meat Marketing Specialist and a Food Technologist in the meat grading and food safety programs at USDA. He earned his B.S. and M.S. in animal science from the University of Illinois, Urbana, and his Ph.D. in nutrition from Howard University in Washington, D.C.



James K. Hammitt is Professor of Economics and Decision Sciences at Harvard University. His research and teaching concern the development and application of quantitative methods of decision and risk analysis to health and environmental policy. He studies the management of health and environmental issues with important scientific uncertainties and social preferences over health and environmental risks. Professor Hammitt holds degrees in applied mathematics and public policy from Harvard. He was Senior Mathematician at the RAND Corporation in Santa Monica and Pierre-de-Fermat visiting professor at the University of Toulouse.

Scott Hurd is currently Associate Professor, College of Veterinary Medicine, Iowa State University, and Director of World Health Organization Collaborating Center for Risk Analysis and Hazard Surveillance and Intervention in Food Animals. Dr. Hurd conducts risk assessment to quantify the impact of various on-farm management practices such as antibiotic resistance due to use in food animals and salmonella control. He has extensive experience in systems and risk assessment modeling. He was analyst on the first BSE (Bovine Spongiform Encephalopathy) risk assessment in the United States, published in 1990. He has also conducted quantitative risk assessments for Classical Swine Fever, Tuberculosis in Michigan white-tailed deer, Avian Influenza, Salmonella Enteritidis in shell eggs, and Xenotransplantation from swine. Most recently, he published a quantitative analysis of the public health risk from using macrolide antibiotics in food animals and an analysis of the public health benefits from antibiotic use in poultry. He received his Ph.D. in epidemiology and economics from Michigan State University, D.V.M. from Iowa State University, and B.S. from Virginia Tech.

Angela Lasher, Ph.D., has been an economist at the Center for Food Safety and Applied Nutrition (CFSAN) at FDA since 2001. Dr. Lasher's responsibilities include collecting and analyzing data on businesses and their products that are regulated by CFSAN, writing cost benefit analyses for proposed CFSAN regulations, and advising Center and agency management regarding the economic impact of present and proposed CFSAN policies. Angela has worked on economic issues relating to retail food safety, food bioterrorism, foodborne illness, produce safety, good food manufacturing practices, and transmissible spongiform encephalopathies (TSEs). In addition to her regulation development and writing duties, Angela is the Director of the Interagency Economic Peer Review (IEPR) group. As director, Angela coordinates the peer review of significant economic analyses between the various federal health and safety agencies. Previous to her employment at CFSAN, Angela worked for the Joint Economic Committee (JEC) of the U.S. Senate under Florida Senator Connie Mack (retired). While a member of the JEC, Angela worked on issues related to biotechnology, information technology, and basic medical research—including a seminal report on the benefits of medical research and the role of NIH in that research. Dr. Lasher earned her Ph.D. in economics from the University of Kentucky in 1999. Her doctoral dissertation focused on the role that corporation reputation plays in the FDA's new drug approval process.

Dom Mancini has served as the Branch Economist for Health, Transportation, and General Government, Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget since 2002. Located in the Executive Office of the President, OIRA reviews regulations and information collections for most federal government agencies, and advocates the use of economic and analytical tools for agency decision making. Dr. Mancini's primary responsibility is to review regulatory impact, flexibility, and unfunded mandates analyses for economically significant proposed and final rules. He also participates in developing guidelines for federal agencies to follow in their analyses, such as OMB Circular A-4, and preparing OMB's annual Report to Congress on the Costs and Benefits of Federal Regulation. Before joining OMB, he served from 2000-2002 as an Economist in FDA's Center for Food Safety and Applied Nutrition (CFSAN), where his primary responsibility was to prepare Regulatory Impact Analyses for food safety regulation. He received his Ph.D. in economics; with a focus on health economics, industrial organization, and econometrics; from the University of North Carolina, Chapel Hill, in 2000.

Robert McDowell is Sr. Staff Economist with the Risk Analysis Systems staff in the Animal Plant Health Inspection Service in USDA. Before joining the risk staff in APHIS, he was an agricultural economist (at times the only economist) in the Policy Analysis and Program Evaluation group in APHIS. Prior to that he worked in the Pest Control Economics Branch in USDA-ERS. In his present position he normally abstains from economics but instead is involved in epidemiology, risk analysis, and risk mitigation design activities in the areas of plant, animal, and human health, including food safety, and predictive toxicology.

Al McGartland is lead economist and the Director of the National Center for Environmental Economics (NCEE) at the U.S. Environmental Protection Agency. He is responsible for developing interdisciplinary risk and benefit assessment methods to be used in EPA's regulatory analyses, and to assess the benefits and costs of environmental policies. Most recently, He has been focusing on improving methods for quantifying uncertainty in benefit-cost analysis. As the director of NCEE, he advises senior policy-making officials on the economics of environmental policies and helps translate research into applied policy contexts. The NCEE issues EPA's Guidelines for Preparing Economic Analyses, conducts numerous studies to assess the benefits and costs of environmental programs, and conducts key research on environmental economic issues. Dr. McGartland also supports numerous interagency initiatives, including projects on agriculture and environmental risks, benefits, and costs in China. Prior to his work at EPA, He reviewed environmental regulations and supporting analyses at the Office of Information and Regulatory Affairs in the Office of Management and Budget. He also served as the economic advisor to the Chairman at the Commodity Futures Trading Commission, and he was a vice president at Abt Associates, Inc., a public policy and economics consulting firm. He received his Ph.D. in economics from the University of Maryland. He has published in several journals; including the *American Economic Review*; the *Canadian Journal of Economics*; the *Journal of Environmental Management*; the medical journal, *Lancet*; and the *Journal of Environmental Economics and Management*. He also has contributed to numerous books and reports on environmental economic issues.

Cristina McLaughlin has been working as a CFSAN Economist since 1991. Most of her work at FDA involves analyzing costs and benefits of FDA regulations and also finding out new ways to design risk assessments or reviewing other risk assessments so that they can be used in estimating costs and benefits of FDA regulations. Some of her previous work included estimating the economic impact of mycotoxins in the United States and reviewing risk assessments—such as the 2004 USDA/FSIS Draft Risk Assessment of Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Egg Products—as it is applicable to cost benefit analysis. More recently, Cristina has been invited to the European Union as a key speaker of the International Enviro Info Conference to present how risk assessments and cost-benefit analyses together make better tools for decision making. She is currently a member of the program committee at the Society for Risk Analysis (SRA) and has also served as chair for the Economics and Benefits Analysis Specialty Group and the Bio Stressors specialty group of SRA. Cristina also serves as a member of the JIFSAN Food Safety Risk Analysis Clearinghouse Steering Committee.

Mike Ollinger is an economist at ERS, where he has worked since graduating from Washington University in St. Louis in 1991. His recent research has focused on food safety, particularly as it relates to industry responses, FSIS regulation, and various structural change issues to industry responses and FSIS regulation, and various structural change issues.

Tanya Roberts is a Senior Economist at the Economic Research Service, USDA. She earned her Ph.D. in economics from the University of Washington in Seattle in 1979. Tanya pioneered ERS' estimates of the social costs of bacterial and parasitic foodborne diseases, and testified before Congress in 1987. She was a member of the USDA's risk assessment team for E. coli O157:H7 in ground beef and was the economics editor for food safety on ERS' website. Tanya's current research interests include the public and private economic incentives for food safety innovations, the economics of new rapid tests for pathogens, integrating risk assessment into benefit/cost analyses of control options, and a benefit/cost evaluation of innovations for Salmonella control in broilers.

James D. Schaub is Director of the Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) at the USDA, a position he has held since 2000. He leads a staff of scientists and economists in a comprehensive program for risk assessment and economic analysis focusing on food safety, animal diseases, plant diseases, invasive species, and environmental health. Dr. Schaub has served on the Methyl Bromide Technical Options Committee of the United Nations Environment Program since 2002. From 1991 to 2000, he was a senior economist in the Office of the Chief Economist of USDA where his work involved food safety, livestock markets, and trade. From 1979 to 1991, Dr. Schaub was a research economist with USDA's Economic Research Service where his work focused on oilseed markets and trade policy. He received his Ph.D. in economics from North Carolina State University and B.A. from Loyola College of Maryland.