Fera/JIFSAN

12th Annual Joint Symposium

June 15-17, 2011

Greenbelt Marriott Hotel
6400 Ivy Lane
Greenbelt, Maryland USA

Sponsored by

Food and Environment Research Agency (Fera)
York, United Kingdom

and the

Joint Institute for Food Safety and Applied Nutrition (JIFSAN)
University of Maryland
College Park, Maryland USA

Dealing with Uncertainty in Risk-Based Decision Making Response

CONTENTS

Symposium Objective

This is the twelfth in a series of annual symposia in food safety and applied nutrition jointly organized by The Food and Environment Research Agency (Fera), York, UK, and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), University of Maryland. Each year, a different theme is selected.

The increasingly global nature of the food supply presents new challenges for assuring food safety and for responding to emergency situations. During the past two decades there has been a tremendous effort throughout the international food safety community to make decisions that are science-based; risk-based; transparent and consistent. Food safety risk managers need to make decisions on a daily basis in the face of uncertainty. Understanding the sources of these uncertainties within the information provided to the risk managers is an integral part of the decision making process. It provides a means of communicating effectively the public health and economic impact of a given decision to stakeholders.

The focus of the 2011 Annual Fera/JIFSAN Joint Symposium will be on dealing with uncertainty in risk-based decision making and response. The symposium will provide an overview of the sources and characterization of uncertainty, and consideration when making food safety decisions and communication. Invited speakers are drawn from regulatory agencies, public interest groups, universities and research institutions in Europe and North America. Symposium sessions will include discussions on sources of uncertainty, tools for characterizing uncertainty, and new methods and models for reducing uncertainty during data collection.

Organizing Committee

Dr. Gregory Noonan, FDA, Co-Chair
Dr. Juliana Ruzante, JIFSAN, Co-Chair
Dr. Andy Hart, Fera, Co-Chair
Dr. Jianghong Meng, JIFSAN
Dr. Paul Brereton, Fera
Dr. Elizabeth Calvey, FDA
Dr. Vasiliki Flari, Fera
Dr. Roy Macarthur, Fera

PROGRAM

12th Annual Fera/JIFSAN Joint Symposium

Dealing with Uncertainty in Risk-Based Decision Making and Response

Greenbelt Marriot Hotel
Greenbelt, MD

June 15-17, 2011

Wednesday, June 15, 2011

12:00	**Registration**
1:00	Welcome and Introductions *Jianghong Meng, Director, JIFSAN*
1:15 - 1:45	**Keynote Presentation** "The Power of New Information in Risk-Based Decision Making" *Donald Zink, Food and Drug Administration, College Park, MD USA*
1:45 - 2:15	Detailed Case Study I (Peanut Butter) *Jenny Scott, Food and Drug Administration, College Park, MD USA*

Session 1: Sources of Uncertainty in Food Safety Risk Assessment – Current Practice

Session Chair: Andy Hart, Fera

2:15 – 2:45 (1A)	Sources of Uncertainty and Current Practice for Addressing Them: Analytical Perspective *Roy Macarthur, Fera, York, United Kingdom*

2:45 – 3:15 (1B)	Sources of Uncertainty and Current Practice for Addressing Them: Toxicological Perspective *David Bussard, EPA, Washington, DC USA*
3:15 – 3:45	Break
3:45 – 4:15 (1C)	Sources of Uncertainty and Current Practice for Addressing Them: Exposure perspective *Clarence Murray III, Food and Drug Administration, College Park, MD USA*
4:15 – 4:45 (1D)	Sources of Uncertainty and Current Practice for Addressing Them: Epidemiology Perspective *Chensheng (Alex) Lu, Harvard University, Cambridge, MA USA*
4:45 – 5:25	General Discussion (Roundtable) – *Including Lessons Relevant to Case Study*
5:25 – 5:30	Final notes and Announcements
5:30	Adjourn

Session 2: Improving Data Collection to Quantify and/or Reduce Uncertainty

Session Chair: Juliana Ruzante, JIFSAN

Thursday, June 16, 2011 AM

7:30 AM	**Registration & Continental Breakfast**
9:00 - 09:05	Introduction *Juliana Ruzante, JIFSAN*

9:05 – 9:35	Detailed Case Study II (Chemical) *Wayne Anderson, Food Safety Authority of Ireland, Ireland*
09:35 - 10:05 (2A)	Designing Studies to Better Understand Food Source Attribution *Robert Hoekstra, Centers for Disease Control and Prevention, Atlanta, GA USA*
10:05 - 10:35 (2B)	Designing Rapid Risk Assessments *Vasiliki Flari, Fera, York, United Kingdom*
10:35 - 11:00	Break
11:00 - 11:30 (2C)	Designing Studies to Define Baseline Prevalence and Identifying Out of Compliance/Violations *John Luchansky, U.S. Department Agriculture, Wyndmoor, PA USA*
11:30 – 12:30	General Discussion (*Including Application of Approaches to Case Study)*
12:30 - 12:35	Final Notes – Announcements
12:35 - 1:35	Lunch

Session 3: Tools Used for Characterizing Uncertainty

Session Chair: Roy Macarthur, Fera

June 16 PM

1:35 - 2:05 (3A)	Uncertainty Analysis – Characterizing the Total Uncertainty when Combining the Different Sources (Quantitative and Qualitative) *Andy Hart, Fera, York, United Kingdom*

2:05 - 2:35 (3B)	Using Quantitative Risk Assessment and Accounting for Variability and Uncertainty *Daniel Gallagher, Virginia Tech, Blacksburg, VA USA*
2:35 - 3:05	Break
3:05 - 3:35 (3C)	Dealing with Uncertainty in Risk-Benefit Analyses: Balancing Health Benefits and Risks (e.g., Consuming Seafood) *Helen Owen, Fera, York, United Kingdom*
3:35 – 4:05 (3D)	The Role of Expert Judgment in Characterizing Uncertainty *Roger Cooke, Resources for the Future, Washington, DC USA*
4:05 – 4:35	General discussion (Round table) – *Including Lessons Relevant to Case Study*
5:05 – 5:10	Final Notes and Announcements
5:10	Adjourn
6:00 PM	**Symposium Participants Dinner** *(Barbecue)*

Session 4: Informed Decision Making

Session Chair: Greg Noonan, Food and Drug Administration

June 17 AM

8:00 AM	**Registration & Continental Breakfast**
09:00 - 09:05	Introduction *Greg Noonan, Food and Drug Administration*

09:05 - 09:35 (4A)	Role of Science, Uncertainty and Risk Perception in Making Informed Decisions: A Government Perspective *Andrew Wadge, Food Standards Agency, United Kingdom*
09:35 - 10:05 (4B)	Role of Science, Uncertainty, and Risk Perception in Making Informed Decisions: An Industry Perspective *Patrizia Barone, Unilever, Englewood Cliffs, NJ USA*
10:05 - 10:35 (4C)	Communicating the Risk/Benefit to Stakeholders *Trevor Butterworth, STATS.org, Arlington, VA USA*
10:35 - 11:00	Break
11:00 - 12:00	General Discussion *(Including Lessons Relevant to Case Study Where Relevant)*
12:00 - 12:10	Final Notes – Fera/JIFSAN 2012 Robert Edwards, *Fera, York, United Kingdom*
12:10	End of Symposium

Symposium

Host and Co-Hosts

JIANGHONG MENG, D.V.M., M.P.V.M., PH.D
Director, JIFSAN
Symposium Host

Dr. Jianghong Meng a Professor within the Department of Nutrition and Food Science, and Director of the Joint Institute for Food Safety & Applied Nutrition (JIFSAN) at the University of Maryland, College Park, Maryland USA. Dr. Meng received his veterinary medicine degree in China, and Mater of Preventive Medicine and Ph.D. from the University of California, Davis. His research interests focus on food safety microbiology. Dr. Meng has extensive research experience in the identification and characterization of foodborne pathogens and bacterial antimicrobial resistance. He has published over 100 research articles and book chapters on food microbiology and safety.

Dr. Meng is a member of American Society for Microbiology, Institute of Food Technologists, and International Association of Food Protection, and served on Editorial Board of Journal of Food Protection and Applied & Environmental Microbiology. He was appointed by the Secretary of the US Department of Agriculture member of National Advisory Committee on Microbiological Criteria of Foods (NACMAF) in 2005 and 2007. Dr. Meng also serves on National Academies' Committee on Review of Risk-Based Approach to Public Health Attribution, Microbiology Expert Committee of United States Pharmacopeia, and Steering Group of Partnership Training Institute Network (PTIN), Asia Pacific Economic Corporation.

PAUL BRERETON, PH.D
***Head,* Food and Health Research Programme**
Symposium Co-Host

Dr. Paul Brereton is Head of Food and Health Research Programme at the Food and Environment Research Agency based in York, UK. He has published over 60 peer reviewed papers on food safety and quality and currently sits on the Editorial Board of the Journal of the Science of Food and Agriculture.

Paul currently manages TRACE, an EU integrated project of ~€20M, that comprises a portfolio of international research, training and dissemination activities on food traceability and authenticity. He has close links with the food industry, UK Public sector, academia and the European Commission.

ROBERT EDWARDS
Chief Scientists
Food and Environmental Research Agency
York, United Kingdom
Symposium Co-Host

Dr. Robert Edwards was previously Head of the School of Biological and Biomedical Sciences and co-Director of the Centre for Bioactive Chemistry at Durham University. Dr. Edwards is a plant health biochemist with 25 years experience working in and with the international chemical industry. His research interests include metabolite profiling, pesticide metabolism in plants, plant/stress interactions and bio-refining.

In addition to his role as Chief Scientist at Fera, he maintains his current research interests in counteracting herbicide resistance in weeds, wheat biotechnology and bio-refining through a Chair position in Crop Protection in the Centre for Novel Agricultural Products, Department of Biology, University of York.

SPEAKERS
&
ABSTRACTS

DONALD L. ZINK
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
College Park, MD USA

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.

JENNY SCOTT

Food and Drug Administration
Center for Food Safety and Applied Nutrition

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.

Dealing with Uncertainty – Peanut Butter Case Study

Jenny Scott
Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD USA

Abstract

Between September 1, 2008 and March 31, 2009 there were 714 reported cases of *Salmonella* Typhimurium in 46 states (and one case in Canada) that were ultimately attributed to peanut butter and peanut paste containing products from Peanut Corporation of America (PCA). The uncertainty was initially extremely large - investigations began in late November, but we were uncertain of any food source until January when one brand of institutional peanut butter was identified as the likely source for several institutional clusters of illness. This led investigators to PCA, but we did not know if the single brand was solely responsible for all cases, nor did we know the root cause of the contamination. Case control studies led to the implication of 2 brands of peanut butter crackers made with peanut paste from PCA, but we did not know all the products made with PCA peanut butter/peanut paste, how extensive the contamination event was (in terms of products produced in the plant or the timeframe of production of contaminated products), who received the contaminated ingredients, what products were made with the contaminated ingredients, or whether these products were causing illnesses. As a result of these uncertainties, we did not know exactly what to tell consumers. Following investigations into operations at PCA's Georgia facility, our uncertainties about what products needed to be recalled were reduced – contamination data indicated that all products from the facility should be removed from the market. We encountered additional uncertainties when it was determined that illnesses in Colorado were related to products coming from a second company facility in Texas – why was the same strain associated from products coming from both the Georgia and Texas plants? We were uncertain how to communicate with consumers in a way that they would take the recall seriously, what the best ways were to reach consumers, what to tell them to do with the product, and how to communicate what products were involved without implicating products that were not. In some cases we were uncertain what to tell manufacturers about the safety of products made with PCA ingredients due to the absence of data validating kill steps, and we were uncertain about procedures plants should use to clean up contamination introduced by the ingredients. Regardless of the uncertainty, FDA made decisions and communicated what the agency did know, even as events changed what we knew almost daily.

ROY MACARTHUR, PhD

Food and Environment Research Agency

Dr. Roy Macarthur is the lead statistician for food analysis and sampling at Fera. His main interests are method validation, fitness for purpose of analytical methods, measurement uncertainty and how to consider these together with other sources of uncertainty such as sampling.

Dr. Macarthur's recent work has included validation of analytical methods for the measurement of GMOs; and how to describe and validate the performance of qualitative methods of detection.

Sources of Uncertainty and Current Practice for Addressing Them Analytical Perspective

Roy Macarthur, PhD
Food and Environment Research Agency
York, United Kingdom

Abstract

Analytical results provide information about the concentration, presence, or absence of analyte in the samples that are presented to the analyst. We will discuss how uncertainty is addressed by analysts for the measurement of three classes of analyte: chemical; microbiological and biotechnological, and how large the uncertainty associated with results is likely to be for each of those classes.

We will mention the information that will not usually be provided by analysts such as uncertainty associated with sampling, or the potentially large errors that come from true blunders in the lab or in the office. And we will consider the information that may be provided by analysts but that cannot necessarily be taken at face value such as 'limit of detection'.
Finally, we will look at how analysts describe the performance of qualitative methods of detection and current work (IUPAC / AOAC/ MoniQA) to improve and standardize how qualitative uncertainty is addressed.

David A. Bussard

National Center for Environmental Assessment
Environmental Protection Agency

Mr. David Bussard is the Director of the Washington Division of EPA's National Center for Environmental Assessment. This Division conducts some of EPA's more complex and consequential toxicological reviews, such as the reviews of the toxicity of trichloroethylene, perchlorethylene and formaldehyde. The Division also helps develop methods for the quantitative assessment of risk and methods for evaluating biological issues regarding health risk. In addition, the Division develops and maintains EPA's Exposure Factors Handbook, does a range of integrated risk assessments on special issues that arise. This has brought Mr. Bussard into EPA deliberations on how to evaluate evidence and how to quantify uncertainty in human health toxicity and risk assessment.

The Division also does ecological work. It has developed with colleagues in Cincinnati publications and a web-based system to help local, State and Regional scientists evaluate potential causes of observed degradation in fresh water streams. It has applied that expertise in various analyses important to decisions about water management, such as a recently released study of the stream ecology impacts of mountain-top mining.

Prior to joining the National Center for Environmental Analysis, Mr. Bussard managed rulemakings and national program implementation in EPA's hazardous waste regulatory program and in EPA's Office of Toxic Substances, and was a policy analyst in EPA's Office of Policy, Planning and Evaluation. In these positions, and in research prior to joining EPA, Mr. Bussard was directly involved in numerous instances of using uncertain risk information to make real-world regulatory decisions, both from a decision-making perspective and an economic analysis perspective. Mr. Bussard managed the development of hazardous waste and solid waste landfill facility standards and treatment and combustion standards for hazardous waste and municipal waste, and many other program design decisions for that program.

Mr. Bussard has a BA in Biochemistry from Harvard College, received a Michael Rockefeller fellowship from Harvard after college, and then did public policy research and coursework at Harvard's Kennedy School of Government before joining EPA. He was staff to the cross-disciplinary Harvard Faculty Project on Regulation.

Sources of Uncertainty and Current Practice for Addressing Them: Toxicological Perspective

David Bussard
National Center for Environmental Assessment
Environmental Protection Agency
Washington, DC USA

Abstract

"Toxicologist" evaluates and presents information on uncertainty when they identify the hazards and dose-response of exposure to an environmental chemical. To put this into context, the talk will also discuss how environmental toxicologists traditionally focused on defining a "safe" or "de minimis risk" dose. Decision-makers and economics-trained analysts often want to understand how to estimate the marginal difference in expected disease incidence associated with alternative risk management options. Finally, parts of the public have strong concerns about understanding subpopulations that are particularly sensitive to a risk agent and some developing understanding of the biology may make that issue more salient.

CLARENCE WILLIAM MURRAY, PhD
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Dr. Clarence Murray III received his bachelor's degree in chemistry in 1998 from Norfolk State University and his doctoral degree in organic/polymer chemistry in 2003 from the University of North Carolina at Chapel Hill. After the completion of his dissertation, Dr. Murray accepted a position as a consumer safety officer with the Office of Food Additive Safety in the Petition Review Division. For four years, Dr. Murray worked on various color and food additive petitions and consumer inquiries regarding color and food additives. In 2007, Dr. Murray joined the Chemical Hazard Assessment Team in the Office of Food safety as a chemist/exposure analyst and since then has been involved in the exposure assessment of anthropogenic and naturally derived contaminants in foods.

Sources of Uncertainty and Current Practice for Addressing Them Exposure Perspective

Clarence William Murray III
Food and Drug Administration
Center for Food Safety and Applied Nutrition
College Park, MD USA

Abstract

Dietary exposure assessment provides an evaluation of the likely exposure from an environmental contaminant in foods. The dietary exposure is quantified by multiplying the environmental contaminant concentration in a specific food with the consumption records for a specific food from a food consumption survey. The result derived is a dietary exposure estimate and is typically expressed for a total population or a specific subpopulation. The accuracy of the dietary exposure estimate depends on the sources of uncertainty that may occur from the environmental contaminant concentration data, or from the food consumption data, or from both. For the environmental contaminant concentration, common sources of uncertainty may come from non-detect values found in a data set of detected values and from using summary statistics to describe the concentration. In the case for the food consumption survey, a common source of uncertainty can come from using a short term food consumption survey to describe long term dietary behaviors. The purpose of this presentation is as follows: 1.) characterize the sources of uncertainty encountered in a dietary exposure assessment and 2.) provide current practices used to address these uncertainties.

CHENSHENG (ALEX) LU, PhD

Harvard School of Public Health

Dr. Chensheng Lu is the Mark and Catherine Winkler Associate Professor of Environmental Exposure Biology in the Department of Environmental Health, Harvard School of Public Health. He received the Ph.D. degree in Environmental Health from the University of Washington (Seattle, WA) in 1996. He was an Assistant Professor at the Rollins School of Public Health, Emory University in Atlanta GA from 2004 to 2008, before joining Harvard School of Public Health in 2008. His primary research interest is to assess human exposure to environmental chemicals, such as pesticides and endocrine disruptors, using biomarker approach and to link exposures to health outcomes.

His extramural research program consists of funding mainly from National Institute of Environmental Health Sciences (NIEHS) and US EPA's Science to Achieved Results program (STAR). The current ongoing research projects include a community-based intervention study aiming to reduce young children's exposures to pesticides via the implementation of the Integrated Pest Management (IPM) practice in one of the Boston Housing Authority developments, which he serves as the Principal Investigator (PI). He is also a PI of a study to determine how chronic exposures to endocrine disrupting chemicals would affect epigenetic methylation in children, and a co-investigator in a study to examine the interplay between liver enzymes and BPA/phthalates in relations to type-2 diabetes risk. He recently completed a random-sampling population-base study aiming to assess how the variations of dietary consumption patterns affect pesticide exposures.

He currently serves as an *ad hoc* member on the Scientific Advisory Panel established by US EPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and by US EPA Food Quality Protection Act (FQPA). He is a member of Scientific Experts of European Food Safety Authority (EFSA) since 2009. He also serves as the Associate Editor, Environmental Health Perspectives (EHP) and the Journal of Exposure Science and Environmental Epidemiology (JESEE), 2 leading scientific peer-review journals in the field of Environmental Health.

THE CONTRIBUTION OF WITHIN- AND BETWEEN-SUBJECT VARIATIONS TO DIETARY PESTICIDE EXPOSURES

Chensheng (Alex) Lu
Harvard School of Public Health
Harvard University
Boston, MA USA

Kathleen Attfield, Harvard School of Public Health, USA
Xihong Lin, Harvard School of Public Health, USA

Abstract

Background and Aims: Organophosphate and synthetic pyrethroid insecticides are employed in wide broadcast agricultural use, and off market use and residues from imported fruits and vegetables provide additional sources of dietary exposure. These pesticides are known for their neurological and neurodevelopmental effects in children and evidence is building for neurological affects with chronic low level exposures. Studies of children's pesticide exposures often use models utilizing single spot urine sampling and boost study power by increasing enrollment. However, this design has the central assumption of greater between- than within-subject variances. With the availability of repeated measures data over a 12-month period, this assumption can be tested.

Methods: Repeated measurements of urinary metabolite data from the Children Pesticide Exposure Study - Washington (CPES-WA) was employed for an analysis of dietary exposure with linear mixed effects modeling including season, age, and gender as covariates and accounting for values below the limit of detection with maximum likelihood estimation.

Results: Within subject variance exceeded between subject variance by a factor of eight: 16 versus 2. Season is a significant contributor to the model at $p<0.001$, while gender and age were not statistically significant covariates.

Conclusion: Analysis of components of variance for repeated measures showed 8-fold greater contribution of within-subject variation to predicting pesticide exposure levels than between-subject variance. Therefore, repeated measures with fewer subjects may be a more efficient design for understanding children's pesticide exposure levels than single spot urine measurements involving a great number of study participants.

WAYNE ANDERSON, PhD
Food Science and Standards
Food Safety Authority

Dr. Wayne Anderson joined the Food Safety Authority of Ireland in 1999 as Chief Specialist: Food Science and is now acting Director of Food Science and Standards Division. Prior to this he spent 11 years in the food industry, 10 of which were with Unilever. His role in the FSAI involves direction of science including risk assessment. Dr. Anderson has lectured nationally on risk analysis and has conducted quantitative risk assessments on fluoride in infant formula and also on marine biotoxins in shellfish. He has participated in the WHO microbial risk assessment programme as well as the WHO/FAO expert consultation on the use of risk assessment outputs in risk management. He has published papers in the area of food preservation systems, predictive microbiology and risk communication. Dr. Anderson is a Fellow of the Institute of Food Science and Technology Ireland and a Fellow of the Institute of Food Science and Technology UK. He holds a primary degree in biochemistry and a PhD in predictive microbiology.

Making Decisions Despite Uncertainty: The Irish Dioxin Crisis 2008

Dr. Wayne A. Anderson
Food Science and Standards
Food Safety Authority
Ireland

Abstract

Uncertainty can sometimes be used as a reason not to act or as a reason to over-react in an overly precautionary way. Uncertainty can be reduced with more information but reliable information is at a premium in a crisis situation. During food crises the option to do nothing is not an option and decisions are made in the full knowledge that they will be analysed in hind sight; sometimes with a favourable outcome, sometimes not so favourably. Crises are high profile affairs, and with profile comes opinion from a diversity of sources. Differences in opinion often stem from differences in how uncertainty is approached and this makes risk communication difficult.

In December 2008, the Irish Authorities ordered the largest recall of food products ever seen in the State following the discovery of dioxin contamination of pork and beef products (Tlustos, 2009a). Close collaboration between the authorities in Ireland and colleagues in other Member States allowed the rapid identification of a common source of contamination, this being feed produced in one plant from recycled bread, manufactured using a direct heating process. The original source of the contamination is thought to be recycled transformer oil used in the direct drying process. The rapid identification of the source of contamination in turn meant contaminated pork and pork product could be removed from sale very quickly and thus consumer protection was ensured, both in Ireland and in other countries.

A full commodity recall was not an easy decision, neither was it totally based on science which for some risk assessors and scientists, may be hard to accept (JCAFF, 2009; DAFF, 2009). Whilst only approximately 8% of the national pig herd was exposed to contaminated feed, the accepted level of traceability in the pork processing industry, which complies with the minimum legal requirements, meant that it was not possible to distinguish between contaminated and non-contaminated pork in production representing 98% of Irish pork entering the food chain. Therefore a decision was taken to recall all Irish pork and pork products produced from 1 September 2008 up to the date of the recall in December.

Risk assessment was necessary to underpin the recall decision. This was required in hours rather than days. Potential sources of uncertainty were reduced because of prior work in Ireland to develop a comprehensive and reliable food consumption database (IUNA, 2001). However, other sources of uncertainty, including information on feed inclusion rates and subsequent distribution of dioxin concentrations in pork fat, were not so easy to reduce and certain conservative assumptions had to be made. Uncertainty surrounding the onset of the crisis was reduced due to collaboration with other Member States who had information concerning dioxin concentration in rendered fat (Tlustos et al, submitted) and the availability of archive samples of the affected feed ingredient. Consequently the risk assessment conducted by the Food Safety Authority (FSAI) was fit for purpose but had underlying uncertainties that were qualitatively articulated but which

could not be quantified in the time available to us. Nevertheless, the European Food Safety Authority (EFSA) was charged with the task of a pan-European risk assessment and we were obliged to share our data and risk assessment with that organisation. This was a critical part of the crisis as Ireland's reputation and that of the FSAI would have been badly damaged if the EFSA risk assessment had differed markedly from the Irish risk assessment. However, EFSA were able to confirm that the consumption of contaminated Irish pork would not have a major impact on health (EFSA, 2008).

In some quarters, this was interpreted to mean that the Authorities over-reacted; that there was no health risk and the recall was unnecessary. However, the converse was true. The risk assessment was based on exposure to the amount of contaminated pork on the market between the date of onset of contamination and the recall. If the product had not been recalled then the exposure would have continued, increasing the body burden of consumers. This shows the difficulties in communication of risk and the selective translation of the message by the media and by the public (Tlustos, 2009b).

Although risk assessment and protection of public health were at the heart of the recall decision, other legitimate factors were also taken into account. Risk perception, trade relationships and confidence in Ireland as a major food exporter were additional factors. The decision we took and the way the FSAI handled the crisis have been subjected to favourable scrutiny in several publications (Jacob et al 2010, Casey et al 2010). Safe Irish pork was back on the shelves within 6 days and the long term damage to the Irish pork industry was never realised. Follow up studies on dioxin levels in human breast milk are due to be published soon. These will confirm the predictions of both the FSAI and EFSA risk assessments. There has been no appreciable increase in the body burden of dioxins in the Irish population.

References

Casey, D.K., Lawless, J.S., Wall, P.G. (2010) A tale of two crises: the Belgian and Irish dioxin contamination Incidents. British Food Journal Vol. 112 No. 10, 2010 pp. 1077-1091

Department of Agriculture, Fisheries and Food (2009) Report of the Inter-Agency Review Group on the Dioxin Contamination Incident in Ireland in December 2008. Available at http://www.agriculture.gov.ie/media/migration/publications/2010/DioxinReport211209revised190110.pdf

EFSA (2008) Statement of EFSA on the risks for public health due to the presence of dioxins in pork from Ireland. Available at http://www.efsa.europa.eu/en/efsajournal/doc/911.pdf

Irish Universities Nutrition Alliance (2001) North/South Ireland Food Consumption Survey Published by: Food Safety Promotion Board. Available at http://www.iuna.net/docs/NSIFCSummary.pdf

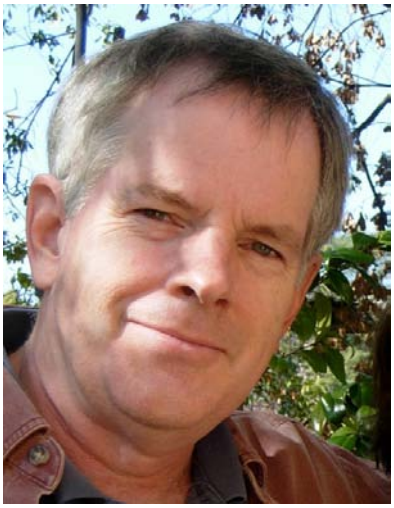
Jacob, C.J., Lok, C., Morley, K., Powell, D.A. (2010) Government management of two media-facilitated crises involving dioxin contamination of food Public Understanding of Science February 5, 2010

Joint Committee on Agriculture, Fisheries and Food (JCAFF) (2009) Report on the contamination of Irish pork products. First Report. PRN No. A9/0686. Available at http://www.oireachtas.ie/documents/committees30thdail/j-agriculturefisheriesfood/Reports_2009/20090526-1.pdf

Tlustos, C. (2009a) The dioxin contamination incident in Ireland 2008. Organohalogen Compounds Vol. 71, 2009 / page 001155

Tlustos, C. (2009B) The dioxin crisis in Ireland 2008 – Challenges in risk management and risk communication. Organohalogen Compounds Vol. 71, 2009 / page 001152

Tlustos, C., Sheridan, M., O'Sullivan, D., Anderson, W., Flynn, A. (submitted) The Dioxin Contamination Incident in Ireland 2008: Analytical Results and Congener Patterns. Submitted to Food Additives and Contaminants



ROBERT MICHAEL HOEKSTRA, PhD

National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control

Dr. Robert (Mike) Hoekstra has served as consulting mathematical statistician at the Centers for Disease Control for the last twelve years. He has worked primarily with groups responsible for foodborne illness both in domestic as well as international settings. His work has spanned a wide variety of epidemiologic and laboratory science problems and a wide variety of pathogens commonly transmitted through food. This includes risk factor studies of *Campylobacter*, *E. coli* O157, *Listeria*, *Salmonella*, and *Shigella*, description, modeling, and interpretation of surveillance data, and investigation of outbreaks of foodborne illness. While these activities continue, his current focus is on projects estimating the burden of domestic foodborne illness and on several efforts toward estimating the attribution of foodborne illness to food commodities. Before joining CDC, Mike worked as an academic statistician, teaching and researching topics in Bayesian statistical methods before the spread of MCMC. He earned a PhD from the University of Florida, working with Malay Ghosh on problems in approximate sequential Bayes estimation.

Improving Data Collection to Quantify and/or Reduce Uncertainty Designing Studies to Better Understand Food Source Attribution

Robert Michael Hoekstra
Biostatistics and Information Management Office
Division of Foodborne, Waterborne, and Environmental Diseases
Centers for Disease Control
Atlanta, GA USA

Abstract

Attribution of illness to food commodity is a simple process of relating episodes of human illness through consumption or handling of foods to instances of commodity contamination…except that the available data on human illness, food consumption, and contamination are nowhere configured to make relating them simple. The totality of agents that cause illness is not known. Surveillance for the agents that are known is not complete. Surveillance reports rarely come with food specified as the cause, much less the commodity. Outbreak investigations can produce cases of human illness that are tightly linked to specific food exposures, but such tight links exist for only a fraction of reported outbreak cases, and outbreak cases are, in turn, only a small fraction of all cases. Case control studies are typically aimed at attributing illness to causal food exposures in the much larger population of sporadic illness. These studies link multiple food exposures to cases, but do so in a very noisy fashion. The actual causal exposures are in turn inferred from control food exposures, also noisy and with different potential biases. Consumption models, like that of Hald, link counts of human illness aggregated by type to commodity contamination levels by type, through food consumption estimates, yielding ecological associations. Further, commodity contamination levels can depend on the point in the food chain that they are measured, creating potentially different attributions. Quantitative microbiological risk assessment offers another route to attribution, building causal pathways from reservoir to consumption via probabilistic models applied to the food chain. These are examples of existing ways to relate illness to contaminated food. They are diverse, not exhaustive, and no single method can be deemed definitive given the large inherent uncertainties in the data and in the model structures themselves. We present design considerations for each these examples along with a paradigm for synthesizing an understanding of their collective food source attribution outputs.

VILLIE FLARI, PhD

Food and Environment Research Agency

Dr. Villie Flari is a Risk Analyst at the Food and Environment Research Agency (Fera), an executive research agency of Defra. She has been active in the field of Risk Analysis since 2003, particularly working on environmental and food safety risk problems. She is specialized in the following fields of Risk Analysis: (i) applying expert opinion elicitation methodologies to elicit subjective information, including uncertainties of experts; (ii) communicating scientific uncertainties to policy makers/decision makers; (iii) feasibility of applying risk assessment methodologies during investigations of emergency events; (iv) decision making support tools.

Rapid Risk Assessments – Are They Possible?

Villie Flari
Food and Environment Research Agency
Defra, York, United Kingdom

Abstract

Recent food safety scandals, e.g. involving chemicals such as melamine or dioxins; biological contamination of food products with known or new pathogens, indicate that ensuring food safety to protect public health remains a globally significant challenge, particularly in view of: a) increasing volume and diversity of food products' trade; b) increasing public demand for health protection; c) possible climate change effects on patterns of foodborne illnesses; d) changes in agricultural practices; e) changes in human behavior and ecology.

The presentation will focus on the application of innovative risk assessment methodologies, e.g. structured approaches to elicit expert judgment, multi criteria decision analysis modeling, uncertainty tables' approach, Bayesian exposure modeling in the food safety area. Examples relevant to either strategic (e.g. assessing the safety of nanotechnology-enabled food products) or tactical decision making (e.g. past emergency responses to food threats that could originate from chemical or biological contaminants) will be employed as platforms to discuss the possible applicability and the advantages of these methodologies.

JOHN B. LUCHANSKY, PhD
U.S. Department of Agricuture

Dr. John Luchansky earned his B.S degree from Penn State (conferred with distinction) and both a M.Sc. and Ph.D. degree from Iowa State, all in Microbiology. Following a post-doc appointment at N.C. State in the Department of Food Science, he joined the faculty of the Food Research Institute at the University of Wisconsin. Since 1999 John has served as a Research Microbiologist with the USDA/ARS in Wyndmoor, PA. He has authored about 120 peer-reviewed manuscripts and over 80 published symposia, reports, and book chapters, and is an inventor on 6 U.S. patents. He has given over 300 invited presentations, including 35 at international venues, and has authored over 180 abstracts/posters at scientific meetings. He has served as mentor to some 35 graduate students and 24 undergraduate students, and has hosted nearly 40 international/visiting scientists. His honors and awards include appointment as an Institute of Food Technologists (IFT) Scientific Lecturer from 1994 to 1996, and the recipient of both the Research and Development Award (2000) and Myron Solberg Award (2007) from the IFT. John was appointed to two terms on the National Advisory Committee on Microbiological Criteria for Foods, and has served as a Councilor, Chair, and/or Executive Committee member for both IFT and the International Association for Food Protection (IAFP). The IAFP awarded John and the Microbial Food Safety Research Unit of the USDA/ARS with the Food Product Association Food Safety Award (2006), and he was also the recipient of the IAFP Maurice Weber Laboratorian Award (2008). John and his team were also the recipients of both the USDA/ARS and the Federal Laboratory Consortium Technology Transfer Awards (2008). Collectively, Dr. Luchansky and his collaborators have generated a series of ground breaking publications and technologies used by industry to enhance the safety of their products and by regulators to make science-based policy decisions that benefit the overall health and well being of consumers worldwide.

Tackling the True Prevalence and Levels of *Listeria monocytogenes:* Market Basket Surveys of Ready-to-Eat Retail Foods

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Abstract

Listeria monocytogenes remains a serious threat to public health due to its prevalence, persistence, and pathogenicity in our food supply, particularly when associated with ready-to-eat (RTE) foods. For the past decade or so, considerable resources have been directed to reduce human illness attributable to RTE foods, yet despite these efforts, food borne listeriosis still occurs. The Food and Drug Administration (FDA) and Food Safety and Inspection Service (FSIS) developed a quantitative risk assessment in 2001 and used it to subsequently compare the relative risk of listeriosis among 23 categories of RTE foods in 2003. A study in 2006 (Draughon et al., 2006) provided additional insight into the prevalence and levels of this pathogen on deli-sliced versus prepackaged deli meats, and showed a greater prevalence on the former than on the latter. In fact, more recent risk assessments have also revealed that appreciably more illness/death due to listeriosis from deli meats can be attributed to retail sliced rather than prepackaged products. To minimize the load and occurrence of the pathogen and concomitantly continue efforts to develop and implement effective interventions to ensure that an infectious dose of *L. monocytogenes* will not reach the consumer's table, it is imperative to quantify the prevalence, levels, and types of this pathogen in target foods. To this end, we conducted a multi-collaborator study to quantify the prevalence of *L. monocytogenes* in frankfurters, a higher-risk, high-volume and mass produced food, consumed by a significant segment of the population, including those at elevated risk (Wallace et al., 2003). The pathogen was recovered from 532 of 32,800 pounds/packages (1.6%) of frankfurters using the USDA Agricultural Research Service (ARS) package rinse method. Enumeration, when possible, showed pathogen levels of about 70 to 190 MPN (most probable number) per package; about 90% of the 1100 retained isolates were serotype 1/2a and displayed the same pulsotype. In a related study of similar scope and magnitude by Gombase et al. (2003), a total of 31,705 food samples (e.g., cheese, milk, raw fruits and vegetables, and deli salads) were tested, of which 577 samples tested positive for *L. monocytogenes* for an overall prevalence of 1.8%. Levels of the pathogen in positive samples ranged from <0.3 MPN per gram to 1.5×10^5 CFU (colony forming units) per gram. Since the data reported by Wallace et al. (2003) and Gombas et al. (2003) were collected some ten years ago, further studies were warranted to determine if the prevalence and populations of *L. monocytogenes* have increased, decreased, or remained static in response to the considerable efforts by food safety professionals across government, academia, and industry over the past decade to lower the likelihood of listeriosis associated with RTE foods. Thus, in collaboration with both FDA and FSIS, the ARS is conducting a Market Basket Survey to obtain more current information on the association of *L. monocytogenes* with RTE foods at retail to evaluate the relative public health risk. These baseline data will shed new light on the prevalence of this pathogen and prove useful to risk assessors and regulators worldwide because of the design and scope of the study wherein these data are being generated.

Draughon, A. F. 2006. A collaborative analysis/risk assessment of *Listeria monocytogenes* in ready-to-eat processed meat and poultry collected in four FoodNet states. Symposium S-16. Contamination of ready-to-eat foods: transfer and risk: *Listeria monocytogenes* and other microorganisms. International Association for Food Protection 93rd Annual Meeting, Calgary, Alberta, Canada, 13 to 16 August 2006.

Gombas, D. E., Y. Chen, R. S. Clavero, and V. N. Scott. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. J. Food Prot. 66:559-569.

Wallace, F. M., J. E. Call, A. C. S. Porto, G. J. Cocoma, ERRC Special Projects Team and J. B. Luchansky. 2003. Recovery rate of *Listeria monocytogenes* from commercially prepared frankfurters during extended refrigerated storage. J. Food Prot. 66:584-591.

ANDY HART, PhD

Food and Environment Research Agency

Dr. Andy Hart leads Fera's Risk and Numerical Sciences team, which undertakes research in the areas of risk and uncertainty analysis, and provides expertise in statistics, spatial analysis and informatics to customers both inside and outside Defra. A key focus is developing improved qualitative and quantitative approaches for dealing with variability and uncertainty in human and environmental risk assessment. The team has applied probabilistic methods to a number of problem areas including ecological risks of pesticides, plant health risks from invasive species, animal disease, human exposure to food contaminants, and the net health impact of dietary choices (risk-benefit analysis). Dr. Hart's personal interests include developing practical methods for expression of unquantified uncertainties in risk assessment and policy advice, and testing these in case studies with a range of collaborators in different problem areas. He is a member of the European Food Safety Authority (EFSA) expert panel on pesticides (PPR Panel) and was a member of EFSA and IPCS/WHO working groups that developed guidance documents on uncertainty in exposure assessment. Dr. Hart is also a member of an ILSI-Europe Expert Group on data selection for benchmark dose modeling of substances that are genotoxic and carcinogenic.

Uncertainty Analysis – Combining Quantitative and Qualitative Assessments

Andy Hart
Food and Environment Research Agency
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Abstract

The principle that uncertainty should be considered in risk assessment is well established. The Codex Working Principles for Risk Analysis state that expression of uncertainty in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

In many assessments, a qualitative expression of uncertainty may be sufficient. When quantification is needed, a range of deterministic and probabilistic methods are available. However, it is never practical to quantify all uncertainties affecting an assessment, and quantifying one uncertainty often introduces others. Some uncertainties may be too 'deep' to be quantified, beyond the reach of current science, and may merit consideration of other strategies such as social appraisal. The time and resources available for assessment are often limited, especially in crisis situations, and there is a degree of resistance to quantification from both risk assessors and risk managers. Taking all these considerations into account, there is a need for a flexible strategy for uncertainty analysis, using different combinations of quantitative and qualitative methods to meet the needs of different assessments.

This presentation concentrates on 'uncertainty tables' as a practical qualitative approach, which can be used in conjunction with different quantitative methods. An uncertainty table is a simple tool to help the risk assessor summarize the sources of uncertainty affecting an assessment, and evaluate their impact on the assessment outcome. Two types of assessment question are distinguished – quantitative and categorical – which require different types of uncertainty table. For quantitative questions, such as estimating exposure, uncertainty is expressed in terms of how different the true value might be. For categorical questions, such as whether a chemical is a genotoxic carcinogen, uncertainty is expressed as a likelihood or probability. In each case, a tabular format is used to list the uncertainties and show their influence on the assessment of uncertainty. This procedure also helps assessors to identify deeper uncertainties, whose impact on the assessment cannot be evaluated.

The tabular methods presented here have evolved from tabular formats used by several risk assessment bodies in Europe and North America, combined with ideas from some other approaches including expert elicitation, pedigree analysis and weight of evidence assessment. They are illustrated with a simple example, and other case studies are in preparation.
In many assessments, uncertainty tables may provide sufficient characterization of uncertainty for risk management decisions to be taken. In cases where more refined characterization of uncertainty is needed, the assessor may proceed to quantifying some of the uncertainties, using appropriate methods. However, this should be accompanied by revision of the uncertainty tables, to characterize those uncertainties that remain unquantified.

In order to provide an overall characterization of uncertainties, the results of the quantitative and qualitative assessments need to be combined. This may be done simply by means of a narrative statement expressing the assessor's overall judgment, but more sophisticated options are also possible. Any deep uncertainties that are present should be highlighted.

As well as providing a practical method for characterizing unquantified uncertainties, uncertainty tables can also help assessors decide which uncertainties are worth quantifying. They can therefore play a key role in a flexible strategy for uncertainty analysis.

Daniel Gallagher, PhD

Virginia Polytechnic Institute

Dr. Daniel Gallagher is an Associate Professor in the Department of Civil and Environmental Engineering at Virginia Tech. He has co-authored over 50 journal articles and proceedings papers. His research interests include risk assessment, food safety, environmental statistics, and environmental modeling. Recent projects include a risk assessment for *Listeria monocytogenes* contamination in food, the use of consumer complaints as early warnings for water utilities, and modeling organic contaminant diffusion into plastic drinking water pipes. Dr. Gallagher is a recipient of an NSF Presidential Young Investigator award and a recipient of both an AAAS/EPA Fellowship and an AAAS/Risk Policy Fellowship. He is a registered professional engineer in North Carolina.

Using Quantitative Risk Assessment and Accounting Variability and Uncertainty

Daniel Gallagher
Civil and Environmental Engineering
Virginia Polytechnic Institute
Blacksburg, VA USA

Abstract

In order to investigate uncertainty inclusion in food safety metrics, a second order Monte Carlo model of *Listeria monocytogenes* in ready-to-eat deli meats that simulated Listeria concentrations from the food processing plant through transport, retail, the consumer's home, and consumption was developed. The model accounted for growth inhibitor use and retail cross contamination, and used Latin Hypercube sampling for uncertainty iterations. The FAO/WHO dose response model was used for evaluating illnesses. A fixed appropriate level of protection (ALOP) risk metric was established as a risk of illness per serving. For each uncertainty iteration, Brent's root finding algorithm was used to solve for the corresponding performance objective (PO) risk metric as an allowable Listeria concentration (cfu/g) at the processing plant where regulatory monitoring would occur. Over all 240 uncertainty iterations, an uncertainty distribution of this PO was formed. Points on this distribution represent the probability that the resulting risk per serving is less than or equal to the target ALOP for a given PO. Deconvolution testing confirmed that regulatory PO setting would have the impact expected. Assuming the most likely industry response, no dose response uncertainty, and a target ALOP of -6.38 log10 risk of illness per serving (the median of the current estimated risk of illness distribution), a plant PO of -1.74, -2.75, and -3.39 log10 cfu/g would be required for 60%, 70%, and 80% confidence respectively that the target ALOP is not exceeded. These are all more stringent than the current typical monitoring level -1.40 log10 cfu/g. In general, uncertainty from the dose-response portion of the model and from the nature of the industry response dominated the uncertainty. This work highlights some of the difficulties of the current risk metric framework with regard to uncertainty.

Helen Owen
Food and Environment Research Agency

Helen Owen's current research concerns the use of statistics to quantify uncertainty, for example, the quantification of uncertainties in risk-benefit assessments using 2D Monte-Carlo simulation and the analysis of uncertainty in spatial data. Much of her degree (MSc Statistics, University of St Andrews) focused on statistical models for wildlife populations.

Ms. Owen has designed and developed statistical software applications for a variety of different modeling contexts:

- 'QALIBRA', risk-benefit software (graphical web-interface developed by Fera's IST team) for risk assessors, working for regulatory authorities or in the food industry, who need to consider the potential risks and benefits to health when setting food policy, developing a new food product, or advising consumers on dietary choices. See www.qalibra.eu

- 'BREAM Calculator', a graphical user interface (GUI) for calculating both the airborne spray and the bystander contamination (either dermal or inhalation exposure) for a specific crop-spraying scenario

- 'Uncertainty Table', a GUI for listing, describing and combining unquantified sources of uncertainty in risk assessments to establish the total effect of the combined sources on the initial estimate

Ms. Owen has a particular interest in the presentation and communication of statistics, and their associated uncertainty, to non-statistical audiences.

Dealing with Uncertainty in Risk-Benefit Analyses: Balancing Health Benefits and Risks (e.g., Consuming Seafood)

Helen Owen[1], Andy Hart[1] and Jeljer Hoekstra[2]
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[2] National Institute for Public Health and Environment (RIVM)
United Kingdom

Abstract

Changes in diet present both risks and potential benefits to consumers. The balance of risk and benefit is of interest to food authorities developing food policy and consumer advice, to businesses developing new food products, and to consumers considering dietary changes. Usually, the risks and potential benefits associated with the consumption of a particular food are presented separately. This is unsatisfactory, because the recipient will not have the ability to combine the risks and benefits in an objective way that allows them to estimate the size of or even the direction of the net effect of consuming a particular food. Information on risk and benefit should be combined to provide an indication of the overall effect of particular dietary choices, i.e. the net health impact. However, variability and uncertainty affecting risks and benefits cause uncertainty about the direction and magnitude of the net health impact. The central goal of QALIBRA (2011a) is therefore to develop improved approaches for the assessment of the potential net health impacts from dietary choices that take account of both variation between consumers and uncertainty about harms and benefits, and to effectively communicate the resulting net health impact and the uncertainty about the impacts to the user. The QALIBRA software integrates adverse and beneficial health effects using Disability Adjusted Life Years (DALYs) (Murray, 1994) or Quality-Adjusted Life Years (QALYs). DALYs measure health loss and QALYs measure health gain (the inverse). Starting with estimated intakes of relevant adverse and beneficial foods or substances (e.g. from existing models of dietary exposure) and the corresponding dose-response relationships, the QALIBRA software can calculate the net health impact across a target population for a new policy, product or advice. Examples of foods which have been analysed using the QALIBRA approach include fish (Hoekstra, 2011b) and phytosterol enriched margarines (Hoekstra, 2011c).

QALIBRA allows the user to quantify uncertainty in every input to the calculation, and uses Monte Carlo simulation to show the effect of those uncertainties as probability intervals on the outputs.

Useful aspects of the QALIBRA approach include:

- a consistent conceptual framework in which to think about and organize a risk-benefit assessment, and identify the data required
- a flexible approach, allowing gradual progression from simple assessments using point estimates to refined assessments using distributions to quantify uncertainty
- choice of tabular and graphical outputs, and guidance on their interpretation
- organized storage of input data
- optional sharing and discussion of assessments and data with other users

The software is web-based and free to registered users after completing a short online training session. For more details on the QALIBRA approach, visit www.qalibra.eu

Acknowledgements:
The authors acknowledge the contributions of everyone involved in the QALIBRA project, its Science Advisory Panel, and the participants of QALIBRA workshops. The project was funded by the European Commission's 6th Framework Programme; contract number FOOD-CT-2006-022957. The participation of Fera was partly supported by funding from the UK Food Standards Agency (project T01042).

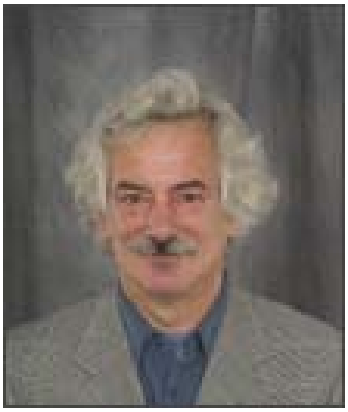
References:

A. Hart, J. Hoekstra, H. Owen, M. Kennedy, M. Zeilmaker, N.de Jong, H. Gunnlaugsdottir (2010a). Quantifying uncertainty and variability in health risk-benefit assessment using DALYs or QALYs, Submitted

Hoekstra, J., Hart, A., Owen, H., Zeilmaker, M., Bokkers, B., Thorgilsson, B., Gunnlaugsdottir, H. (2011b) Fish, contaminants and human health: quantifying and weighing benefits and risks. Submitted

Hoekstra, J., Fransen, H.P., van Eijkeren, J.C.H., Verkaik-Kloosterman, J., de Jong, N., Owen, H., Kennedy, M., Hart, A. (2011c) Benefit-risk assessment of phytosterols in margarine: a QALIBRA case study. Submitted

Murray, C.J. (1994) Quantifying the burden of disease: the technical basis for disability-adjusted life years. *Bull World Health Organ* **72** , 429-45.



ROGER COOKE, PhD

Resources for the Future

Dr. Roger Cooke joined Resources for the Future in September 2005 as the first appointee to the Chauncey Starr Chair in Risk Analysis. His research has widely influenced risk assessment methodology, particularly in the areas of expert judgment and uncertainty analysis. He is recognized as one of the world's leading authorities on mathematical modeling of risk and uncertainty. His recent research has encompassed health risks from oil fires in Kuwait following the first Gulf War, chemical weapons disposal, nuclear risk, nitrogen oxide emissions, and microbiological risk. Dr. Cooke's current research interests include structured expert judgment methodologies and uncertainty analysis, and his work focuses on the implementation of uncertainty analysis in policy-related decision-making.

Expert Judgment and Stakeholder Preference Modeling with Probabilistic Inversion

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Chaucey Star Senior Fellow
Resources for the Future
Washington, DC USA

Abstract

Rational decision theory involves uncertainty quantification and valuation. Uncertainty quantification is the province of structured expert judgment and has been extensively developed and deployed. By comparison the utility side of decision theory has languished. This is partly because the community has been sent on a fool's errand. As we have know since Arrows impossibility theorem – if not from Condorcet's voting paradox, it is not possible to characterize a set of rational agents as a rational agent whose preferences can be represented as expected utility with non-dictatorial preference aggregation. All attempts to find "the" utility function characterizing a group must fail. The alternative is to characterize a group via a distribution over the set of utility functions – sometimes called random utility theory. Recently, new techniques have been developed to do this, and are gaining some traction in applications. Recent applications include valuing health states, ecosystem threats, great lake ecosystems, risks from zoonoses and risks from nano enabled foods.

The stakeholders may be domain experts, but they may also be from the policy or media domains, or may be interested citizens. Given N choice alternatives, stakeholders rank order preferences or state preferences pair wise, or choose the k out of N - there are a great number of formats. Under mild assumptions we can find a distribution over all utility functions that best reproduces the discrete choice data. In other words the distribution over utility functions is such that x% prefer alternative A to B, y% prefer B to both C and A, z% prefer C to A, etc. with the percentages from the stakeholder data. Linear or higher order utility models based on attributes of choice alternatives are easily accommodated.

Finding a best fitting distribution over utilities is a problem of probabilistic inversion, which has been a focus of the risk/mathematics group in Delft for a number of years. Good algorithms exist and freeware is or will soon be available on the Risk and Environmental Modeling website. The talk will discuss a recent application to risks of nano e

ANDREW WADGE, PhD
Foods Standards Agency

Dr. Andrew Wadge began his career at Westminster Medical School carrying out research on the effects of environmental pollution upon health. He continued research in this area and was awarded a PhD from King's College London in 1985.

After a short spell of post-doctoral research, he joined the Department of Health where he worked on the health effects of environmental pollution advising ministers on issues such as asthma and air pollution. In April 2000, he moved to the Agency where he was headed the Chemical Safety Division and was subsequently made Director of Food Safety. Andrew was appointed Chief Scientist in the FSA in 2006.

DEALING WITH UNCERTAINTY IN DECISION MAKING
A GOVERNMENT PERSPECTIVE

Andrew Wadge
Chief Scientist
Food Standards Agency
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Abstract

In the real world, decision making often/usually has to happen with a less than complete evidence base. There can also be issues arising due to an uncertain regulatory framework eg where new developments are taking place in advance of legislation. How the uncertainties are managed and communicated by risk managers are key to building and maintaining the trust of consumers. Both good and bad examples of how this has been done in areas such as chemical and microbiological safety of food and new technologies in food production will be discussed. This will highlight issues such as how to deal with divergent views and how eg uncertainty arising from such divergences can be (mis)used to push through measures which the science does not support. A balance needs to be struck between the need to protect consumers and the risks of unfairly implicating innocent products and the resulting costs and burdens on industry.

Openness and transparency, being clear on what the science says (and doesn't say) and how any key gaps will be addressed are cornerstones to dealing with uncertainty in decision making. Getting it right is difficult!!

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.

Role of Science, Uncertainty and Risk Perception in Making Informed Decisions: An Industry Perspective

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ABSTRACT

"Decision making is a process of sufficiently reducing uncertainty and doubt about alternatives to allow a reasonable choice to be made from among them….Very few decisions are made with absolute certainty because complete knowledge about all the alternatives is seldom possible. Thus, every decision involves a certain amount of risk." (R. Harris, 2009)

In the food safety arena the role of science, uncertainty and risk perception has become a major nexus of both conflict and renewed policy debate. This has highlighted the need for fundamental changes in the relationship between science, risk policy / regulation and the public. As the UK House of Lords report on Science and Society (2000) succinctly puts it: "Scientists and regulators have to understand the public as much as the public need to have confidence in science."

This presentation will focus on various factors that affect how risks are perceived by consumers as well as how industry builds consumer confidence and trust through a risk-based decision-making framework built into the innovation process. Examples will be given during the presentation.

TREVOR BUTTERWORTH

Daily iPad Newspaper

Trevor Butterworth is a weekly columnist for the Daily, the iPad newspaper produced by News International. He also contributes to The Financial Times and The Wall Street Journal, and has written for Forbes. com, the Atlantic.com, The Washington Post and The Los Angeles Times among other publications. He is editor-at-large at STATS.org, a non-partisan, non-profit project affiliated with George Mason University in Virginia that examines the use and abuse of statistics and science in the media and in public policy. Mr. Butterworth attended Trinity College Dublin (BA, M.Phil), Georgetown University, and Columbia University (MS). He has lived in the U.S. since 1993.

Communicating the Risk/Benefit to Stakeholders

Trevor Butterworth
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Abstract

To the great newspaper magnate Joseph Pulitzer, journalism was a "lookout on the bridge of the *ship of state.*"... He peers through the fog and storm to give warning of dangers ahead… He is there to watch over the safety and welfare of the people who trust him." Pulitzer's vision became that of American journalism in the 20th and 21st century: The press is a watchdog; its function is to assess and report when the public is at risk. And yet these same metaphors also offer a rebuke. As the philosopher Arthur Schopenhauer put it, "all journalists are, in the very nature of their calling, alarmists; and this is their way if giving interest to what they write. Herein they are like little dogs, if anything stirs, they immediately set up a shrill bark." This paper will examine the clash between sentinel and scaremonger in public health reporting and ask, who benefits?

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