EFSA@10 | CHALLENGING BOUNDARIES IN RISK ASSESSMENT – SHARING EXPERIENCES

7 – 8 NOVEMBER 2012

AUDITORIUM PAGANINI, PARMA, ITALY

efsa anniversary 10 efsa anniversary

Committed *since 2002* to ensuring that Europe's food is safe

efsa
European Food Safety Authority

WELCOME MESSAGE

Catherine Geslain-Lanéelle
Executive Director, EFSA

Dear delegates,

It gives me great pleasure to welcome you to Parma and to this scientific conference which EFSA has organised to mark its tenth anniversary. It provides a unique opportunity for many who have contributed to our scientific work over the past decade to share their experiences – a decade when we have seen significant advances in science and technology and during which EFSA's science has had to grow and adapt. Ten years is a pivotal birthday for any organisation and we are using the occasion not just as a retrospective exercise but to ensure that we have a vision on the challenges that lie ahead. This is essential in ensuring that our science remains fit for purpose and meets the expectations of risk managers.

The title we have chosen, "Challenging boundaries in risk assessment: sharing experiences", in many ways captures the essence of our work: faced with new and emerging technologies, we indeed frequently find ourselves pushing the boundaries of risk assessment and in doing so we work closely with more than 1,000 scientists who contribute to EFSA's annual work programme.

Our organising committee has put together a stimulating mix of speakers and topics which we trust will provide ample opportunity for discussion over the next two days. For an organisation like EFSA, tasked with scientifically assessing food-related risks, staying at the forefront of the science is paramount. We are very fortunate to gather together many of the leading experts in risk assessment, not just from Europe but also from across the globe, to discuss some of the most challenging issues that risk assessors are facing.

Before I finish, I would like to pay tribute to all those scientists who have contributed – and those who continue to contribute – to our work over the past decade and who have helped us to fulfil our mission in protecting European consumers. Your contribution is greatly appreciated, not just by EFSA, but by the 500 million citizens across Europe who enjoy safe, nutritious food on their plates thanks in large measure to your expertise and public spiritedness.

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FOREWORD

Hubert Deluyker
Director of Science Strategy and Coordination, EFSA

Ten years ago the European Union unveiled a new regulatory framework to ensure the safety of food and feed across Europe – one that would inspire confidence in the decision-making processes underpinning food law, their basis in science and the independence of the institutions protecting public health.

Since its inception in 2002, EFSA's scientific advice has been central to European decision-making on the protection of the consumer against threats in the food chain.

Over the past decade the Authority has developed guidance aimed at harmonising and modernising methodologies related to risk assessment of food and feed. Our Scientific Committee has clarified the horizontal fundamentals of risk assessment – for example, with guidance on data validation and uncertainty – whilst at the same time innovating in specific vertical areas such as mammalian toxicology (with the benchmark dose approach, and the margin of exposure approach for compounds that are both genotoxic and carcinogenic).

In the past years, the Authority's operating context has evolved considerably, driven by, for example, scientific and technological advancement and the changing legislative framework. To deal with this EFSA has developed a science strategy.

These evolutions are already reflected in EFSA's scientific work programme where in recent years the emphasis has increased towards the evaluation of regulated products and more prominent attention to the assessment of environmental risk, risk-benefit and the post-market monitoring of authorised products.

These trends, are not only affecting the nature and volume of EFSA's work but also its risk assessment methods, and major evolutions in the methodologies used for safety assessments are expected in the years ahead.

As outlined in EFSA's Science Strategy 2012-2016, EFSA aims to continue to help set the pace in the development of state-of-the-art methodologies while maintaining a predictable regulatory environment. We can achieve this ambition only through continued scientific dialogue and debate in the wider scientific community. This conference aims to address this need. Due to the continuous evolutions in regulatory science that can be anticipated, we propose to meet on a regular basis, e.g. every two years to continue this scientific exchange.

I wish you a productive and enjoyable conference.

PROGRAMME

MORNING 09.00 – 12.30 INTRODUCTORY PLENARY SESSION

WEDNESDAY 7 NOVEMBER 2012

Introductory Plenary Session		Chairs: *Per Bergman, European Food Safety Authority (EFSA)* and *Diane Benford, Food Standards Agency, UK*

Room 1		
08.15 – 09.00	Registration participants	
09.00 – 09.10	Welcome by EFSA's Executive Director	*Catherine Geslain-Lanéelle, Executive Director, European Food Safety Authority (EFSA)*
09.10 – 09.30	Opening of the conference – Is food too risky to eat?	*Anne Glover, Chief Scientific Adviser, European Commission*
09.30 – 09.50	Advancing regulatory science, innovation and scientific excellence to support public health	*Jesse Goodman, Food and Drug Administration (FDA), USA*
09.50 – 10.10	Looking back: 10 years of risk assessment development in EFSA	*Vittorio Silano, University of Rome II, Italy*
10.10 – 10.30	EFSA Science Strategy 2012 – 2016	*Hubert Deluyker, European Food Safety Authority (EFSA)*
10.30 – 11.10	Coffee/Tea Break	
11.10 – 11.30	Achieving fit-for-purpose risk assessments	*Steve Hathaway, New Zealand Ministry of Primary Industries, New Zealand*
11.30 – 11.50	Public health-based risk ranking of (microbial) hazards in the food chain	*Arie H. Havelaar, RIVM and Utrecht University, The Netherlands*
11.50 – 12.10	Integrating new methodologies: Challenges for risk assessment, food policy and communication	*Thomas Burke, Johns Hopkins University, USA*
12.10 – 12.30	New frontiers in dietary exposure assessment	*Mike Gibney, University College Dublin, Ireland*
12.30 – 14.00	LUNCH	

AFTERNOON 14.00 – 17.30 PARALLEL SESSIONS

WEDNESDAY 7 NOVEMBER 2012

Parallel Session 1 Identifying and characterising hazards: new trends	Coordinator: Anna F. Castoldi	Chair: *Claudia Heppner, European Food Safety Authority (EFSA)* Rapporteur: *Alan Reilly, Food Safety Authority of Ireland*

Room 1		
14.00 – 14.20	1. Microbe: host, food interactions, implications for food safety	*Colin Hill, University College Cork, Ireland*
14.20 – 14.30	*Discussion*	
14.30 – 14.50	2. Chemical hazard in food and feed safety	*Johanna Fink-Gremmels, Utrecht University, The Netherlands*
14.50 – 15.00	*Discussion*	
15.00 – 15.20	3. REACH: how to deal with 30,000 chemicals	*Pilar Rodríguez Iglesias, European Chemicals Agency (ECHA)*
15.20 – 15.30	*Discussion*	
15.30 – 16.00	Coffee/Tea Break	
16.00 – 16.20	4. Comparative risk assessment strategies for food and feed derived from genetically modified plants and future challenges	*Harry Kuiper, (retired) formerly RIKILT, Wageningen University & Research Centre, The Netherlands*
16.20 – 16.30	*Discussion*	
16.30 – 16.50	5. Transitioning from the current paradigm for chemical risk assessment	*Alan Boobis, Imperial College London, UK*
16.50 – 17.00	*Discussion*	
17.00 – 17.20	6. Micro-RNAs and epigenetics in human pathology: a new paradigm for chemical-induced inherited effects?	*Timothy Gant, Health Protection Agency (HPA), UK*
17.20 – 17.30	*Discussion*	
18.00 – 20.00	COCKTAIL RECEPTION	

AFTERNOON 14.00 – 17.30 PARALLEL SESSIONS

WEDNESDAY 7 NOVEMBER 2012

Parallel Session 2 **Having an eye for the environment**	**Coordinator:** **Giuseppe Stancanelli**	**Chair:** ***Paulo Sousa, University of Coimbra, Portugal*** **Rapporteur:** ***Sarah Brunel, European and Mediterranean Plant Protection Organization (EPPO)***

Room 2		
14.00 – 14.20	1. Protection goals in environmental risk assessment	*Tony Hardy, Chair of the Scientific Committee, European Food Safety Authority (EFSA)*
14.20 – 14.30	*Discussion*	
14.30 – 14.50	2. Challenges pertaining to the comparative assessment of potential adverse effects of GM plants on non-target organisms	*Salvatore Arpaia, Italian National Agency for New Technologies, Energy and Economic Sustainable Development (ENEA), Italy*
14.50 – 15.00	*Discussion*	
15.00 – 15.20	3. Environmental risk assessment of plant pests integrating analysis of impacts on biodiversity and on ecosystem services	*Gianni Gilioli, University of Brescia, Italy*
15.20 – 15.30	*Discussion*	
15.30 – 16.00	Coffee/Tea Break	
16.00 – 16.20	4. Invasive species risks: can we predict the environmental consequences of biological invasions?	*Philip Hulme, Lincoln University, New Zealand*
16.20 – 16.30	*Discussion*	
16.30 – 16.50	5. What can environmental monitoring tell us about dioxin exposure via different kinds of food?	*Niklas Johansson, Karolinska Institutet and Swedish EPA, Sweden*
16.50 – 17.00	*Discussion*	
17.00 – 17.20	6. Environmental monitoring	*Peter Pärt, European Environment Agency (EEA)*
17.20 – 17.30	*Discussion*	
18.00 – 20.00	COCKTAIL RECEPTION	

AFTERNOON 14.00 – 17.30 PARALLEL SESSIONS

WEDNESDAY 7 NOVEMBER 2012

Parallel Session 3 **Making sense of dietary exposure**	Coordinator: **Davide Arcella**	Chair: ***Catherine Leclercq, Italian Agricultural Research Council, Italy*** Rapporteur: ***Christina Tlustos, Food Safety Authority of Ireland (FSAI)***

Room 3		
14.00 – 14.20	1. Dietary exposure assessments at EFSA: bridging past experience and future challenges	*Mary Gilsenan, European Food Safety Authority (EFSA)*
14.20 – 14.30	*Discussion*	
14.30 – 14.50	2. Use of short-term dietary data for the estimation of usual intake	*Victor Kipnis, National Cancer Institute, USA*
14.50 – 15.00	*Discussion*	
15.00 – 15.20	3. Total Diet Studies: providing more realistic occurrence levels for calculating exposure	*Ruth Charrondiere, Food and Agriculture Organisation (FAO)*
15.20 – 15.30	*Discussion*	
15.30 – 16.00	Coffee/Tea Break	
16.00 – 16.20	4. Probabilistic dietary exposure assessment	*Andy Hart, The Food and Environment Research Agency (Fera), UK*
16.20 – 16.30	*Discussion*	
16.30 – 16.50	5. Mixture identification from co-exposure modelling as a first step towards hazard characterisation	*Amélie Crépet, French Agency for Food, Environmental and Occupational Health and Safety (ANSES), France*
16.50 – 17.00	*Discussion*	
17.00 – 17.20	6. Biomarkers of exposure in food safety risk assessment	*Rudolf Kaaks, German Cancer Research Center (DKFZ), Germany*
17.20 – 17.30	*Discussion*	
18.00 – 20.00	COCKTAIL RECEPTION	

WEDNESDAY 7 NOVEMBER 2012

Parallel Session 4 **Expressing risks**	Coordinator: **Djien Liem**	Chair: ***Djien Liem, European Food Safety Authority (EFSA)*** Rapporteur: ***Qasim Chaudhry, The Food and Environment Research Agency (Fera), UK***

Room 4		
14.00 – 14.20	1. Trends in chemical risk assessment and integration of new methodologies	*Josef Schlatter, (retired) formerly Federal Office of Public Health, Switzerland*
14.20 – 14.30	*Discussion*	
14.30 – 14.50	2. Framing of risk assessment questions	*Takis Daskaleros, European Commission*
14.50 – 15.00	*Discussion*	
15.00 – 15.20	3. Fit for purpose risk assessment: qualitative vs quantitative approaches	*Angelika Tritscher, World Health Organization (WHO)*
15.20 – 15.30	*Discussion*	
15.30 – 16.00	Coffee/Tea Break	
16.00 – 16.20	4. Considering risks and uncertainties related to combined exposures	*Bette Meek, University of Ottawa, Canada*
16.20 – 16.30	*Discussion*	
16.30 – 16.50	5. A consistent and quantitative approach to risk-benefit assessment and risk ranking: the role of burden of disease estimates	*Alessandro Cassini, European Centre for Disease Prevention and Control (ECDC)*
16.50 – 17.00	*Discussion*	
17.00 – 17.20	6. Communicating risk and uncertainty: the role of metaphor and analogy	*David Spiegelhalter, University of Cambridge, UK*
17.20 – 17.30	*Discussion*	
18.00 – 20.00	COCKTAIL RECEPTION	

AFTERNOON 14.00 – 17.30 PARALLEL SESSIONS

WEDNESDAY 7 NOVEMBER 2012

Parallel Session 5 **Efficacy assessment in food and feed**	**Coordinator:** **Jaume Galobart**	**Chair:** ***Hildegard Przyrembel, (retired) formerly Federal Institute for Risk Assessment, Germany*** **Rapporteur:** ***Alberto Mantovani, Istituto Superiore di Sanità, Italy***

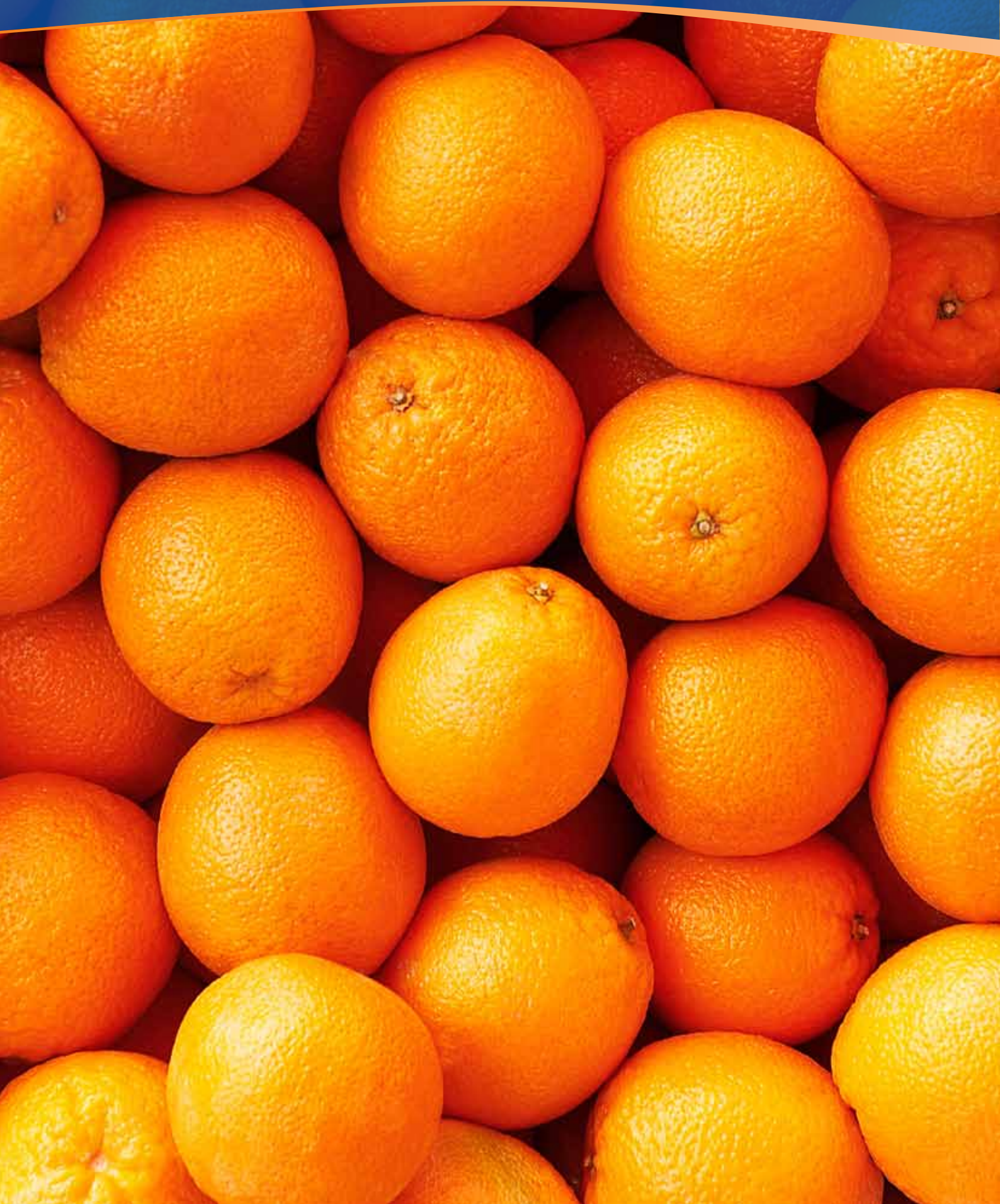
Room 5		
14.00 – 14.20	1. Assessment of scientific substantiation of health claims on foods in the EU	*Albert Flynn, University College Cork, Ireland*
14.20 – 14.30	*Discussion*	
14.30 – 14.50	2. Efficacy assessment experiences in the European Medicines Agency	*Francesco Pignatti, European Medicines Agency (EMA)*
14.50 – 15.00	*Discussion*	
15.00 – 15.20	3. Assessment of safety and efficacy for the target species: technological, sensory and nutritional feed additives	*Jürgen M. Gropp, University of Leipzig, Germany*
15.20 – 15.30	*Discussion*	
15.30 – 16.00	**Coffee/Tea Break**	
16.00 – 16.20	4. Assessment of safety and efficacy for the target species: zootechnical feed additives	*Andrew Chesson, University of Aberdeen, UK*
16.20 – 16.30	*Discussion*	
16.30 – 16.50	5. Efficacy requirements for the approval of new pesticides active substances	*Ingrid den Hoed, Chemicals Regulation Directorate, UK*
16.50 – 17.00	*Discussion*	
17.00 – 17.20	6. Criteria for the assessment of biocides in decreasing food-borne pathogens in food of animal origin	*Birgit Nørrung, University of Copenhagen, Denmark*
17.20 – 17.30	*Discussion*	
18.00 – 20.00	**COCKTAIL RECEPTION**	

MORNING 09.00 – 12.30 FINAL PLENARY SESSION

THURSDAY 8 NOVEMBER 2012

Final Plenary Session		Chairs: *Bernhard Url, European Food Safety Authority (EFSA)* and *Alicja Mortensen, Technical University of Denmark*
Room 1		
09.00 – 10.30	Feed-back from previous day	*Round table by chairs/rapporteurs from parallel sessions*
	Interventions from the floor	
10.30 – 11.15	Coffee/Tea Break	
11.15 – 11.45	The identification of future food safety risks	*Terry Donohoe, Food Standards Agency (FSA), UK*
11.45 – 12.00	Research and risk assessment: two sides of the same coin?	*Henrik Caspar Wegener, Technical University of Denmark*
12.00 – 12.30	Closing of conference	*Tony Hardy, Chair of the Scientific Committee, European Food Safety Authority (EFSA)* *Hubert Deluyker, European Food Safety Authority (EFSA)*
12.30	ADJOURN	

SESSION GUIDE



Introductory Plenary Session

Chair

PER BERGMAN
DIRECTOR OF SCIENTIFIC EVALUATION OF REGULATED PRODUCTS, EFSA

WEDNESDAY 7 NOVEMBER 2012
09.00 – 12.30
Room 1

Dr Per Bergman is Director of the Scientific Evaluation of Regulated Products directorate at EFSA. The directorate supports EFSA's work in evaluating substances, products and claims intended to be used in the food chain in order to give scientific opinion and advice to risk managers for the protection of public, plant and animal health as well as the environment. He joined EFSA in 2008 as head of the GMO Unit. Before joining EFSA, his career was based in the Swedish university and public sector, the most recent appointment being as senior scientific advisor on GMO issues at the Swedish Ministry of Agriculture.

Chair

DIANE BENFORD
FOOD STANDARDS AGENCY, UK

WEDNESDAY 7 NOVEMBER 2012
09.00 – 12.30
Room 1

Dr Diane Benford is head of the Chemical Risk Assessment Unit at the UK Food Standards Agency. The unit has overall responsibility for advice on possible adverse human health effects of all types of chemicals in food. Diane's role at the FSA also includes acting as scientific secretary to the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). In a personal capacity, she has been a member of the EFSA Scientific Panel on Contaminants in the Food Chain (CONTAM) since 2005, and was recently elected chair of the panel.

Welcome

CATHERINE GESLAIN-LANÉELLE
EXECUTIVE DIRECTOR, EFSA

WEDNESDAY 7 NOVEMBER 2012
09.00 – 09.10
Room 1

Catherine Geslain-Lanéelle has been EFSA's Executive Director since July 2006. Her renewed five-year mandate started on 1 July 2011.

In 2000, Ms Geslain-Lanéelle was appointed Director General of the Food Department within the French Agricultural Ministry at the height of the BSE crisis in France. She became Regional Director of Agriculture and Forestry for the Ile de France region in 2003. She has held a number of international positions and was Deputy Director of the French Department of International Trade from 1998 to 2000. She also worked at the European Commission from 1991 to 1993 as a National Expert in the area of food safety.

Catherine Geslain-Lanéelle has a Master of Science from the Institut National Agronomique Paris-Grignon and from the Ecole Nationale du Génie Rural, des Eaux et des Forêts.

Opening of the conference – Is food too risky to eat?

ANNE GLOVER
CHIEF SCIENTIFIC ADVISER,
EUROPEAN COMMISSION

WEDNESDAY 7 NOVEMBER 2012

09.10 – 09.30

Room 1

Professor Anne Glover was Chief Scientific Adviser for Scotland from 2006-11 before joining the European Commission in 2012 as Chief Scientific Adviser to the President. She is a personal chair of molecular and cell biology at the University of Aberdeen, Scotland, and her current research focuses on how organisms respond to stress at a cellular level.

She is an elected fellow of the Royal Society of Edinburgh, Society of Biology, Royal Society of Arts and the American Academy of Microbiology. She was recognised as a Woman of Outstanding Achievement in 2008 and was awarded a CBE for services to Environmental Science in 2009.

Advancing regulatory science, innovation and scientific excellence to support public health

WEDNESDAY 7 NOVEMBER 2012

09.30 – 09.50

Room 1

JESSE GOODMAN

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
U.S. FOOD AND DRUG ADMINISTRATION, USA

Revolutionary changes in diverse areas ranging from the life sciences to informatics to engineering and to social sciences and communications are converging and offer the potential for new approaches and technologies to transform medicine and public health globally. However, advances in basic sciences are not being efficiently translated into products that help people and populations. In fact, both how products are developed and how developers work with regulatory agencies to evaluate them largely remain dependent on approaches that have changed little in the last 40 years.

Transforming regulatory science, including the methods, tools and models used to assess product safety, efficacy and quality, offers tremendous potential to improve the speed, economics and predictive accuracy of product development and evaluation. The ecosystems of product development, science and health are complex, and transformative change requires engagement and ideas from all sectors. This presentation will review key priorities from the FDA's Strategic Plan for Regulatory Science and selected recent and ongoing activities, including through collaboration and partnerships, to help enable change that can bring needed products to people more quickly, safely, and economically.

JESSE GOODMAN

Dr Jesse Goodman is Chief Scientist at the Food and Drug Administration in the Department of Health and Human Services. Before joining the FDA, he was Professor of Medicine and Chief of Infectious Diseases at the University of Minnesota, where his laboratory isolated *Anaplasma phagocytophilum*, agent of a new tick-borne disease. He has been elected to the American Society for Clinical Investigation and the Institute of Medicine of the National Academy of Sciences. He is an active clinician, board certified in medicine, oncology and infectious diseases, and is Infectious Diseases Consultant at the Walter Reed National Medical Centers and the National Institutes of Health.

Looking back: 10 years of risk assessment development in EFSA

WEDNESDAY 7 NOVEMBER 2012

09.50 – 10.10

Room 1

VITTORIO SILANO

UNIVERSITY OF ROME II, ITALY

By June 2012, more than 3,000 scientific outputs had been published in the EFSA Journal. As many as 2,200 of these outputs were scientific opinions adopted by EFSA's Scientific Committee and ten Scientific Panels in their respective areas of competence. The remaining ones are mainly technical reports on related issues.

EFSA's work in risk assessment has been characterised by three main approaches: reviewing, updating and harmonising existing methodologies and developing new methodologies, when needed; carrying out a public consultation on each methodology developed, paying careful attention to all relevant contributions received and formally adopting the resulting methodology through a scientific opinion providing the background for the elements characterising the guidance documents; and applying the methodologies developed in reply to requests for opinions or identified by self-tasking, and systematically assessing, internally and externally, the quality of the work carried out. This approach has resulted in the adoption by EFSA of as many as 100 innovative risk assessment methodologies in 10 years and to their application to thousands of specific issues. This presentation deals with some distinctive features and results of this fundamental activity that has made a major contribution to improving risk assessment in the food/feed sector at a European level and worldwide.

VITTORIO SILANO

Vittorio Silano is contract professor at the University of Rome II and member of the EFSA CONTAM Panel. He was chair of EFSA's Scientific Committee for nine years. Between 1968 and 1982, Mr Silano was a researcher at the Italian Institute of Health in Rome and between 1982 and 1986 Director of the Laboratory of Toxicology. Between 1989 and 2008, he worked at the Italian Ministry of Health where he was first Director General of several technical Directorates and then head of the Department for Human Health Protection, Veterinary Public Health and International Relations. Mr Silano has been a member of several editorial boards of scientific journals.

EFSA Science Strategy 2012 – 2016

WEDNESDAY 7 NOVEMBER 2012

10.10 – 10.30

Room 1

HUBERT DELUYKER

DIRECTOR OF SCIENCE STRATEGY AND COORDINATION, EFSA

Ten years ago, EFSA was established as the independent risk assessment body of the European Union. Since then, EFSA has published over 2,500 scientific outputs which enabled the most appropriate decision-making to protect consumers. These have had a significant impact both on regulated products, and on general public health issues like zoonoses or contaminants. In a space of a decade European food safety has made resounding progress.

However, in the intervening years, the Authority's operating context has evolved considerably, marked, for example, by advancements in the scientific and technological environment as well as by changes in the European and International legislative framework.

In developing its science strategy for 2012-2016, EFSA took into account the evolutions raised above and has identified four key strategic objectives which will provide the focus for its scientific activities over the coming five years.

These are:

- further develop excellence of EFSA's scientific advice;
- optimise the use of risk assessment capacity in the EU;
- develop and harmonise methodologies and approaches to assess risks associated with the food chain;
- strengthen the scientific basis for risk assessment and risk monitoring.

This strategy will ensure that EFSA can continue to support the future European food safety system through up-to-date, science-based risk assessments. It will thereby contribute to improving the health and welfare of humans and animals as well as plant health, fulfilling EFSA's mission to protect consumers and providing food operators with a predictable regulatory environment. As a result, technological innovation and sustainable growth will be fostered.

Looking forward, we will strive to ensure that scientific assessment evolves and develops to meet the critical challenges that lie ahead in an ever-changing environment. The strategy will thus remain a "live document", regularly reviewed to be in line with changes in the working environment.

HUBERT DELUYKER

Dr Hubert Deluyker is EFSA's Director of Science Strategy and Coordination. The directorate coordinates the implementation of EFSA's Science Strategy and reinforces engagement and cooperation with stakeholders and international partners.

Dr Deluyker joined EFSA in 2004. He established and was acting head of EFSA's Assessment Methodology Unit (currently Scientific Assessment Support Unit) prior to becoming the Director of EFSA's former Scientific Co-operation and Assistance Directorate from 2007 to May 2011, and Director of the Risk Assessment and Scientific Assistance Directorate from May to October 2011.

From 1989 to 2004 he was a clinical research scientist in the field of animal health for Pfizer Belgium, where he led a range of multidisciplinary and multinational research and development projects.

Achieving fit-for-purpose risk assessments

WEDNESDAY 7 NOVEMBER 2012

11.10 – 11.30

Room 1

STEVE HATHAWAY

NEW ZEALAND MINISTRY OF PRIMARY INDUSTRIES

Following the signing of the World Trade Organisation Sanitary and Phytosanitary Agreement in the mid-1990s, food safety risk assessment has benefited from a decade or so of academic experience, particularly in the case of biological hazards. During this time, competent authorities in different countries have become increasingly open in sharing practical experiences in risk analysis and this has been assisted by the facilitatory role of FAO and WHO in developing generic risk-based models for specific hazard/food commodity combinations e.g. *Campylobacter* in broiler chickens, *Cronobacter sakazakii* in powdered infant formula.

While specific risk estimates still suffer from biological variability in inputs and model uncertainty, risk managers are increasingly finding value in relative risk estimates and ranking of the impact of different interventions as the evidence base for risk management decisions. Achieving "fit-for-purpose" risk assessments in such circumstances benefits from recognition of the importance of well-formulated risk management questions, as well as taking a flexible approach to the risk assessment methodology that is applied in generating answers.

In some cases, simple spreadsheet models for hazard levels in different segments of the food chain may effectively substitute for more detailed probabilistic models covering all steps in the food chain.

STEVE HATHAWAY

Professor Steve Hathaway trained as a veterinarian, followed by many years working on regulatory aspects of food safety with a particular interest in risk analysis and applied research to support standard development. As Director (Science and Risk Assessment), he leads a group of more than 40 scientists that provide science and risk assessment inputs on food safety and biosecurity (animal and plant health) matters to the New Zealand Ministry of Primary Industries. He has had extensive involvement with Codex, OIE, FAO and WHO in developing regulatory aspects of risk analysis, international standard setting and practical approaches to judgement of the equivalence of different food control systems. He chairs the Codex Committee on Milk and Milk Products.

Public health-based risk ranking of (microbial) hazards in the food chain

WEDNESDAY 7 NOVEMBER 2012

11.30 – 11.50

Room 1

ARIE H. HAVELAAR

RIVM AND UTRECHT UNIVERSITY,
THE NETHERLANDS

Priority setting is of increasing importance in risk-based food safety management. Finite resources and a steadily growing number of concerns require structured and transparent processes to decide on resource allocation, both with regard to risk assessment as well as to risk management.

A large number of tools have been proposed to support risk-based priority setting. They vary from simple decision trees to complex modelling approaches. Even though every question is unique, and may require a unique approach, there is a need for developing a toolbox to assist in priority setting that is applicable under different constraints in relation to time, budget and data needs.

This presentation will give a general overview of risk ranking methodologies, followed by several examples in the domain of microbiological hazards. These examples will be based on the author's work on prioritising food-borne diseases and emerging zoonoses, as well as on the experiences of EFSA's Scientific Panel on Biological Hazards and the international literature. The applicability of these approaches to other domains of food safety will be discussed.

ARIE H. HAVELAAR

Arie Havelaar is deputy head of the Laboratory for Zoonoses and Environmental Microbiology at the National Institute for Public Health and the Environment (RIVM) in Bilthoven and professor of microbial risk assessment at the Institute for Risk Assessment Sciences at the Veterinary Faculty of Utrecht University. He is vice-chair of EFSA's Scientific Panel on Biological Hazards and chair of the WHO Food-borne Disease Burden Epidemiology Reference Group.

Mr Havelaar graduated in chemical engineering with a specialisation in technical microbiology at the Delft University of Technology. He obtained his PhD at Utrecht University and an MSc in epidemiology at the Netherlands Institute of Health Sciences.

Integrating new methodologies: Challenges for risk assessment, food policy, and communication

WEDNESDAY 7 NOVEMBER 2012

11.50 – 12.10

Room 1

THOMAS BURKE

JOHNS HOPKINS UNIVERSITY,
BLOOMBERG SCHOOL OF PUBLIC HEALTH, USA

Advances in toxicity testing, chemical monitoring, and risk assessment methods have major implications for the future of food safety policy and practice. The US National Academy of Sciences report *Science and Decisions (The Silver Book)* provides a roadmap for the future of hazard identification, risk assessment, and risk management.

This presentation will outline the major recommendations of this report and discuss the implications and challenges for regulatory and public health agencies, and the food industry. Issues will include application of new toxicity screening tests to develop "bright lines" for determining safe levels of chemical contaminants or additives. Are old assumptions about human health thresholds valid in light of newer more sensitive methods to detect effects? How will new measurements of potential toxicity be applied to food protection?

Interpretation of emerging testing results will be a major challenge, including the determination and communication of the human health implications. New approaches to cumulative risks of multiple exposures and the consideration of the range of susceptibility in populations will also be discussed. The credibility of food protection efforts will depend upon the effective translation of evolving science to decision makes and the public. New approaches to risk assessment and management can provide the foundation for progress.

THOMAS BURKE

Thomas Burke is Associate Dean and Professor of Health Policy at the Johns Hopkins Bloomberg School of Public Health. He directs the Hopkins Risk Sciences and Public Policy Institute. Dr Burke was previously Deputy Commissioner of Health for the State of New Jersey. He is a member of the US EPA Science Advisory Board and chaired several National Academy of Sciences committees including the Committee on Improving Risk Analysis Approaches which produced the report *Science and Decisions*. He is a fellow of the Society for Risk Analysis and a lifetime national associate of the National Academies.

New frontiers in dietary exposure assessment

WEDNESDAY 7 NOVEMBER 2012
12.10 – 12.30
Room 1

MIKE GIBNEY
INSTITUTE OF FOOD & HEALTH,
UNIVERSITY COLLEGE DUBLIN, IRELAND

Dietary exposure to chemical substances (additives, pesticides, veterinary drug residues, food packaging materials, flavouring and contaminants) is a key step in the process of their safety evaluation. Screening techniques that have been used to date at European level are showing their limitations and there is a need for more refined assessments of dietary exposure. These need to take into account the high variability in food consumption among countries and the variability in occurrence of chemicals in foods available on the market.

Simple crude estimates of exposure will remain important, but refined exposures are also needed not just in actual exposure measurements, but also in scenario building in the area of innovation in food chemical intake. Industry involvement is essential in developing datasets for refined probabilistic modelling as is the harmonisation of databases across member states. This presentation will cover the background to food chemical intake exposure but will also cover the output of the largest publicly funded project, FACET (www.ucd.ie/facet), co-funded by industry. This project focuses on a validated and publicly available piece of software for the estimation of human exposure to food additives, food contact materials and flavouring substances.

MIKE GIBNEY

Michael Gibney is Professor of Food and Health at University College Dublin and is Director of the UCD Institute of Food and Health. He is a former president of the Nutrition Society. He served on the EU's Scientific Committee on Food from 1985 to 1997 and then chaired the BSE working group as a member of the Scientific Steering Committee of the EU from 1997 to 2000. His research interests lie in metabolic and molecular nutrition, in public health nutrition and in probabilistic risk analysis. Professor Gibney has served in the faculties of the University of Sydney, the University of Southampton and Trinity College Dublin. He has published over 250 peer reviewed papers.

Parallel Session 1
Identifying and characterising hazards: new trends

Chair

CLAUDIA HEPPNER
HEAD OF THE FOOD INGREDIENTS AND PACKAGING UNIT (FIP), EFSA

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 1

Dr Claudia Heppner is the head of the Food Ingredients and Packaging Unit (FIP) at EFSA. She joined EFSA in 2002 and has been the head of the Unit on Contaminants (CONTAM) and served as acting Director of the Risk Assessment and Scientific Assistance (RASA) Directorate.

Before joining EFSA Claudia worked for the Secretariat of the European Commission's Scientific Committee on Food and for an international life science company in the area of fungicide discovery and product development where she managed several multidisciplinary research projects.

She holds a PhD in agricultural sciences from the Georg-August-University Göttingen, Germany, a degree in rural economics from the University of Kassel-Witzenhausen and diploma in agricultural sciences from the Georg-August-University Göttingen.

Rapporteur

ALAN REILLY
FOOD SAFETY AUTHORITY OF IRELAND

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 1

Professor Alan Reilly is chief executive of the Food Safety Authority of Ireland and adjunct associate professor at the Institute of Food and Health, University College, Dublin. A graduate of University College, Dublin and of Brunel University, UK, he has worked for over 38 years in the area of food safety. Before joining the FSAI in 1999, he worked in the Food Safety Programme of the World Health Organization in Geneva. He has worked at the Natural Resources Institute of the University of Greenwich, UK, and as a visiting associate professor at the College of Fisheries, University of the Philippines. He is a member of the Advisory Forum of the European Food Safety Authority and a board member of the Irish National Accreditation Board. He is also the chairman of the Scientific Advisory Board of the European Food Information Council. He acts as an adviser to national and international food safety organisations.

Microbe: host, food interactions, implications for food safety

WEDNESDAY 7 NOVEMBER 2012

14.00 – 14.20

Room 1

COLIN HILL

UNIVERSITY COLLEGE CORK,
IRELAND

It is surprisingly difficult to predict the outcome when a contaminated meal is consumed. Some individuals may have no symptoms, others may become sick and others may even die. What are the variables which contribute to this heterogeneity in outcomes? Obviously the health and age of the host and the identity and amount of the contaminating microbe consumed are key variables (and underpin much of the food safety legislation in this area), but there will also be other important factors which may not always be given the appropriate level of attention by regulators. To what extent should we consider the recent history of the contaminating organism, strain variability and even food constituents as important factors in assessing the risk to consumers?

In this presentation I will outline the importance of strain to strain variability, the impact of the recent challenges overcome by the contaminating organism, and the role of food constituents in affecting the outcome of an interaction between a pathogen and a host. Should we be looking towards food safety regulations which can take these factors into account?

For example, *Listeria monocytogenes* is usually unable to cope with gastric acid and will be rapidly inactivated during gastric transit. However, in the presence of glutamate – a common component of many diets – the pathogen can easily translocate the stomach and cause disease. But not all *Listeria* can perform this strategy. Should risk assessment guidelines include aspects such as dietary components and genetic variability?

COLIN HILL

Colin Hill is Professor of Microbial Food Safety in the Microbiology Department of University College Cork, Ireland. His main interests are in infectious disease, particularly in defining the mechanisms of virulence of food-borne pathogens and in developing strategies to prevent and limit the consequences of microbial infections in the gastrointestinal tract. He has published more than 300 peer-reviewed papers. In 2005 Professor Hill was awarded a DSc by the National University of Ireland in recognition of his contributions to research. In 2009 he was elected to the Royal Irish Academy and in 2010 he received the Metchnikoff Prize in Microbiology.

Chemical hazard in food and feed safety

WEDNESDAY 7 NOVEMBER 2012

14.30 – 14.50

Room 1

JOHANNA FINK-GREMMELS

INSTITUTE FOR RISK ASSESSMENT SCIENCES,
UTRECHT UNIVERSITY, THE NETHERLANDS

Food and feeds are composed of numerous chemical substances and only a few are identified as a chemical hazard based on the mode of action (MOA) and toxicokinetic profile. Chemical substances in food and feed can be allocated to two categories: chemicals that are intentionally used in food and feed production, and contaminants.

For intentionally used chemicals, such as production aids and additives, a rich data set covering all established toxicological endpoints and their dose-dependency is requested from the applicant during the pre-marketing approval process that determines the rules for safe application. Remaining scientific challenges are the assessment of the toxicological relevant internal dose in humans, which depends on the inter-individual variability of ADME parameters (population kinetics), and apparent non-linearity in the extrapolation between external and internal dose, particularly in individuals with chronic diseases. Moreover, non-conventional endpoints such as the effect of chemicals on endogenous microbiota, biofilm formation, antimicrobial resistance, as well as immuno-modulatory effects under real-life conditions, become part of chemical hazard identification.

In contrast to intentionally used substances, the available data for chemical contaminants is highly variable. For heavy metals and certain polyhalogenated aromatic substances , the data base is rich, whereas it is often extremely limited for natural substances such as secondary plant, fungal and bacterial metabolites. Historically, hazard identification focused on substances with genotoxic and potential carcinogenic properties. Recently, endpoints such as developmental (neuro) toxicity, endocrine and immunological effects have gained increasing attention. Current interest focuses on MOA-based assessment of complex mixtures of chemical hazards, the identification of concomitant routes of exposure including occupational exposure and the indoor environment, and new technologies such as nanotechnology.

JOHANNA FINK-GREMMELS

Johanna Fink-Gremmels qualified as a veterinarian in Hannover, Germany, and later as a European veterinary specialist in pharmacology and toxicology. In 1985 she was appointed director for food toxicology in the Federal Research Institute for Meat Research of the Ministry of Food, Agriculture and Consumer Protection, Germany. She became a full professor at Utrecht University, the Netherlands, in 1991. She is involved in various professional organisations and served on the Scientific Committee for Veterinary Measures related to Public Health of DG SANCO and for nine years on EFSA's Panel on Contaminants in the Food Chain (CONTAM).

REACH: how to deal with 30,000 chemicals

WEDNESDAY 7 NOVEMBER 2012

15.00 – 15.20

Room 1

PILAR RODRÍGUEZ IGLESIAS

EUROPEAN CHEMICALS AGENCY (ECHA)

The overall purpose of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation is to ensure a high level of protection of human health and the environment. Industry has to ensure that chemical substances are used safely. This is achieved by using information on the properties of substances to assess their hazards both for classification and risk assessment, and hence to develop appropriate risk management measures to protect human health and the environment. The European Chemicals Agency (ECHA) is the central body implementing REACH.

In addition, REACH promotes the use of alternatives to testing on animals for the assessment of hazards. It has shifted the responsibility for establishing the safe use of chemicals to companies manufacturing and importing chemicals as a substance on their own, in mixtures or in articles in the EU. Substances produced or imported at one tonne or more per annum must be registered and their safe use demonstrated in a registration dossier.

Evaluation assists companies in achieving compliance with REACH. It verifies the adequacy of the information provided in registration dossiers and helps to identify potential substances requiring EU-wide risk management. This is achieved by generating information on the properties of the substances, identifying the uses, assessing the risks involved, and recommending appropriate risk management measures.

A key motivation for developing REACH was to fill information gaps for the large number of substances already in use in the EU, as for many there was inadequate information on their hazards and risks they pose. REACH registrants have to provide information on the intrinsic properties and hazards of the substance in the registration dossier. The standard information required depends on the tonnage manufactured or imported; the higher the tonnage, the more information needed. In addition for substances at 10 tonnes per annum or above, the registration dossier must include a chemical safety report (CSR).

This presentation summarises the current experience under REACH and addresses the scientific challenges in getting high-quality information to enable safe manufacture and use of chemicals, as well as using data intelligently to identify and address chemicals of concern.

**The author is a staff member of the European Chemicals Agency. The views expressed are solely the author' views and do not represent an official position of the Agency.*

PILAR RODRÍGUEZ IGLESIAS

Pilar Rodríguez Iglesias is head of the European Chemicals Agency (ECHA) Unit Committees Secretariat, which provides the Secretariat and chairs of the ECHA committees. Before joining ECHA, she was head of the European Food Safety Authority's Unit on Dietetic Products, Nutrition and Allergies and associate R&D manager at Nestlé Research Centre in Lausanne, Switzerland. She is a medical doctor by training specialising in gastroenterology and hepatology.

Comparative risk assessment strategies for food and feed derived from genetically modified plants and future challenges

WEDNESDAY 7 NOVEMBER 2012

16.00 – 16.20

Room 1

HARRY KUIPER

(RETIRED) FORMERLY INSTITUTE OF FOOD SAFETY, RIKILT, WAGENINGEN UNIVERSITY & RESEARCH CENTRE, THE NETHERLANDS

The EFSA GMO Panel has developed a robust and systematic approach for the risk assessment of genetically modified plants (GMPs) and derived food and feed, and for the assessment of their environmental impact. These contributions have evolved the well-known concepts of substantial equivalence and of familiarity to provide practical guidance. The strategy is based on an analysis of the genetic modification process and a comparison of the characteristics of the GMP with a non-modified conventional counterpart (comparator) with a well-established history of safe use. Criteria have been developed for the selection of appropriate comparators for GM plants containing single or stacked events, and for the design, performance and analysis of field trials. Furthermore, strategies have been designed for the toxicological and allergenicity assessment of newly or differently expressed proteins, and for the safety assessment of new constituents, of modified levels in the content of natural food and feed constituents, and of whole GM food/feed.

New and rapidly evolving plant breeding techniques pose new challenges for risk assessment of GMPs. EFSA is addressing whether there is a need for new or updated guidance for risk assessment, and what risks the new techniques could pose for humans, animals and the environment, irrespective of whether or not they fall under the GMO legislation.

The development of new GM crops may require further adjustment of current risk assessment strategies, particularly as GMPs become available with tolerance to abiotic stress (drought, salinity) or with altered compositional traits (changed fatty acid profile, high amylopectin starch, elevated vitamin levels). In certain cases appropriate comparators may not be available for a comparative risk assessment, and thus a strategy for a comprehensive safety and nutritional assessment of the derived food/feed products should be developed.

HARRY KUIPER

Dr Harry Kuiper is a retired scientist from the Institute of Food Safety, RIKILT, Wageningen University & Research Centre, the Netherlands. He studied food science at the Agricultural University Wageningen, completed a PhD study at the University of Groningen on structure-function relationships of hemocyanins and worked in the medicine department at the University of Rome. He was member of the EU Scientific Committee on Plants from 1997-2003, and chaired the EFSA Scientific Panel on Genetically Modified Organisms from 2003-2012. He has been co-ordinator of EU-funded projects regarding food safety.

Transitioning from the current paradigm for chemical risk assessment

WEDNESDAY 7 NOVEMBER 2012

16.30 – 16.50

Room 1

ALAN BOOBIS

IMPERIAL COLLEGE LONDON, UK

Current toxicity testing is relatively effective in protecting human health. However, toxicology is undergoing a profound paradigm shift. There are too many chemicals to test using conventional approaches, animal models may not be predictive of all endpoints, combined exposures need to be evaluated, and biological knowledge has advanced markedly, all leading to the need for new approaches to toxicity testing.

This will require a new generation of *in silico* and *in vitro* methods, where perturbations of toxicity pathways are identified and effects in vivo are predicted using physiologically based models. Conventional validation will not be appropriate and hence there will need to be agreement on how the tests will be assessed for reliability. Toxicity testing should be proportionate to the potential degree of concern.

More consideration will need to be given to margin of exposure, taking into account relevant human exposure, mode of action and uncertainty. Challenges include the use of tiered approaches within a regulatory environment, how to assess the utility and added value of new approaches, how best to integrate the old with the new, how to interpret and communicate risk assessments based on probabilities rather than deterministic values, and how to communicate uncertainty, particularly as it is often not symmetric about the risk estimate.

ALAN BOOBIS

Alan Boobis is professor of biochemical pharmacology at Imperial College London and director of the Health Protection Agency's Toxicology Unit. His research interests include drug metabolism, chemical carcinogenesis and mechanisms of toxicity. He has published over 220 original papers and is a member of several national and international expert advisory committees on chemical risk assessment. He obtained an OBE in 2003 for his work on the risk assessment of pesticides.

Micro-RNA's and epigenetics in human pathology: a new paradigm for chemical-induced inherited effects?

WEDNESDAY 7 NOVEMBER 2012

17.00 – 17.20

Room 1

TIMOTHY GANT

HEALTH PROTECTION AGENCY (HPA), UK

MicroRNA (miRNAs) are short RNA sequences that have an important role in the control of gene expression through regulation of protein translation rate from mRNAs. As such they provide a means by which the cell can rapidly synthesise new protein from pre-existing mRNAs in response to a cellular stress.

MiRNA genes are located in the genome primarily within the intronic regions of protein coding genes or within separate genomic regions called polycistrons. In either case their transcription is controlled from promoters whose activity can be influenced by chemicals or pathophysiological processes either via transcription factors or epigenetic modification. There is a substantial quantity of published data showing the role of miRNAs in physiology, pathophysiological processes and cellular responses to many forms of chemical toxicity.

Finally, some miRNAs are transferred on fertilisation where they have the potential to influence phenotype in the embryo. It has been hypothesised that this may occur through a role for miRNAs in controlling the demethylation and remethylation cycle that occurs during gamete formation and after fertilisation. In this short talk some of these roles will be reviewed and their potential relevance for chemical toxicity discussed.

TIMOTHY GANT

Dr Tim Gant is head of the Health Protection Agency's Toxicology Department, visiting Professor at the University of Surrey, UK, and a research fellow at Imperial College. The Department of Toxicology (approximately 45 staff) consists of six groups: Nanoparticle Inhalation Research, General Toxicology, Xenobiotic Toxicity, Air Pollution, Internal Dosimetry, and Biomathematics. He has served on the External Scientific Advisory Panel of the European Chemical Industry Council for seven years and chaired for four of those years. He is currently chair of the Scientific Sub-committee of the British Toxicological Society and a member of the Executive Committee.

Parallel Session 2
Having an eye for the environment

Chair

PAULO SOUSA
DEPARTMENT OF LIFE SCIENCES,
UNIVERSITY OF COIMBRA, PORTUGAL

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 2

Professor Paulo Sousa has worked at the University of Coimbra since 2003. With over 90 papers published, his main research topics involve: effect assessment of PPPs towards soil fauna in Mediterranean and tropical systems (single species and micro/mesocosm tests); assessment of the ecological relevance (and effects) of soil-water transfer pathways of PPPs in Mediterranean and tropical systems; development and implementation of trait-based approaches for RA of PPPs in soil and evaluation of the interaction of PPPs and climate change on soil organisms and soil processes. He has worked with EFSA for more than five years and joined the PPR Panel in 2009.

Rapporteur

SARAH BRUNEL
EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION (EPPO)

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 2

Sarah Brunel trained as an agronomist and has worked for the last seven years for the European and Mediterranean Plant Protection Organisation, which provides recommendations on plant health to its 50 member countries. At EPPO, Ms Brunel is in charge of invasive alien plants, pest risk analysis, environmental issues and modelling. She is also an expert for the IUCN Species Survival Commission, the European Environment Agency and the Bern Convention.

Protection goals in environmental risk assessment

WEDNESDAY 7 NOVEMBER 2012

14.00 – 14.20

Room 2

TONY HARDY

CHAIR OF THE SCIENTIFIC COMMITTEE, EFSA

Protection goals for the environmental risk assessment (ERA) of plant protection products are described in European legislation in a general way but specific protection goals (SPGs) are not defined precisely. However they are crucial for designing appropriate risk assessment schemes.

EFSA's Panel on Plant Protection Products and their Residues (PPR) was tasked with developing and updating guidance on the ERA of pesticides, which required identifying SPGs to develop targeted risk assessment schemes. The ecosystem services approach was identified and used as an overarching concept to develop specific protection goals. Options for seven key drivers for ecosystem services – microbes, algae, non target plants (aquatic and terrestrial), aquatic invertebrates, terrestrial non target arthropods including honeybees, terrestrial non-arthropod invertebrates, and vertebrates – were developed for those ecosystem services that could potentially be affected by the use of pesticides. Such SPGs need to be defined in six dimensions: biological entity, attribute, magnitude, temporal and geographical scale of the effect, and the degree of certainty that the specified level of effect will not be exceeded. Protection may be at the population, individual or functional group level. Biodiversity impacts need to be assessed at least at the scale of the watershed/landscape. Examples of derived protection goals for aquatic organisms, in-soil organisms and bees will be discussed. This approach has applications beyond pesticides and may offer a way forward to focus risk assessment where legislated protection goals are not adequately defined.

TONY HARDY

Professor Tony Hardy has more than 35 years of risk assessment experience on national and international regulatory pesticide and food safety committees. After degrees at Oxford and Aberdeen Universities, in 1976 he joined the UK Ministry of Agriculture, Fisheries and Food central laboratories, which became the Central Science Laboratory Agency in 1990, and retired as Science Director in 2009. He chaired the EC Scientific Committee on Plants for five years prior to the establishment of EFSA in 2002. He chaired the EFSA Plant Protection Products and their Residues (PPR) Panel for nine years and is now chair of the Authority's Scientific Committee.

He has a scientific background as a research ecologist, environmental chemist and ecotoxicologist, and the main areas of his research and risk assessment experience are in the environmental impact of agricultural chemicals (pesticides) on wildlife, the development of field trials and methods to assess impact on individuals and populations, the environmental impact of farming systems on target and non-target wildlife, the environmental risk assessment of genetically modified organisms, and the wider food safety risk assessment of various chemical and biological agents, pathogens and contaminants.

Challenges pertaining to the comparative assessment of potential adverse effects of GM plants on non-target organisms

WEDNESDAY 7 NOVEMBER 2012

14.30 – 14.50

Room 2

SALVATORE ARPAIA

ITALIAN NATIONAL AGENCY FOR NEW TECHNOLOGIES, ENERGY AND ECONOMIC SUSTAINABLE DEVELOPMENT (ENEA), ITALY

One of the main concerns for a possible adverse environmental effect of the cultivation of genetically modified (GM) crops is the threat to the biodiversity in the environments where such plants will be cultivated. In particular, animal biodiversity could be at risk if non-target organisms that come in contact with GM plants and/or their products are harmed.

In agro-ecosystems, the preservation of functional biodiversity is an important protection goal in ecological terms, but it is also paramount for guaranteeing the sustainability of agriculture (i.e. providing ecological services such as plant pollination, natural pest control). In fact, it can be assumed that a significant change in biodiversity structure may result in a change in function; therefore, preserving functional biodiversity may guarantee the quality of agro-ecosystems. Increasing biodiversity is known to enhance agro-ecosystem resilience and stability and consequently to increase ecosystem functioning.

The approach of studying functional biodiversity to assess possible impact in agro-ecosystems is therefore an important principle underlying a science-based environmental risk assessment (ERA) and it is part of the rationale of several approaches, including the EFSA guidance documents on ERA for GM crops. A growing scientific literature is strengthening confidence in existing ERA results, however there are challenges that need to be considered in evaluating the biosafety of GM events. How to consider the specificity of receiving environments, the definition of specific environmental protection goals, the availability of experimental protocols and models supporting the estimates of long-term effects are the main areas where additional scientific results may further improve ERA. In the EU due to the complex nature of landscapes, the proximity of agricultural areas to (semi-) natural habitats suggests that possible consequences in nearby habitats also need to be considered.

SALVATORE ARPAIA

Professor Salvatore Arpaia is a researcher at the Italian Agency for New technologies, Energy and the Environment. He earned a PhD in Agricultural and Environmental Sciences in 1999 from Wageningen University, the Netherlands. He has extensive research experience relevant to insect ecology, insect pest management, biological control, molecular ecology, agricultural biotechnology, environmental risk assessment in particular related to GMOs and specific expertise on statistical analyses for ecological data. Professor Arpaia is currently the project coordinator, on behalf of ENEA, of two EU-funded research projects dealing with environmental risk assessment of GMOs (AMIGA and MAN-GMP-ITA) and he teaches Entomology and Zoology at the University of Basilicata. Since 1996 he has been a member of the EFSA GMO Panel.

Environmental risk assessment of plant pests integrating analysis of impacts on biodiversity and on ecosystem services

WEDNESDAY 7 NOVEMBER 2012

15.00 – 15.20

Room 2

GIANNI GILIOLI

UNIVERSITY OF BRESCIA, ITALY

The assessment of environmental impacts is one of the most difficult parts of a pest risk assessment. The high level of uncertainty in such assessment and the diversity of the methods employed emphasises the difficulty of developing a widely accepted assessment scheme based on standardised procedures that will provide accurate and consistent results.

To deal with the complexity of the environmental risk assessment in PRA and to overcome some limitations identified in the available assessment procedures, EFSA requested the Panel on Plant Health to develop a methodology for assessing the environmental risks posed by harmful organisms that may enter, establish and spread in the European Union. The scheme is described in the EFSA Guidance on the Environmental Risk Assessment of Plant Pests and includes both structural and functional components of the environment that might be threatened by invasive plant pests.

The structural components are investigated by considering the impact of the plant pest on biodiversity at different organisational levels, and the potential consequences on genetic, species and landscape diversity. Functional components are evaluated by estimating how plant pests modify the ecosystem services. The objective is to understand how an invasive species might modify the functional traits that influence the provision of ecosystem services by considering trait-service clusters. The assessment is performed in an explorative scenario of a defined level of spatio-temporal resolution, to explore how an invasive pest as an exogenous driving force may trigger modification in the target environment. To ensure the consistency and transparency of the assessment, a rating system has been developed based on a probabilistic approach with an evaluation of the degree of uncertainty.

The proposed scheme has been preliminary tested by using examples of invasive species and suggests further opportunities for research.

GIANNI GILIOLI

Professor Gianni Gilioli is a researcher at the University of Brescia, Italy. His research focuses on the development of mathematical models and methods for risk evaluation and the design of management schemes in population and ecosystem ecology. He has a particular interest in applications to ecosystem management, epidemiology, and sustainable development in different ecosystems and social-ecological contexts. Since 2009 he has been a member of the EFSA PLH Panel.

Invasive species risks: can we predict the environmental consequences of biological invasions?

WEDNESDAY 7 NOVEMBER 2012

16.00 – 16.20

Room 2

PHILIP HULME

BIO-PROTECTION RESEARCH CENTRE, LINCOLN UNIVERSITY, NEW ZEALAND

Invasive alien species pose significant environmental and/or economic problems, and methods to assess the potential risk of species introductions are key components in the management of invasions. Risk assessment is a scientifically based process that is used to identify hazards, characterise their adverse impacts, evaluate the level of exposure of a target to those hazards, and estimate the risk. In general, invasive species risk assessment requires the identification of one or more negative consequences (usually termed a hazard) likely to result from the successful establishment of an alien genotype or species and an estimate of the likelihood of each consequence.

The risk is the product of each consequence and likelihood. In an ideal world both likelihood and consequence of species introductions would be known perfectly and measured without error and this would allow perfect assessment of potential risks. Different levels in the knowledge of consequences and likelihoods shape the most appropriate strategies to address the threats posed by biological invasions. To date most effort in developing invasive species risk assessments has focused on likelihoods and much less thought has been given to quantifying consequences.

In this session I shall address the challenges involved in quantifying the consequences of invasive species, and predicting the outcomes of a species introduction for natural environments. Current risk assessment approaches are limited by problems in obtaining an objective measure of the hazards posed by alien species, challenges of predicting complex hierarchical and nonlinear systems, difficulties in quantifying uncertainty and variability, as well as cognitive biases in expert judgement. Other approaches include scenario planning that seeks qualitative inputs regarding hypothetical events to facilitate long-range planning using multiple alternatives each explicit in their treatment of uncertainty. This represents a change from prevention towards adaptive management where the difficulty in prediction is acknowledged and investment targets early detection, mitigation and management.

PHILIP HULME

Philip Hulme holds the Chair in Plant Biosecurity at Lincoln University and leads the World-Leading Biosecurity Theme at the Bio-Protection Research Centre, New Zealand. Prior to taking up his current position he was the Head of Ecosystem Dynamics at the NERC Centre for Ecology & Hydrology in the UK. His primary research focus is in quantifying, predicting and managing the risks arising from biological invasions. He coordinated major European programmes on biological invasions including DAISIE (Delivering Alien Invasive Species Inventories for Europe) and within ALARM (Assessing Large Scale Risk to Biodiversity using Tested Methods).

What can environmental monitoring tell us about dioxin exposure via different kinds of food?

WEDNESDAY 7 NOVEMBER 2012

16.30 – 16.50

Room 2

NIKLAS JOHANSSON

KAROLINSKA INSTITUTET AND SWEDISH EPA, SWEDEN

There are many sources of information on the occurrence of POPs as dioxins in food. In some cases there is information on occurrence of individual compounds in wildlife (e.g. fish and birds). These samples are often not directly representative for food, but the result of the analyses these non-food samples could give general information on the likelihood of the occurrence of the substances in food.

In environmental monitoring of wildlife, samples are collected according to protocols including species, sex, age, site and time of the year. Environmental monitoring of contaminants is often performed as a recurrent activity which enables identification and quantification of temporal trends. This type of environmental monitoring is usually carried out in background areas, i.e. areas without any known point sources. Environmental monitoring protocols could also contain grids and or transects including possible (point) sources. Data from this type of environmental monitoring is used for identification and quantification of (individual) sources but such data based on fish and other biota can also contribute to our general knowledge on human exposure to certain contaminants via different routes.

A third group of environmental monitoring is called emission control which is performed in order to control the effect of emission reducing actions taken at point sources. The emission control is performed in polluted areas but as it often is carried out as a recurrent activity (annually or more frequent) at several sampling sites in a gradient from the source, it can also give information on temporal trends in areas relative remote from sources. Emission control is performed in air and/or water and when in water it often includes biota such as fish with standardised species, sex, age and size.

Environmental monitoring of contaminants performed as a recurrent activity enables identification and quantification of temporal trends including a certain amount of extrapolation into the future. The simultaneous use for food and environmental purposes therefore needs to be refined and further investigated.

NIKLAS JOHANSSON

Dr Niklas Johansson has worked for the Swedish Environmental Protection Agency (SEPA) since 1978. For a decade he was in charge of research planning and funding on projects and programmes on Toxicology and Health Effects. He has also specialised in the occurrence and effects of persistent organic pollutants (POPs). He also holds a position at the Karolinska Institute (IMM Institute of Environmental Medicine) and has served for six years on EFSA's CONTAM Panel.

Environmental monitoring

WEDNESDAY 7 NOVEMBER 2012

17.00 – 17.20

Room 2

PETER PÄRT

EUROPEAN ENVIRONMENT AGENCY (EEA)

A good environment is a guarantee of good, safe food. Environmental monitoring programmes have been instrumental in discovering and detecting contaminants which could affect the human food chain and be a risk to human health. Much of today's environmental legislation originates from, and builds on, monitoring programmes. There are several international monitoring programmes collecting information on pollutants in the environment. The United Nations Environment Programme (UNEP) is monitoring and reporting persistent organic pollutants (POPs) under the Stockholm Convention. The Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) monitors pollution in the North Atlantic region, and the Helsinki Commission (HELCOM) monitors the Baltic region. The Arctic Monitoring and Assessment Program (AMAP) monitors pollution in the Arctic region.

In addition, several EU Member States have national monitoring programmes that cover the environment and the human population. The European Commission is financing the Consortium to Perform Human Biomonitoring on a European Scale (COPHES), which is developing a standardised protocol for human biomonitoring in Europe, and DEMO-COPHES, which is applying the COPHES methodology to selected pollutants in a project involving 21 European countries. The European Environment Agency (EEA) is collecting data on, for example, air pollution (AIRBASE – the European Air Quality Database) and water pollution (WISE – Water Information System of Europe). An important aspect of the EEA's work is analysing future scenarios in the frame of resource efficiency and sustainable agriculture particularly in relation to risks to human health and environmental quality (use of chemicals and pesticides, chemical mixtures, endocrine disrupters) and to propose ways forward. The Eye-on-Earth is an interactive web-based system being developed to make environmental information accessible to the general public. It will be an important channel for communication of environmental quality information.

PETER PÄRT

Dr Peter Pärt has worked for the European Commission's DG Joint Research Centre since 1997, most recently as Advisor in Human Health and Environment Interactions for the JRC-Institute of Environment and Sustainability. Since 1 January 2011 he has been seconded to the European Environment Agency in Copenhagen, where his work focuses on environment and human health interactions, and chemicals in the environment. Before he worked for the European Commission he was lecturer in ecotoxicology at Uppsala University, Sweden. He was Editor-in-Chief of *Aquatic Toxicology* (Elsevier) from 1995 to 2005. His scientific background is in comparative physiology, aquatic toxicology and ecotoxicology in general.

Parallel Session 3
Making sense of dietary exposure

Chair

CATHERINE LECLERCQ
ITALIAN AGRICULTURAL RESEARCH COUNCIL, ITALY

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 3

Dr Catherine Leclercq is a nutritionist and expert in dietary exposure assessment. As a senior researcher at INRAN (Italian National Research Institute on Food and Nutrition, recently merged into the Italian Agricultural Research Council, CRA) she leads the research group Food Safety –Exposure analysis. She has been the Italian project leader of EU projects dealing with dietary exposure to chemical substances: the Montecarlo project, the NOFORISK project and the FACET project. Dr Leclercq has been involved with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) since 2002 and served on Panels of the European Food Safety Authority (EFSA) since 2003.

Rapporteur

CHRISTINA TLUSTOS
FOOD SAFETY AUTHORITY OF IRELAND

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 3

Christina received her Master's degree in Human Nutrition in 1998 from the University of Vienna, Austria. She has worked for the Food Safety Authority of Ireland (FSAI) since 1999. Christina has been involved in the regulation, monitoring and risk assessment of chemical contaminants in food, and in particular, exposure to chemical contaminants from food. She is currently a member of the EFSA Working Group on Exposure and also serves as exposure expert on the Working Group for EFSA's Panel on Food Additives and Nutrient Sources added to Food.

Dietary exposure assessments at EFSA: bridging past experience and future challenges

WEDNESDAY 7 NOVEMBER 2012

14.00 – 14.20

Room 3

MARY GILSENAN

HEAD OF THE DIETARY AND CHEMICAL MONITORING UNIT, EFSA

Dietary exposure to food-borne hazards is an integral part of the risk assessments carried out by EFSA's Scientific Panels. A number of methods exist to estimate dietary exposure. The choice of method is governed by the purpose of the assessment, including the substance in question, as well as the availability of food consumption and occurrence data. This presentation will include an overview of the key approaches used by EFSA to estimate dietary exposure to food-borne hazards during the past 10 years.

The quality of an exposure assessment is to a large extent influenced by the quality of food consumption and occurrence input data. To this end, EFSA's Dietary & Chemical Monitoring Unit was established in 2005 to collect, collate and analyse food consumption and occurrence data for exposure assessments by EFSA's panels. Much of the work of the unit is also focused on development of more improved and standardised exposure assessment methodologies to improve EU risk assessments. This presentation will also cover some of the key achievements made by EFSA in the area of food consumption and chemical occurrence data collection to date, as well as future activities and challenges towards achieving more improved dietary exposure assessments at EU level.

MARY GILSENAN

Mary has been Head of the Dietary and Chemical Monitoring Unit at EFSA since July 2012. The unit deals with collection, collation and analysis of food consumption and chemical occurrence data for exposure assessments. Mary held previous roles at Leatherhead Food Research in the UK, Unilever global R&D in the Netherlands and the Institute of European Food Studies in Ireland. She completed a PhD from Trinity College Dublin, which focused on the application of probabilistic modelling to food additive exposure assessments.

Use of short-term dietary data for the estimation of usual intake

WEDNESDAY 7 NOVEMBER 2012

14.30 – 14.50

Room 3

VICTOR KIPNIS

BIOMETRY, US NATIONAL CANCER INSTITUTE, USA

The most precise methods of estimating dietary intake data are based on their short-term assessment, such as the 24-hour dietary recall or food records. Modelling short-term reported intakes is associated with numerous statistical challenges. First, short-term measurements represent a snapshot of intakes on a given day or several days. Thus, even if unbiased, due to large day-to-day variation, usual (i.e., long-term average) dietary intake is assessed with considerable measurement error that has to be accounted for. Second, some dietary components are consumed daily by almost everyone (e.g., total fat or grains), while others are episodically consumed (e.g., fish, whole grains), so that short-term data are often zero-inflated. Finally, there is increasing interest in exploring dietary intakes collectively to assess the totality of diet or dietary patterns. Dealing with such multiple dietary components, it is important to take into account that they are usually interrelated. Based on the previously suggested NCI method for modelling short-term repeat dietary measurements, I will present a novel multivariate model for estimating usual dietary patterns that accounts for measurement error and zero-inflation. The available software for maximum likelihood fitting of nonlinear mixed effects models cannot handle this multivariate extension for more than two dietary components. Therefore, the model is fitted using the MCMC-Metropolis methodology, with uncertainty estimation coming from balanced repeated replication. I will discuss the application of this model in estimating the population distribution of usual dietary intakes, including estimation of percentages above/below given cut-offs. As an illustration, I will consider the distribution of the Healthy Eating Index, a multi-component dietary quality index based on the US NHANES survey involving ratios of interrelated dietary components to energy. Finally, I will address possible extensions to estimating lifetime exposure.

VICTOR KIPNIS

Dr Victor Kipnis is Mathematical Statistician in the Biometry Research Group at the US National Cancer Institute. One of the most important aspects of Dr Kipnis' work has involved statistical issues surrounding the design and analysis of nutritional studies. A widely recognised international leader in the field, he has given numerous talks and keynote addresses at national and international conferences. Dr Kipnis has also authored and co-authored a number of pivotal publications examining the structure of dietary measurement error, its effects on study results, and methods of adjusting for it in nutritional epidemiology and surveillance.

Total Diet Studies: providing more realistic occurrence levels for calculating exposure

WEDNESDAY 7 NOVEMBER 2012

15.00 – 15.20

Room 3

RUTH CHARRONDIERE

FOOD AND AGRICULTURE ORGANISATION (FAO)

Exposure assessment is an essential part of risk assessment and should be as close as possible to the true exposure of the population. Occurrence data from food control and monitoring are often the only available data for exposure assessment. However, they often include inedible parts and are at the higher end of the distribution because of their targeted sampling. This results in overestimated exposure.

Occurrence data from Total Diet Studies (TDS) represent data as consumed by the population, i.e. the foods analysed for TDS are only the edible portion of the foods, probably washed and prepared as eaten, e.g. raw or cooked or processed. In addition, the analytical methods used for TDS often have lower limits of detections/quantifications resulting in a lower exposure for middle and upper bound exposure estimations. In TDS, all important foods in the diet are included in order to estimate the total exposure to a chemical through the average diet. Therefore, TDS occurrence and exposure data are closer to real exposure.

The drawbacks of TDS are that sampled foods are pooled together before analysis and that only few samples are analysed (compared to food control or monitoring). The higher the degree of pooling, the higher the risk of missing a contamination and not being able to attribute the occurrence data to different population groups. In general, only selected areas, time periods and foods are sampled which cannot represent all possible foods consumed in a population at all times and places. Therefore, mainly chemicals which are equally distributed throughout the food supply are well captured in a TDS and those with a punctual appearance not really.

EFSA, FAO and WHO have published in 2012 the document *Towards a harmonised Total Diet Study approach: a guidance document* which aims to harmonise the methodology of TDS worldwide and to ensure TDS data is more harmonised, comparable and of better quality.

It is hoped that in the future more TDS are conducted on chemicals appropriate for this approach, which could then allow better national and international exposure estimates.

RUTH CHARRONDIERE

Dr Ruth Charrondiere is a nutritionist and has worked on dietary assessment, food composition, biodiversity, sustainable diets and exposure assessment. She has worked at the Food and Agricultural Organization of the United Nations (FAO) since 2002. Previously, Dr Charrondiere sat on EFSA's ANS panel and was a member of the EFSA working group on Total Diet Studies. She has over 35 scientific publications.

Probabilistic dietary exposure assessment

WEDNESDAY 7 NOVEMBER 2012

16.00 – 16.20

Room 3

ANDY HART

THE FOOD AND ENVIRONMENT RESEARCH AGENCY, UK

Most dietary exposure assessments are deterministic: they use point estimates of consumption and concentration, generating point estimates of exposure, and they address variability and uncertainty by using conservative assumptions. Probabilistic approaches use distributions to quantify variability and uncertainty in exposure assessment. They are considered primarily as a tool for refined or higher tier assessments, to provide more realistic estimates of exposure in cases where conservative deterministic estimates indicate potential concern. Probabilistic modelling can also be used to calibrate deterministic approaches, by estimating how conservative they actually are. Basic issues in probabilistic assessment concern the separation of variability and uncertainty, the choice between parametric and empirical distributions and the need to focus on upper tail exposures. Other factors are the importance of dependencies and the need to take account of unquantified uncertainties. Addressing these issues requires high levels of expertise in statistics in addition to the other disciplines relevant to exposure assessment. This together with the lack of established guidance has limited the use of probabilistic methods in regulatory assessments. The PPR Panel recently completed a guidance document for probabilistic exposure assessment of pesticides. This focuses on providing a foundation for basic probabilistic assessments, and identifies options for more refined approaches. The basic assessments use alternative assumptions to explore the impact of some sources of uncertainty, including the shape of residue distributions and the treatment of censored data (non-detects). These may then be addressed using more sophisticated methods in a refined probabilistic assessment when needed. Outputs focus on estimating the proportion of the population exceeding toxicological reference doses, together with confidence intervals, rather than an arbitrary quantile of exposure. Particular attention is paid to examining the robustness of estimates in the upper tail. Further work is required to implement these approaches, and to develop further improvements in statistical methodology for probabilistic exposure assessment.

ANDY HART

Andy Hart works at the Food and Environment Research Agency (Fera), a UK Government research agency. His primary focus is developing improved approaches for the analysis of risk and uncertainty and applying them to different areas of health and environmental risk. Dr Hart has served three terms as a member of EFSA's PPR Panel, and chaired its Working Group on developing a guidance document on probabilistic dietary exposure assessment. He has also served on EFSA Scientific Committee Working Groups on transparency, terminology and uncertainty in exposure assessment.

Mixture identification from co-exposure modelling as a first step towards hazard characterisation

WEDNESDAY 7 NOVEMBER 2012

16.30 – 16.50

Room 3

AMÉLIE CRÉPET

FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY (ANSES), FRANCE

Due to the large number of chemicals found in the environment, individuals are exposed daily to complex mixtures of chemicals which can interact and cause health diseases. Thus, chemical mixtures may lead to a risk for humans. This risk is difficult to characterise. One reason lies in the multitude of possible combinations of chemicals which it is unrealistic to test for combined toxicological effects.

In this presentation, the topic of chemical mixtures will be tackled as a previous step to be performed before hazard characterisation. Co-exposure to chemicals will be modelled to identify the main mixtures which are relevant to test for their combined effects. Because individuals have different food behaviours and habits, they may be exposed to different mixtures. The first step will be to cluster individuals into sub-groups with similar profiles of co-exposure and then to study the exposure correlations of each sub-group to define mixture. Groups can also be directly constructed from their consumption patterns. Two statistical methods will be presented to determine these sub-groups. Probabilistic methods to calculate co-exposures by combining food surveys with concentration data will also be explained. The new challenges related to exposure assessment to mixtures will be presented as well as the method to define food vector of mixtures. The methods will be illustrated by an example on pesticides residues in food provided by the French research program PERICLES (ANR 2008-CESA-016-01).

AMÉLIE CRÉPET

Dr Amélie Crépet has a PhD in applied mathematics to food risk assessment. She has worked in this field since 2002 and at ANSES since 2007. Dr Amélie has developed probabilistic and Bayesian models related to food risk analysis for general and specific groups of consumers aimed at improving knowledge of exposure modelling assessment to environmental contaminants, pesticides residues, pathogenic bacteria and food allergens.

She has experience in coordinating research programmes: the national PERICLES project on exposure to mixtures of active substances and their possible combined effects on human cells and a national project on risk assessment to food allergens called MIRABEL.

Biomarkers of exposure in food safety risk assessment

WEDNESDAY 7 NOVEMBER 2012

17.00 – 17.20

Room 3

RUDOLF KAAKS

GERMAN CANCER RESEARCH CENTER (DKFZ), GERMANY

The assessment of individuals' habitual intake levels of specific foods and nutrition is notoriously difficult. Most large-scale epidemiological studies on diet and chronic disease risks have made use of food frequency questionnaires, alone or in combination with more detailed assessments in subgroups, e.g. by 24-hour diet recalls. Interestingly, a number of epidemiological studies have shown associations of blood-based markers of nutrients with risks of cancer and other chronic diseases where FFQ-based assessments failed to do so. These observations suggest that biomarkers may be a useful alternative or complement to questionnaire-based measurements, in studies that aim to determine possible etiologic relationships between specific dietary components and disease development. The majority of biomarkers are based on measurements of concentrations of specific nutrients in blood or other tissues. These markers can only provide information about individuals' relative ranking by dietary intake level, but cannot easily be translated into quantitative dietary intakes. An exception to this is a relatively small number of markers that are based on physiological knowledge about the quantitative recovery, e.g. in urine, of specific elements such as nitrogen or potassium, or stable isotopes administered to the study subjects (e.g. the doubly labelled water method for assessment of energy expenditure). Besides the direct use of biomarkers as measurements of individuals' exposure levels in epidemiological studies, markers can be used in sub-studies for the calibration of questionnaire assessments to correct for biases in relative risk estimates induced by random assessment errors. The key advantage offered by biomarkers, in this context, is that their random errors can be assumed to be relatively independent of those of measurements based on self-reports. The statistical analysis of such calibration studies, however, relies on some essential model assumptions, which will be discussed.

RUDOLF KAAKS

Professor Rudolf Kaaks has been Chair of Cancer Epidemiology at the University of Heidelberg and head of the Division of Cancer Epidemiology at the German Cancer Research Center (DKFZ), Heidelberg, Germany since 2006. Previously he worked as an Epidemiologist at IARC, Lyon and in 2001 became head of the Hormones and Cancer Group at this institution.

After receiving his Master of Science in Human Nutrition & Epidemiology at the University of Wageningen in 1987, Professor Kaaks worked as a junior researcher at the Utrecht University (1987-1988). He was awarded a PhD in Nutritional Epidemiology in 1994.

Parallel Session 4
Expressing risks

Chair

DJIEN LIEM
HEAD OF THE SCIENTIFIC COMMITTEE UNIT, EFSA

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 4

Dr Djien Liem has been the Head of EFSA's Scientific Committee Unit since January 2003. His work on dioxins includes chair of the Dutch Working Groups on Dioxins in Food and on Dietary Intakes, and he was national delegate in the framework of World Health Organization (WHO) studies on dioxins and related compounds. Dr Liem also coordinated a pan-European Scientific Co-operation project from 1998-2000 for the European Commission on the assessment of dietary intake of dioxins and related compounds. In 2000 he was seconded to the EC's Scientific Committee on Food where he played a key role in the preparation of scientific evaluations.

Rapporteur

QASIM CHAUDHRY
THE FOOD AND ENVIRONMENT RESEARCH AGENCY, UK

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 4

Dr Qasim Chaudhry is a Principal Research Scientist at the Food and Environment Research Agency (FERA). He is a Chemist and Biochemical Toxicologist by training, with over 30 years experience of leading scientific R&D into modes of toxic action of chemicals, *in silico* predictive toxicology, and risk assessment of chemicals and nanomaterials. He is a member of the EC's Scientific Committee on Consumer Safety, and EFSA's Scientific Committee. He is a visiting Professor at University of Chester, and author/co-author of over 50 scientific publications that include research papers, reviews, book chapters and edited books.

Trends in chemical risk assessment and integration of new methodologies

WEDNESDAY 7 NOVEMBER 2012

14.00 – 14.20

Room 4

JOSEF SCHLATTER

(RETIRED) FORMERLY FEDERAL OFFICE OF PUBLIC HEALTH, SWITZERLAND

The presence of chemicals in food may be a consequence of the intentional use of these substances but is often unavoidable as substances may occur ubiquitously or are of natural origin. Risk assessments of chemicals in food attempt to assess whether or not human exposure to a chemical in food is likely to be associated with adverse health effects. Whenever possible and required, a health-based guidance value (HBGV) such as an acceptable daily intake is established. Before authorisation of an intentionally used (regulated) substance for food-use, an applicant must submit a full set of toxicological data to adequately demonstrate its safety. However, the assessment of natural constituents of food and of contaminants relies on scientific information that is in the public domain, which is often incomplete. Furthermore such substances may be both genotoxic and carcinogenic, or the available data may be inadequate to establish a HBGV. In such cases the margin of exposure approach is used or, in the absence of reliable toxicological data, read across to similar substances. Alternatively, the threshold of toxicological concern approach is applied. As the sensitivity in chemical analysis continues to increase, more substances at very low levels in foods will be found. It is likely there will be an increasing need for assessments of the effects of combined exposure and for risk-benefit assessments. Further areas where developments are likely include further integration of animal and human data, greater use of information obtained in mechanistically based *in vitro* assays, linked to mode of action, high content analysis, such as toxicogenomics, quantitative structure activity relationships and other *in silico* approaches. Increasing availability of biomarker data and physiologically based toxicokinetic modelling will support assessments based on internal doses. Mathematical approaches will also be extended to other areas, such as the assessment of uncertainty.

JOSEF SCHLATTER

Josef Schlatter is a member of EFSA's Scientific Committee and was Chair of EFSA's Panel on Contaminants in the Food Chain between 2003 and 2012. He is the former head of Nutritional and Toxicological Risks Section of the Federal Office of Public Health in Switzerland. He worked at the Federal Office of Public Health from 1984 to 2012 and, before that, at the Institute of Toxicology of the Swiss Federal Institute of Technology (ETH) and University of Zürich. He published about 120 scientific papers during his career, mainly dealing with general risk assessment principles, risk assessment of chemical carcinogens, natural toxins or contaminants. A biology graduate from the ETH in Zürich, Josef Schlatter completed his doctoral thesis and a post-doctoral fellowship at the Institute of Behavioural Science of the ETH.

Framing of risk assessment questions

WEDNESDAY 7 NOVEMBER 2012

14.30 – 14.50

Room 4

TAKIS DASKALEROS

HEALTH AND CONSUMERS DIRECTORATE GENERAL, EUROPEAN COMMISSION

There is a perception among scientists and regulators that risk assessments as currently carried out often do not inform the risk management process as well as they should. To examine this notion and address identified issues, the Commission Scientific Committees – consisting of the Scientific Committee on Consumer Safety, SCCS, the Scientific Committee on Health and Environmental Risks, SCHER and the Scientific Committee on Emerging and Newly Identified Health Risks, SCENIHR – reviewed the current risk assessment practices and in a preliminary opinion have concluded that:

- the outputs of risk assessment need to be more policy- and management-relevant and this ought to be facilitated by more dialogue between risk assessors and risk managers;
- to be "management-relevant", risk assessments need to inform in light of trade-offs between the benefits of interventions for human health and environment and the costs of restrictions for the economy;
- risk assessments should be expressed in terms of likely impacts on human health and ecosystem processes and services rather than in terms of the more prevalent risk characterisations; this would require more dialogue between risk assessors and socio-economists, and stakeholders involvement;
- risk-assessment opinions may be improved by including the evaluation of different possible scenarios, including risk-management options; making full characterisation of the whole populations/ecosystems at risk with attention to particularly sensitive subpopulations/species; including clear expressions of uncertainty; making explicit disclosure of hypotheses used without supporting evidence.

TAKIS DASKALEROS

Takis Daskaleros works at the European Commission as Head of Sector for Health and Environment Risk in the Unit in charge of Risk Assessment at the Health and Consumer Protection Directorate General. He trained as a medical microbiologist, molecular biologist, and toxicologist, and has worked in the areas of research, consumer safety, and risk assessment since he joined the Commission in 1996.

Fit for purpose risk assessment: qualitative vs quantitative approaches

WEDNESDAY 7 NOVEMBER 2012

15.00 – 15.20

Room 4

ANGELIKA TRITSCHER

WORLD HEALTH ORGANIZATION (WHO)

The number and complexity of requests for food-related risk assessments is increasing. This is partially due to increasing analytical capabilities, increased monitoring and surveillance and greater awareness and concern about food safety. Microbiological risks are limited by a finite number of pathogens but these need to be considered in combination with specific foods and processing steps. Increasing evidence of viruses and parasites as causes of food-borne diseases leads to an increased need for risk assessment for pathogens along the food chain. Also there are tens of thousands of man-made chemicals around us, many of them also found in food. In addition to probably hundreds of naturally occurring substances with toxic potential, this leads to an unmanageable need for risk assessments. In the context of food and food production, implications of new technologies and risk benefit considerations are also of increasing importance. All this leads to calls for 'fit-for-purpose' risk assessment, i.e. risk assessments targeted to a specific need. But what are the needs, and who defines them? The first step leading into a risk assessment is problem formulation, ideally followed by preliminary risk assessment or preliminary risk profiling. In these initial steps the level of concern, e.g. toxic potential, potential public health implications, estimated exposure, production amount and use patterns of chemicals, is defined. A tiered approach is then needed for the actual risk assessment, where the level of detail, including qualitative versus quantitative approaches, needs to be driven by the level of concern, and necessarily also by the data availability. The development of a step-wise approach or decision tree tool would be important, also to ensure consistency in the decision-making process. Moreover, since most food risks are of global relevance, in order to preserve limited resource, it is important to harmonise risk assessment principles and methods and collaborate internationally.

ANGELIKA TRITSCHER

Dr Tritscher is currently Acting Director of the Department of Food Safety and Zoonoses at the World Health Organization (WHO). Before joining the WHO in 2003 she worked as toxicologist in the Food Safety Group at the Nestlé Research Center in Lausanne, Switzerland. Dr Tritscher has also carried out research at the National Institute of Environmental Health Sciences in North Carolina, USA, focusing on mechanistic aspects and human health risk assessment for dioxins. She graduated in food science and continued her PhD in biochemical toxicology, focusing on mechanism of hormonal carcinogenesis.

Considering risks and uncertainties related to combined exposures

WEDNESDAY 7 NOVEMBER 2012

16.00 – 16.20

Room 4

BETTE MEEK

UNIVERSITY OF OTTAWA, CANADA

A framework to maximise efficiency in assessing the impact of combined exposures to multiple chemicals has been issued by the World Health Organization (WHO) International Programme on Chemical Safety (IPCS). It was developed through an expert group process, public review and collaboration with other international organisations. The framework includes problem formulation, followed by stepwise consideration of both exposure and hazard in several tiers of increasingly data-informed analyses. These analyses build on recent developments in assessment in a range of programs internationally, incorporating predictive approaches in early tiers and increasingly refined, more data-informed and probabilistic analyses in later tiers.

Recommendations regarding terminology and the status of development of the framework, its content, review and application are described. Evolving experience in its application is illustrated by example with special emphasis on the critical content of problem formulation, the role of predictive tools in grouping of chemicals for consideration and the importance of explicit delineation of relative uncertainty and sensitivity for tiered assessment.

Priorities in increasing the efficiency of risk assessment not only for combined exposures, but more generally based on experience acquired in developing the framework and its application in case studies are identified and recommendations included.

BETTE MEEK

Dr Meek is currently the Associate Director of Chemical Risk Assessment at the McLaughlin Centre for Population Health Risk Assessment, University of Ottawa. She previously managed several chemical risk assessment programmes within Health Canada. She has contributed to or led initiatives in areas such as weight of evidence analysis for mode of action, chemical specific adjustment factors, physiologically-based pharmacokinetic modelling, combined exposures and predictive modelling. She has authored over 175 publications in this area and received several awards. Dr Meek has a background in toxicology receiving her M.Sc. in Toxicology from the University of Surrey and her Ph.D. in risk assessment from the University of Utrecht.

A consistent and quantitative approach to risk-benefit assessment and risk ranking: the role of burden of disease estimates

WEDNESDAY 7 NOVEMBER 2012

16.30 – 16.50

Room 4

ALESSANDRO CASSINI

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC)

Composite health measures are a valuable instrument to express, aggregate and compare benefits and risks. Ranking of food-borne pathogens for example, is very different when only incidence is considered.
Moreover, once the baseline DALY estimates are computed, it is possible to expand to dynamic studies and forego risk-benefit assessments, impact of intervention studies, economic analysis, and model forecasting scenarios. The benefit of using a composite metric is that outcomes of these studies can be expressed as a single net health impact value.

Likewise, a quantitative and comparable methodology for assessing public health relevance of food-borne diseases is required for evidence-based food safety management. In fact baseline estimates are the necessary primary step to risk-ranking through attribution to, for example, given food/transmission pathway or food groups.

The Burden of Communicable Diseases in Europe (BCoDE) project aims at developing an evidence-based methodology for health policy decision-making.

Funded by an ECDC grant, implemented by a European consortium including both academic centres and national health institutes employing experts from several European Countries, the project primary objective is to estimate the burden of communicable diseases using a composite health measure (DALYs: Disability Adjusted Life Years) encompassing mortality and morbidity, duration and disability of each acute infection as well as for the related short and long-term sequelae.

Another objective of BCoDE is the identification of gaps in data availability and quality, resulting in appraisal of surveillance systems, as well as proposals for improving methodologies to adjust for underreporting in notification data.

EU-wide DALY estimates of communicable diseases are possible through the BCoDE toolkit, a user-friendly software application available to EU Member States supporting their national burden of communicable diseases estimation.

The methodology adopted (i.e. DALY, adjustments for under-estimation of incidence data) and findings related to food-borne diseases will be presented, and potential use of the BCoDE toolkit in relation to food safety management will be introduced.

ALESSANDRO CASSINI

Dr Cassini leads the Burden of Communicable Diseases in Europe (BCoDE) project at the ECDC with the remit of estimating and expressing the burden of communicable diseases and related conditions by means of composite health measures (e.g. DALYs). Before joining ECDC in 2009, he worked for a private consultancy firm in London, advising mainly on matters related to market access, health technology assessment and overall appraisal of unmet needs. Dr Cassini is a medical doctor by training, with a specialisation in Public Health and Preventive Medicine and an MSc in Health Policy Planning and Financing.

Communicating risk and uncertainty: the role of metaphor and analogy

WEDNESDAY 7 NOVEMBER 2012

17.00 – 17.20

Room 4

DAVID SPIEGELHALTER

UNIVERSITY OF CAMBRIDGE, UK

Mathematical models are vital whenever we admit we cannot predict precisely what is going to happen, for example in weather forecasting, insurance, nuclear safety, natural disasters, the effect of new medical interventions and, more controversially, in climate change and finance. Such models get so complex that multiple simulations of 'possible futures' may be necessary, which allow us to quantify chances of future events, which then need to be communicated to the public and policy-makers. If we take a Bayesian perspective, then any probability assessment is only a construction based on available information and judgment, and multiple metaphors can be adopted to create a narrative around these quantities.

And models are 'just models', and are always wrong or inadequate to some extent, and so how can we express this deeper uncertainty? Is there a need for a qualitative scale, or can we use subjective or default quantitative assessments? I will look at a range of suggestions that have been made - from contexts varying from climate change, environmental protection, toxicology, and health-care interventions.

DAVID SPIEGELHALTER

David Spiegelhalter's background is in medical statistics, particularly the use of Bayesian methods in clinical trials, health technology assessment and drug safety.

In his post as Winton Professor for the Public Understanding of Risk he leads a small team that attempts to improve the way in which the quantitative aspects of risk and uncertainty are discussed in society. He gives many presentations to schools and others, advises organisations on risk communication, and is a regular newspaper columnist on current risk issues. Professor Spiegelhalter was elected FRS in 2005 and awarded an OBE in 2006 for services to medical statistics.

Parallel Session 5
Efficacy assessment in food and feed

Chair

HILDEGARD PRZYREMBEL
(RETIRED) FORMERLY FEDERAL INSTITUTE FOR RISK ASSESSMENT, GERMANY

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 5

Prof. Przyrembel is a paediatrician specialised in inborn errors of metabolism (Ulm, Düsseldorf, Rotterdam). She has been a professor and lecturer in Paediatrics at Humboldt University in Berlin since 1991. She was Director and Professor in the Department for Food Safety of the Federal Institute for Risk Assessment, Berlin (1990 -2007). She was an expert on the former Scientific Committee on Food (2000-2003) and a Member of EFSA's NDA Panel (2003-2012). She has been involved in defining the scientific basis for European and international regulation of infant food and the risk assessment of nutrients, foods and food patterns and the evaluation of health claims.

Rapporteur

ALBERTO MANTOVANI
ISTITUTO SUPERIORE DI SANITÀ, ITALY

WEDNESDAY 7 NOVEMBER 2012
14.00 – 17.30
Room 5

Alberto Mantovani, DVM, holds a MSc in Veterinary Public Health and has worked since 1985 in the field of toxicology at the Italian National Health Institute (ISS) where he is Head of the Food and Veterinary Toxicology Unit. Since 2011, he has been a member of the Italian Committee for Food Safety (Ministry of Health). He was a member of EFSA's FEEDAP Panel (2003-2012), including a spell as vice-chair (2009-2012). He has also contributed as an expert to opinions by other Panels (CONTAM, CEF) and the Scientific Committee. Since July 2012 he has been a member of EFSA's PPR Panel.

Assessment of scientific substantiation of health claims on foods in the EU

WEDNESDAY 7 NOVEMBER 2012

14.00 – 14.20

Room 5

ALBERT FLYNN

UNIVERSITY COLLEGE CORK, IRELAND

The EU Regulation (EC) No. 1924/2006 specifies that health claims should be substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. This presentation focuses on the application of this standard by the European Food Safety Authority (EFSA) in its evaluation of health claims. In reviewing each claim, EFSA's Panel on Dietetic Products, Nutrition and Allergies makes a scientific judgement on whether a cause and effect relationship is established between the consumption of the food and the claimed effect. The evidence is weighed taking into account strength, consistency, specificity, dose-response and biological plausibility. Human data are central for the substantiation of health claims and evidence is considered according to a hierarchy of study designs, with randomised controlled trials considered to have the least likelihood of bias. Individual studies are assessed with respect to quality of design, execution, analysis and reporting. Selection of relevant studies for substantiation requires that studies should match the claim with respect to the food and the outcomes measured and should be carried out in subjects that are representative of the population group for which the claim is intended.

To date, EFSA has concluded in favour of substantiation for over 200 claims on nutrients and food constituents for body functions, for growth and development of children and for the reduction of risk factors for disease. The Panel's advice is used as the basis for authorisation decisions by the European Commission and the Member States (with scrutiny by the European Parliament). Because of the scientific and technical complexity of health claims, EFSA has placed considerable focus on consultation with stakeholders in developing extensive guidance for applicants. EFSA's work on assessment of scientific substantiation of health claims will help set future directions for research and innovation.

ALBERT FLYNN

Albert Flynn, PhD, is Professor in Nutrition at University College Cork, Ireland, where he has served on the faculty since 1981. He has published widely on human nutrition, public health and food safety and has extensive experience in providing scientific advice on human nutrition and food safety issues related to food policy and regulation. He served as Chair of the Scientific Panel on Dietetic Products, Nutrition and Allergies of the European Food Safety Authority, Parma, Italy, from 2003 to 2012 and as a member of the Scientific Committee on Food of the European Commission from 1997 to 2003.

Efficacy assessment experiences in the European Medicines Agency

WEDNESDAY 7 NOVEMBER 2012

14.30 – 14.50

Room 5

FRANCESCO PIGNATTI

EUROPEAN MEDICINES AGENCY (EMA)

The primary aim of European pharmaceutical law is to safeguard public health, whilst encouraging the development of the pharmaceutical industry and the creation of a single market for pharmaceuticals in the European Union. In order to obtain an authorisation to place a drug on the market, applicants are required to submit the results of pharmaceutical and pre-clinical tests and clinical trials to enable a sufficiently well-founded and scientifically valid opinion to be formed as to whether the potential risks are outweighed by the therapeutic efficacy of the product. The marketing authorisation will be refused if the benefit-risk balance is not favorable or if the therapeutic efficacy is insufficiently substantiated. A standard approval is valid for five years and can be renewed (indefinitely or for another five years) on the basis of a re-evaluation of the benefit-risk balance. The basic principles and requirements for the demonstration of efficacy are laid down in the EU pharmaceutical legislation. In general, for new applications, the primary evidence of therapeutic efficacy is derived from the main efficacy studies ("pivotal" studies), which provide information about efficacy versus comparators and efficacy in relevant subgroups in terms of primary and secondary endpoints. General requirements are further detailed in international guidelines and European Medicines Agency (EMA) guidelines, as well as a number of disease-specific guidelines. Pivotal clinical studies have to be designed as controlled clinical trials if possible, randomised and as appropriate versus placebo and versus an established medicinal product of proven therapeutic value. In this presentation, legal requirements, evidentiary standards, methodological issues and EMA experience on efficacy assessment will be reviewed.

FRANCESCO PIGNATTI

Dr Francesco Pignatti graduated as medical doctor at the University of Rome "La Sapienza" and in 1997 obtained a Master's degree in Biostatistics from the University of Limbourg, Belgium. From 1995 to 1999 he worked at the European Organisation for the Research and Treatment of Cancer (EORTC), in Brussels. In 1999 he joined the European Medicines Agency (EMA). Since 2009 he has been Head of Oncology, Hematology and Diagnostics in the sector for Safety and Efficacy of Medicines.

Assessment of safety and efficacy for the target species: technological, sensory and nutritional feed additives

WEDNESDAY 7 NOVEMBER 2012

15.00 – 15.20

Room 5

JÜRGEN M. GROPP

UNIVERSITY OF LEIPZIG, GERMANY

During the authorisation process for feed additives, for most additives only its potential efficacy can be assessed, since the number and extent of efficacy studies to be submitted is limited. Consequently, efficacy assessment provides only a yes or no answer; comparative qualitative considerations are neither possible nor wanted (by applicants). The requirements for efficacy and safety studies and their nature (*in vitro* or *in vivo*) are set by a legal framework (Regulation (EC) 429/2008) and EFSA/FEEDAP guidance. For technological additives other than mycotoxin and radionuclide binders, *in vitro* studies are considered satisfactory. For additives which are also used in food (i.e. flavouring substances and some colorants), no studies are needed, which is problematic considering the different matrix and dose in food and feed. The efficacy of nutritional additives (vitamins, trace elements) is mostly assessed on the basis of literature; new compounds require *in vivo* studies.

Safety of an additive for the target species is assessed considering the maximum proposed/recommended feed concentration. For new compounds, a tolerance study with the aim of providing a limited evaluation of short-term toxicity of the additive to the target animals is necessary. These studies require a detailed description of the experimental design, including endpoints and certain duration of studies. A graded system of endpoints is introduced depending on tolerance to overdoses. For substances with a long history of use (i.e. nutritional additives) target animal safety can be assessed by literature data. For additives assessed for food use, a different consecutive three step system has been introduced due to the multitude of additives (i.e. flavourings) and the scarcity of target animal data. It is based on (i) a comparison of human and animal exposure, (ii) the use of laboratory animal toxicity data and (iii) finally the use of TTC values.

JÜRGEN M. GROPP

Veterinarian and professor of Animal Nutrition and Nutrition Diseases, retired since 2003. Former Director of the Institute of Animal Nutrition, Nutrition Diseases and Dietetics, Faculty of Veterinary Medicine, University of Leipzig, Germany (1993 - 2003), Professor at the Institute for Physiology, Biochemistry and Nutrition Physiology, Faculty of Veterinary Medicine, Ludwig-Maximilian-University, Munich, Germany (1980-1993). Member of the Scientific Committee for Animal Nutrition, European Commission (1997-2003); of the European Food Safety Authority (EFSA)'s Scientific Panel on Additives and Products or Substances used in Animal Feed (2003-2012); and, since 2012, EFSA's Scientific Panel for Genetically Modified Organisms.

Assessment of safety and efficacy for the target species: zootechnical feed additives

WEDNESDAY 7 NOVEMBER 2012

16.00 – 16.20

Room 5

ANDREW CHESSON

UNIVERSITY OF ABERDEEN, UK

Zootechnical feed additives, one of five categories of feed additives, are defined in Regulation (EC) 1831/2003 as additives used to affect favourably the performance of animals in good health or the environment. Like other categories of additives, there is a requirement in the legislation for the demonstration of safety and efficacy. However, demonstrating efficacy is not specified and remains contentious. Current requirements usually involve long-term animal trials which are expensive and time consuming. Consequently, there is a continual debate about whether it is sufficient simply to demonstrate credibility, whether short-term studies could substitute and, if long-term studies are necessary, then how many and for how long.

One important element of this discussion is the need to link any effect on performance to an economic benefit for the user. Defining the scope of a study is also a potential difficulty given the focus on animals in good health made in the legislation to distinguish feed additives from veterinary products. Many zootechnical additives have effects only when individual or groups of animals are challenged and are in less than perfect condition. For zootechnical additives based on a single compound or a mix of compounds safety can be assessed in the same manner as other categories of additives. However, a majority of zootechnical additives consists of live microorganisms or products derived from microbial fermentation. Such additives can be directly tested for animal safety, but surrogate methods to assess consumer safety are often not appropriate or necessary.

For this reason the Qualified Presumption of Safety concept was developed for a range of microorganisms commonly introduced into the food chain, to enable potentially pathogenic or toxigenic strains to be distinguished from other strains. Well-tested methods of assessment exist for most zootechnical products; it is novelty which presents the greatest challenge to the risk assessor.

ANDREW CHESSON

Professor Andrew Chesson was until June 2012 chair of EFSA's FEEDAP Panel and a member of its Scientific Committee. Previously he was vice chair of the European Scientific Advisory Committee on Animal Nutrition (SCAN) and a regular contributor to the work of the corresponding plant (SCP) and food (SCF) committees. He has contributed to the risk assessment of a wide range of products and processes at a Community level and has undertaken and continues to fulfil similar advisory roles in the area of safety assessment within the UK (through the Food Standards Agency and Defra) and with international bodies. He is a member of the UK Advisory Committee on Novel Foods and Processes (ACNFP) and a former member of the Advisory Committee on Animal Feedstuffs (ACAF). He was also Vice Chair of the OECD Task Force on Novel Foods and was responsible for the production of two major OECD reports on risk assessment.

Efficacy requirements for the approval of new pesticides active substances

WEDNESDAY 7 NOVEMBER 2012

16.30 – 16.50

Room 5

INGRID DEN HOED

CHEMICALS REGULATION DIRECTORATE, UK

Efficacy is the balance between the positive effects of pesticide treatment (e.g. pest control) and any negative effects (e.g. direct crop damage). The net result is the overall improvement in yield or quality of the crop, which must be sufficient to justify the use of the pesticide.

Under Council Directive 91/414/EEC there was no detailed consideration of efficacy of new active substances, with assessments conducted almost totally at the Member State level within the Annex III 'product' package.

Consideration of efficacy for active substance approval is a new requirement under Regulation (EC) 1107/2009. This states in Chapter II, Article 4(3), that a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: a) it shall be sufficiently effective and c) it shall not have any unacceptable effects on plants or plant products.

The rationale for this requirement is clear. The efficacy of an active substance determines the good agricultural practice (GAP) and therefore the 'risk envelope.' These for the most part form the basis for all other aspects of the risk assessment. Therefore, it is very important that the GAP for active substances are based on realistic assumptions that particularly encompass the 'worst case' GAP.

Guidance will be available shortly to clarify the efficacy requirements for new active substances. The principal objective of the efficacy evaluation of a new active substance is, however, to confirm that the doses are realistic for the GAP submitted for approval and representative for all subsequent authorisations. The aim should also be to avoid a duplication of evaluation work for at least some of the individual GAPs, which may otherwise result if efficacy is comprehensively considered for all uses at approval of the active substance and at product authorisation.

INGRID DEN HOED

Ms den Hoed graduated in 1989 from Imperial College (Wye) with a BSc in Agriculture and has since worked at ADAS as a livestock consultant and in the UK Government commissioning and monitoring public funded R&D. In 2003, she became Senior Herbicide and Plant Growth regulator specialist within the Chemicals Regulation Directorate's Efficacy section. She is responsible for the evaluation of efficacy data in support of pesticide approvals/authorisations and also provides advice, particularly on herbicide issues, to industry, Government Departments and other organisations. She is also a member of several EPPO panels and the UK Weed Resistance Action Group.

Criteria for the assessment of biocides in decreasing food-borne pathogens in food of animal origin

WEDNESDAY 7 NOVEMBER 2012

17.00 – 17.20

Room 5

BIRGIT NØRRUNG

FACULTY OF HEALTH AND MEDICAL SCIENCE,
UNIVERSITY OF COPENHAGEN,
DENMARK

In 2010, EFSA's BIOHAZ Panel revised the joint AFC/BIOHAZ guidance on the submission of data for the evaluation of the efficacy of substances for the removal of microbial surface contamination of foods of animal origin. The guidance is intended to provide guidelines for dossiers of applications to be submitted to the European Commission, for authorisation of these types of substances.

The guidance document includes examples of study designs at the laboratory and at the slaughterhouse for showing that the substance to be tested demonstrates efficacy. It also includes the factors that should be considered when monitoring the efficacy of a substance that has already been authorised and is in use. The guidance document refers generically to all candidate substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption.

This presentation includes a short introduction to food-borne pathogens and biocides and provides an overview of the guidelines including how they have been used in several specific efficacy assessments.

BIRGIT NØRRUNG

Birgit Nørrung, DVM, Ph.D, is Vice-dean of the Faculty of Health and Medical Science, University of Copenhagen. She has published more than 100 papers, proceedings, reports, and book chapters in the area of microbiological food safety. Her main research interest is applied research related to risk assessment and control of zoonotic microorganisms and food-borne viruses. She was a member of the European Food Safety Authority (EFSA)'s Panel on Biological Hazards (BIOHAZ) from 2003-2012 including spells as vice-chair and chair.

Final Plenary Session

Chair

BERNHARD URL
DIRECTOR OF RISK ASSESSMENT AND SCIENTIFIC ASSISTANCE, EFSA

THURSDAY 8 NOVEMBER 2012

09.00 – 12.30

Room 1

Dr Bernhard Url is Director of Risk Assessment and Scientific Assistance (RASA) at EFSA. His directorate carries out risk assessments and monitoring on general health and safety priorities in areas such as biological hazards, chemical contaminants, animal health and welfare and plant health.

Prior to joining the authority in June 2012, Dr Url was Managing Director of the Austrian Agency for Health and Food Safety (AGES), which also represents Austria on EFSA's Advisory Forum.

From 2008 to March 2012, he also served as a member of EFSA's Management Board.

A veterinarian by training, Dr Url brings high-level management experience from public and private food safety organisations to his role at EFSA. During his 10 years at AGES, he was in charge of technical and scientific affairs and dealt with a wide range of food safety-related areas. This also involved helping to centralise Austria's previously federal-based food safety system. Prior to AGES he spent five years as an assistant professor at the Institute of Milk Hygiene and Milk Technology at the University of Veterinary Medicine in Vienna before running a food quality control laboratory from 1993 to 2002.

Dr Url has published widely in the field of veterinary medicine with a particular focus on *Listeria* and milk hygiene.

Chair

ALICJA MORTENSEN
NATIONAL FOOD INSTITUTE, DEPARTMENT OF TOXICOLOGY AND RISK ASSESSMENT, TECHNICAL UNIVERSITY OF DENMARK, DENMARK

THURSDAY 8 NOVEMBER 2012

09.00 – 12.30

Room 1

Dr Alicja Mortensen started working in food safety in 1988 at the Danish Food Administration. Between 2004 and 2006 she was a senior scientist in the Danish Institute for Food and Veterinary Research and since January 2007 has been a senior scientist at the National Food Institute at the Technical University of Denmark. Her research concerns the effects of fats, sterols and stanols, phytochemicals, hormone replacement therapy and phytoestrogens on atherosclerosis, of phytoestrogens on intestinal and mammary cancer, use of transgenic animal models in carcinogenicity testing, and the safety of nanoparticles. She advises the Danish Veterinary and Food Administration on safety of chemicals in food and food supplements. In July 2008 she joined EFSA's ANS Panel, which she currently chairs.

The identification of future food safety risks

THURSDAY 8 NOVEMBER 2012

11.15 – 11.45

Room 1

TERRY DONOHOE

FOOD STANDARDS AGENCY, UK

Spotting the signals of new or re-emerging risks is a major challenge for risk managers and risk assessors.

There is a myriad of data sources to draw from. The data are of varying relevance, quality, timeliness and veracity. How do you "see the wood for the trees" and how do you ensure that appropriate action is taken and that communications are proportionate and appropriate?

Since 2010 EFSA has piloted a programme for the identification, assessment and communication of emerging risks. An EFSA scientific colloquium considered the challenges and opportunities associated with the detection of emerging risks and the EMRISK Unit has recently published a report on the lessons learned from its pilot programme.

The Food Standards Agency (FSA) has developed an emerging risks programme that is complementary to EFSA's. Core intelligence is drawn from the FSA's historical incidents and food fraud data. Research and surveillance data, media reports and expert opinion are also utilised. Outputs from recently commissioned horizon scanning projects will provide further intelligence about the key drivers that might affect food safety in the future.

Key challenges remain around understanding vulnerabilities in global food chains and their potential impact on future new and re-emerging risks. Work is under way both in the UK and internationally to develop methodologies to aid such understanding.

The involvement of stakeholders is crucial to the detection and assessment of future food safety risks and to the success of both EFSA and FSA's emerging risks programmes. Formal and informal networks have been set up at local, national and international levels to provide opportunities for intelligence gathering and sharing. A key stakeholder network is EFSA's Emerging Risks Exchange Network.

This presentation will consider the progress of work on emerging risks, the lessons learned thus far and future challenges and opportunities.

TERRY DONOHOE

Terry Donohoe is head of strategy and policy in the Food Standards Agency's Chemical Safety Division.

He joined the agency in 2002 and was initially responsible for developing, refining and optimising procedures and protocols for the full range of incidents likely to affect food safety. Since 2010 he has been responsible for developing and implementing the agency's systems for the identification and characterisation of potential new or re-emerging risks.

He is a member of EFSA's Emerging Risks Exchange Network and has given presentations on the FSA's approach to identifying emerging risks at national and international meetings.

Research and risk assessment: two sides of the same coin?

THURSDAY 8 NOVEMBER 2012

11.45 – 12.00

Room 1

HENRIK CASPAR WEGENER

TECHNICAL UNIVERSITY OF DENMARK

Risk assessment is a tool to support decision making in circumstances where there is a considerable amount of uncertainty. The degree of uncertainty, and the consequent need for use of assumptions or "guesstimates" to produce an estimation of risk, is widely dependent on the availability and quality of data.

Research data constitute an important part of the data for risk assessment, although other data, such as those gained from monitoring and control activities, also contribute. The quality of data from published research is generally perceived as superior to data from other sources, because of the inherent quality assurance process. Although research data in food safety are abundant, in most risk assessments there is a major lack of adequate of data, primarily because data from research rarely fits the specific needs of the risk assessors. Therefore, many risk assessments result in an uncertain risk estimate, and a long and specific list of data needs. This is particularly the case for microbial risk assessments.

In an ideal world, the research community and funding bodies at large would be aware of the data needs of risk assessors, and systematically strive to generate this information. However, in the real world, the research which is funded, and the way research is conducted, is much more diverse, and from the perspective of risk assessment much less optimal. This presentation will discuss the apparent paradoxes and dilemmas at the interface between risk assessment and research, and offer suggestions for solutions.

HENRIK CASPAR WEGENER

Henrik Wegener's main field of work has been surveillance, research and risk assessment in relation to microbial food safety. He has been involved in the implementation of Danish, European and WHO/FAO integrated surveillance and control schemes for food-borne zoonoses, and has worked on the development of national and international strategies for the prudent use of antimicrobials in food animals. In 2006 he became the director of the National Food Institute, and in 2011 chief academic officer and vice executive president of the Technical University of Denmark. He has published more than 100 scientific papers and book chapters, as well as numerous other publications.

Closing of conference

THURSDAY 8 NOVEMBER 2012

12.00 – 12.30

Room 1

TONY HARDY

CHAIR OF THE SCIENTIFIC COMMITTEE, EFSA

Professor Tony Hardy has more than 35 years of risk assessment experience on national and international regulatory pesticide and food safety committees. After degrees at Oxford and Aberdeen Universities, in 1976 he joined the UK Ministry of Agriculture, Fisheries and Food central laboratories, which became the Central Science Laboratory Agency in 1990, and retired as Science Director in 2009. He chaired the EC Scientific Committee on Plants for five years prior to the establishment of EFSA in 2002. He chaired the EFSA Plant Protection Products and their Residues (PPR) Panel for nine years and is now chair of the Authority's Scientific Committee.

He has a scientific background as a research ecologist, environmental chemist and ecotoxicologist, and the main areas of his research and risk assessment experience are in the environmental impact of agricultural chemicals (pesticides) on wildlife, the development of field trials and methods to assess impact on individuals and populations, the environmental impact of farming systems on target and non-target wildlife, the environmental risk assessment of genetically modified organisms, and the wider food safety risk assessment of various chemical and biological agents, pathogens and contaminants.

HUBERT DELUYKER

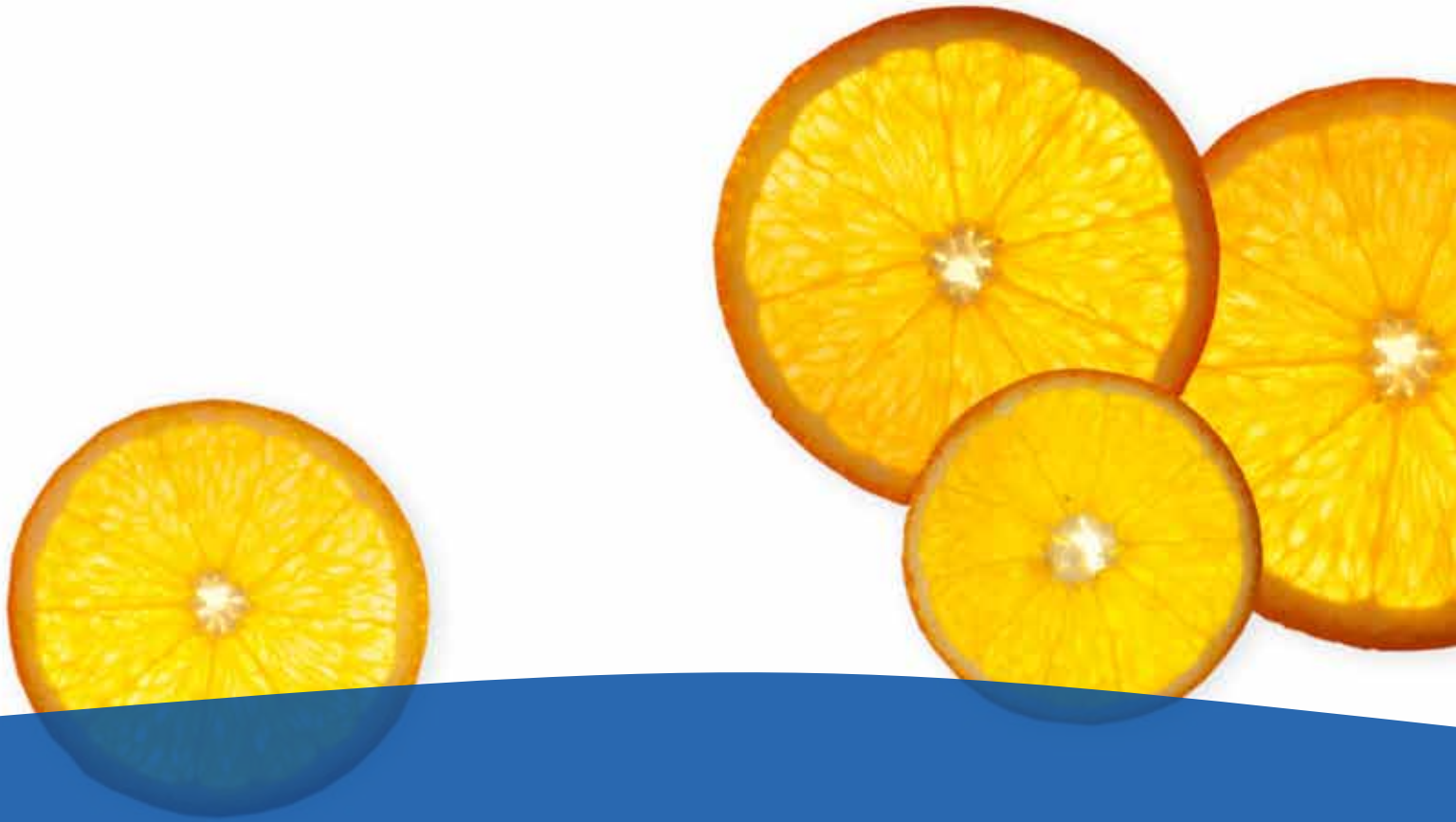
DIRECTOR OF SCIENCE STRATEGY AND COORDINATION, EFSA

Dr Hubert Deluyker is EFSA's Director of Science Strategy and Coordination. The directorate coordinates the implementation of EFSA's Science Strategy and reinforces engagement and cooperation with stakeholders and international partners.

Dr Deluyker joined EFSA in 2004. He established and was acting head of EFSA's Assessment Methodology Unit (currently Scientific Assessment Support Unit) prior to becoming the Director of EFSA's former Scientific Co-operation and Assistance Directorate from 2007 to May 2011, and Director of the Risk Assessment and Scientific Assistance Directorate from May to October 2011.

From 1989 to 2004 he was a clinical research scientist in the field of animal health for Pfizer Belgium, where he led a range of multidisciplinary and multinational research and development projects.

SPEAKER INDEX



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