Briefing note

Plenary session: What does the future hold for assessment science

Organiser: Dr Hubert Deluyker, EFSA and Dr José Tarazona, EFSA

1. Introduction

In its EFSA Strategy 2020 EFSA has developed a conceptual framework, a step-by-step methodology and a plan for the transformation of the EFSA into an Open Science organisation over the next five years. In so doing, it meets key features associated with openness as already recommended in the Phillips report following the BSE crisis (Phillips et al., 2000): openness is essential to achieve trust, it requires recognition of uncertainty, the public's response to it is rational, its means that scientific assessment is to be open and transparent and be made public. The EFSA transformation aims for integrating this basic principle with the demands of a 2020 information-based society.

An open assessment approach according to Phillips is not just about transparency but also about being open-minded, paying attention to scientific uncertainties, opening up to scientific advice (who is allowed to contribute)(Stilgoe and Burrell (in Doubleday and Wilsdon, 2013)).

Jasanoff (2003) cautions though that timely participation does not necessarily improve decision-making. Transparency may in fact exacerbate rather than quell controversy as it becomes an instrument to challenge scientific points on political grounds. On the other hand the author argues that public participation which is constrained by established formal discourses, such as risk assessment, may not admit novel viewpoints.

Sarewitz (2011) argues that: 'Science would probably provide better value to politics if it articulated the broadest sense of plausible interpretations, options and perspectives, imagined by the best experts, rather than forcing convergence to an allegedly unified voice.' It thus implies the evaluation of large and varied bodies of scientific information by a diverse group.

Risk assessment is indeed a 'building block' exercise; combining available knowledge and information at the time of the assessment, as well as assessment scenarios and expert judgement for covering knowledge gaps and uncertainty. An open assessment approach is thus not just a transparent reporting of the selected approaches, but also of the other alternative options and its consequences on the final risk outcome. Even more important, risks should be presented in terms that are relevant and clear for the citizens. In this regard, human health risks are easily understood provided that 'technical argot' is limited and properly explained. The situation is much more difficult in other areas, particularly for environmental health. The latter requires environmental risk assessment paradigms addressing impacts directly relevant to citizens, as further discussed in a breakout session.

For a given question, EFSA relies on a Scientific Panel of some 20 scientists to adopt opinions in a predefined domain and another 5-15 scientists for preparatory work in working groups. The problem, according to Jasanoff (2003) is how to institutionalise polycentric, interactive, and multipartite processes of knowledge-making within institutions that have worked for decades at keeping expert knowledge away from the vagaries of populism and politics.

The risk assessment process is further subject to changes concerning the data, the expertise, the methods, and its capacity for addressing those issues that are really relevant for the citizens. These discussions take place in a context of continued rapid evolution of technology (including ICT) and best management practices in general, which impact work practices of knowledge workers and change societal expectations. The continuous availability of ever larger amounts of data may also affect the way scientific advice is generated and presented to citizens.

Will these new technologies be an instrument to help drive the engagement further: by inviting a much wider scientific community to address a particular question, allowing to broaden the scientific contextualization of a topic, to add diverse streams of scientific reasoning; and to better anchor the outcomes in the scientific community and, gradually, also in society. This concept is different from the traditional 'public consultations'; it would for example invite scientists to spend two or three hours of their spare time to work on a specific question that is posed on the web. Additionally, one could invite interested citizens to contribute with observations to data collections. Personal habits and behavioural patterns are key elements in food safety assessments. For example, getting distributions of food consumption patterns for different population groups can be a challenge for accurate exposure predictions, and ICT tools offer new opportunities for collecting this information. Such engagement of the civil society will also contribute to increasing trust.

Rapid changes in digital technology enable scientists and consumers alike faster and more efficient access to data and information. Opening up governmental data for re-use can have major benefits for citizens, businesses, and society and for the governments themselves. The European Commission's policy builds on three mutually reinforcing strands:

- stimulating the knowledge economy through better availability of data as its raw resource, leading to growth and jobs;
- increasing transparency of public administration; and
- better evidence-based policy making at all levels of government, resulting in better public services.

This policy on Open Data is at the same time an important element of a wider strategy aiming at enhancing the transition towards a data-based economy, as confirmed in the recently adopted Commission Communication 'Towards a thriving data-driven economy' (Chapter 4.2.1. Availability of data and interoperability). The Open Science movement, which has thus entered the sphere of EU institutions, is unleashing the innovative potential of re-use of data. For example, The European Medicines Agency (EMA) has been releasing clinical-trial reports on request as part of its access-to-documents policy since 2010. Similarly, the work of EFSA is tending to demands for more openness and transparency across its spectrum of stakeholders. Equally, scientists and scientific publishers who generate and publish much of the data that is needed for scientific assessments need to address the various aspects of Open Science including open access to publications, open peer review and transparent reporting, allowing external reliability checks, and use and re-use of information beyond the initial publication. This raises issues such as incentives for data re-use and, more generally, the prestige derived from engaging in scientific work that has an important societal impact.

Finally, the debate should consider that the scientific assessment has a component related to the behaviour and freedom of individuals. In the 2020 information society, scientific assessment is therefore not just a tool for risk managers, it is also expected to support

individual decision making by informed citizens, requiring the development of new approaches for presenting the scientific assessment outputs.

Scientific advice for policy development is based on available scientific evidence. As Stilgoe and Burrell (in Doubleday and Wilsdon, 2013) mentioned: 'Usable, relevant, credible evidence for policy is very different from just expecting our scientists to deliver the goods when policymakers come knocking'. They also state: 'There is often confusion in policy, between the science that we want – Nobel prizes and papers in Nature – and 'the science we need' – locally relevant and commissioned for particular purposes. Both are necessary, but the relative detachment of science from other social institutions means less attention is paid to the latter.'

It is thus worthwhile to carefully reflect on best practices to identify, prioritise and address the needs for information of scientific assessment. This often concerns applied research, generating scientific information crucial for scientific assessment. Beyond the identification of research needs and agents of public health concern for study; there is also a need to develop study strategies and approaches.

In this process, it is important both to highlight scientific regulatory needs to researchers and, vice versa, for scientific risk assessors to take into account relevant scientific developments. The latter includes implementing new-approach tools and methods within the existing regulatory paradigm as well as how these might be used for new regulatory paradigms. Examples include High Throughput Screening (HTS)/Tox 21 and how different data streams can be integrated for coming up with health assessments (e.g. systematic review methods and the use of adverse outcome pathways (AOP) approaches for connecting scientific observations with relevant consequences on health and the environment.

2. Objectives

The objective of this plenary session is to reflect on general developments that affect the conduct of assessment science work. These themes provide a basis for further discussion in the subsequent breakout sessions.

The first keynote speaker invites us to reflect on the context in which food safety operates by raising the following questions: 'What can today's science-based approach to food safety assessment take away from historical experience?' and 'To what extent are local and national experiences germane to an era of transnational commerce and translocal decision-making?'

The next keynote speaker explores the apparent tension between science and innovation on the one hand and democracy and public values on the other.

The third keynote presents the US National Toxicology Program (NTP), an interagency, government, research program, a cooperative effort to coordinate toxicology testing programs within the federal government, strengthen the science base in toxicology, develop and validate improved testing methods, and provide information about potentially toxic chemicals to health regulatory and research agencies, scientific and medical communities, and the public.

The final keynote speech brings the perspective of the UK Government Chief Scientific Adviser where risk is a central theme to his work. Innovation in food production is essential to feed our growing global population in the face of climate change. Informed, independent scientific advice is a critical component to help to ensure effective policy development.

3. Scientific programme

What does the future hold for assessment science? – 14 October 2015			
Chairs		Prof. Angeles Rodríguez Peña, COST, Belgium Mr Michael Scannel, Food and Veterinary Office, European Commission, Brussels Dr Bernhard Url, EFSA Executive Director, Italy	
Rapporteurs		Dr Hubert Deluyker, EFSA Dr José Tarazona, EFSA	
Time		**Title**	**Speaker**
Section 1			
14.30	30'	The science of assessment and the assessment of science: new frontiers in food safety evaluation	**Prof. Sheila Jasanoff**, Harvard University, USA
	10'	Q&A	
15.10	30'	From risk regulation to innovation democracy	**Prof. Andy Stirling**, University of Sussex, UK
	10'	Q&A	
15.50	30'	Coffee break	
16.20	30'	Identification, prioritization and conduct of applied research and analyses impacting policy development: lessons learned from the US National Toxicology Program (NTP)	**Dr Nigel Walker** National Institute of Environmental Health Sciences/NIH, USA
	10'	Q&A	
17.00	30'	Scientific support for effective policy development: putting it in practice	**Prof. Sir Mark Walport** Government Office for Science, UK
	10'	Q&A	
Section 4: Panel discussion			
17.40	15'	Moderated panel discussion	Chairs and all speakers
	5'	Concluding remarks	Chairs

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Briefing note

Session: Open Risk Assessment: Data

Organiser: Dr Mary Gilsenan, EFSA

1. Background

Since its foundation, EFSA and EU Member States have made significant progress in the area of data collection for risk assessment and risk monitoring. In harmonising European monitoring and surveillance programmes, in partnership with competent authorities and research organisations in Member States, EFSA has become a central hub of European data on food consumption and occurrence of food-borne hazards. For example, some 14 million records are collated annually at European level within the framework of the pesticide residue monitoring programmes as well as some 900,000 analytical records on contaminants in food and feed. Beyond EFSA's use of these data, they remain largely unexploited. In addition, for some risk assessments, EFSA relies on published scientific information as well as scientific studies sponsored and submitted by industry.

The environment in which the Authority operates has evolved significantly since its foundation. The growth of digital technology has granted scientists and consumers alike the faster and more efficient access to data and information. The 'open data' movement, which has entered the sphere of EU institutions, is unleashing the potential for reuse of data. For example, the European Medicines Agency (EMA) has been releasing clinical trial reports on request as part of its access-to-documents policy since 2010[1]. Similarly, the work of EFSA is increasingly subject to demands for more openness and transparency across its spectrum of stakeholders.

EFSA is developing a data roadmap which outlines its future ambitions relating to data with a focus on achieving more open data to facilitate data reuse, and data interoperability to facilitate data exchange between EFSA and other organisations. EFSA aims to be an advocate for openness by engaging with data providers to adopt open data concepts and standards within its risk assessment remit; in doing so, better access to and use of data from a wider evidence base will make risk assessment more robust and keep it relevant to scientific and technological progress as well as societal concerns.

2. Objectives

The objective of this session is to discuss and debate the opportunities and challenges associated with open data, data interoperability as well as data quality by sharing experiences in various sectors within and outside EFSA's remit.

The session will start with a keynote speaker from the European Commission providing the vision of the European Commission's Open Science Initiative with open access to scientific

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002181.jsp&mid=WC0b01ac058004d5c1,
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf

publications, research results and data anchored at its core. Next, the vision of European Institutions on Europe's Open Data Strategy and the EU Open Data Portal will be discussed, followed by presentations on data visualisation and data interoperability to unleash the potential of data. The final talks will include a discussion on open data covering proprietary studies, e.g. opening clinical trial data from industry dossiers, data collected by public institutions in the Member States and collated by a European Agency, as well as monitoring data collected by the private sector.

3. Scientific programme

Open risk assessment: data – 15 October 2015			
Chairs		**Dr Ana Canals**, Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN), Spain **Dr Angelika Tritscher**, World Health Organization, Switzerland	
Rapporteurs		**Mr Fabrizio Abbinante**, EFSA, Italy **Ms Eileen O'Dea**, Food Safety Authority of Ireland **Dr Mary Gilsenan**, EFSA, Italy	
Time		**Presentation topic**	**Speaker**
Section 1: Keynote			
9.00	20'	European Commission's open science initiative: co-creating added value with data	**Dr Jean-Claude Burgelman,** European Commission, Belgium
	10'	Q&A	
Section 2: Re-use and interoperability			
9.30	15'	The European Commission's open data strategy and the EU Open Data Portal	**Dr Ivo Volman**, Publications Office of the European Union, Luxembourg
	10'	Q&A	
9.55	20'	Data visualizations: drawing actionable insights from science and technology data	**Prof Katy Börner**, Indiana University, USA
	10'	Q&A	
10.25	15'	Data interoperability and linked data technologies	**Mr Dave Weller**, Thomson Reuters, UK
	5'	Q&A	
10.45	30'	Coffee Break	
Section 3: Scope of open data			
11.15	15'	Opening clinical trial data	**Prof Hans-Georg Eichler,** European Medicines Agency (EMA), UK
	5'	Q&A	
11.35	15'	Data collection by public bodies: joint EFSA-Member State activities	**Dr Leif Busk,** National Food Agency, Sweden **Mr Stefano Cappe**, EFSA
	5'	Q&A	
11.55	15'	Metro's Global Standard Traceability Solution	**Ms Britta Gallus,** Metro Group, Germany
	5'	Q&A	
Section 4: Panel Discussion			
12.15	40'	Moderated panel discussion	Chairs and all speakers
	5'	Concluding remarks	Chairs

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Briefing note

Session: Weighing evidence and assessing uncertainties

Organiser: Dr Jean Lou Dorne, EFSA

1. Background

Methodologies for weighing evidence and assessing uncertainties are becoming increasingly important to increase transparency, robustness and confidence in evidence-based risk assessments and to support risk managers in the decision-making process. Major challenges to develop harmonised methodologies for weighing evidence and assessing uncertainties in the food and feed safety area still remain, partly because of the multidisciplinary nature of the topics and the complexity of the data involved (NRC, 2009; Hardy et al., 2014). To cite but a few topics, these range from microbiology, animal health and welfare, epidemiology, toxicology, ecology and plant health to bioinformatics and statistics. Additionally, the beginning of the 21st century has seen the emergence of new approaches in risk assessment, including omics, systems biology, computational methods and tools (i.e. *in silico* tools), which are generating a vast amount of data and evidence (Big Data) that scientists are struggling to integrate in the current risk assessment paradigm (EFSA, 2014). This break-out session aims to stimulate a discussion on the 21st-century challenges to integrate complex evidence and assess uncertainties to support risk assessment and the decision-making process in the context of food and feed safety.

2. Objectives

This session aims to discuss the state of the art and future challenges for the 21st century in relation to weighing evidence and assessing uncertainties as key methodologies needed to deliver scientific advice. In order to address the objectives of the session, a global overview of weight of evidence and uncertainty analysis will set the scene. Weight of evidence approaches will then be illustrated for specific areas of scientific advice in food and feed safety, including chemical risk assessment, biological and environmental risk assessment and validation of animal-free risk assessment methods, considering both the hazard and exposure dimensions in each area. Finally, a global overview on international developments in uncertainty analysis for risk assessment and risk management will bring the session back to the global perspective. .

This break-out session is of high relevance to the current international scientific scene in risk assessment, food and feed safety, public health and environmental protection. The outcome of the session will provide, through a discussion platform, a map of the current and future challenges in weighing evidence and assessing uncertainties for (1) the general public, (2) the broad scientific community involved in human health, microbiological, and environmental risk assessment, (3) scientists involved in developing new approaches in risk assessment, and (4) risk managers.

This break out session will start with a keynote speaker setting the scene and discussing the 'past, present and future' of weight of evidence methods and uncertainty analysis followed by 10 minutes of questions and answers. The session will then provide specific examples of weight of evidence methodologies applied to key food and feed safety areas including:

- weight of evidence approaches applied to the mode of action framework and biological relevance for chemical risk assessment (Meek et al., 2014);
- current and future challenges in the application of weight of evidence methods for microbiological risk assessment (FAO/WHO, 2009);
- latest developments of weight of evidence methodologies for environmental risk assessment (Suter, 2011); and
- opportunities and challenges of the application of the weight of evidence methodology to the validation of animal-free risk assessment within a systems toxicology framework (European Commission, 2014).

For each of the speakers, 5 minutes of questions and answers will allow short discussions on specific issues.

Finally, a global overview of recent international developments in uncertainty analysis from a risk assessment and a risk management perspective will conclude (WHO, 2014), prior to a moderated panel discussion (30 minutes) and concluding remarks from the chair of the session (15 minutes).

3. Scientific programme

Weighing evidence and assessing uncertainties – 15 October 2015			
Chairs		**Mr Prabhat Agarwal**, European Commission, Belgium **Dr Derek Knight**, European Chemicals Agency (ECHA), Finland	
Rapporteurs		**Dr Bernard Bottex**, EFSA, Italy **Dr Jean Lou Dorne**, EFSA, Italy	
Time		**Presentation topic**	**Speaker**
Section 1: Introduction and Keynote to set the scene			
9.00	5'	Introduction of the session by the Chairs	**Mr Prabhat Agarwal**, European Commission **Dr Derek Knight**, European Chemicals Agency (ECHA), Finland
9.05	30'	Weighing evidence and assessing uncertainties: where have been, where are we going?	**Dr Lorenz Rhomberg**, Gradient, USA
	10'	Q&A	
Section 2: Weighing evidence and assessing uncertainties for scientific advice			
9.45	15'	Weighing evidence of biological relevance: from empirical testing in rats to 21st century mode of action analysis	**Dr Harvey Clewell**, The Hamner Institute for Health Sciences, USA
	5'	Q&A	

Time		Presentation topic	Proposed Speaker
10.05	15'	Weighing evidence and assessing uncertainty in microbiological risk assessment: approaches for preparing appropriate scientific support for decision making in complex questions?	**Prof. Matthias Greiner**, Federal Institute for Risk Assessment (BfR), Germany
	5'	Q&A	
10.25	15'	Uncertainty, variability and weight of evidence: how well do we know environmental risks?	**Dr Glen Suter**, US-EPA, US
	5'	Q&A	
10.45	30'	Coffee break	
Section 3: Future challenges			
11.15	20'	Coming to grips with unfamiliar uncertainties of a new predictive toxicology paradigm	**Prof. Maurice Whelan**, European Commission, Joint Research Center, Italy
	5'	Q&A	
11.40	20'	Assessing and communicating uncertainties for risk assessment and risk management: recent international developments	**Dr Andrew Hart**, Food and Environment Research Agency (Fera), UK
	5'	Q&A	
Section 4: Panel discussion			
12.05	30'	Moderated panel discussion	Chairs and rapporteurs
	15'	Concluding remarks	

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Briefing note

Session: Expertise for the future

Organisers: Mr Stylianos Koulouris and Ms Thomai Oikonomidou, EFSA

1. Background

EFSA depends on a system of scientific panels, working groups and the expertise of its staff to perform its role in providing high-quality scientific opinions through food safety risk assessment. The centralisation of the evaluation at EU level intends to increase efficiency but may also represent a challenge with regard to maintaining and developing expertise in the areas of food, feed, plant, animal and environmental risk assessment.

The food risk assessment requires a multidisciplinary and inter-disciplinary approach: excellence in relevant fields of science is a prerequisite, but also knowledge of the full risk analysis process, EU food law, consumer behaviour, international relations and skills in risk communication are needed.

To handle future challenges regarding food safety risk assessment in an ever-changing and increasingly complex environment, the appropriate expertise needs to be identified and a model of specialised and continuous training is required.

This break-out session aims to discuss the state of the art and the future of education in risk assessment. The following issues are addressed: training needs; new technologies implemented in risk assessment training; current developments in higher education and training on food safety risk assessment and regulatory science in the EU and worldwide; challenges in training on general risk assessment, food safety risk assessment and environmental risk assessment; best practices and techniques; future developments in capacity building for risk assessment training; and the increased need for training of professionals.

2. Objectives

The objectives of the session are to raise awaireness regarding developments and challenges in training on food, feed, plant, animal and environmental risk assessment and look at ways to build capacity for training in food risk assessment at global level. It also aims to discuss the state of the art and the future of education in risk assessment, considering the rapidly changing and increasingly complex environment where the appropriate expertise should be identified and a model of specialised and continuous training is more than necessary.

The session openes with a keynote speech, where the importantance of digital technologies in determining future learning interventiones and their importance in shaping the expertise of the future for risk assessments are explored.

3. Scientific programme

Expertise for the Future – 15 October 2015			
Chair		**Prof. Pier Sandro Cocconcelli**, Università Cattolica del Sacro Cuore, Italy **Mr Dominique Gombert**, ANSES, France	
Rapporteur		**Dr Dimitra Kardassi**, EFSA, Italy	
Time		**Presentation topic**	**Speaker**
Section 1: Opening and Keynote speech			
9.00	35'	Expertise for the future: harnessing the power of digital technologies	**Prof. Gráinne Conole,** University of Leicester – Institute of Learning Innovation, UK
	10'	Q&A	
Section 2: Risk assessment graduate programmes and short courses			
9.45	15'	Recent advances in food chemical risk assessment training and capacity building	**Dr Paul Brent,** Project Leader of the World Bank Global Food Safety Partnership (GFSP), Developing training in Chemical Risk Assessment, Australia
	5'	Q&A	
10.05	20'	Food safety risk assessment capacity building: educational cooperation programme in Europe	**Prof. Wolfgang Kneifel,** University of Natural Resources and Life Science, Austria
	5'	Q&A	
10.25	15'	Training in epidemiology and microbiological risk assessment	**Dr Arnold Bosman**, European Centre for Disease Prevention and Control (ECDC), Sweden
	5'	Q&A	
10:45	30'	Coffee break	
Section 3: The evolution of education beyond traditional learning methods			
11.15	15'	Short courses in food safety risk assessment	**Prof. Andreas Hensel,** Federal Institute for Risk Assessment (BfR), Germany
	5'	Q&A	
11:35	15'	Environmental risk assessment training and capacity building	**Prof. Amadeu Soares,** University of Aveiro, Portugal
	5'	Q&A	
11.55	15'	Beyond traditional learning – Ways for professionals to stay up-to-date on health risk assessment	**Prof. Johanna Zilliacus,** Karolinska Institute, Sweden
	5'	Q&A	
Section 4: Panel discussion			
12.15	40'	Moderated panel discussion	Chairs and all speakers
	5'	Concluding remarks	Chairs

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Briefing note

Session: Nutrition challenges ahead

Organiser: Dr Valeriu Curtui, EFSA

1. Background

With the rapid development of science and technology, progress is being made towards an in-depth understanding of the link between nutrition and health. There is accumulating evidence that perinatal nutrition, nutritional epigenetics and programming at an early developmental stage may be associated with health outcomes later in life (May Ruchat et al., 2014). The genetic background and the gut microbiome may also influence the individual response to dietary patterns. Indeed, diet-related disease risk appears to be modulated by an interaction between genetics and nutrition (Bilack and Rodriguez, 2012), and genome sequencing and gut microbiome mapping have fostered interest about the role of personalised nutrition in the prevention of diet-related non-communicable diseases, such as obesity, diabetes and cardiovascular diseases.

At a global level, the provision of nutritious food to the continuously-growing population of the planet in a sustainable manner represents a striking challenge. Are modern food technologies, and new molecules and formulations, the solution? Could natural unexploited resources, such as traditional foods, solve the problem? Or is there a need for both? Supplementation and food fortification have contributed to combating micronutrient deficiencies, but a diversified diet can also be a rich source of naturally available nutrients. Nutrient content varies between foods and among varieties/cultivars/breeds of the same food, and therefore bio-diverse diets may play an important role in ensuring nutrient adequacy (Fanzo et al., 2013). An important part of the human population is suffering from malnutrition, either by deficit (protein-energy malnutrition, vitamin and mineral deficiencies) or excess (obesity) (FAO/WHO, 2014). Solutions to this double-burden of disease are of paramount importance, given the multifactorial nature of malnutrition in all its forms and its evidence-based association with adverse health outcomes (Kaput et al., 2014).

2. Objectives

The objective of the session is to raise awareness about new developments and challenges in nutrition in the 21st century, and provide a vision for a possible way forward. On one hand, the session will highlight the progress made in understanding the relationship between nutrition, genetic background, the gut microbiota and health at the individual level, and challenge nutrient-based, 'reductionist' (*vs*. diet-based, 'holistic') approaches. On the other hand, it will explore possible options for facing the ever-growing need for food and key nutrients, e.g the potential of traditional foods of third countries and local, diversified food production systems, as well as the use of food sources only marginally considered in the past (e.g. insects).

3. Scientific programme

Session title: Nutrition challenges ahead – 15 October 2015			
Chairs		**Prof. Androniki Naska**, University of Athens Medical School, NDA Panel member **Dr Junshi Chen**, China National Center for Food Safety Risk Assessment (CFSA)	
Rapporteur		**Dr Silvia Valtueña Martínez**, EFSA	
Time		**Presentation topic**	**Speaker**
Section 1: Keynote			
9.00	30'	Nutrition in the twenty-first century	**Prof. Thomas Sanders**, King's College London, UK
	15'	Q&A	
Section 2: Food for me			
9.45	25'	Metabolic programming: Implications for feeding infants and children	**Prof. Mary Fewtrell**, University College London, UK
	5'	Q&A	
10.15	25'	Personalised nutrition for the gut microbiome: feed it, change it, swap it?	**Dr Kieran Michael Tuohy**, Fondazione Edmund Mach di San Michele all'Adige, Italy
	5'	Q&A	
10.45	30'	Coffee break	
Section 3: Food for us			
11.15	15'	Novel foods	**Dr Klaus Riediger**, AGES-Austrian Agency for Health and Food Safety, Austria
	5'	Q&A	
11.35	15'	Under-used food sources of key nutrients	**Prof. Nanna Roos**, Copenhagen University, Denmark
	5'	Q&A	
11.55	15'	Using agro-biodiversity for healthier diets within sustainable food systems	**Dr Gina Kennedy**, Bioversity International, Italy
	5'	Q&A	
Section 4: Panel discussion			
12.15	40'	Moderated panel discussion	Chair and all speakers
	5'	Concluding Remarks	Chairs

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Briefing note

Plenary session: Science, innovation & society

Organiser: Dr Hubert Deluyker, EFSA

1. Background

This session focuses on emerging areas in biomedical research that are of key relevance to toxicology but may directly affect the nature of EFSA's work. The impact on the way risk assessment is conducted in the area of food may be through the identification of novel ways through which chemicals affect human health or through the provision of novel tools that could support regulatory assessment methods.

The four topics that are envisaged cover areas which are currently the subject of major biological research and development and are anticipated, with time, to have major effects on regulatory assessment methods. These themes provide a basis for further discussion in subsequent breakout sessions.

A first area of extensive research is that on disorders of the nervous system, both in children and in the elderly. It is estimated that in industrialized countries as many as 15% of the children suffer from neurodevelopmental behavioural disorders (e.g. learning disabilities, developmental delay, attention deficit hyperactivity disorder), and that the prevalence of neurodegenerative diseases (e.g. Alzheimer's disease, other dementias and Parkinson's disease) in the aging population is increasing. In recent years scientists have made great strides in understanding the genetic and environmental multifactorial aetiology of neurodevelopmental and neurodegenerative diseases. Specifically, while genetic factors play a role, exposure to environmental chemicals may be implicated, and thus a healthy vs. diseased state may depend on the interaction between genes and environment. The molecular bases and the mechanisms by which the combination of multiple genetic and environmental factors may contribute to the pathogenesis of these diseases remain elusive, posing thus a challenge for risk assessors. Other emerging research areas that may impact the regulatory assessment approach for this area include the role of inflammation and activation of the immune system in the progression of neurodegenerative diseases and the investigation of the effects of chemicals on the developing neuroendocrine system.

The endocrinology of the reproductive system has many facets and aspects of relevance to most biological disciplines particularly in biomedical sciences, ecology and chemical risk assessment. The development and function of the reproductive system in both sexes is coordinated/integrated with all bodily systems to ensure that reproduction is optimally timed and executed. The primary mechanism via which this integration and coordination is achieved is via the production and action of sex steroid hormones – testosterone and other androgens in men, oestrogens and progesterone in women. However, other body systems have also to 'talk' to the reproductive system and this is also achieved via the production of hormones, examples being leptin from fat cells, insulin from the pancreas and osteocalcin from bone. These systems feedback information on developmental and functional status either directly (by effects on the gonads) or indirectly (via the brain), and the complexity and multiplicity of these feedback

systems is continuing to be uncovered via research. In the context of risk assessment, perturbations of reproductive endocrine functions by chemical stressors are of concern because of their potential deleterious effects on developmental stages (particularly during susceptible windows of development) or reproductive functions of organisms. Over the last three decades, understanding of the endocrinology of the reproductive system and the toxicological consequences of exposure to chemical stressors has considerably increased. This has enabled scientists to develop reproductive and developmental toxicity guidelines and tests for regulated compounds including a number of guidelines including the conceptual framework for the testing and assessment of endocrine disrupters. However, there is still a need to further reflect on issues such as biological relevance.

The human gut is the natural habitat for a large and dynamic bacterial community, but a substantial part of these bacterial populations are still to be described. They encode our 'other genome' with millions of genes, vastly surpassing the coding capacity of the human genome. Gut microbes mainly contribute to the breakdown and bioconversion of dietary components that are not degraded by our own digestive system, such as most plant-based complex polysaccharides and phytochemicals. The microbial metabolites provide energy but also act as signalling molecules that generate systemic immune and metabolic responses and hence can profoundly affect human physiology and health. It is noteworthy that the type and biological activity of the bacterial metabolites released in our gut heavily depend on diet. For example, colonic fermentation of dietary fibre results in production of short chain fatty acids (SCFAs) of which butyrate and propionate have well-documented beneficial effects on gut and systemic health. On the other hand, bacteria can convert dietary protein into metabolites that increase risk for atherosclerosis and colorectal cancer. Hence, intestinal bacteria appear pivotal in mediating the health effects of foods.

Epigenetic changes are implicated in serious adverse health effects, including cancer, endocrine disruption and other diseases through the modulation of cellular communication systems that homeostatically regulate cell proliferation, differentiation, apoptosis and senescence. Epigenetic regulation may be affected by environmental stressors. Therefore, 'epigenetic toxicity' has emerged as a significant concept that must be integrated in the risk assessment process. To understand 'epigenetic' mechanisms, the pathogenesis of human carcinogenesis can serve as a model. Most cancers, except teratomas, are the result of a multi-stage, multi-mechanism process or the 'initiation/promotion/progression' concept. Initiation step is an irreversible step taking place in a single cell of any organ, most likely by a mutation caused either by an error of DNA repair or by an error of DNA Replication. Promotion, on the other hand, is an epigenetic mechanism, which is threshold-dependent, species-, gender- and organ-specific. It must occur after initiation, for long periods of regular exposures, has oxidative stress-related properties, and occurs in the absence of 'anti-promoters'. Chemical agents (e.g., aflatoxins, TCDD, PCB's, chemicals in cigarette smoke or grilled red meat, etc...) demonstrate properties of tumour promoters or epigenetic agents. Epigenetic agents include some regulated substances which are subject to risk assessment according to current legal requirements, but whose potential to adversely impact the cellular epigenetic systems is largely unknown. Epigenetic effects may differ in relevant characteristics from other effects/adverse outcome pathways currently considered in risk assessment: e.g. the time lapse between exposure and adverse outcomes may differ significantly from 'classical' toxic effects when epigenetic mechanisms are implicated. An example of such epigenetic influences concerns the impact of in utero exposure to cigarette smoke on childhood obesity. As the current risk assessment approach is not addressing epigenetic effects appropriately, the

development of specific test methods for hazard assessment of stressors with an epigenetic mode of action remains a key challenge for the scientific community.

2. Objectives

The objective of this session is to explore scientific developments in areas of key relevance that may affect the nature of EFSA's work, in particular the guidance that EFSA develops and uses.

The four topics that are covered in this session are (i) disorders of the nervous system, (ii) the endocrinology of the reproductive system, (iii) the human gut microflora and (iv) epigenetic changes. The objectives are as follows

- To integrate our current knowledge of the way neuronal communication occurs in the brain and how under pathological conditions such as those elicited by environmental chemicals a loss of neuronal activity and information processing occurs.
- To present recent developments in the area of reproductive endocrinology and to understand how exogenous chemicals can influence development by affecting the integration of the different body systems with reproduction.
- To provide an understanding of why gut microbes can affect human health through the formation of signalling molecules and immunomodulatory compounds and how food chemicals can modulate these responses by acting as stressors of the gut microflora.
- To understand how 'epigenetic' mechanisms can lead to the pathogenesis of human carcinogenesis and other diseases.

3. Scientific programme

Science, innovation & society – 15 October 2015			
Chairs		Prof. Anthony Hardy, EFSA Scientific Committee, Italy Prof. Jean-Louis Bresson, Université Descartes & Hôpital Necker-Enfants Malades, France	
Rapporteurs		Prof. George Kass, EFSA Dr Frank Boelaert, EFSA	
Time		**Title**	**Speaker**
Section 1			
14.30	30'	Food and health: the role of intestinal micro-organisms in human health	**Dr Anne Salonen,** University of Helsinki, Finland
	10'	Q&A	
15.10	30'	Key developments in the research on reproductive endocrinology	**Prof. Pierluigi Nicotera**, German Center for Neurodegenerative Diseases, Germany
	10'	Q&A	
15.50	30'	Coffee Break	
16.20	30'	Key developments in the research on reproductive endocrinology	**Prof. Richard M. Sharpe**, University of Edinburgh, UK
	10'	Q&A	

Time	Title	Speaker	Time
17.00	30'	Understanding complex mechanisms in determining adverse and beneficial health effects with nutrition/diets: from basic science of hazard identification to the concept of 'One Health-One Planet'	**Prof. James E. Trosko,** Michigan State University, USA
	10'	Q&A	
Section 4: Panel discussion			
17.40	15'	Moderated panel discussion	Chairs and all speakers
	5'	Concluding remarks	Chairs

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Briefing note

Session: Open Risk Assessment: Methods and Expertise

Organiser: Mr Didier Verloo, EFSA

1. Background

EFSA's raison d'être is to support risk managers in the decision-making process. The information resulting from the risk assessment thus needs to be of value to them i.e. addressing the issue at hand in a manner that is relevant. In addition, EFSA's work is only relevant if there is stakeholder trust in its work.

The European food safety system has created an institutional separation between risk assessment and risk management. For the risk management, the European Commission, the European Parliament and competent authorities in the Member States are responsible for the preparation and enforcement of legislation on food safety, animal and plant health and animal welfare in the European Union.

EFSA has recently launched a number of activities to further contribute to producing more robust, transparent and open scientific assessments. Open scientific assessment can be defined as a decision support process where there is not only full transparency (showing what has been done and how it is done) but also an interaction with the outside world on the data, the methodologies used and the outcome. In line with the Authority's intention to further open up its activities to wider scrutiny and participation, EFSA has recently published a discussion paper on Transformation to an "Open EFSA" (EFSA, 2014).

EFSA and other scientific advisory bodies recognise a need to improve the transparency and openness of scientific assessments in line with today's normative and societal expectations. In this context, the framing of the scientific question posed by the requestor (in most cases a decision maker/stakeholder) is important to ensure that the question represents the problem to be addressed and that it is agreed and clearly expressed prior to the start of the assessment. Methodology, expertise, analyses and information needs should ensure that the assessment is fit for purpose, based on the available evidence and appropriately tailored to answer the question posed.

The move to open science and open data along with the increasing amount of evidence relevant for risk assessment published in open literature means that the amount of available information grows every minute. EFSA wants to explore how this vast amount of knowledge can be used in its risk assessments in a transparent and traceable way. In this sense, recent developments using machine-learning techniques (cognitive analytics) are being explored.

2. Objectives

EFSA proposes to explore the future challenges and the latest thinking and techniques on openness that will assist the organisation in moving beyond dialogue towards sustainable stakeholder interaction. This will facilitate the discussion on the needs of EFSA and on target

audiences throughout the process, from risk assessment initiation through societal decision-making and communication.

3. Scientific programme

Open risk assessment: methods & expertise – 16 October 2015			
Chairs		**Dr Elke Anklam**, European Commission, Joint Research Center, Belgium **Dr Robert Doubleday**, Centre for Science and Policy, University of Cambridge, UK **Dr Hiroshi Satoh**, Food Safety Commission, Cabinet Office, Government of Japan **Prof. Reiner Wittkowski**, Federal Institute for Risk Assessment (BfR), Germany	
Rapporteurs		**Mr Didier Verloo**, EFSA, Italy **Mr Tom Meyvis** , EFSA, Italy	
Time		**Presentation topic**	**Speaker**
Section 1: Keynote			
9.00	30’	From ‘Science in Society’ to ‘Science with Society’?	**Prof. Gerard H. de Vries** University of Amsterdam, Netherlands
	15’	Q&A	
Section 2: Problem formulation risk assessment initiation			
9.45	15’	Regulatory impact assessment using socio-economic analysis	**Prof. Tomas Öberg** European Chemical Agency (ECHA), Finland
	5’	Q&A	
Section 3: Expertise			
10.05	15’	The role of crowdsourcing in Risk Assessment.	**Mr Steven Drew** InnoCentive, USA
	5’	Q&A	
10.25	15’	User motivation and knowledge sharing in idea crowdsourcing	**Ms Miia Kosonen** Mikkeli University of Applied Sciences, Finland
	5’	Q&A	
10.45	30’	Coffee break	
Section 4: Methods			
11:15	15’	How to support decisions with online collaborative models?	**Dr Jouni T. Tuomisto** National Institute for Health and Welfare, Finland
	5’	Q&A	
11.35	15’	Extracting evidence from unstructured data: potential applications of IBM Watson for risk assessment	**Mr Cameron Brooks** IBM Watson Group, Public Sector Solutions, USA
	5’	Q&A	
Section 5: Communication			
11.55	15’	Implementing the risk profile: the German risk assessor’s experience	**Dr Mark Lohmann** Federal Institute for Risk Assessment (BfR), Germany
	5’	Q&A	
Section 5: Panel discussion			
12.15	40’	Moderated panel discussion	Chairs
	5’	Concluding remarks	Chairs

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Briefing note

Session: Novel chemical hazard characterisation approaches

Organiser: Dr Manuela Tiramani, EFSA

1. Background

There is a fundamental change in thinking in the regulatory community, due to a better understanding of the underlying biology behind how chemicals cause adverse effects to human health and the environment. The huge amount of data available from new techniques such as 'omics' and high-throughput screening methods has an impact. The key topics are adverse outcome pathways (AOPs) and modes of action (MoA) as the underlying theory and integrated assessment and testing approaches (IATAs) as means of combining multiple lines of evidence to predict the hazard of a chemical. Complex endpoints cannot be predicted by a single non-standard test; instead it is necessary to use a weight of evidence (WoE) or IATA where information and evidence can be incorporated flexibly.

Scientific and technological advances including the sequencing of human genome, the growth of computing power and computational biology, are triggering a revolution in biology and toxicology, making available a huge number of new tools to investigate chemical effects. The benefits of these new advances are the possibility of studying effects on cells, tissues and organisms in a timely and cost-efficient manner (Seidle et al. 2012). In addition, one of the main themes in the current research is the need to move away from whole animal testing towards the use of alternative *in vitro* methods, in agreement with the 3R concept. In June 2009 the framework for the replacement of *in vivo* repeated dose systemic toxicity testing was created through a call for proposals under the Health Theme of the 7th European Framework Programme (FP7), which resulted in the SEURAT Research project ('Safety Evaluation Ultimately Replacing Animal Testing'), which is composed of six research projects and started on 1 January 2011 (it will run for five years).

In 2014, the EU-funded collaborative project Predict-IV (Profiling the toxicity of new drugs: a non-animal based approach integrating toxicodynamics and biokinetics) was finalised: it aimed at developing strategies to improve the assessment of drug safety by a combination of non-animal based test systems, cell biology, mechanistic toxicology and *in silico* modeling (Mueller et. al 2014). In 2013 the European Commission's Scientific Committees – 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) – prepared an opinion to define the roadmaps for the changes that will likely impact in the future human and ecological risk assessment. One of the roadmaps of the new toxicology paradigm is represented by Tox21, which indicates the need of researching, developing, validating and translating innovative chemical testing methods that characterise toxicity pathways. A way of combining pathway-based tests likeTox21 is Integrated Testing Strategies (ITS). ITS has been, so far, partially considered in test guidance for regulations, as there is still little guidance on the composition, validation, and adaptation of ITS for different purposes. Similarly, Weight of Evidence and Evidence-based Toxicology approaches require different pieces of evidence and test data to be weighed and combined (Hartung, 2013).

2. Objectives

The session is structured to provide the audience with an extensive overview of the main topics under development in the field of hazard characterisation. The keynote presentation will introduce the main challenges for the 21st century research; specific presentations will follow to deepen specific arguments. A panel discussion will conclude the session. The following key topics will be presented and discussed:

- The frontiers of predictive toxicology
- Systems biology approach and predictive toxicology
- Computational toxicology

3. Scientific programme

Novel chemical hazard characterisation approaches – 16 October 2015			
Chairs		**Dr Emanuela Testai**, Istituto Superiore di Sanità, Department of Environment and Primary Prevention, Italy **Dr William Slikker**, Food and Drug Administration/National Center for Toxicological Research, USA	
Rapporteur		**Dr Manuela Tiramani**, EFSA	
Time		**Presentation topic**	**Speaker**
Section 1: Keynote			
9.00	30’	The frontiers of predictive toxicology	**Prof. Thomas Hartung**, Johns Hopkins University, USA
	15’	Q&A	
Section 2: Systems biology approach and predictive toxicology			
9.45	15’	Alternative and integrated testing strategies	**Prof. Horst Spielmann**, Freie Universität Berlin, Germany
	5’	Q&A	
10.05	15’	The study of modes of action: the AOP	**Prof. Ellen Fritsche**, IUF – Leibniz Research Institute for Environmental Medicine, Germany
	5’	Q&A	
10.25	15’	*In vitro* data and *in silico* models for predictive toxicology – The SEURAT project	**Dr Elisabet Berggren**, European Commission, Joint Research Centre, Italy
	5’	Q&A	
10.45	30’	Coffee break	
Section 3: Computational toxicology			
11.15	15’	QSAR and computational tools	**Dr Emilio Benfenati**, Istituto di Ricerche Farmacologiche Mario Negri, Italy
	5’	Q&A	
11.35	15’	In vitro and high throughput screening (HTS) assays	**Dr Raymond Tice**, NIEHS, USA
	5’	Q&A	
11.55	15’	Organs-on-Chips: A living platform for generating human relevant data	**Dr Remi Villenave**, Emulate, USA
	5’	Q&A	
Section 4: Panel discussion			
12.15	40’	Moderated panel discussion	Chair and all speakers
	5’	Concluding remarks	Chair

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Briefing note

Session: Microbiological risk assessment

Organisers: Dr Winy Messens and Dr Valentina Rizzi, EFSA

1. Background

Microbiological risk assessment (MRA) is defined by CODEX (CODEX, 2007) as 'a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation'. This clear and short definition 'hides' a complex discipline with a broad spectrum of approaches; from qualitative to quantitative assessments, focused on part (or specific step) of the food chain to the whole chain (or farm-to-fork). In addition the outcome of the MRA may range from a number of human cases to the (economic) cost of the disease.

This complexity is also reflected in the number and diversity of risk assessment tools currently available. EFSA has conducted in the past years several MRAs for which a model was designed to fit the needs of the particular question (Romero-Barrios et al., 2013), while other models aim at becoming generic tools that can be used for a variety of purposes. In parallel to this, developments have been made to better measure the impact of foodborne diseases on the human population and to use this information for prioritising risks (EFSA BIOHAZ Panel, 2012, 2015). Work is also being undertaken to bring a more structured way to deal with uncertainty in these MRAs, something that is challenging particularly when communicating the risk estimates to the risk manager and the general public.

The subjects selected for this session will provide good examples of this complex scenario, covering issues such as the estimation of the burden of disease in a global context, how to prioritise microbiological risks and to deal with uncertainty, challenges in risk assessment for viruses and the contribution of typing methods to risk assessment.

2. Objectives

The session aims to discuss topics at the forefront of MRA, looking at the lessons learned from applying current methodology for individual risk assessment and ongoing scientific developments. The aspects that will be considered are the ranking of microbiological risks, risk assessment of individual hazards throughout the food chain and scientific advice in emergencies, examining both the methodological challenges posed and the opportunities that lie ahead.

3. Scientific programme

Microbiological risk assessment – 16 October 2015			
Chair		**Dr Steve Hathaway**, Ministry for Primary Industries, New Zealand **Prof. Birgit Nørrung**, University of Copenhagen, Denmark	
Rapporteurs		**Dr Winy Messens**, EFSA, Italy **Dr Valentina Rizzi**, EFSA, Italy	
Time		**Title**	**Speaker**
Introduction and welcome			
9.00	5'	Opening of the session and welcome	Chair
Section 1: Keynote			
9.05	30'	World Health Organization estimates of the global burden of foodborne disease, 2010	**Prof. Arie Havelaar**, University of Florida, USA
	10'	Q&A	
Section 2: Risk ranking			
9.45	20'	Methodology and uncertainty impact on risk ranking of microbiological hazards: present and future	**Prof. Kostas Koutsoumanis**, Aristotle University of Thessaloniki, Greece
	10'	Q&A	
10.15	20'	Improving the usability and communicability of burden of disease methods and outputs: the BCoDE toolkit application	**Dr Alessandro Cassini**, European Centre for Disease Prevention and Control (ECDC)
	10'	Q&A	
10.45	30'	Coffee break	
Section 3: Challenges for microbiological risk assessment			
11.15	15'	The contribution of typing methods to risk assessment	**Dr Flemming Scheutz**, Statens Serum Institute, Denmark
	5'	Q&A	
11.35	15'	Challenges in risk assessment for viruses	**Prof. Marion Koopmans**, Erasmus MC Viroscience Department, Netherlands
	5'	Q&A	
11.55	15'	Approaches to deal with uncertainty in emergency assessments: the case of the EHEC outbreak in 2011 in Germany	**Prof. Dr Gordon Müller-Seitz**, Technical University Kaiserslautern, Germany
	5'	Q&A	
Section 4: Panel Discussion			
12.15	30'	Moderated panel discussion	Chair and all speakers
	15'	Concluding remarks	Chair

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Briefing note

Session: Drivers for emerging issues in animal and plant health

Organiser: Dr Frank Berthe, EFSA

1. Background

The history of agriculture includes many developments related to plant and animal health, some of which have had a major impact on the sector itself. There are many examples, among which one could cite the impact of Rinderpest or Phylloxera, or more recently, the detection of *Xylella fastidiosa* in the European Union in late 2013 or the emergence of the Schmallenberg virus in 2011.

Human activities have often driven the appearance of emerging issues. The more humans expand the footprint of the global population, encroach into natural habitats, alter these habitats to extract resources, intensify food production, and move animals, people commodities and their pathogens, the greater the potential for infections to emerge or re-emerge and for pathogens and pests to spread (Jones et al., 2008; Bebber et al., 2014).

Producing food plays a major role in this. Food production is a human activity which is believed to have the largest impact on the planet. As an example, food production uses twice the amount of water compared to all other human activities combined. The risk of emergence of new pathogens and spread of existing ones has also increased as a consequence of deep and global changes in the way food is produced and consumed, as well as many other factors that characterise the anthropocene, an epoch that begins when human activities have had a significant global impact. This is probably a long-term trend considering that by 2050 the global population is expected to be over 9 billion. The income of a substantial part of the global population is expected to be nearly three times that of today, with expected changes in food habits, such as increased demand for meat. These new habits, and shifting demands, will result in an effort to increase food production that will place a greater burden on the resources of the planet.

At the same time, climate change is likely to increase pressure on the availability of food – because of reduced reliability on seasons, and extreme climatic events such as droughts or heavy rains. Climate change will also provide new habitats for living organisms, including invasive species, as well as pests and pathogens.

Population displacements due to multiple and overlapping political and humanitarian crisis, which have occurred in several parts of the globe over the last few years, will probably be a feature of the future and will also represent a potential for emerging infections and spread of pests and pathogens.

Change is not only a threat to plants and animals but may have direct and indirect consequences on public health either because of impact on livelihoods, including food shortage, or because of zoonotic impact such as new pathogens to humans or antimicrobial resistance (Greger, 2007; Liverani et al., 2013). Indeed, the overlapping drivers of diseases and environmental changes, as well as their knitted implications, point towards the relevance

of a concept like 'One Health', an integrated view and approach to human, animal and environmental health.

Most drivers for emerging issues are common to public, veterinary, plant and ecosystem health. In order to avoid a dilution of efforts in identifying, describing and monitoring those drivers, such efforts should be collectively developed by the relevant communities. Several initiatives have engaged in fostering synergies and bring together public and animal health, social development, ecology, economics, and other sectors to investigate connections between health and environmental change. Their objective is to generate scientific evidence and policy options in order to limit the impact of emerging diseases and, even more importantly, to prevent them from occurring.

The endeavour is to understand the influence of human behaviour and to incorporate this understanding into our approach to emerging risks. For this we probably face two major challenges: one is cultural; the second, methodological. We have to look at systems not from the standpoint of specific hazards but for the dynamics of the systems themselves and a broad spectrum of possible outcomes. The second challenge is to make sense of the vast amounts of data that are available in our modern age.

2. Objectives and scope

The main objective of this session is to prepare for a cultural and methodological shift in our approach to emerging risks for plant, animal, ecosystem and human health.

A cultural change is required, which relates to our capacity to look at systems not from a narrow standpoint of a specific hazard but for the dynamics of the system, and a spectrum of possible outcomes related to plant, animal, ecosystem or human health.

A methodological challenge is also required, which relates to our capacity to make sense of the vast amounts of data that are available in our modern age.

The session will be structured around three sections covering lessons learned from historical outbreaks, a review of how hosts, pathogens and their environment are interlinked, and finally how to use drivers to improve our capacity to prevent and detect emergence. The session will also aim at exploring how natural and social sciences can find synergies in systemic analysis of emerging issues providing better identification, description and monitoring of their drivers. It will conclude with an interactive panel discussion. The format is expected to stimulate active participation of the audience.

3. Scientific programme

Drivers for emerging issues – 16 October 2015			
Chairs		**Prof. Guy Poppy**, Food Standards Agency and University of Southampton, UK **Dr Jan Schans**, Netherlands Food and Consumer Product Safety Authority (NVWA)	
Rapporteurs		**Dr Frank Berthe**, EFSA **Dr Caryl Lockhart**, Food and Agricultural Organization (FAO), Italy **Dr Stefano Pongolini**, Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia-Romagna, Italy **Dr Jane Richardson**, EFSA	
Time		**Title**	**Speaker**
Introduction and welcome			
9.00	5'	Opening of the session and welcome	**Dr Jan Schans**, Netherlands Food and Consumer Product Safety Authority (NVWA)
Section 1: Learning our lessons			
9.05	20'	People, animals, plants, pests and pathogens: connections matter	**Dr William Karesh**, EcoHealth Alliance, USA
	5'	Q&A	
Section 2: Hosts, pathogens and their environment			
9.30	20'	Relations between hosts, pathogens and environment: joining the dots	**Prof. Matthew Baylis**, University of Liverpool, UK
	5'	Q&A	
9.55	20'	Discovering novel pathways of cross-species pathogen transmission	**Prof. Tony Goldberg**, University of Wisconsin-Madison, USA
	5'	Q&A	
10.20	20'	Broad brush analysis of livestock disease drivers, ecology and pathogen evolution	**Dr Jan Slingenbergh**, independent advisor
	5'	Q&A	
10.45	30'	Coffee break	
Section 3: Drivers in action			
11.15	20'	Horizon scanning for emergence of new viruses in animal and public health	**Dr Paul Gale**, Animal and Plant Health Agency, UK
	5'	Q&A	
11.40	20'	Mapping complexity: visualising a world of change	**Dr Tommaso Venturini**, SciencesPo médialab, France
	5'	Q&A	
12.05	10'	A vision for a global operation room	**Prof. Mike Catchpole**, European Centre for Disease Prevention and Control (ECDC), Sweden
Section 4: Panel discussion			
12.15	40'	Moderated panel discussion	Chairs and all speakers
	10'	Concluding remarks	Rapporteurs and chairs

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Briefing note

Session: Advancing environmental risk assessment

Organiser: Dr Yann Devos, EFSA

1. Background

Maintaining a healthy environment and conserving biodiversity are major goals of environmental protection, as they contribute to human well-being and economic prosperity through the provision of ecological services, including ecosystem services. Biodiversity is also intrinsically valuable and therefore worth protecting. Environmental risk assessment (ERA) of regulated products, such as plant protection products (PPPs), genetically modified organisms (GMOs) and feed additives, is an important safeguard to ensure the desired level of protection of the environment and biodiversity. ERA evaluates the potential adverse effects on the environment of certain actions, and has become an important support to inform regulatory decision-making. Significant advances have been made in the field in recent years. However, ERA still faces a number of challenges such as the integration of multiple stressors and harmonisation of risk assessment approaches across disciplines. Therefore, potential avenues to overcome some of these challenges and advance ERA approaches further will be explored during this break-out session.

PPPs, GMOs and feed additives are subject to a risk analysis and regulatory approval before entering the market in the EU. In this process, the role of the European Food Safety Authority (EFSA) is to independently assess and provide scientific advice to risk managers on any possible risk that the use of PPPs, GMOs and feed additives may pose to human and animal health and the environment. EFSA also assesses the potential risks related to the introduction and spread of new alien pests in the EU and the impact of their management on the ecosystem. The decision on the level of acceptable risk is taken by risk managers who weigh policy options to accept, minimise or reduce characterised risks.

2. Objectives

This break-out session will explore challenges pertaining to ERA and potential avenues to advance it further. The outcome of the session may assist scientists, risk assessors and decision-makers/regulators attending it to better determine the strengths and limitations of current ERAs, and to define research needs in the field of ERA. The session will focus on the following avenues for advancing ERA: harmonising approaches to make protection goals operational, paying greater attention to the relevance and quality of scientific studies to support ERAs, and moving towards integrated ERA to account for multiple stressors.

- *Making protection goals operational*: Legal frameworks require the protection of human, animal and plant health, and the environment (including biodiversity). This demands defining and specifying relevant protection goals, and deriving scientifically measurable entities that represent these protection goals. A challenge, however, is that protection goals outlined in legislation are often too general and vague to be scientifically

assessable. Therefore, it is important that these general and broad protection goals are translated into scientifically testable hypotheses and concise and concrete measurable endpoints. The ecosystem service concept has gained wide acceptance within the international scientific community and is currently widely recognised as a useful framework for policy-makers to safeguard the sustainability of ecosystems and to protect biodiversity. Investigating the environment through the framework of ecosystem services enables to recognise the wide range of benefits to humans provided by ecosystems and biodiversity, to identify how changes in these environmental components influence human well-being, and to account for both economic and environmental considerations. Therefore, it will be discussed whether the ecosystem services concept can form the basis for developing a harmonised approach for making protection goals operational across different ERAs conducted by EFSA. The multi-layered relationship between biodiversity and ecosystem services and whether the use of the ecosystem services concept will protect biodiversity will also be explored.

- *Demarcating ERA studies from ecological research*: Not all information on the ecology of regulated stressors available in the scientific literature (*nice to know*) is equally relevant and appropriate to their ERA (*need to know*). This is because ecological research and ERA differ in the sources of problems, the nature of hypotheses under test, and even the methods for testing hypotheses. To avoid obscuring ERAs with uninformative data, the use of problem formulation has been advocated. Robust ERAs should begin with an explicit problem formulation where plausible and relevant exposure scenarios and the potential adverse effects from those exposures are identified. Problem formulation enables a structured, logical approach to identifying harmful effects requiring characterisation, while excluding non-harmful effects as irrelevant. It helps to identify what is known, missing information and scientific uncertainties that may limit the assessment, and thus what needs to be evaluated in order to generate useful and informative data. Therefore, the relevance of problem formulation to maximise the relevance of ERA studies for decision-making will be explored.
- *Ensuring data quality*: It is obvious that the testing of policy-related hypotheses should be as rigorous and objective as any hypothesis testing in any other branch of science. Yet, the critical evaluation of the quality of experimental studies in support of ERA remains a contentious issue of debate in some jurisdictions, especially in the area of GM plants. Ecotoxicological laboratory studies are a major part of the studies performed to assess potential adverse effects of GM plants on non-target organisms and the valued ecosystem services they contribute to. Ecotoxicological laboratory studies on non-target effects of GM plants will therefore be used as a case study to discuss good practices to comply with when designing laboratory studies and when analysing/interpreting the generated data. In addition, the use of scientific publications to complement standard GLP studies will be addressed.
- *Considering multiple stressors*: The potential risks associated with the simultaneous or sequential exposure to different regulated stressors are rarely directly considered in ERAs, which typically considers specific stressors in isolation according to the relevant legislation. Moreover, ERA schemes may deviate for different types of regulated stressors. Therefore, possible actions to facilitate the transition towards an integrated ERA of multiple stressors will be considered. The environmental assessment of multiple stressors requires moving to landscape assessments, mapping the risk and likelihood for co-occurrence of different stressors in the spatial and temporal scales. Available tools,

methods and research needs in this area will be discussed. Bees will be used as a case study, as they are potentially exposed to a range of stressors of natural or anthropogenic origin in natural and agro-ecosystems. Moreover, an increasing body of scientific literature underpins the multi-factorial origin of bee losses and colony weakening.

3. Scientific programme

Advancing environmental risk assessment – 16 October 2015			
Chairs		**Dr Helmut Gaugitsch**, Umweltbundesamt (Environment Agency Austria), Austria **Dr Jock Martin**, European Environment Agency (EEA), Denmark	
Rapporteurs		**Dr Yann Devos**, EFSA, Italy **Dr Agnès Rortais**, EFSA, Italy **Dr Reinhilde Schoonjans**, EFSA, Italy **Dr Franz Streissl**, EFSA, Italy	
Time		**Title**	**Speaker**
Introduction and welcome			
9.00	5’	Opening of the session and welcome	**Dr Helmut Gaugitsch**, Umweltbundesamt (Environment Agency Austria), Austria
Section 1: Keynote to set the scene			
9.05	20’	An introduction to ERA: advances and challenges	**Prof. Alan J Gray**,Centre for Ecology and Hydrology, UK
	5’	Q&A	
Section 2: Making protection goals operational for use in ERAs			
9.30	20’	The ecosystem service approach to make protection goals operational	**Prof. Lorraine Maltby**, University of Sheffield, UK
	5’	Q&A	
9.55	20’	Protection Goals, Assessment Endpoints, Ecosystem Services and Biodiversity	**Dr Glenn Suter**, U.S. Environmental Protection Agency, USA
	5’	Q&A	
Section 3: Relevance and reliability of studies supporting ERA			
10.20	20’	ERA vs. ecological research – The importance of a good problem formulation	**Dr Joe Smith**, Advisor in Science and Regulation, Australia
	5’	Q&A	
10.45	30’	Coffee break	
Section 3: Relevance and reliability of studies supporting ERA			
11.15	20’	Methods used to assure high quality studies for ERA – non-target arthropod testing of transgenic plants as a case study	**Dr Jörg Romeis**, Agroscope, Institute for Sustainability Sciences, Switzerland
	5’	Q&A	
Section 4: Integrated ERA			
11.40	20’	Multiple stressors: bees as a case study	**Dr Jeffrey S Pettis**, USDA-ARS, USA
	5’	Q&A	
Section 5: Panel Discussion			
12.05	45’	Moderated panel discussion	Chairs and all speakers
	10’	Concluding remarks	Rapporteurs and chairs

4. References

Section 2: Making protection goals operational for use in ERAs

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Section 3: Reliability of studies supporting ERA

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Section 4: Integrated ERA

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