European Food Safety Authority

PESTICIDES UNIT

Environmental risk assessment of pesticides: 25 years of scientific advancements since the adoption of Directive 91/414/EEC

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Abstracts and Biographies

Welcome and introduction

Bernhard Url
European Food Safety Authority (EFSA)
Speaker

Dr Bernhard Url was appointed Executive Director of EFSA in June 2014, having served as Acting Executive Director for seven months. Dr. Url joined EFSA in June 2012 as Head of the Risk Assessment and Scientific Assistance Department. A qualified veterinarian by training, he brings high-level management experience from food-safety organisations to his role at EFSA. Prior to joining the Authority, Dr. Url was Managing Director of the Austrian Agency for Health and Food Safety (AGES), which represents Austria on EFSA's Advisory Forum. From 2008 to March 2012, he also served as a member of EFSA's Management Board. Prior to AGES Dr. Url 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 graduated from the University of Veterinary Medicine in Vienna in 1987 and became a Doctor of Veterinary Medicine in 1990. He has published in the field of veterinary medicine with a particular focus on listeria and milk hygiene.

Guilhem de Seze
European Food Safety Authority (EFSA)
Speaker

Guilhem de Seze joined EFSA on 1 September 2016 to head the department of Scientific Evaluation of Regulated Products. Guilhem arrived from the European Chemicals Agency (ECHA) in Helsinki, which he joined in its early years, in February 2008; there he occupied different positions, initially contributing to the development of ECHA's work processes and IT systems. From January 2011 he was a Head of Unit, first for Substance Identification and Data Sharing and then for Evaluation; both units are responsible for assessing scientific and technical information about chemical substances and their hazardous properties. Before joining ECHA, Guilhem worked in the field of hazardous chemicals management in academia and in the chemical industry for over ten years. Guilhem holds a PhD. in Chemical Engineering from Louisiana State University, USA, specialising in environmental exposure to pollutants.

TOPIC 1
Overview of the EU regulatory framework for pesticides (pre-marketing and post-marketing)

Jose V. Tarazona
European Food Safety Authority (EFSA)
Chairperson

Dr Jose V. Tarazona is the Head of the Pesticides Unit at the European Food Safety Authority (EFSA). A doctor in Veterinary Medicine with a PhD in Toxicology, from 1982 to 2009 he was a researcher at the Spanish National Institute for Agriculture and Food Research and Technology (INIA), serving also as Head of the Division of Environmental Toxicology and Director of the Department of the Environment. He has been involved in the scientific advisory board of the European Union since 1992; was a member of the CSTE, vice-chair of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), and vice-chair of the Scientific Committee on Health and Environmental Risks (SCHER). He has been member of the UNEP POPs Review Committee and external expert-consultant for different European bodies, OECD, WHO and UN, chairing OECD and UN Expert Groups within the GHS strategy. Before moving to EFSA, from 2009 to 2013 he was Chair of the Committee for Risk Assessment and Scientific Chair of the Evaluation Directorate at the European Chemicals Agency (ECHA).

Dimitra Kardassi
European Food Safety Authority (EFSA)
Rapporteur

Dimitra Kardassi is a chemist with a PhD in Physical Chemistry from the National Technical University of Athens (Greece). She worked for more than 10 years in the Hellenic Food Authority (Greece) and held a senior position in the Authority for her final three years (2011-2014). She represented Greece in several European Commission and Council working groups of experts and headed the national delegation in Codex Committee meetings. She contributed to many legislative proposals of the Commission in food safety areas and acted as project manager of European funded projects. She joined the Pesticides Unit of the European Food Safety Authority (EFSA) in 2014 as Scientific Officer in the Scientific Coordination team, where her responsibilities include the coordination of the peer review of the risk assessment of active substances. Dimitra holds a Master of Science in Nutrition and Public Health.

Jürgen Sturma
European Food Safety Authority (EFSA)
Speaker

Jürgen Sturma is a biologist. He studied at the Universitiy of Braunschweig, Germany. Before joining the Federal Biological Research Centre for Agriculture and Forestry (BBA) in Germany, he gained his first experiences at the Fraunhofer Institute for Wood Research in Braunschweig. Working for the European evaluation procedure for pesticides he moved from the BBA to the Federal Office of Consumer Protection and Food safety (BVL) in Germany. Jürgen joined EFSA in 2006 as a scientific co-ordinator in the Pesticides Unit.

EU regulatory framework of pesticides: from Directive 91/414/EEC to Regulation (EC) No 1007/2009

The use of pesticides to control pests and to guarantee to a certain extent food and feed has a long history. In 1845 potato blight (*Phytophotora infestans* infection) led to famine in Ireland. 12% of the population died and 2 million people emigrated. In the 1870s *Plasmopara viticola* infections had a severe effect on wine growing areas. During the 19th century field application of pesticides began. Copper and nicotine were introduced as pesticides. At a national level scientific institutes and research centres were created to support agriculture, e.g. in 1905 the Biological Research Centre for Agriculture and Forestry in Germany. In 1939 the insecticide DDT was developed and in 1942 the herbicide 2,4,D.

First European measures regulating pesticides were introduced through Council Directive 79/117/EEC , which prohibited the placing on the market and use of plant protection products containing certain active substances, e.g. DDT and Hexachlorobenzene.

Council Directive 91/414/EEC, which came into force in 1993, provided the basis for the European evaluation process for active substances used in plant protection products, and had a direct impact on the national laws of EU Member States. The Directive includes the 'famous' Annex I, a list of actives substances that can be put on the market in EU Member States. Detailed lists of data that are required for the EU evaluation process are provided in the Directive. The European Commission implemented the ECCO Project to develop and support the EU evaluation process for active substances. The project supported the European Food Safety Authority from 2003 until 2005. The ECCO project built the

scientific network with EU Member States, and created the necessary processes, procedures and core documents – in short, it prepared the basis for the current procedure. Regulation (EC) No 1107/2009, entering into force two years later, set out new rules for the evaluation and approval of active substances, and the old data requirements from Directive 91/414/EEC were replaced in 2013. The new regulation provides the basis for a more harmonised structure for the various processes of approval and renewal of active substances.

Bénédicte Vagenende
European Food Safety Authority (EFSA)
Speaker

Bénédicte Vagenende studied Biochemical Engineering at the Faculty of Agronomical and Applied Biological Sciences at the University of Ghent (Belgium). She has worked as a scientific officer at the European Food Safety Authority (EFSA) since 2008 and took up the role of team leader of the Pesticides Coordination Team in 2014. Before joining EFSA she was a scientific staff member at the Laboratory of Crop Protection at the University of Ghent and a purchase manager at Group Aveve (Belgium).

Peer review of pesticide active substances in the EU

The peer review of pesticide active substances in the EU is a well-established process that since 2003 has been conducted by the EFSA Pesticides Unit, in collaboration with EU Member States.

This talk will aim to clarify the main steps of the scientific peer review process, from receipt of the dossier to finalisation of the EFSA conclusion. It will also highlight the changes and improvements that have taken place over the years, as well as the current challenges and possible improvements.

An overview will be given of the peer review procedures and mandates EFSA is working on. Furthermore, the cooperation between EFSA and other risk assessment bodies will be clarified, including the role and importance of the Pesticide Steering Network.

TOPIC 2
ERA: current assessment methodologies

Anthony Hardy
EFSA's Scientific Committee
Chairperson

Chair of EFSA's Scientific Committee, Professor Hardy is a biologist and environmental chemist who for more than 30 years has worked in the UK's Ministry of Agriculture, Fisheries and Food; the Department for Environment, Food and Rural Affairs; and the Central Science Laboratory for more than 30 years. He has worked on the impact of agricultural pesticides on wildlife and has been involved in national and international risk assessment and ecotoxicology. Prior to his appointment as Chair of EFSA's Scientific Committee, Professor Hardy had been Chair of EFSA's Panel on Plant Protection Products and their Residues since 2003.

Colin Brown
University of York
Rapporteur

Professor Colin Brown was appointed to a chair in environmental science within the Environment Department at the University of York in September 2004 and was Head of Department from 2010-2015. He has more than 25 years' experience of research into the fate and effects of pesticides in the environment and was previously Head of the Centre for EcoChemistry at Cranfield University. Colin has advised UK Government on the environmental fate and behaviour of pesticides through membership of the Advisory Committee on Pesticides and as chair of its Environmental Panel. He has chaired a European FOCUS working group on Environmental Risk Assessment, and the BioResources Group of the Society of Chemical Industry. He chairs the conference on Pesticide Behaviour in Soils, Water and Air held every four years in York.

Domenica Auteri
European Food Safety Authority (EFSA)
Speaker

Domenica Auteri is a biologist with a post-graduate degree in toxicology. She has been working in the field of environmental risk assessment of pesticides for more than 20 years, particularly within the European legislative framework related to the approval of pesticides. She joined EFSA in 2008. In 2011, she took the role of team leader of the ecotoxicology peer review team in the Pesticides Unit. Before joining EFSA, Domenica worked at the International Centre for Pesticides Health Risk Prevention, an Italian public organisation dealing with pesticides risk assessment. She was involved in the peer-review of pesticides and was a member of the Italian Advisory Board for registration of Plant Protection Products. Domenica was also the leader of several projects aimed at developing tools and guidance for the post-approval management of pesticides in Italy, such as the implementation of risk mitigation measures and the prioritization of substance for monitoring purposes.

Laura Padovani
European Food Safety Authority (EFSA)
Speaker

After receiving a PhD in Chemistry, Biochemistry and Ecology of pesticides at the University of Milan, Laura Padovani worked at the Agricultural and Environmental Chemistry Institute of the Catholic University in Piacenza (Italy) in the areas of agricultural chemistry and the environmental fate and behaviour of xenobiotics. In 2005 she joined the Pesticides Unit at the European Food Safety Authority (EFSA) as a scientific officer responsible for peer reviewing the environmental exposure assessments of active substances used in plant protection products provided by designated Member States.

Regulatory environmental risk assessment of pesticides: past, present and future

The protection of non-target species is one of the goals of environmental risk assessment (ERA). Before authorising a pesticide for use, an ERA is required. The ERA includes the fate and behaviour of the pesticide active substances in the soil, water and air compartments, including the estimation of the predicted exposures and the evaluation of the effects and risks for several groups of non-target species: birds and other terrestrial vertebrates; aquatic organisms; bees and non-target arthropods; earthworms, other soil macro-organisms and micro-organisms; other non-target organisms (flora and fauna) and biological methods for sewage treatment.

In the last 25 years, following the EU harmonisation of the pesticides risk assessment process, several scientific methodologies have been developed by adopting a tier approach where tiers are characterized

by an increasing complexity starting with simple conservative assessments (worst-case assumptions) towards more realistic evaluations (i.e. more realistic assumptions). In the area of ecotoxicology, the methodologies were included in guidance documents which help to address first and higher tier risk assessments (SANCO/4145/2000 for birds and mammals, SANCO/10329/2002 and SANCO/3268/2001 for terrestrial and aquatic organisms respectively, and ESCORT2 for non-target arthropods). The need for an adequate link of the effect and exposure assessments required at all tiers in the environmental risk assessment has been reflected also in the development of guidance documents in the environmental fate area (e.g. the EFSA Guidance Document for predicting environmental concentrations of active substances in soil, which provides guidance on the exposure assessment procedure for all types of concentrations that are potentially needed for assessing ecotoxicological effects). Other achievements in the environmental exposure assessment area have been reached: to evaluate laboratory and field dissipation studies to obtain soil degradation rate parameters (SANCO/12117/2014); to address the groundwater exposure (SANCO/13144/2010); and to perform environmental risk assessment of pesticides emitted from protected crop systems (SANCO/12184/2014).

However, the science behind ERA is constantly evolving e.g. more structured data, metadata and availability of tools. In this context, EFSA's role is to revise and develop updated ERA approaches by taking into account new scientific knowledge. EFSA developed several opinions and guidance documents for ERA, including an overarching opinion on the definition of specific protection goals based on the ecosystem service concept. Relevant milestones were the scientific opinions and guidance on birds and mammals, bees, aquatic organisms, non-target terrestrial plants, and non-target arthropods.

Other challenges are coming such as areas not yet explicitly covered by the current regulatory ERA (i.e. amphibian and reptiles); population modelling for aquatic organisms, and landscape risk assessment.

Kees Romijn
Bayer
Speaker

Kees Romijn is head of Regulatory Policy at Bayer. Kees began his involvement in environmental risk assessment in the EU 25 years ago, working for the Dutch research institute RIVM, and building risk assessment models for birds and mammals. In 1994, he joined the PPP industry and worked within environmental risk assessment for plant protection products and biocides, in various functions. Kees is the current chair of the European Crop Protection Environmental Expert Group (ECPA-EEG). In this role, he provided input to EU legislation (91/414 and 1107) as well as numerous EFSA guidance documents. The ECPA-EEG is a source of know-how and data that has enabled current ERA practices in the EU to develop.

ERA – achievements and challenges to current assessment and methodologies – an Industry position

My involvement in environmental risk assessment for plant protection products in the EU started 25 years ago – prior to the first 91/414 drafts. The quality of our assessments, and the methodologies used, have changed significantly over this period. Most of all I have seen a great deal of harmonisation happening, for testing guidelines (OECD) and testing requirements (EU), the development of risk assessment models (SETAC/FOCUS), risk assessment scenarios (SETAC/EFSA), and lately an increased effort to derive meaningful Protection Goals giving ERAs a higher relevance.

Much of the above I consider a major achievement, both in terms of keeping animal testing within limits as well as increasing the quality and relevance of ERAs. The major challenge to the development of ERA has in my opinion has always been the question as to how to deal with the high level of complexity in the real world environment, its ecosystems and the services these ecosystem provide. 25 years of experience in regulatory ERAs have taught me that 2 things are important 1) keep it simple, and 2) accept that you have to make decisions based on scenarios.

For me the biggest success stories of 25 years of ERA in the EU are: the principles of a tiered testing scheme (start simple – add relevance where needed) and the development of the FOCUS scenarios. Through a multi-stakeholder approach (the key to the success of the FOCUS scenarios), we have been able to move from a situation of country specific risk assessment approaches with variable levels of quality and relevance, to an ERA methodology where good science and agreed practice are combined. Working with FOCUS scenarios has allowed a true European development of ERA skills, where previously know-how was limited to a few individuals and Member States.

At present, we know how to assess the relevant environmental risks that the use of plant protection products may pose. We are however still struggling at times with the tendency to add complexity. Unfortunately, our skills in risk communication have not kept up with the progress we have made in assessing risks. After looking into large sets of data and combining all scientific wisdom gathered over 25 years, I feel it is relatively poor to end up with a polar high/low risk conclusion. We could do so much more to allow good decision making and thus gain societal acceptance.

Angeliki Lyssimachou
PAN Europe
Speaker

Angeliki Lyssimachou is an environmental toxicologist with 12 years of experience in the field of endocrine disruption related to aquatic animals. She has a degree in Environmental Science, an MSc in Applied Marine Science and completed her PhD in the Consejo Superior de Investigaciones Cientificas in Spain on the mechanisms of endocrine disruption in fish and molluscs. She has worked in different laboratories in Europe as a researcher, including the UK, Greece, Spain, Norway and Portugal, on the disciplines of molecular biology, biochemistry, ecotoxicology, environmental toxicology and chemistry. She communicates her scientific work through publications in peer-reviewed journals and presentations at international conferences. Over the last 5 years she has been actively involved in issues related to environmental pollution and social ecology in Spain. Since 2014 she has worked for Pesticides Action Network Europe, the regional centre of a global network organisation that aims to replace the use of harmful pesticides with ecologically friendly alternatives. Her work is focused on endocrine disrupting pesticides.

Achieving a better environmental protection by improving pesticide ERA

Our environment receives a wide range of anthropogenic pressures: expansion of cities, road networks and traffic, air pollution, industrial and domestic river effluents, and of course the expansion of agricultural land and use of pesticides. Pesticides are intended to be toxic to pests and are also toxic to other living organisms and non-target species. Their use contributes to the degradation of ecosystems we experience today. For example, pesticides are an underlying cause of the decline in the population of pollinators and the chronic toxicity observed in aquatic ecosystems. The Pesticide Regulation underscores to protect these ecosystems but our current Environmental Risk Assessement (ERA) and Risk Management is failing to do so. Improvement is necessary not only in ERA but also in the implementation of the pesticide regulation by Member States.

Theo Brock
Alterra, Wageningen UR
Chairperson

Theo Brock is employed at Alterra (Wageningen University and Research) to scientifically support ecological risk assessment procedures for pesticides and other contaminants in surface waters. He has published more than 100 scientific papers on topics covering aquatic ecology, wetland ecology and ecotoxicology. He participated in the organising committee of the HARAP, CLASSIC and ELINK workshops (all organised by SETAC) that addressed higher-tier aquatic risk assessment procedures for pesticides and linking exposure to effect estimates. He chaired a Dutch working group that developed decision trees for the effect assessment of pesticides in edge-of-field and larger surface waters, addressing the requirements of the WFD and Regulation (EC) 1107/2009. He was/is active in several working groups of EFSA's PPR Panel and Scientific Committee amongst others to draft guidance and scientific opinions on environmental risk assessment procedures. Currently he is vice-chair of the PPR Panel and a member of the editorial board of the scientific journal Integrated Environmental Assessment and Management (IEAM).

Katarzyna Klimczak
Polish Institute of Environmental Protection - National Research Institute
Rapporteur

Katarzyna Klimczak has been involved in activities related to the environmental risk assessment of pesticides for 16 years. In 2000, she graduated with honours in agriculture at Warsaw University of Life Sciences – SGGW with a specialisation in protection of agricultural environment. In 2000-2012, she was employed in the Risk Assessment Department of the Institute of Environmental Protection – National Research Institute, where she was responsible for the evaluation of the ecotoxicology section for the national registration of plant protection products. Since 2004 (when Poland joined the EU), she has been involved in activities related to active substances evaluation at EU level. In 2007, she earned her PhD in the Department of Soil Environment Sciences of Warsaw University of Life Sciences – SGGW, specialisingin contamination of soil by organic pollutants and their impact on other environment compartments. Since 2012, Katarzyna has been an external expert of the Polish Ministry of Agriculture and Rural Development. Currently, she is responsible for the evaluation of plant protection products in the areas of fate and behaviour and ecotoxicology for purposes of both national and zonal registration. She is also involved in the evaluation of active substances in the area of ecotoxicology for purposes of their authorisation at the EU level. She is a regular participant in expert meetings, workshops related to the evaluation of pesticides as well as conferences on ecotoxicology, ecology, plant protection and other topics useful in the risk assessment of pesticides.

Giovanna Azimonti
International Centre for Pesticides and Health Risk Prevention (ICPS)
Rapporteur

Giovanna Azimonti is a physicist working as a senior adviser at the International Centre for Pesticides and Health Risk Prevention (ICPS) – University Hospital Luigi Sacco, a centre of reference for pesticides at the regional health service in Lombardy, Italy. ICPS is one of the national collaborating centres of the Italian Ministry of Health for pesticides risk assessment in the registration process. At ICPS she acts as coordinator of risk assessment for registration of plant protection products at national and zonal level and for active ingredients for EU registration; she is the contact point with the Italian Ministry of Health. Her expertise is in environmental fate and behaviour assessment of chemicals. In the last 20 years, she has evaluated the e-fate section of several active substances and of more than 300 plant protection products. She evaluated the e-fate section of several veterinary medicines. She has been adviser to the Italian National Advisory Committee on Pesticides as an expert on the environmental fate and behaviour section since 1995. Since 2007 she has been an adviser to the Italian National Advisory Committee on Veterinary Medicines as an expert on the environmental fate and behaviour section. She was a member of the EMA working group on ERA from 2008 to 2012. She is the coordinator of the national group involved in the definition of environmental criteria for national authorisation, on behalf of the Italian Ministry for the Environment. Since December 2015, she has been a member of EFSA's FEEDAP Panel. Since September 2015, she has been participating in the working group that is developing an EFSA Guidance Document for predicting environmental concentrations of substances in soil.

Véronique Poulsen
French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
Speaker

Dr. Véronique Poulsen has 20 years' experience as an ecotoxicologist. She heads the Ecotoxicology and Environmental fate Unit in the Regulated Products Assessment Department at ANSES. She obtained her PhD in research on aquatic microcosms at INERIS (National Institute of Industrial Environment and Risks, France). Her team of 30 ecotoxicologists and environmental risk assessors is in charge of the risk assessment of pesticides prior to their authorisation. She has been involved in the organisation of many workshops at EU and international level, related to pesticide risk assessment methodology (e.g. aquatic macrophytes, bees, endocrine disruptors, non-target terrestrial plants, ecosystem services) and regulation of pesticides.

MS experience with aquatic assessment methodologies

In recent years, to increase the quality of water and aquatic ecosystems, aquatic systems have been subject to high protection goals by European Member States. Additionally, aquatic ecotoxicology and research projects on aquatic ecosystems have been developed for many years. Consequently, aquatic risk assessment conducted for plant protection products has evolved in terms of data requirements, which have risen to address new concerns, and in terms of new methodologies. For example, new statistical methods have been developed to assess and conclude on the effects observed in cosm studies. These new methods help risk assessors to conclude on cosm studies, and define more robust endpoints. It should however be kept in mind that a high level of expertise is still needed to assess these studies.

Additionally, during the last ten years, the link between fate and effects has been considered more and more in aquatic risk assessment, in particular refined risk assessment. Such an approach intends to better reflect real exposure of aquatic organisms, and enable a more realistic risk assessment. However, in order to increase the confidence in the risk assessment conclusions, exposure models (i.e. FOCUS SW) should be revised to improve the robustness of the PEC calculations.

Differences may be observed between the outcome of the risk assessment conducted at EU level and those conducted at national/zonal level. These differences are essentially due to the consideration of mitigation measures that have to be taken into account at national level. Moreover, many studies are often submitted in the dossiers by applicants in order to refine the risk assessment. This leads to a high workload for Member States.

Aquatic risk assessment has been improving and evolving for many years. In the coming years, it is probable that modelling (TK/TD and ecological modelling) will be one of the major tools that will be developed and used, but will also be subject to discussions. In this case, additional work will be needed at EU level to obtain a validated tool box that could be used by risk assessors.

Mark Clook
Chemicals Regulation Division
Speaker

Mark Clook has worked in pesticide regulation since 1991 and currently is head of the Ecotoxicology Team at the Chemicals Regulation Division (CRD). CRD is part of the UK Health and Safety Executive (HSE) and is the body responsible for the regulation of pesticides. Mark has carried out a wide range of study evaluations and associated risk assessments and as a result has extensive experience of environmental risk assessment. This experience extends to being involved in attending and chairing numerous peer review meetings and participating in several workshops as well as contributing to EFSA opinions on the Science behind the Guidance Document on Risk Assessment for birds and mammals as well as the EFSA Guidance Document on the risk assessment of plant protection products and bees (*Apis mellifera*, *Bombus* spp. and solitary bees).

UK experiences of conducting pesticide environmental risk assessments for the terrestrial compartment

Over the last 25 years, the United Kingdom has moved from assessing the environmental risk from pesticides under UK legislation to assessing them under EU legislation. Alongside this came the development of numerous guidance documents to aid the implementation of the legislation. Much of this guidance – both official EU documents (e.g. SANCO 4145/2000) and "unofficial" (e.g. ESCORT) – has been associated with assessing the risk to terrestrial organisms, i.e. birds, mammals, bees, non-target arthropods and non-target plants. The UK contributed to the development of much of this guidance as well as participating in several workshops (e.g. ESCORT 1 and 2). Whilst all this work has aided the understanding of the risk, the way in which it was carried out was potentially ad hoc and as a result left certain areas better addressed than others – e.g. the area of non-target arthropods had both a workshop and a guidance document dedicated to it, whereas the area of non-target plants only had a couple of pages. The role of developing guidance has now fallen to the European Food Safety Authority (EFSA) under mandate from the Commission. This has, potentially, addressed the above problems; however this process is not without its issues. The presentation will cover a brief history of various workshops and guidance documents. It will also raise some questions about what we have done over this 25-year period compared to what we do now and consider where there is room for improvement.

Michael Stemmer
Austrian Agency for Health and Food Safety (AGES)
Speaker

Michael Stemmer finalized his PhD study in soil sciences (soil microbiology and biochemistry) in 1997. From 1999 to 2005 he worked as a soil scientist at the University of Natural Resources and Applied Life Sciences in Vienna. Since 2005 he has been employed at the Austrian Agency for Health and Food Safety as a regulatory environmental expert covering the exposure assessment for active compounds and their metabolites in the environment. From 2012 Michael was a member of several working groups of EFSA's PPR panel as an external expert, and in 2015 he became a member of the panel.

MS experience with soil exposure methodologies

Assessing the soil exposure of pesticides and their degradation products is a fundamental part of the environmental risk assessment to be conducted for approval under Directive 91/414/EEC and Regulation 1107/2009. Already in 1997 FOCUS had recommended estimating soil exposure of pesticides using a simple equation assuming a homogenous mixing depth in soil of 5 cm and a predefined soil density of 1.5 kg dm^{-3}, taking into account degradation/dissipation rates in order to account for possible accumulation. Already at that time there were considerations for EU wide 'realistic worst case' soil scenarios as were later implemented for the groundwater and surface water exposure assessment. However, such scenarios were not established owing to uncertainties in pan EU soil data maps at that time. In 2006 the simple soil exposure assessment was further amended by FOCUS to account for degradation products as well as non-linear degradation in soil. Up to now these recommendations have been the basis for the soil exposure of almost all active substances approved under Directive 91/414/EEC and Regulation 1107/2009. For applicants as well as regulatory authorities this assessment is quite convenient as it is simple, fast and transparent, although it suffers from several shortcomings and limitations from a scientific point of view. This presentation will focus on the application of the current test methods (lab and field) and guidance documents relevant to address the soil exposure at this stage, and to review them with an analysis of the pros & cons of their characteristics in a regulatory framework.

Leon van der Wal
Organisation for Economic Co-operation and Development (OECD)
Speaker

Leon van der Wal obtained a PhD in Environmental Toxicology and Chemistry in 2003, and has over 15 years of experience in the risk assessment of chemicals. He has worked as a consultant in the area of risk assessment and risk management for national and international governmental agencies as well as private national and multinational companies. In 2009 he joined the European Commission's Joint Research Centre where he worked in the Review Programme of Biocides and was responsible for environmental risk assessment. He joined the Organisation for Economic Co-operation and Development (OECD) in 2014 where he works in the Test Guidelines, Biocides and Pesticides programmes on, among other things, the development of Test Guidelines and Guidance Documents related to bees/pollinators. He is coordinating the efforts of the Validation Management Group on Ecotoxicity which focus on the validation of methods to detect endocrine disruption. Other related activities include Integrated Pest Management (IPM).

Harmonising Environmental Risk Assessments of pesticides; OECD development of Test Guidelines and methodologies

The Organisation for Economic Co-operation and Development (OECD) consists of 35 Member countries, which work together with many partner countries and other stakeholders to develop and co-ordinate international activities, amongst others via its Environment, Health and Safety Programme.

The OECD's Environment, Health and Safety Programme objectives are to:

- assist OECD Member countries' efforts to protect human health and the environment through improving chemical safety and biosafety;
- make chemical control policies more transparent and efficient and save resources for government and industry; and
- prevent unnecessary distortions in the trade of chemicals, chemical products and products of modern biotechnology.

To that end, the OECD assists countries in developing and harmonising methods for assessing the risk and management of chemicals and in collecting and disseminating information.

The OECD Guidelines for the testing of chemicals are a collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories to assess the safety of chemical products. Their development is overseen by the Working Group of National Coordinators of the Test Guidelines Programme (WNT).

OECD Test Guidelines are extensively used for environmental risk assessment of chemicals, providing information on, for instance, mortality, reproduction, developmental effects and endocrine disruption for various aquatic and terrestrial species. Recent WNT activities have included the development of Adverse Outcome Pathways (AOPs) and the use of Integrated Approaches to Testing and Assessment (IATA) in collaboration with the OECD Task Force on Hazard Assessment.

The Working Group on Pesticides (WGP) coordinates collaboration between countries specifically with respect to agricultural pesticides, which has resulted in guidelines and guidance documents for testing and assessment (e.g. pollinator testing, pesticide residue testing, terrestrial field dissipation studies), the development of indicators (e.g. on pesticide risk reduction) and information resources on the internet (e.g. on managing spray drift, integrated pest management).

One area of high priority is the work on bees/pollinators, and the WGP closely collaborates with the WNT in the further development of guidelines to determine and manage risk to pollinators.

An overview of above-mentioned OECD activities in environmental risk assessment will be provided.

James Garratt
Enviresearch
Speaker

James Garratt is the founder and Managing Director of Enviresearch. He is a scientist with a special interest and passion for the assessment of the risks of chemicals to the environment. James has been working with environmental models since 1996. His work has included many assessments of chemical fate for commercial clients, in particular where advanced (or higher-tier) assessments are required. He has also contributed to the advancement of science through his work on risk assessment in greenhouses; the MERLIN-Expo modelling tool; and sensitivity analysis in drainflow modelling. He is a member of the Institute of Professional Soil Scientists (IPSS) and the Society for Environmental Toxicology and Chemistry (SETAC). He is a Chartered Scientist and is a regular reviewer of academic papers for research journals. In his spare time, James likes to work on research into forest hydrology

and climate change at Newcastle University. He also organises the vegetable judging at the annual Benwell Village Show.

The best bits and the worst bits: how consultants view the environmental regulations since 91/414

Consultants play a key role in the chain of activity in pesticide risk assessment. Applicant companies may use consultants if their company lacks either the technical expertise or the human time resource to prepare assessments in a timely manner. This gives consultants a broad view of a range of techniques that may be employed and a broad view of the requirements of the various authorities. The consultant view is therefore a good indicator of the overall quality of the process of risk assessment.

A survey of consultants has been conducted to establish areas where consultants are clear in their opinions of how risk assessment has changed over the past 25 years. The survey looked at all the major areas of risk assessment and canvassed views in several areas:

- the levels of conservatism and realism in assessments;
- the process of conducting assessments (guidance documents, data sources and other information);
- the role of expert opinion compared to numerical cut-off criteria in evaluating assessments;
- the balance between environmental protection and maximising production;
- interactions with regulators.

At the time of writing this abstract, the full results have not been collated. However, from the results so far, there is a trend that consultants feel that assessments have become more conservative. There is no clear consensus on whether they are more or less realistic than before. Guidance documents have become substantially more comprehensive and consistent, but this has not necessarily translated into clarity or consideration of all relevant views. There is concern that the current systems can lead to multiple variations on a single assessment that are only marginally different from each other. Assessments are increasingly judged by numerical criteria rather than by expert opinion, which is generally thought to be a bad thing. In the talk, the full results from the survey will be presented.

Ralf B. Schäfer
University of Koblenz-Landau
Speaker

Professor, Dr. rer. nat. Ralf B. Schäfer (Phd 2008) leads the working group "Quantitative Landscape Ecology" and has been professor at the University of Koblenz-Landau since 2010. He teaches aquatic ecotoxicology, statistics, ecological modelling, spatial data analysis and GIS. His main expertise is the exposure and effects of organic toxicants on freshwater invertebrates and ecosystem processes using field investigations and different statistical and spatial modelling techniques. He has been involved in several field studies on pesticides and organic toxicants in different European regions and South-East Australia. In 2008, he received the Best Publication Award of SETAC Europe. His work has been published in over 80 papers and book chapters, including in high impact journals such as PNAS and Science.

What can we learn from landscape eco(toxico)logy for regulatory ecological risk assessment?

Regulatory ecological risk assessment (ERA) of plant protection products under regulation 1107/2009 follows a tiered approach to evaluate effects on non-target organisms. Lower tiers rely on data from single species experiments, whereas higher higher tiers are informed by community-level experiments. The regulation results, in the case of approval, to a regulatory acceptable concentration that should guarantee no unacceptable effects in the environment. In my contribution, I present field studies on the exposure and effects of pesticides in freshwater ecosystems and discuss these in the context of regulation. In particular, I will focus on the following questions: How frequent are RAC exceedances and what are the consequences of exceedances? How reliable is upscaling of landscape-level effects from current test systems dealing with single products? I outline the challenges for regulation associated with the (1) upscaling to higher levels of biological organisation from lower levels, (2) context-dependency of ecological systems and (3) the presence of potentially interacting multiple stressors and chemicals. I conclude with suggestions regarding the future of ERA.

TOPIC 3
ERA: new challenges and emerging trends

Lorraine Maltby
University of Sheffield
Chairperson

Lorraine Maltby is Professor of Environmental Biology at the University of Sheffield, UK, and a NERC/Scottish Government Fellow. Her fellowship is focused on strengthening the uptake of science into policy and her research aims to understand how ecosystems respond to environmental stressors and the consequences for the benefits nature provides to people. Lorraine has served on UK government advisory committees and is a past Chair of the Environment Panel of the Advisory Committee on Pesticides. She is currently a member of the Scientific Committee of the European Centre for Ecotoxicology and Toxicology of Chemicals and was a member of the working group that produced the EFSA scientific opinion on protection goals.

Chris Lythgo
European Food Safety Authority (EFSA)
Rapporteur

Chris Lythgo works in the Pesticides unit at the European Food Safety Authority. He is leader of a team responsible for peer reviewing the assessments of physical chemical properties, methods of analysis and environmental exposure carried out by the EU Member State competent authorities (which have responsibility for the regulatory regime for plant protection products) that underpin EU level decision making. He obtained his BSc (honours) degree at the University of Leeds and MSc through research on bioreactor systems and bacteria-mediated biotransformations at the University of Manchester Institute of Science and Technology. Between 1994 and 2005 he worked at the UK Pesticide Safety Directorate where at different times he completed both environmental exposure and consumer exposure / risk assessments. Between 1986 and 1993 he worked as an analyst in government laboratories and for a food manufacturing company.

Christopher M. Holmes
Waterborne Environmental
Speaker

Mr. Holmes has over 25 years' experience in the Geographic Information Systems (GIS), remote sensing, information processing and computer programming fields. He holds a Bachelor's degree in Computer & Information Science, a Master's degree in Geography, and a graduate certificate in Remote Sensing and Image Processing. At Waterborne Environmental, he has managed numerous environmental characterization and exposure assessment studies for the crop protection, home & personal care, and veterinary medicines industries in both domestic and international settings. Since the late 1990s, he has worked on the integration of GIS and remote sensing technologies into existing models for the environmental risk assessment of plant protection products in the US and Europe. Mr. Holmes participates in the advancement of ecological risk assessment methodologies via conference presentations, publications, workshops, and meetings with regulatory agencies. He was a member of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment. Mr. Holmes continues to be involved in the evolution of the ecological risk assessment process for threatened and endangered species in the US, and is an active member of Crop Life America's Environmental Risk Assessment Committee. Previously he worked as a software engineer to develop the multispectral imaging section of a large image processing tool to be used by US government agencies, and as a technical analyst for a large software development company.

Historical perspectives on landscape-based pesticide assessments in the US over the last 25 years

The last 25 years have seen important and rapid changes in the conduct of pesticide risk assessments, especially as it relates to the use of geoinformation in the estimation of potential exposure. These landscape-based assessments have enabled efficient predictions of exposure, and subsequent evaluation of risk, across large geographic areas down to site-specific locales. These approaches have been applied across all tiers of the risk assessment paradigm, from simple scenario definition to informing probabilistic and spatially explicit assessments. Activities in the area of spatial data management, remote sensing and image processing, spatial analyses with increasingly available and user-friendly GIS software, and publicly available datasets will be discussed. This presentation will cover a brief history of approaches and advancements in landscape-based pesticide exposure assessment in the US over the last 25 years – from the characterization of crop/soil/weather scenarios in the 1990s up to modern online, spatially-explicit tools for risk assessment under development by the US EPA. Current issues such

as endangered species risk assessment have benefited from these developed methodologies coupled with available geoinformation on use sites, species information and protected areas. The intent of this presentation is to bring perspective to where we are today, and to put some of the current conference discussions into a broader historical context.

Christopher Topping
Aarhus University
Speaker

Christopher Topping is Professor MSO in Ecological Modelling at Aarhus University, Denmark. He has been working with modelling environmental impacts of primarily agricultural practices and agricultural policy affecting wildlife management and risk assessment for over 20 years. His primary field is development and testing of complex multi-faceted agent-based models (ABMs), leading towards simulation of social-ecological systems and the use of models for wildlife management and environmental risk assessment of agricultural chemicals, crops, and practices. He is a member of the EFSA Plant Protection Products and Residues Panel (PPR) and has been involved in EFSA working groups since 2009.

Landscape scale simulation for terrestrial population modelling and ERA

Landscape-scale simulation modelling considers multiple farm to regional scales. Simple landscape representations have been used in population modelling since 1980s but over the last decade much more detailed models have become available that can explicitly represent details of agricultural systems necessary to include when developing landscape scale population models for ERA. For these models the key focus is development of the baseline against which pesticide induced changes can be compared. These must represent a realistic population resiliance to perturbation as well as spatio-temporal dynamics. A number of these detailed models have been developed using the ALMaSS framework and applied to ERA. The results of these simulations indicate that a re-prioritising of factors considered in traditional risk assessment is needed to take into account both population and landscape levels. Factors that have an important bearing on the outcome of landscape ERA include the effect of 'action at a distance', the spatial configuration of landscapes, the importance of toxicity, species specific population ecology, the scale considered, and the general context dependency of the ERA on landscape conditions. This context dependency is a challenge, but also provides a clear indication of the direction in which landscape-scale ERA needs to develop. This development is aided by advances in landscape scale data collection and integration. Large landscapes can already be easily and quickly generated for Denmark from standard GIS data, suggesting that generally applicable models for large areas of Europe may not be far off.

Andreas Focks
Alterra, Wageningen UR
Speaker

Andreas Focks works in mechanistic modelling and statistical analysis of the effects of chemical stressors on the biotic environment, at levels of individuals, populations and communities. He has worked since 2013 as ecological modeller at the research institute Alterra, as part of Wageningen University and Research Centre in the Netherlands. He was amongst others involved in the EU MarieCurie ITN CREAM, and the CEFIC-LRI–financed project ChimERA. Currently, he works mainly on toxicokinetic-toxicodynamic modelling of chemical effects in a programme of the Dutch government, on the modelling and detection of chemical effects at community levels within the EU 7th framework project Solutions, and on the development of integrated exposure and effect models at landscape scales in connection with the definition of ecological scenarios. Since 2008, Andreas has (co-)authored 24 papers in peer reviewed journals.

Towards a landscape scale risk assessment: development of a coherent and flexible framework for the integration of exposure and effect modelling[1]

Chemical fate and ecological modelling approaches allow for the linking between exposure and effect dynamics in space and time and hence for the spatially explicit, landscape-level quantification of risk in aquatic and terrestrial systems. In the future, landscape scale approaches could be adopted to supplement higher tier regulatory assessment for pesticides in the EU to make environmental risk assessment of chemicals more relevant and realistic.

At the same time ecological models are proposed to support experiment-based environmental risk assessment for a set of application areas. Examples of integrated approaches at landscape scales exist in the literature, but are scarce and of an ad-hoc nature (i.e. they do not derive their approaches from

[1] Andreas Focks, Hans Baveco, Jos Boesten, Louise Wipfler and Paul J. Van den Brink.

generic integration principles for risk assessments). The lack of a common understanding and a reference framework impedes further development and harmonisation of integrated exposure and effect modelling approaches.

In this presentation we will present some ideas about possible improvement of current risk assessment. A concept for a framework for landscape-scale integrated exposure and effect modelling will be outlined. An example for such integrated modelling approach will be shown, and it will be indicated how the collection of landscape-scaled data in geographical information systems can support such modelling approaches by providing scenario information. An outline will be given on how spatial landscape elements can be evaluated in their effect on the in situ risk of compounds by the use of landscape scale modelling approaches, hence linking from risk assessment to risk management, or from prospective risk assessment to post-registration monitoring.

Alberto Pistocchi
Joint Research Centre (JRC)
Speaker

Alberto Pistocchi has a Master in Philosophy, a Master in Environmental Engineering and Land Planning and a PhD in Georesources engineering and Geotechnologies from the University of Bologna, Italy. He is an associate professor of Land Planning, a chartered civil/environmental engineer and the author of several scientific publications. Since gaining his PhD, he has been one of the founders of GECOsistema srl, Italy, an SME providing solutions for spatial decision support systems in the field of environmental assessment. He has been the coordinator of masterplans for the regional river basins of Emilia Romagna, Italy, and a consultant in water engineering, environmental assessment and land planning, before joining the European Commission's DG Joint Research Centre where he has worked on the development of methods for GIS-based chemical fate and transport modelling and risk assessment. He presently serves as a project manager and quantitative policy analyst on integrated water resources assessment and the management of river basins.

Landscape and climate parameters for the mapping of pesticides ERA

The JRC produces or makes use of a broad array of spatial data concerning landscape and climate characteristics at the European scale, and beyond. These encompass weather and climate parameters, soil characteristics, topography, hydrography, land cover and human activities to which pesticide emissions can be associated.

In this contribution, we briefly review the data requirements of a spatial environmental risk assessment (ERA) of chemicals, the extent to which such requirements are, or can be, fulfilled, and the main gaps hampering a broader take-up of spatial ERA. We stress how spatial ERA aims at producing a more realistic picture of risks taking into account both the variability of exposure to chemicals, and the superposition of multiple chemicals emitted from different sources. We discuss how the different data gaps may hinder one or both aims, and propose some considerations on priorities in data collection, sharing and the trade-offs between model complexity and usability considering the ERA objectives.

Jose V. Tarazona
European Food Safety Authority (EFSA)
Speaker

See bio p.3

Coupling science and regulatory needs: Towards the integration of ecological and landscape diversity in prospective environmental risk assessments

Addressing the diversity of environmental and ecological conditions has always been a challenge in environmental risk assessments. For pesticides, where the risk is linked to the intended conditions of use under good agricultural practices, the complexity is increased by the variability in the agricultural landscape conditions. Traditionally, this diversity has been covered by the identification of "realistic worst-case conditions" or the use of "representative scenarios". The verification of these conditions and scenarios, e.g. getting evidence supporting the assumption that the conditions are worst-case and the scenarios representative, requires a significant effort of data collection and information processing, and has been the main challenge for decades. Recent technological developments have facilitated the collection, integration and use of massive amounts of data, including spatial information. These developments open the door for a new conceptual approach: instead of worst-case conditions or few scenarios, the environmental assessment could cover the full geographic area and landscape conditions where the pesticide is expected to be used; the information could then be aggregated according to the risk managers' needs: e.g. zones and conditions were low risk is expected without restrictions, zones and conditions where mitigation measures or restrictions are needed, and finally zones and conditions where the identified risk cannot be sufficiently controlled by mitigation measures.

For prospective risk assessments supporting the approval of active substances, or authorisation of Plant Protection Products, ecological, environmental and landscape diversity must account for both spatial and temporal variability. Elements can be grouped in two main sets: those to be handled as spatially-explicit GIS data in the risk assessment, and those that, in a prospective assessment, cannot be handled as spatially-explicit elements, but are relevant for the decision making. The selection depends on the predictability of each element during the risk assessment process, while the granularity is linked to the available information and the decision-making needs. For example, long-lasting elements, such as river catchment areas or political borders, can be presented explicitly and at different granularities according to the needs. This is also applicable where large data sets are available, such as climatic conditions, allowing the use of probabilistic methods for addressing temporal variability at the desired granularity. Other elements, such as proximity to water bodies or protected areas, field margin conditions, etc., may be better characterised through conditions leading to mitigation options, such as buffer zones or in-field non-crop areas.

As part of its 2020 strategy, EFSA, in partnership with all stakeholders, will embark on the development of new conceptual models, coupling the scientific developments in landscape assessment and ecological modelling with the regulatory needs. The expected benefits, limitations, challenges and opportunities will be presented here for further discussion.

ROUNDTABLE
Moving to landscape based mapping for ERA (from generic scenarios to mapping risks)

Lorraine Maltby
University of Sheffield
Chairperson

See bio p.12

Christopher M. Holmes
Waterborne Environmental
Speaker

See bio p.12

Christopher Topping
Aarhus University
Speaker

See bio p.13

Andreas Focks
Alterra, Wageningen UR
Speaker

See bio p.13

Alberto Pistocchi
Joint Research Centre (JRC)
Speaker

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Jose V. Tarazona
European Food Safety Authority (EFSA)
Speaker

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Pernille Thorbek
Syngenta
Speaker

Dr Pernille Thorbek has worked with ecological modelling for risk assessment of plant protection products for over 10 years. She has supervised 13 PhD students, 10 postdocs, authored 50 scientific papers and led the development of over 30 models. She was a pioneer in the application of ecological models to regulatory risk assessments and the development of good modelling practice. She works for Syngenta where she applies ecological models to risk assessments and to stewardship schemes to improve farmland biodiversity.

Mengjiao Wang
Greenpeace
Speaker

Dr Mengjiao Wang is a research scientist at the Greenpeace Research Laboratories, which is based at the University of Exeter, UK. She provides scientific advice and analytical support on various research projects and policy development work relating to chemical management and contamination of the environment, including pollution arising from unsustainable agriculture, the textile and coal chemical industries, as well as electronic waste (e-waste) recycling and disposal. Mengjiao's work involves close liaison with Greenpeace offices around the wold. Prior to working with Greenpeace International, Dr. Wang worked in the environmental consulting industry in Hong Kong, focusing on the monitoring and

remediation work of contaminated river sediment. Mengjiao holds a PhD in Marine Environmental Science.

Keith Sappington
United States Environmental Protection Agency
Speaker

Mr. Keith Sappington has conducted applied environmental research to support human and ecological risk assessments and water quality criteria for over 30 years. Mr. Sappington currently serves as a Senior Science Advisor in the Office of Pesticide Programs (OPP) at the U.S. Environmental Protection Agency (US EPA), where he conducts ecological risk of assessments of pesticides and develops associated technical guidance. His primary areas of expertise include aquatic toxicology, bioaccumulation modelling, contaminated sediment testing and assessment, and assessing risks of pesticides to insect pollinators. At OPP, Mr. Sappington has led efforts for assessing the risks of Persistent, Bioaccumulative and Toxic (PBT) pesticides, integrating sediment toxicity testing into benthic invertebrate risk assessments, and developing guidance for assessing pesticide risks to bees. Mr. Sappington also served for ten years in the EPA's Office of Research and Development and the Office of Water where he managed ecotoxicological research related to methyl mercury and contaminated sediments, developed guidance for assessing metals bioaccumulation by aquatic organisms, and revised aquatic life and human health water quality criteria guidelines. Prior to his employment by the EPA, Mr. Sappington served as a Senior Analyst at Abt Associates, where he conducted risk assessments and related analyses to support various EPA regulatory programs. At the State of Maryland Department of Environment, he supported a whole effluent toxicity testing program for municipal waste water treatment plants and developed water quality criteria. In addition to his regulatory and consulting experience, Mr. Sappington conducted four years of applied laboratory and field ecotoxicological research at Virginia Tech and the University of North Texas. He holds a Master's in Zoology and a Bachelor's degree in Biology from Virginia Tech. He has authored numerous book chapters, peer reviewed articles, and government reports related to ecological risk assessment. Mr. Sappington has presented his work at various national and international workshops and scientific peer review meetings.

Marco Vighi
IMDEA-Water
Speaker

Degree in Biology at the University of Milano, in 1969. Research assistant at the Water Research Institute (Italian National Research Council): 1969-1983. Associate professor of Zoology and Agricultural Ecotoxicology at the Faculty of Agriculture of the University of Milano: 1983-1997. Full professor of Ecology and Applied Ecology at the University of Milano Bicocca (Department of Earth and Environmental Sciences): 1998-2015. Since December 2015, he is principal investigator at the IMDEA Water Institute, Alcalà de Henares (Madrid), Spain. Member of the Scientific Committees on Toxicology and Ecotoxicology (CSTE, CSTEE, SCHER) of the European Commission from 1991 to 2013. Since March 2016, he is member of the SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). Consultant for several international organisations (UNPD, UNEP/POPRC, WHO, FAO). The scientific activity has been addressed to several aspects of applied ecology and ecotoxicology:

- eutrophication of marine and fresh waters;
- toxicology of micro pollutants on aquatic and terrestrial ecosystems at different levels of organisation (from individuals to complex communities);
- quantitative Structure-Activity Relationships (QSAR) for organic chemicals;
- combined effect of mixtures of chemicals;
- environmental distribution and fate of contaminants;
- long range transport of persistent organic pollutants (POPs);
- ecological risk assessment.

He has published more than 180 scientific papers and books on applied ecology and on ecotoxicology.