BIOGRAPHIES AND ABSTRACTS

SESSION I

Claudia Roncancio Peña | EFSA, Head of Methodology and Scientific Support Unit

Currently, Mrs. Roncancio Peña is Head of the Methodology and Scientific Support Services at the European Food Safety Authority (EFSA) based in Parma (Italy). Previously, she led EFSA's Units on Feed Additives and Food Ingredients and Packaging. Before joining EFSA in 2004, Roncancio Peña was working at the European Commission - DG Environment and at the University of Liege (Belgium). She has long standing experience in Risk Assessment in different areas in food and feed and has acquired strong expertise in regulatory science. She finds that working in multidisciplinary environments enriches our knowledge and supports co-creation of projects. She has been actively supporting EU initiatives, in particular the One-Substance-One-Assessment.

Prof. James Kevin Chipman | Chair of EFSA's Working Group on Genotoxicity

James Kevin Chipman. PhD, FRSB, FRCPath, FBTS. Emeritus Professor and former Pro-Vice-Chancellor at the University of Birmingham UK.

Research on molecular mechanisms of cellular toxicity and ecotoxicology with an emphasis on toxicogenomics, genotoxicity and epigenetics.

Former Member of UK Committee on Toxicology, and the UK Department of Health Committee on Safety of Medicines.

Former President of the British Toxicology Society and Director of the International Union of Toxicology. Current member of EFSA CONTAM Panel and various working groups including the cross-cutting Working Group on Genotoxicity.

Dr. Alexis Nathanail | EFSA, Coordinator of EFSA's Working Group on Genotoxicity

Dr. Alexis Nathanail obtained his PhD from the University of Helsinki (Finland) in the area of food safety and his M.Sc. degree in toxicology from the Medical University of Vienna (Austria). He is a European Registered Toxicologist (ERT) and Diplomate of the American Board of Toxicology (DABT). Currently he is working as Senior Scientific Officer at the European Food Safety Authority (EFSA) and is the coordinator of EFSA's Working Group (WG) on Genotoxicity, responsible for the revision of the genotoxicity guidance framework. Alexis has also been involved in the coordination of the Read-across and Botanicals WGs of EFSA, as well as in the assessment of novel foods and in the development and management of various research activities and projects of EFSA. Previously, Alexis worked as Senior Product Safety Manager at Unilever's Safety and Environmental Assurance Centre (SEAC), as Scientific Officer at the European Chemicals Agency (ECHA) and Researcher/Project Manager at the Finnish Food Safety Authority (Evira).

Presentation Abstract – Revision of EFSA's Genotoxicity Guidance Framework and Stakeholder Workshop

This opening presentation serves as an introduction and overview of EFSA's on-going revision of its genotoxicity guidance framework, and also outlines the purpose of this Stakeholder Workshop. EFSA's Scientific Committee has initiated, as a self-task, the revision of the Scientific Opinion on genotoxicity testing strategies applicable to food and feed safety assessment (EFSA, 2011) and the additional follow-up guidance documents used by EFSA and relevant stakeholders (Member States, industry, etc.). The aim of the revision is to produce a single guidance document with all relevant aspects included therein, considering state-of-the-art methods and approaches for the genotoxicity assessment of substances and mixtures. This Workshop is part of EFSA's engagement activities, with the aim to implement a transparent process by reaching out to relevant stakeholders and receive feedback on the proposed revision and new information on novel methodologies that can be considered in the updated guidance.

Dr. Riccardo Crebelli | Expert of EFSA's Working Group on Genotoxicity

Riccardo Crebelli (RC) was director of research at the Italian National Institute of Health (Istituto Superiore di Sanità) from which he retired in 2020. During his activity at the ISS, he has directed the section on genetic toxicology and mutagenesis from 1995 until his retirement.

The main fields of experimental research of RC were genetic effects of environmental and food-borne chemicals and complex mixtures, biomarkers of exposure, susceptibility and effect in human populations exposed to genotoxins, methods and strategies for genotoxicity assessment.

RC served as expert in genetic toxicology in national and European advisory bodies. He first joined EFSA as Panel member in 2002. At present, he is member of the Panel on Food Contact Materials and several EFSA working groups, including the Scientific Committee Working Group on Genotoxicity.

RC is author of over 100 publications in peer-reviewed journals, and over 800 indexed EFSA documents, chapters of books, technical reports and educational publications. The main areas of his publications include environmental and chemical mutagenesis, risk assessment, environmental and occupational health.

Presentation Abstract – Genotoxicity Testing Strategy Draft Proposal

The EFSA guidance on genotoxicity testing strategies applicable to food and feed safety assessment was published in 2011. Since then, several separate guidance documents have been issued by EFSA in order to address specific aspects of genotoxicity assessment, such as the assessment of mixtures and aneugenicity, as well as the refinement of evaluation criteria, in particular related to the evidence of target tissue exposure in in vivo testing and the quality of data to be used in the weight of evidence assessment. In the ongoing revision of the 2011 guidance, in addition to the integration of different EFSA genotoxicity documents in a single guidance, a revision of the current testing strategy was considered appropriate in the light of experimental evidence accrued after the publication of the former guidance and recent technical progress in the area of genotoxicity. The main aspects revisited and currently under discussion, which are covered in this presentation, include: i) the composition of the base set of in vitro tests, with particular reference to the possible use of mammalian gene mutation tests (TG476 and TG490) as an alternative to the Ames test (TG471); ii) the implementation of New Approach Methodologies (NAMs) in the genotoxicity testing strategy, following the IATA (Integrated Approaches for Testing and Assessment) principles, with the aim to minimise and optimise the use of experimental animals in genotoxicity assessment; iii) the strategy for the in vivo follow-up of in vitro positives, with consideration of the recently introduced OECD

TG470 and the ongoing activities concerning the validation of the micronucleus tests in liver and gastro-intestinal tract, and iv) the role of emerging powerful molecular methods in genotoxicity assessment.

Dr. Birgit Mertens | Sciensano, Expert of EFSA's Working Group on Genotoxicity

Birgit Mertens is a senior toxicologist (ERT) at Sciensano and leads the Risk and Health Impact Assessment service, a team of about 30 members. She coordinates and participates in various (inter)national research projects on the development, application, and regulatory implementation of new approach methodologies (NAMs) and next-generation risk assessment (NGRA) strategies, with a particular focus on genotoxicity. Within the European Partnership for the Assessment of Risks from Chemicals (PARC), she co-leads the project on developing an integrated approach to testing and assessment (IATA) for genotoxicity (P6.1.1.c_Y1_IATA_Gentox). She has published over 60 peer-reviewed scientific papers and contributed to numerous (inter)national scientific advisories. She serves on different (inter)national working groups and scientific committees related to hazard and risk assessment (e.g., OECD genotoxicity expert groups, Belgian Scientific Committee REACH) and is the current president of the Belgian Environmental Mutagenesis Society.

Presentation Abstract – Quantitative Genotoxicity Assessment Draft Proposal

In recent years, there has been growing interest in applying quantitative approaches to genotoxicity assessment, particularly in cases involving non-DNA-reactive mechanisms such as aneugenicity or indirect modes of action such as oxidative stress and topoisomerase inhibition. In such scenarios, quantifying the biological response to establish a point of departure (PoD) can support the use of a Margin of Exposure (MoE) approach in risk assessment. However, in the absence of robust mechanistic evidence supporting an aneugenic or indirect genotoxic mode of action, implementing quantitative genotoxicity assessment remains challenging.

Benchmark dose modelling is currently considered the most appropriate approach for quantitatively analysing genotoxicity data. To date, most experience with BMD modelling has come from in vivo genotoxicity studies. In line with the 3Rs principles (Replacement, Reduction and Refinement), further research is necessary to explore the predictive capacity of in vitro genotoxicity data for in vivo effects. This involves extrapolation from in vitro PoDs using in vitro to in vivo extrapolation (IVIVE) models. However, caution is warranted when using such models due to significant biological differences between in vivo conditions and in vitro systems.

This presentation will discuss the possible integration of the quantitative genotoxicity assessment in the revised EFSA genotoxicity guidance document.

Dr. Pascal Phrakonkham | European Chemicals Agency (ECHA)

Pascal Phrakonkham is a Scientific Officer at the European Chemicals Agency (ECHA). He is Human Health expert in one of the REACH Dossier Evaluation Units and also co-coordinator of the Mutagenicity-related activities across the Agency together with his colleague Frank Le Curieux.
Regarding his background, he graduated in Pharmacy in 2003 from the University of Lyon, in France, where he also completed his Master's degree in Metabolism, Endocrinology and Nutrition.
He also holds a PhD in Food Toxicology obtained in 2007 from the University of Burgundy and the French National Research Institute for Agriculture, Food and Environment (INRAE) in Dijon, in France, where he studied the effects of dietary endocrine disruptors on several processes related to carcinogenesis.
After his PhD, he worked as Research Scientist in the Pharmacology Department of a biotechnology company developing anticancer drugs in Paris, before joining the Joint Research Centre of the European Commission in Ispra, in Italy, in 2009.
There, he was Scientific and Technical Officer at the European Centre for the Validation of Alternative Methods (EURL-ECVAM), in the area of Mutagenicity and Carcinogenicity.
In 2012, he joined ECHA and worked first in the Guidance team on the update of the different sections of the REACH Guidance related to information requirements for Human Health, including Mutagenicity. He then moved to the Hazard Assessment Directorate in 2018, where he still works.

Presentation Abstract – Mutagenicity Assessment Under REACH and BPR

In the European Union (EU), Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and the Biocidal Products Regulation (EU) No 528/2012 (BPR), define the information to be provided for the placing on the market of industrial chemicals and biocidal products, respectively. Both Regulations fall under the remits of the European Chemicals Agency (ECHA).
The information requirements for the mutagenicity endpoint under REACH and BPR are similar overall and follow a tiered approach: (i) in vitro mutagenicity test battery, (ii) in vivo genotoxicity test(s) in somatic cells triggered in case of positive results in vitro, and (iii) in vivo genotoxicity test(s) in germ cells triggered in case of positive results in somatic cells.

However, there are some differences in the legal provisions for mutagenicity between the two Regulations. In addition, the REACH legal text was revised in 2022 to further clarify the in vitro and in vivo tests to be performed in each tier, the conditions for triggering follow-up studies, and the conditions for adapting the information requirements, where applicable. The corresponding REACH Guidance document is being updated by ECHA accordingly.

This presentation will give an overview of the current information requirements for mutagenicity under REACH and BPR, and briefly describe the recommended testing strategies for mutagenicity assessment, including commonalities and differences. How the recent changes under REACH have been focused on improving the impact of mutagenicity assessment, in particular in terms of support to classification and labelling, will also be emphasised. A status update on the corresponding Guidance documents will also be provided.

Dr. Fransisca van Doesum-Wolters | European Medicines Agency (EMA)

Ciska van Doesum-Wolters is a European Registered Toxicologist (ERT) with over two decades of experience in non-clinical development and translational science. She holds a Master of Science in Bio-Pharmaceutical Sciences from the University of Leiden and earned her PhD in Medicine from Utrecht University.

Before joining the European Medicines Agency (EMA), Ciska built a distinguished career in the pharmaceutical and biotechnology industry, where she held various scientific and strategic roles focused on advancing drug development from early research through to clinical translation. Her work spanned safety pharmacology, toxicology, and regulatory science, contributing to the development of both small molecules and biologics.

In 2023, she joined EMA as a Senior Scientific Officer in the Translational Science Office, where she plays a key role in fostering cross-agency collaboration. Among her responsibilities is the coordination of joint activities between EMA, the European Food Safety Authority (EFSA), and the European Chemicals Agency (ECHA), particularly in the context of the One Substance – One Assessment initiative. Her work supports the integration of scientific evidence across sectors to enhance regulatory consistency. Ciska’s expertise in translational toxicology informs her contributions to regulatory guidance development and scientific strategy at the EU level.

Presentation Abstract – Relevant Guidance Documents, Frameworks and On-going Activities at Other EU Agencies – EMA's View

In this presentation, Ciska van Doesum will provide a comprehensive overview of current guidance documents, testing frameworks, and regulatory strategies related to genotoxicity assessment in both human and veterinary medicinal products, as viewed by the European Medicines Agency (EMA). It highlights two key international guidelines: ICH guideline S2 (R1) on genotoxicity testing and data interpretation for pharmaceuticals intended for human use and VICH GL23: Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing, outlining their respective standard batteries of tests and implementation timelines.

Both guidelines outline two testing options, each beginning with a gene mutation test in bacteria. Option 1 allows for a combination of in vitro and in vivo assays to evaluate gene mutations and chromosomal damage. Option 2 requires an in vivo assessment of genotoxicity in two different tissues, reflecting, the same strategy that would be used to follow up on a positive in vitro result. Several in vivo assays can be used as part of Option 2, including those that can be integrated into repeat-dose toxicology studies, enhancing efficiency and reducing animal use. For human medicines, the timing of genotoxicity studies is aligned with clinical development phases as per ICH M3(R2) requiring completion of the complete battery of tests for genotoxicity to be completed before the initiation of Phase II clinical trials. In addition to the guidelines on genotoxicity for drug substances and products, the ICH and EMA have developed guidance documents addressing risk minimisation measures for mutagenic impurities. These include ICH M7(R2) and EMA's veterinary-specific guidance (EMA/CVMP/SWP/377245/2016) and ongoing activities that focus on one of the mutagenic impurities belonging to the cohort-of-concern: nitrosamine impurities and their determination of their acceptable limit using the Carcinogenic Potency Categorization Approach (CPCA). This approach is supported by enhanced Ames testing and in vivo transgenic rodent mutation assays (OECD488), which help refine risk assessments and establish appropriate control measures.

Dr. Nathalie Delrue | Organisation for Economic Co-operation and Development (OECD)

Nathalie Delrue is an Administrator of the Test Guidelines Programme at the Organisation for Economic Co-operation and Development (OECD); Environment Directorate; Environment, Health and Safety division. She joined the OECD Secretariat in 2006 and is managing the development of new and updated Test Guidelines related to human health, in particular skin sensitisation, genotoxicity and carcinogenicity. She

is in charge of the coordination of the Adverse Outcome Pathway development programme, initiated at OECD in 2012. Before joining the OECD she worked in the Toxicological Expertise Unit of the Chronic Risk Direction at INERIS (French Institute for Industrial Environment and Risks). She was in charge of hazard identification/risk assessment for human health in various international chemical programmes (EU, OECD). She holds a doctorate degree in pharmaceutical sciences from University René Descartes (Paris V) and two Master's degrees, one in Biological and Medical Science (Paris V) and one in Water, Health and Environment (Bordeaux 2).

Presentation Abstract – OECD – New Test Guidelines for Genotoxicity Assessment Assays

The number of genotoxicity-related projects submitted to the OECD Test Guidelines Programme workplan is growing - many of which focus on new approach methodologies (NAMs). This is expected to lead to the development and adoption of several new or revised Test Guidelines (TGs) on genotoxicity by the OECD in the coming years and will enhance the availability of innovative tools for genotoxicity assessment, supporting regulatory decision-making under the framework of Mutual Acceptance of Data.
The presentation will provide an overview of current activities at the OECD level related to on-going genotoxicity projects. It will outline the principles behind TG development, review the current Test Guidelines Programme workplan, highlight key challenges encountered during the development of new or the update of existing genotoxicity TGs, and showcase the emergence of a new generation of assays, that offer mechanistic insights and/or integrate advanced technologies, such as omics approaches.

Dr. Katrin Schütte | European Commission, DG Environment

Dr. Katrin Schütte is a policy officer at the Commission's Directorate for the Environment, unit sustainable chemicals. Her responsibilities cover several aspects of REACH, the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes and the development of the Commission Roadmap to phase out animal testing.
Before joining the Commission, Katrin worked for 15 years as a toxicologist and regulatory affairs manager in the consumer products sector.

Dr. Raffaella Corvi | EU Joint Research Centre (JRC)

Raffaella Corvi obtained her PhD at the University of Heidelberg working at the German Cancer Research Centre. She subsequently joined the International Agency for Research on Cancer (IARC), to work on the molecular development of thyroid cancer, including the application of a variety of in vitro tools. Since 2001 she works at the Joint Research Centre (JRC) of the European Commission, which hosts the European Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), where she established the activities in the area of genotoxicity and carcinogenicity. In 2003 she was seconded to the OECD Test Guideline Programme. Currently, she conducts activities that evaluate innovative and integrated approaches to assess chemical safety across sectors and support their regulatory implementation, while also promoting the 3Rs across multiple regulatory sectors. She is currently leading a working group for the revision of germ cell mutagenicity classification criteria at the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and is the European Commission chair of two projects at the European Partnership for Alternative Approaches to Animal testing (EPAA). She is a member of several European and international committees, such as various OECD expert groups, the HESI Global and EFSA Genotoxicity Working Group. She is also acting as contact point between the JRC and the 3Rs European Medicine Agency (EMA) Working Party.

Presentation Abstract – EU Roadmap Towards Phasing Out Animal Testing With Focus on Genotoxicity and Carcinogenicity

In its reply to the European Citizens' Initiative "Safe cruelty-free cosmetics – Commit to a Europe without animal testing" (Communication C(2023) 5041), the Commission committed to the development of a roadmap that will outline milestones and specific actions, to be implemented in the short to longer term, to reduce animal testing and that would be pre-requisites for a transition towards an animal-free regulatory system under relevant pieces of chemical legislation (e.g., REACH, Biocidal Product Regulation, Plant Protection Products Regulation and human and veterinary medicines). The Commission will publish the roadmap in Q1/2026 as a communication accompanied by a staff working document describing more details about the proposed actions. This roadmap should serve as a structured action plan to accelerate the transition away from animal testing in chemical safety assessments by setting clear objectives and actionable steps. The roadmap outlines the key high-level considerations and policy tools required to allow the transition to conducting chemical safety assessments without the use of animals while maintaining or improving protection of human and animal health and of the environment. The roadmap contains recommendations for the transition to non-animal methods, outlines pathways to better coordinate the

identification of regulatory needs and to scale up the development, validation, and implementation of non-animal methods or approaches to meet those needs. The presentation will address general considerations related to the roadmap, as well as high level actions proposed to phase out animal testing in the areas of carcinogenicity and genotoxicity assessments.

SESSION II

Prof. David Kirkland | Kirkland Consulting

Professor Kirkland has a BSc (microbiology) from the University of London and a PhD (cellular cancer studies) from Brunel University. Following 2 post-doctoral fellowships he became Research Director at Toxicol Laboratories. He then joined Microtest Research Limited in 1984, which became part of Covance where, over 25 years, he was Head of Genetic Toxicology, Vice-President of Toxicology and of Scientific and Regulatory Consulting. In 2009 he became an independent consultant. He has extensive experience with regulatory issues relating to genotoxicity data, has published >150 peer-reviewed papers and is a regular podium speaker/chairperson.

He was awarded Fellowship of the UKEMS in 2002, and made Honorary Professor of the University of Wales, Swansea in 2006. In 2010 he received the first Industrial Genotoxicity Group (UKEMS) Distinguished Toxicologist Award, and also the US Environmental Mutagen Society Alexander Hollaender Award for global leadership in the regulation of genetic toxicology testing. In 2014 he was awarded The Kitashi Mochizuki Award by the Japanese Environmental Mutagen Society for promotion of international harmonization of genotoxicity tests through the International Workshops on Genotoxicity Testing (IWGT) of which he was chair of the steering committee for 20 years. In 2015 he received the Jim Parry Award from UKEMS, in 2022 he received the Frits Sobels award from the European Environmental Mutagenesis and Genomics Society, and in 2025 he received the Excellence in Science award from the US Genetic Toxicology Association. For many years he was Special Issues Editor for Mutation Research and editorial board member of the Journal of Applied Toxicology. He was a member of the UK Government Advisory Committee on Mutagenicity for 10 years, was UK expert to OECD for genotoxicity guidelines, and Past President of the European EMGS.

Presentation Abstract – The Core *In Vitro* Test Battery – 2 or 3 Tests?

The core *in vitro* tests recommended in the EFSA 2011 guidance are an Ames test + an *in vitro* micronucleus (MNvit) test, a battery which detects all 3 key modes of action (gene mutations, clastogenicity and aneugenicity). This approach is consistent with other published recommendations. Whilst we showed (Kirkland et al., 2011) that adding a mammalian cell gene mutation (MCGM) test is not justified in terms of the overall detection of rodent carcinogens and various types of *in vivo* genotoxins, a new, specific question has arisen – "Are there any substances that are +ve in TGR or Pig-a tests, that are negative in Ames, but are positive in MCGM?". Five key database publications which contain Ames and TGR data, 1 of which also contained Pig-a data, were therefore reviewed. In total 26 substances were identified that were originally reported in these databases as Ames -ve/TGR +ve. Note there is only 1 substance (procarbazine) which is Ames -ve/Pig-a +ve and it is also TGR +ve. Where possible the original publications/reports that led to these database "calls" have been checked, and more recently published data also considered. Several substances did not have any MCGM data, and in other cases the MCGM was clearly negative, questionable or inconsistent. Some negative Ames calls were based on inadequate testing or conflicting results. Also, a number of TGR datasets were questionable. Only 1 substance, procarbazine, was robustly -ve in Ames, +ve in TGR (and Pig-a) and +ve in MCGM. The different results with procarbazine may well be driven more by metabolic considerations than sensitivity of the different test systems. Moreover, it is a much more potent clastogen than gene mutagen. Given this analysis, do the data justify adding MCGM to the core battery?

Dr. Carol Beevers | Corteva Agriscience

Dr. Carol Beevers has worked within the field of genetic toxicology for more than 25 years, initially as a study director at a large contract research laboratory, then as an independent toxicology consultant, and currently as an in-house subject matter expert at Corteva Agriscience. She is an expert member of the UK Committee on Mutagenicity of Chemicals in Food, Consumer Products, and the Environment (COM) and the UK Food Standards Agency (FSA) Joint Expert Group on Additives, Enzymes and other regulated products (AEJEG). Carol participates in a number of international working groups on genotoxicity testing including the OECD genotoxicity Expert Group. She is the Industry Chair of the Health and Environmental Sciences Institute (HESI) Genetic Toxicology Testing Committee (GTTC) as well as the Chair of the GTTC In Vivo Follow-up work group. Carol is also a member of the organising committee of the International Workgroup on Genotoxicity Testing (IWGT) and Chair of the IWGT In Vivo Strategies work group.

Presentation Abstract – Improving the Performance of the In Vivo Comet Assay and Considerations for Following up In Vivo Comet Positive Results

Following a statistical review of liver comet historical control data (HCD) from 7 laboratories, the IWGT 2022 in vivo work group recommended that comparison of study results to the HCD should not be used in data evaluation unless the HCD distribution is stable and the predominant source of HCD variation is due to the animal, not study factors. The work group also noted that methodological differences in comet studies could result in variable data interpretations, but that more data are required before best practice recommendations can be made. For many laboratories, these recommendations mean that data interpretation will be based solely on pairwise and linear trend relationships of treated versus control groups, but current methodological practices (described by real examples) may not be sufficiently robust for reliable statistical evaluations. In addition, sufficient detail regarding the methodologies used are rarely provided in both GLP study reports and peer-reviewed literature, which confounds distinguishing between real biologically relevant responses from artefacts of the methodologies used. This could lead to inaccurate weight of evidence conclusions regarding the genotoxic potential of a test substance and frequently triggers additional, resource intensive in vivo studies.

Dr. Maricel Marin-Kuan | Nestlé Research

Maricel Marin-Kuan holds a PhD in molecular biology from the University of Lausanne in Switzerland. She is currently a senior scientist in in vitro toxicology at Nestlé Research in Switzerland. Her key contributions include elucidating the mechanism of action of chemical hazards using advanced high-throughput in vitro tools for risk assessment. She provides solutions for addressing food quality and safety challenges to support prioritization and decision-making, including safety by design, new packaging materials, or food-related products. Dr. Marin-Kuan has been involved in innovating and applying strategic in vitro tools to tackle important toxicological issues related to food and food-related items, aiding risk assessment. She collaborates with external groups such as academic institutions, contract research organizations, and industry partners in the in vitro toxicology field.

Prof. Bette Meek | University of Ottawa

Dr. Meek is a past Associate Director of Chemical Risk Assessment at the McLaughlin Centre for Population Health Risk Assessment, University of Ottawa and currently, an Adjunct Professor in the School of Epidemiology and Public Health in the Faculty of Medicine, University of Ottawa. She also holds an Adjunct Professorship in the School of Environment and Sustainability at the University of Saskatchewan. Previously, she managed several chemical risk assessment programs within Health Canada. With colleagues internationally, she has contributed to or led initiatives in evolving methodology in chemical risk assessment, including mode of action/adverse outcome pathways, chemical specific adjustment factors, physiologically-based kinetic modeling, combined exposures and predictive modeling. She has authored approximately 200 publications in this area and received several awards for contribution in this domain.

Presentation Abstract – Genotoxicity Testing to Inform Pathway Analysis (Adverse Outcome Pathways) and Mutagenic Modes of Action

Adverse Outcome Pathways (AOPs) provide convenient integrating organizational constructs for assembling and evaluating mechanistic information at different levels of biological organization in a form designed to support a range of regulatory applications. These include the development of integrated approaches to testing and assessment (IATA) and chemical specific assessment to inform predictive inference and mode of action (MOA) analysis. There has been much experience gained in the last thirteen years since the introduction of the AOP development program by the Organization for Economic Co-operation and Development (OECD) of mechanistic pathways for genotoxicity/mutagenic modes of action. This presentation considers the nature of the evolution of described pathways and the implications for the generation and consideration of genotoxicity data in chemical specific assessment.

SESSION III

BREAKOUT GROUP 1

Dr. Carsten Kneuer | Bundesinstitut für Risikobewertung (BfR)

Carsten Kneuer was trained in experimental pharmacology and toxicology, biochemistry and molecular biology. He also obtained a Master in Toxicology from Birmingham University. Following a Ph.D. and

PostDoc at the Pharmaceutical Department in Saarbrücken and an assistant professorship at the Veterinary Faculty in Leipzig, he joined the German Federal Institute for Risk Assessment, the BfR, in 2007. There, he and his Unit Toxicology of Active Substances within the Department of Pesticide Safety is now responsible for evaluating the mammalian toxicity of pesticides and biocides including their impurities and degradation products. The group is providing regulatory assessments under respective EU legislations as well as for the purpose of classification and labelling on a regular basis. He very much enjoys collaborating with other stakeholders on the advancement of our risk assessment methodology through joint research projects, guideline development programmes and workshops.

Presentation Abstract – Quantitative Assessment of Genotoxicity (Perspective from Pesticide and Biocide Safety)

The presentation entitled "Quantitative Assessment of Genotoxicity" builds on recent related activities of the German Federal Institute of Risk Assessment including a literature review on strategies and tools for quantitative assessment of risk from exposure to genotoxic compounds and an International Symposium held in 2024, identifying existing challenges and perspectives in the field. Following a brief summary on the motivation for those activities, three options for introducing quantitative aspects into the assessment of genotoxic substances are described: Threshold-based, Risk-based for non-thresholded substances, Uncertainty and Mode of Action analysis. These options will be further illustrated using a number of case studies from previous substance evaluations, giving attention to potential inconsistencies between individual cases and approaches followed by different agencies. With the case studies, it is intended to highlight potential points for further discussion and harmonisation through guidance development.

Prof. Julia Catalán | University of Zaragoza, Expert of EFSA's Working Group on Genotoxicity

Julia Catalán, PhD (Vet.), is currently working as Associate Professor of Genetics at the University of Zaragoza (Spain). She is a researcher in the field of Genetic Toxicology, and she has been involved in this field since 1987. From 2010 to 2024, she was working as senior researcher at the Finnish Institute of Occupational Health. She has been involved in studies in mechanisms of genotoxicity, nanotoxicology and human biomonitoring, with participation in different National and European projects. She has been acting as National expert (both from Finland and Spain) of the OECD Working Group on Genotoxicity. She has also contributed as a European expert to the ISES-Europe (European regional chapter of the International Society of Exposure Science) and to the European Medicines Agency (EMA). Recently, she has been appointed as expert to the European Food Safety Authority (EFSA) Working Group on Genotoxicity.

Dr. Maria Carfi' | EFSA

Dr. Maria Carfi' has been serving as a Scientific Officer at the European Food Safety Authority (EFSA) since 2011. In this role she provides support to the Panel on Food Additives and Flavourings (FAF Panel) and its working groups, particularly on the safety assessment of food flavourings. In EFSA she contributed to several scientific activities in the area of genetic toxicology.

Dr. Carfi' studied biotechnology (medical field) and bioinformatics at the University of Milan (Italy). After her graduation, she obtained a PhD in immunotoxicology at the University of Utrecht (The Netherlands). During her doctoral studies, she worked at the European Commission's Joint Research Centre (EC-JRC), focusing on alternative methods to animal testing, particularly related to the immune system.

Following her doctoral studies, she worked at the University of Milan on alternative methods to animal testing in the area of skin sensitisation. Before joining EFSA she worked at the Organisation for Economic Co-operation and Development (OECD) contributing to projects related to guidelines for the testing of chemicals.

Dr. Daniela Maurici | EFSA

Dr. Daniela Maurici serves as a Senior Scientific Officer at the European Food Safety Authority (EFSA) in the Unit "Methodology and Scientific Support – MESE". She joint EFSA in 2007, initially working in the area of genotoxicity, alternatives to animal testing and emerging risk identification. In her current role as Scientific Committee (SC) team leader, she is providing scientific coordination to the EFSA Scientific Committee, the panel responsible for development of cross-cutting guidance documents and cross-cutting risk assessments. She is also responsible for the execution and implementation of the team SC work-programme, including the supervision of the working groups providing the preparatory work for the cross-cutting guidance development and revisions.

Dr. Maurici holds a degree in Biology and a PhD in Oncology from the University of Bologna, Italy. She prepared her PhD thesis in Boston, USA, at the Harvard Medical School and after her PhD, she worked as a post doc at the Internation Agency for Research on Cancer (IARC) in Lyon. Before joining EFSA, she worked at the European Centre for the Validation of Alternative Methods (ECVAM) at the Joint Research Centre in Ispra (Italy).

BREAKOUT GROUP 2

Dr. Stefan Pfuhler | P&G

Dr. Pfuhler received his Ph.D. in Biology from the department of Pharmacology and Toxicology of The University of Ulm in 1997. He joined Procter and Gamble in 2000 and currently serves as a R&D Senior Director Research Fellow in its Global Product Stewardship division. Dr. Pfuhler's research focuses on alternatives to animal testing and in-vitro-only testing strategies, including the validation of 3-dimensional human skin-based genotoxicity assays. He currently serves as chair of the Genotoxicity Work Group of the International Collaboration on Cosmetic Safety (ICCS), co-chair of HESI's Botanicals Consortium Genotoxicity and Mechanism-based Risk Assessment Working Groups, as well as on HESI's Board of Trustees.

Presentation Abstract – Towards a Global Genotoxicity Testing Strategy for Botanical Mixtures

Plants extracts consist of wide spectrum of secondary metabolites, making them complex mixtures which contain phytoconstituents that are challenging to fully analytically characterize, or chemically synthesize. The Genotoxicity Working Group of the Botanicals Consortium is working to develop a screening strategy to identify botanicals with genotoxic potential. A full description of the team's strategy was published in early 2025 (Witt et al., 2025). Botanicals selected by this working group represent a range of genotoxic and non-genotoxic profiles. *Aristolochia fangchi* and *Comfrey* were selected as prime examples for botanicals that contain genotoxic constituents that such a strategy should pick up. Preliminary results from this program will be shared that support the sensitivity of a two-test in vitro battery consisting of the bacterial reverse mutation (Ames) test and the in vitro micronucleus assays, which encompasses all genotoxicity endpoints: gene mutation, clastogenicity and aneugenicity. In addition, data will be shown that exemplify the sensitivity of these in vitro assays to correctly flag critical extracts even when only very

low concentrations of potent genotoxins are present, as well as an example that investigates additivity versus synergism in botanical mixtures.

Dr. Gabriele Aquilina | Expert of EFSA's Working Group on Genotoxicity

Education: Degree in Biology (cum laude), 1981, University of Rome "La Sapienza", Specialization in Microbiology (cum laude), 1985, University of Rome "La Sapienza".
Work experience: Employee of the Istituto Superiore di Sanità, since November 1986 Current position: Research director.
Occupational field: Genetic toxicology. Evaluation of the mutagenic activity of chemicals associated with environmental and/or professional human exposure, analysis of the mechanisms of mutagenesis and genotoxic carcinogenicity.
Main current activities: Italian member of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as expert for human health (current mandate: June 2023 - June 2026), Head of the Italian delegation to the Chemicals and Biotechnology Committee (OECD / EHS Programme), National coordinator of the OECD Test Guideline Programme, Member of the Expert Panel "Food Additives and Flavourings" (FAF) of the European Food Safety Authority (EFSA) (current mandate July 2024 - June 2029), Member of the Working Group on Genotoxicity of EFSA Scientific Committee.

Dr. Rainer Gürtler | BfR, Expert of EFSA's Working Group on Genotoxicity

Dr. Rainer Gürtler is a member of the EFSA Scientific Committee Working Group on Genotoxicity and a member of the EFSA Panel on Food Additives and Flavourings (FAF Panel). Previously, he has been a member of the EFSA AFC, ANS and CEF Panels. His academic background is biology and chemistry with

further training in toxicology and expertise in genetic toxicology. Main areas of his work at EFSA and in the German Federal Institute for Risk Assessment (BfR) are risk assessments of food additives and flavourings. He was involved in the preparation of the EFSA guidance documents on genotoxicity. As a member of an FAO/WHO expert working group, he contributed also to the update of section 4.5 "Genotoxicity" of the FAO/WHO "Principles and Methods for the Risk Assessment of Chemicals in Food, Environmental Health Criteria 240".

Dr. Sara Levorato | EFSA

Sara Levorato is a Scientific Officer at the European Food Safety Authority (EFSA) in Parma. She joined EFSA in 2020, initially working in the Integrated Data (IDATA) Unit, and since 2022, she has been part of the Methodology & Scientific Support (MESE) Unit. In her current role, she coordinates the Scientific Committee's Working Group on Genotoxicity, which provides cross-cutting scientific advice to EFSA's Panels and Units on the implementation and interpretation of EFSA's genotoxicity guidance documents.

Before joining EFSA, Sara worked as a risk assessor at Unilever's Safety and Environmental Assurance Centre (SEAC) in the UK, where she was responsible for the safety evaluation of food ingredients and contaminants, and contributed to the promotion and implementation of strategies that support alternatives to animal testing.

She holds a PhD in Life Sciences and Public Health, and her academic background includes research in the field of in vitro genotoxicity testing of nanomaterials, botanicals and phytochemicals.

Dr. Carla Martino | EFSA

Dr. Carla Martino serves as Senior Scientific Officer at the European Food Safety Authority (EFSA) in the Food ingredient and Packaging Unit. In her current role, she provides support to the EFSA Panel on Food Additives and Flavourings (FAF) and its working groups, particularly on the safety assessment of food flavourings. She has contributed to the development of scientific guidance documents on the data requirements for the authorisation of food additives and flavourings.

Dr. Martino holds a degree in Pharmaceutical Chemistry and a PhD in Cellular Physiopathology from the University of Modena, Italy. Following her doctoral studies, she worked in the pharmaceutical industry in Italy, first in research and development and later in clinical research. Before joining EFSA, she completed a Master in Regulatory Affairs in Pavia, Italy and served as a Scientific Administrator at the European Medicines Agency (EMA) in London. At EMA, she coordinated procedures for the marketing authorisation of medicinal products across Europe, with a focus on advanced therapy medicinal products, including cell therapy, gene therapy and tissue-engineered products.

Dr. Paola Manini | EFSA

Paola Manini joined the European Food Safety Authority (EFSA) in 2009. As a senior Scientific Officer in the FEED team of the FEEDCO Unit, she provides support to the EFSA Panel on Additives and Products or Substances used in animal feed (FEEDAP Panel) and she coordinates the FEEDAP working group on feed flavourings, which is now dealing with the assessment of additives of botanical origin. She has been involved in several EFSA horizontal projects aimed at harmonising methodologies in risk assessment, like the Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals.

Paola Manini graduated in Chemistry at the University of Parma in 1992 and received her PhD in Analytical Chemistry in 1997, with a dissertation on liquid chromatography-mass spectrometry (LC-MS) applied to food and water analysis. She has a master's degree in occupational and environmental Toxicology (1998). From 1997-2009, she worked as researcher at the Laboratory of Occupational and Environmental Toxicology of the University of Parma, in a multidisciplinary research group. Her main research activity was aimed at investigating the metabolism of industrial chemicals and environmental pollutants, the mechanisms of oxidative stress induced by these chemicals, and at developing of new biomarkers of exposure, early effect and susceptibility. Paola Manini is author of 92 peer-reviewed publications and 4 book chapters.

BREAKOUT GROUP 3

Prof. Anthony M Lynch | GlaxoSmithKline (GSK)

Current Role - Executive Director, Genetic and Investigative Toxicology, GSK R&D, Stevenage, UK.
Prof. Lynch graduated from the University of Swansea, where he gained a PhD in Genetic Toxicology. His postdoctoral work at Imperial College was under the guidance of Profs. Alan Boobis and Nigel Gooderham. Anthony joined GSK as a Research Investigator, establishing transgenic gene mutation assays, and over the years has progressed through roles of increasing responsibility, leading to his appointment as Executive Director in 2024. He has co-supervised six PhD students along with numerous MSc and industrial placement students. Anthony has co-authored over 100 publications covering Genetic Toxicology, Mutagenesis, Carcinogenesis, and Photosafety. He is a former President of UKEMS and Treasurer of EEMGS, actively involved in various public-private research collaborations such as IWGT and HESI GTTC, and served on the UK COM. In 2011, he was named an honorary Professor in the College of Medicine at Swansea University and became a Fellow of the Royal College of Pathologists in 2013. This year, Anthony was honoured with the JM Parry award by the UKEMS in recognition of his significant contributions to Genetic Toxicology.

Presentation Abstract – Mechanistic Genotoxicity: NAM & QSAR Approaches and Error Corrected Sequencing

Genetic toxicology has traditionally focused on New Approach Methodologies (NAMs) for regulatory testing, including the use of in silico predictions through quantitative structure-activity relationships (QSAR) and in vitro assays. Over the past 15 years, more mechanistic NAMs, especially in vitro methods, have been developed, leading to updates in existing OECD Test Guidelines (TG) or the development of new ones. More recently, error-corrected sequencing (ECS) is transforming genetic toxicology by allowing highly precise detection of low-frequency, chemically induced mutations through consensus sequencing and advanced bioinformatics, achieving error rates akin to baseline somatic mutation frequencies. These advancements provide notable benefits compared to traditional approaches (Marchetti et al., 2023 and the International Workshop on Genotoxicity Testing, IWGT position paper, 2025; in press) highlights significant progress in validating ECS for regulatory purposes. The strong agreement with transgenic gene mutation assays, combined with enhanced sensitivity and 3R (Replacement, Reduction, Refinement) advantages, supports ongoing initiatives to update OECD Test Guidelines (TG 488, TG 490 and TG 471) to include ECS methods.

Consequently, modern NAMs in genetic toxicology are expected to facilitate the disciplines shift from solely hazard identification to comprehensive risk assessment.

Dr. Maria Dusinska | Expert of EFSA's Working Group on Genotoxicity

Maria Dusinska, RNDr., PhD., DrSc., ERT has over 30 years experience in environment and health field, hazard and risk assessment, genotoxicity and carcinogenicity, nanotoxicology, advanced in vitro models, human biomonitoring and biomarkers. Before she moved to Norway in 2006, she worked at the Slovak Medical University as head of Department of Experimental and Applied Genetics in Bratislava. At NILU, Kjeller, Norway she was Director of GLP laboratory and scientific leader of Health Effects Laboratory. She was also teaching at Oslo University 'Food toxicology' and in Comenius University 'DNA instability and human health'. In 2005-2006 she was national expert working at EC DG RTD Health at Brussels for alternative toxicity tests. Between 2013-2023 she was a member of the Scientific Committee on Consumer Safety (SCCS) and since 2020 she is a member of the EFSA cross-cutting Working Group on Genotoxicity. She has over 500 publications, over 21,000 citations, h-score 74 (Google Scholar). She is editor of Mutation Research, Nanomaterials, Basic Clinical Pharmacology and Toxicology and other journals and was guest editor for many special issues. She coordinated several EC projects (EC FP5 Centre of Excellence in Environmental Health HEAR NAS, FP7 NanoTEST and H2020 NMBP13 RiskGone), and was involved in many EC and national projects. In 2024 she received Fritz Sobel's Award 2024 (EEMGS) and State Award Ludovit Stur Order II. from President of Slovak Republic.

Prof. Stefano Landi | University of Pisa, Expert of EFSA's Working Group on Genotoxicity

Stefano Landi is a Full Professor of Genetics at the University of Pisa whose research investigates genotoxicity, genetic susceptibility and molecular drivers of cancer, with emphasis on malignant pleural mesothelioma and pancreatic cancer. Trained in Pisa, Ferrara, the US EPA, and IARC (Lyon) as a Marie-Curie fellow, he has led nationally and internationally funded projects—including PNRR initiatives—and served as PI on multiple AIRC grants. Author of 170+ peer-reviewed publications and named among Stanford's top 2% scientists, his current interests span microRNAs, single-base gene editing, digital PCR for liquid biopsies, and translational biomarker discovery.

Juan Parra Morte | EFSA

Juan Parra Morte has been Toxicologist in the Pesticide Peer Review Unit of EFSA since 2008. He has been actively involved in the assessment of pesticide active substances, their metabolites and impurities, including the EFSA PPR, the OECD Guidance on Residue Definition and EFSA's outsourced projects on the Genotoxicity Database and QSAR and Read Across for the genotoxicity of metabolites. He has been chairing the EFSA Working Group on NAMs QSARs.