DIE AKADEMIE FRESENIUS

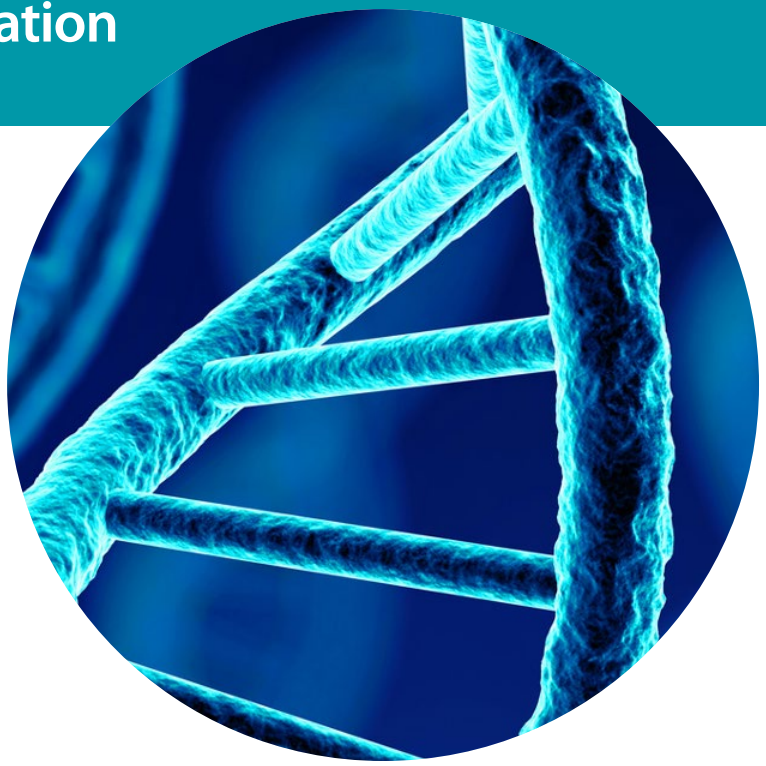
Where Experts Meet!

3rd International Akademie Fresenius Conference

Genotoxic Compounds

Recent developments and implications for assessment and regulation

+++ ONLINE CONFERENCE +++



13 and 14 February 2025

Highlights

Regulatory developments
- Genotoxic compounds in EU food safety policy
- Case studies: Pyrrolizidine alkaloids and 2-chloroethanol stories
- Novelties for mutagenicity under REACH and CLP
- Germ cell mutagenicity

Quantitative risk assessment
- Results of the BfR Symposium on strategies and tools for quantitative risk assessment
- Activities of the Genetic Toxicology Technical Committee (GTTC) on quantitative analyses

Development of test methods and guidelines
- Error-corrected next generation sequencing (ecNGS) and how it is being used
- Transcriptomic biomarkers
- ToxTracker assay to investigate the mode-of-action of genotoxic compounds
- The PARC project
- Novel methodology to assess genotoxicity in food contact materials

Modelling and prediction of genotoxicity
- EFSA Pesticides Genotoxicity Database
- The new OECD QSAR assessment framework
- Plant protection QSAR models through data sharing and regulatory review

The Experts

Raffaela Corvi European Commission Joint Research Centre (JRC) | **Markus Frericks** BASF | **Ulrike Gündel** German Federal Institute for Risk Assessment (BfR) | **Giel Hendriks** Toxys | **Carsten Kneuer** German Federal Institute for Risk Assessment (BfR) | **Catherine Mahony** Procter & Gamble | **Francesco Marchetti** Health Canada | **Maricel Marin-Kuan** Nestlé Research | **Birgit Mertens** Sciensano | **Krista Meurer** BASF | **Juan Parra Morte** European Food Safety Authority (EFSA) | **Stefan Pfuhler** Procter & Gamble | **Benjamin Sachse** German Federal Institute for Risk Assessment (BfR) | **Olga Tcheremenskaia** Istituto Superiore di Sanità | **Frans Verstraete** European Commission | **Paul A. White** Health Canada | **Carole Yauk** University of Ottawa

INSTITUT FRESENIUS

SGS

Thursday, 13 February 2025

Timings are in
Central European Time CET.

Afternoon Session | 12:30 – 17:50 CET

Welcome address by Akademie Fresenius and introduction by the Chairs

Krista Meurer, BASF, Germany
Carsten Kneuer, German Federal Institute for Risk Assessment (BfR), Germany

Regulatory developments

Genotoxic compounds in EU food safety policy, with focus on contaminants

Frans Verstraete, European Commission, Belgium

Case studies

- Pyrrolizidine alkaloids story
- 2-chloroethanol story

Catherine Mahony, Procter & Gamble, UK
Stefan Pfuhler, Procter & Gamble, USA

Current changes in information requirements for mutagenicity under REACH

- REACH – revision 2022 related to information requirements for mutagenicity
- REACH – ECHA's Member State Committee decisions related to the test strategy for mutagenicity
- News in OECD Test Guidelines and current Standard Project Submission Forms (SPSF)

Ulrike Gündel, German Federal Institute for Risk Assessment (BfR), Germany

Update of the UN GHS classification and labelling of chemicals

Raffaella Corvi, European Commission Joint Research Centre (JRC), Italy

Quantitative risk assessment

Risk assessment of genotoxic compounds: Opportunities, challenges and perspectives

- So far, genotoxicity assessment is widely hazard-based
- Controversial discussion about the need for a paradigm shift
- BfR has hosted a symposium to discuss opportunities, challenges and perspectives
- Major results from the symposium

Benjamin Sachse, German Federal Institute for Risk Assessment (BfR), Germany

Update on HESI (Health and Environmental Sciences Institute) and the activities of the GTTC's (Genetic Toxicology Technical Committee) quantitative analyses workgroup

Paul A. White, Health Canada, Canada

Development of test methods and guidelines

The coming revolution: application of error corrected next generation sequencing (ecNGS) to quantify and characterise mutations

- ecNGS: Promises and challenges for genotoxicity and cancer risk assessment
- How Duplex Sequencing is being used to advance mutagenesis and carcinogenesis research

Francesco Marchetti, Health Canada, Canada

Advances in the use of transcriptomic biomarkers for genotoxicity assessment: From validation to implementation

- The journey of the TGx-DDI transcriptomic biomarker as it proceeds through the US FDA qualification process
- State of the science of applying TGx-DDI in integrated testing for qualitative and quantitative applications
- Work to expand the context of use and define suitable application domains (beyond TK6 cells)

Carole Yauk, University of Ottawa, Canada

Book now

Information available online at:
www.akademie-fresenius.com/3643

Friday, 14 February 2025

Timings are in
Central European Time CET.

Morning Session | 9:30 – 12:40 CET

Development of test methods and guidelines

Update on the applications of the ToxTracker assay to investigate the mode-of-action of genotoxic compounds

Giel Hendriks, Toxys, The Netherlands

PARC project to develop an AOP-based IATA for genotoxicity – where are we today and where do we want to go

- Adverse outcome pathways, NAMs for genotoxicity, integrated approaches for testing and assessment

Birgit Mertens, Sciensano, Belgium

Novel methodology to assess genotoxicity in food contact materials

Maricel Marin-Kuan, Nestlé Research, Switzerland

Modelling and prediction of genotoxicity

Update and extension of the EFSA Pesticides Genotoxicity Database

- The availability of high-quality databases covering a broad chemical space and genotoxicity endpoints can provide the foundation for improving the confidence of (Q)SAR models and read-across
- Genotoxicity information of pesticide residues, including active substances and their metabolites, needs to be accessible, unambiguous and well-curated
- EFSA founded a collaborative project intended to: transfer the existing EFSA pesticides genotoxicity database in IUCLID, update the database, extend the database on in vitro micronucleus (IVMN) tests

Juan Parra Morte, European Food Safety Authority (EFSA), Italy

The new OECD QSAR assessment framework (QAF): Guidance for assessing QSAR models and predictions

- Uptake of (Q)SAR predictions of chemical hazards requires establishing confidence
- The QAF enables regulators to evaluate (Q)SARs consistently and transparently and provides clear requirements to meet for (Q)SAR developers and users
- Similar principles may be extended to other NAMs to facilitate regulatory uptake

Olga Tcheremenskaia, Istituto Superiore di Sanità (ISS), Italy

Plant protection QSAR models through data sharing and regulatory review

Markus Frericks, BASF, Germany

15th International Conference

Endocrine Disruptors

20-21 November 2024 in Dusseldorf/Germany and via Live Stream

www.akademie-fresenius.com/endocrine

8th International Conference

Worker, Operator, Bystander and Resident Exposure and Risk Assessment

11-12 February 2025 in Dusseldorf/Germany and via Live Stream

www.akademie-fresenius.com/opex

How will this online conference work?

Our online conference will be live – with interactive participation – and will be held in the English language. Prior to the conference, we will provide you with your login details which will allow you to participate and ask questions from your preferred location. All you need is a stable internet connection and an audio hardware system – and away you go!

Book now

Information available online at:
www.akademie-fresenius.com/3643

Registration

By web **www.akademie-fresenius.com/3643**
By email **registration@akademie-fresenius.com**

Hotline **+49 231 75896-50**
Die Akademie Fresenius GmbH
Alter Hellweg 46, 44379 Dortmund

DIE AKADEMIE FRESENIUS

Participation Fee: € 995.00 plus VAT

Representatives of an authority or a public university are eligible for a reduced fee of **€ 495.00 plus VAT** per person (please provide evidence). The reduced fee cannot be combined with other rebates.

If you are unable to attend the online event, you can order the event documentation for **€ 295.00 plus VAT**. It will be available after the online event through the download area of our website where you will find the latest versions of the presentations as pdf files.

www.akademie-fresenius.com/3643

Book now

Do you have any questions?

Sabine Mummenbrauer
Phone: +49 231 75896-82
smummenbrauer@akademie-fresenius.de

The Organisers

For 30 years, Akademie Fresenius has been your partner for practice-orientated training on all the latest topics surrounding the safety and quality of food, consumer goods and chemical products along the whole production chain. Our portfolio not only includes international conferences but also offers national trade meetings, intensive practical seminars and training in small work groups.
Our events are designed to promote an active exchange amongst our participants and offer the perfect platform for bringing the industry, the scientific sector, the authorities and the consulting field together. Excellent service, all-inclusive. Our wide-ranging advanced training opportunities contribute to giving our customers the competitive edge in all quality assurance, risk assessment, legal, production and technical questions.
Akademie Fresenius is a joint venture between Carl Remigius Fresenius Education Group, one of the largest private and independent education groups in Germany, and SGS Institut Fresenius, one of the leading German providers of chemical laboratory analysis.

You can find details on upcoming and new events at
www.akademie-fresenius.com

Who will benefit from this conference?

Professionals working in the fields of:

- Toxicology
- Hazard, exposure and risk assessment for human health
- Registration & regulatory affairs
- Research and development
- Legal and general counselling

Sectors that should take part:

- Agrochemical, chemical, biocide, pharmaceutical, cosmetic, food, feed and packaging industry
- Research institutes
- Competent authorities, regulatory bodies and research institutes
- Testing laboratories and contract research organisations (CROs)
- Consultancies
- Professional associations

Terms of Participation and Purchase: The registration fee includes the participation in the online event and the event documentation for download. You will receive written confirmation of your registration. Upon receiving our invoice, please transfer the amount due without further deductions before the event begins.

Group Reductions: For joint bookings received from one company we grant a 15% discount from the third participant onwards.

Terms of Cancellation: Cancellations or rebookings to another event are possible in writing without giving reasons and free of charge up to one week before the start of the online event. In the event of later cancellations or non-login to the online event, no participation fees can be refunded. In this case, however, you will receive access to the documentation download after the event. Please note that you can name a substitute participant free of charge at any time.

General Terms and Conditions: By registering, you agree to our General Terms and Conditions as well as to our Privacy Policy. You can find our GTC on the internet (www. akademie-fresenius.com/general-terms) or receive them on request.

Personal Data: The Akademie Fresenius will keep your data for the purpose of organising this event. We will under no circumstances use your data for commercial trade purposes. By registering for this online event, you consent to our occasionally contacting you by mail, email or phone in order to provide you with further information from our company. You can, of course, withdraw your consent whenever you wish. During this online event, image and sound content is transmitted, which may originate from the speakers and from the participants. By registering, you agree that this content may be transmitted within the virtual event space. All participants are prohibited from recording this content. Further information can be found at: www.akademie-fresenius.com/dataprotection.

Picture Credit: © Sashkin – Fotolia.com