



3<sup>rd</sup> 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

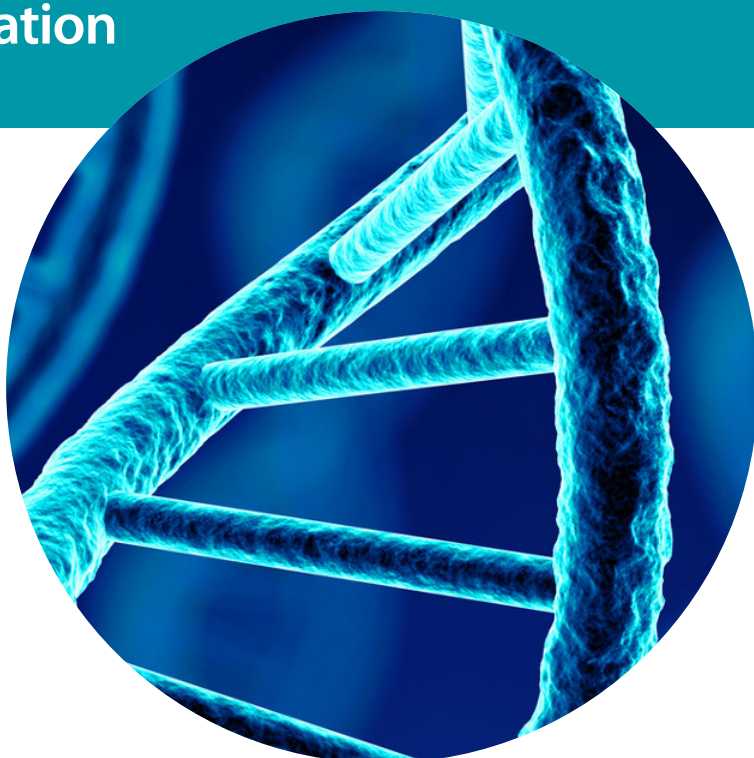
- Results of the BfR Symposium on strategies and tools for quantitative risk assessment
- Activities of the Genetic Toxicology Technical Committee (GTTC) on quantitative analyses

### 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

**Raffaella 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) | **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

## 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

### 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

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Information available online at:  
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## 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

#### 15<sup>th</sup> International Conference

### Endocrine Disruptors

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

[www.akademie-fresenius.com/endocrine](http://www.akademie-fresenius.com/endocrine)

#### 8<sup>th</sup> 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](http://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!

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## 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.

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## Do you have any questions?



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## 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.

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You can find details on upcoming and new events at [www.akademie-fresenius.com](http://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

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

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