DIE AKADEMIE FRESENIUS

Where Experts Meet!

2nd International Akademie Fresenius Gene-Tox Conference

Genotoxicity

Assessment, Regulation, Testing, Modelling and Prediction

+++ ONLINE CONFERENCE +++

3 and 4 November 2022

Highlights

- Update of the GHS classification
- EFSA on their Pesticides Genotoxicity Database
- Genotoxicity assessment of biocides: update from ECHA
- Aneugenicity: guidance, in vivo follow-up testing, choice of methods and appropriate target organs
- Weight of evidence approach for assessing the genotoxic potential of titanium dioxide
- Nitrosamine impurities in drugs
- Revision of OECD Test Guideline 488
- In vitro micronucleus assay for nanomaterial testing: application of the OECD 487 protocol and suggested modifications
- Principle and scoring approaches of the Pig-a gene mutation assay
- Application and OECD validation of the ToxTracker assay
- In vitro 3D tissue models for safety assessment of cosmetics
- Use of QSAR: pesticides, pharmaceuticals, industrial chemicals and FCM

The Experts

Carol Beevers Broughton | **Annette Bitsch** Fraunhofer Institute for Toxicology and Experimental Medicine ITEM | **Kevin P. Cross** Instem | **Stephen D. Dertinger** Litron Laboratories | **Markus Frericks** BASF | **Susanne Glowienke** Novartis | **Rodolfo Gonella Diaza** knoell Germany | **Giel Hendriks** Toxys | **Naveed Honarvar** BASF | **David Kirkland** Kirkland Consulting | **Hans-Jörg Martus** Novartis | **Krista Meurer** BASF | **Paschalina Papadaki** European Chemicals Agency (ECHA) | **Juan Parra Morte** European Food Safety Authority (EFSA) | **Kerstin Reisinger** Henkel | **Jan van Benthem** Dutch National Institute for Public Health and the Environment (RIVM) | **Paul A. White** Health Canada | **Christina Ziemann** Fraunhofer Institute for Toxicology and Experimental Medicine ITEM

INSTITUT FRESENIUS

SGS

Thursday, 3 November 2022

Timings are in
Central European Time CET.

Morning Session 09:30 – 12:30 CET

Welcoming speech by the organisers and the Chairs

Krista Meurer, BASF, Germany
Paschalina Papadaki, European Chemicals Agency (ECHA), Finland

The presentation slots include sufficient time for questions and answers.

Regulatory Developments

Update of the GHS classification

Jan van Benthem, National Institute for Public Health and the Environment (RIVM), The Netherlands

Update on genotoxicity and biocides

Paschalina Papadaki, European Chemicals Agency (ECHA), Finland

Short break

Update and extension of the EFSA Pesticides Genotoxicity Database

- History and the existing database
- EFSA Strategy 2027
- Update and extension of the database
- The overall picture: related projects

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

Assessment of aneugenicity and incorporation of this endpoint in risk assessments

- Definition of aneugenicity and aneugens: target structures, dose-response and AOP
- Recent information and guidances
- In vivo follow-up testing, choice of methods and target organs
- Risk assessment for substances that exhibit aneugenicity but do not induce clastogenicity or gene mutations

Annette Bitsch and Christina Ziemann, both Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, Germany

Afternoon Session 13:30 – 17:15 CET

Modelling and Prediction of Genotoxicity

ICH M7 classification and involvement of QSAR methods

- ICH M7 hazard assessments
- In silico systems and use of expert knowledge
- Case studies for ICH M7 classes 3, 4 and 5
- Compound-specific risk assessment and case studies for ICH M7 class 1 molecules

Susanne Glowienke, Novartis, Switzerland

QSAR and read-across in the assessment of plant protection products

Markus Frericks, BASF, Germany

Use of (quantitative) structure-activity relationship ((Q)SAR) predictions for industrial chemicals and food contact material assessments

- Strategies for identifying potentially mutagenic substances by combination of multiple (Q)SAR tools
- Support of experimental data or read across assessments with (Q)SAR predictions

Rodolfo Gonella Diaza, knoell Germany, Germany

Short break

Quantitative Risk Assessment

Quantitative interpretation of in vivo mutagenicity dose-response data for chemical prioritisation and risk assessment: recent progress and persistent challenges

- Interpretation of genetic toxicity test data: paradigm shaft from qualitative to quantitative
- Quantitative PoD (point-of-departure) metrics for chemical prioritisation and regulatory decision-making
- UFs (uncertainty factors) required for extrapolation below a PoD

Paul A. White, Health Canada, Canada

Nitrosamin impurities in drugs

- Developing assays for a better detection of nitrosamines: the EMA/Fraunhofer project
- Current approaches in developing structure-activity relationships for risk assessment

Kevin P. Cross, Instem, United States of America

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Information available online at:
www.akademie-fresenius.com/3224

Friday, 4 November 2022

Timings are in
Central European Time CET.

Morning Session 09:30 – 12:30 CET

Relevance in Case of Positive Results – Weight of Evidence

Application of a weight of evidence approach to assessment of genotoxic potential – the example of titanium dioxide

- Occurrence and current assessment of titanium dioxide
- Use of structured weight of evidence (WoE) approach for assessing the genotoxic potential
- Results and interpretation of observed genotoxic effects

David Kirkland, Kirkland Consulting, United Kingdom

Development of Test Methods and Guidelines

Feedback from the 8th International Workshop on Genotoxicity Tests (IWGT)

Hans-Jörg Martus, Novartis, Switzerland

Short break

Revision of the OECD Test Guideline 488

- Transgenic rodent gene mutation: methodologies and role in regulatory testing strategies
- Background to the 2020 and 2022 updates to OECD 488
- CRO landscape for conducting these assays

Carol Beevers, Broughton, United Kingdom

Applications of the ToxTracker assay to investigate the mode-of-action of genotoxic compounds

- Mechanistic insight into genotoxicity
- Quantitative genotoxic dose response modelling
- OECD validation of ToxTracker

Giel Hendriks, Toxys, The Netherlands

Afternoon Session 13:00 – 15:00 CET

A status update: adaption of the in vitro micronucleus assay for nanomaterial testing

- OECD 487 protocol for testing the mutagenic potential of nanoparticles
- Application of the assay testing $BaSO_4$, CeO_2, Au_{5nm}, Au_{30nm} and SiO_2: analytical method, control and results
- Conclusion and suggested modifications of the protocol

Naveed Honarvar, BASF, Germany

In vitro 3D tissue models in genotoxicity testing

- Regulatory status
- Strategic fit in the context of cosmetic`s safety assessment

Kerstin Reisinger, Henkel, Germany

Key attributes of the rodent erythrocyte-based Pig-a gene mutation assay

- Pig-a assay principle and scoring approaches
- Mutant phenotype cell attributes that inform study design
- Brief overview of OECD Test Guideline 470

Stephen D. Dertinger, Litron Laboratories, United States of America

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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Information available online at:
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By email **registration@akademie-fresenius.com**

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

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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, you can order the event documentation for **€ 295.00 plus VAT.**

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Do you have any questions?

Claudia Werner
Phone: +49 231 75896-83
cwerner@akademie-fresenius.de

The Organisers

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Who should attend this conference?

Professionals working in the fields of:

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

Sectors that should take part:

- Chemical, biocide, agrochemical, pharmaceutical, cosmetic, food and feed, FCM industries
- 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.

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