DIE AKADEMIE FRESENIUS

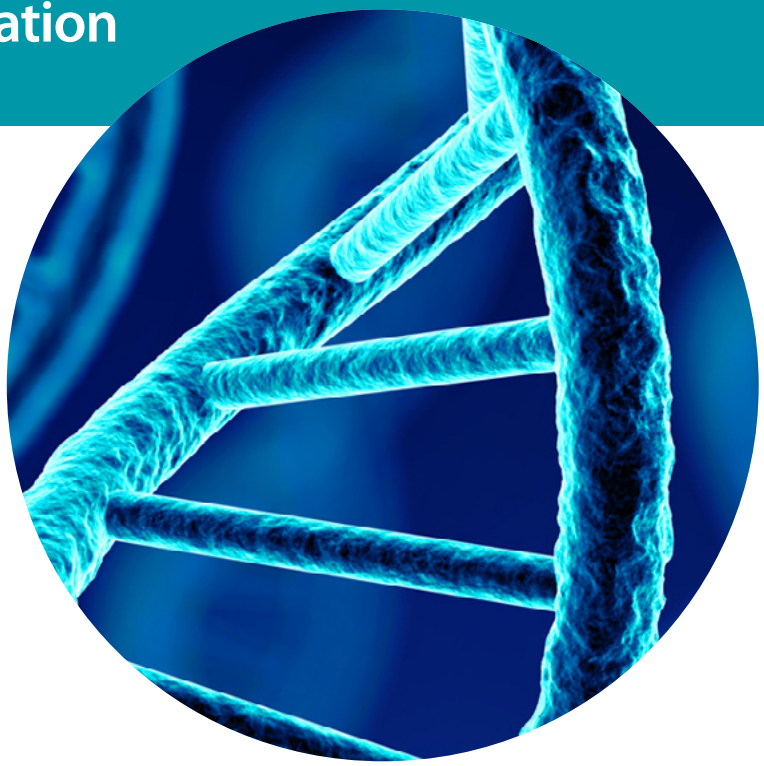
Where Experts Meet!

4th International Akademie Fresenius Conference

Genotoxic Compounds

Recent developments and implications for assessment and regulation

+++ ONLINE CONFERENCE +++



20 and 21 January 2027

Highlights

Regulatory developments and policy direction

- EU Roadmap towards phasing out animal testing
- PARC and regulatory developments
- NAMs in genotoxicity and carcinogenicity assessment
- ICH Q3E implications for genotoxic impurities, extractables and leachables

From hazard to risk: Quantitative approaches

- Aneugens and quantitative assessment strategies
- HESI GTTC activities and IWGT learnings

NAMs and mechanistic tools

- Error-corrected next-generation sequencing (ecNGS)
- Mechanistic assays and OECD developments

Integrated testing strategies

- Current and future role of in vivo testing
- Botanical and cosmetic case studies
- Weight-of-evidence approaches

In silico approaches and data integration

- OECD and EFSA developments for metabolite assessment
- (Q)SAR, read-across and databases
- Integration into non-animal strategies

Direct exchange with the experts – Dedicated Q & A after every presentation

The Experts

Hind Assaf Vandecasteele L'Oréal | **Carol Beevers** Corteva Agriscience | **Cecilia Bossa** Italian National Institute of Health (ISS) | **Melanie K. Bothe** Fresenius Kabi Deutschland | **Raffaella Corvi** European Commission Joint Research Centre (JRC) | **Nathalie Delrue** Organisation for Economic Co-operation and Development (OECD) | **Georg Johnson** GTox | **Carsten Kneuer** German Federal Institute for Risk Assessment (BfR) | **Birgit Mertens** Sciensano | **Krista Meurer** BASF | **Juan Parra Morte** European Food Safety Authority (EFSA) | **Stefan Pfuhler** Procter & Gamble | **Stephanie Smith-Roe** US National Institute of Environmental Health Sciences | **Xiaowen Sun** Pfizer | **Paul A. White** Health Canada | **Carole Yauk** University of Ottawa

INSTITUT FRESENIUS

SGS

Wednesday, 20 January 2027

Timings are in Central European Time CET.

Afternoon Session | 12:30 – 17:30 CET

All presentation slots include dedicated time for questions and discussion, moderated by the Chairs.

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

EU roadmap towards phasing out animal testing: Implications for genotoxicity assessment

- EU Roadmap and implications for genotoxicity testing
- Opportunities for the transition towards non-animal approaches
- Scope and objectives of the EPAA group on genotoxicity
- Planned activities and next steps

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

PARC update

Birgit Mertens, Sciensano, Belgium

Risk assessment of aneugens

Xiaowen Sun, Pfizer, USA

Strategies for genotoxicity assessment

Advances in quantitative approaches: Updated perspectives from the HESI GTTC quantitative analysis workgroup and related IWGT activities

Paul A. White, Health Canada, Canada

Botanical Safety Consortium: Evaluating a two-test battery for in vitro evaluation of the genotoxicity of botanical dietary supplements

Stephanie Smith-Roe, National Institute of Environmental Health Sciences (NIEHS), USA

Advances in Error-Corrected Sequencing (ECS) for regulatory mutagenicity assessment

Carole Yauk, University of Ottawa, Canada

Botanical case study

Stefan Pfuhler, Procter & Gamble, USA

How will this online conference work?

Our online conference will be live – with interactive participation – and will be held in the English language. The conference will be conducted using the meeting tool Zoom. 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. Simply log in on the day of the conference – and away you go!

Thursday, 21 January 2027

Timings are in Central European Time CET.

Morning Session | 08:40 – 13:00 CET

Quantitative risk assessment

A regulatory perspective on the applicability of NAMs in genotoxicity and carcinogenicity assessment in EU: Current practices and future directions

Cecilia Bossa, Italian National Institute of Health (ISS), Italy

The case of nitrosamines: Towards a quantitative risk assessment based on genotoxicity data

Georg Johnson, GTox, UK

Emerging methods

Mechanistic assays in genotoxicity testing under the OECD Test Guidelines Programme

Nathalie Delrue, Organisation for Economic Co-operation and Development (OECD), France

The role of in vivo genotoxicity testing

- Current relevance and limitations
- Future perspectives

Carol Beevers, Corteva Agriscience, United Kingdom

Integrated assessment strategies

Case study: Genotoxicity of a hair dye

Hind Assaf Vandecasteele, L'Oréal, France

OECD and EFSA developments for genotoxicity assessment of metabolites

- OECD guidance on residue definition
- Use of (Q)SAR and read-across
- EFSA workflows and database developments
- Integration into non-animal strategies

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

ICH Q3E Draft Guideline on Extractables & Leachables

- Implications for genotoxic impurities
- Interface with pharma and packaging

Melanie K. Bothe, Fresenius Kabi Deutschland, Germany

Summary by the chairs and end of the online conference

9th International OPEX Conference

Worker, Operator, Bystander and Resident Exposure and Risk Assessment

8 and 9 December 2026 in Dusseldorf/Germany and via Live Stream

www.akademie-fresenius.com/opex

International Online Conference

The Future of Polymers in Detergents, Cleaning Products and Cosmetics

25 and 26 January 2027

www.akademie-fresenius.com/3961

Registration

By web **www.akademie-fresenius.com/3803**
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:

€ 1.095.00 plus VAT

Representatives of an authority or a public university are eligible for a reduced fee of **€ 595.00 plus VAT** per person (please provide evidence). The reduced fee cannot be combined with other rebates.

www.akademie-fresenius.com/3803

Book now

Do you have any questions?



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The Organisers

For more than 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 event, event documentation, and, in the case of on-site events, lunch, coffee breaks, beverages as well as the evening event. You will receive written confirmation of your registration. Upon receiving our invoice, please transfer the amount due without further deductions before the event begins. The price of the event documentation includes the login details for the secure download section of our webpage where you will find the presentations in a pdf format. The login details will be sent to you via email after the event and as soon as advance payment has been received.

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

Terms of Cancellation: For our on-site events, written cancellations or transfers will be accepted free of charge up to four weeks prior to the start of the event. After this date and up to a week prior to the start of the event we will reimburse 50% of the registration fee. We cannot, unfortunately, provide refunds for later cancellations. For our online events, cancellations or rebookings to another event will be accepted free of charge up to one week before the start of the 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 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. At our on-site events, occasionally, we go around taking photos and videos which are then published anonymously on our website. During our online events, 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.

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