

International Akademie Fresenius Conference

NAMs in Toxicological Assessments and Regulatory Perspective

+++ ONLINE CONFERENCE +++

8 and 9 May 2023

Highlights

NAMs in general and examples for "Use of NAMs"

- Establishing scientific confidence in new approach methodologies (NAMs)
- Transforming the evaluation of agrochemicals
- Characterising local acute irritation properties of the fungicides Captan and Folpet
- Integrating NAMs into the European regulatory assessment of endocrine disruptors
- Quantitative in vitro and in vivo extrapolation (QIVIVE) model for predicting reduced anogenital distance
- In vivo developmental neurotoxicity (DNT) testing and assessment to identify the potential for alternative approaches

EFSA's work on NAMs

- · EFSA's roadmap for NAMs
- EFSA project on NAMs for the risk assessment of the pesticide Tebufenpyrad
- Development of integrated approaches to testing and assessment (IATA) case studies on DNT risk assessment
- Development of Adverse Outcome Pathways (AOPs) for endocrine disruption properties
- EFSA Guidance Document on Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals – use of NAMs
- Development of EFSA Guidance on read-across and implementation of NAMs



The Experts

Maria Chiara Astuto European Food Safety Authority (EFSA) | Susanne
Hougaard Bennekou Danish Patient Safety Authority | Tamara Coja Austrian
Agency for Health and Food Safety (AGES) | Bertrand Desprez French
Agency for Food, Environmental and Occuational Health and Safety (ANSES) |
Felix M. Kluxen ADAMA Deutschland | Iris Mangas European Food Safety
Authority (EFSA) | Marina Marinovich University of Milan | Martin Paparella
Medical University of Innsbruck | Martin Scholze Brunel University London |
Christiane Wiemann BASF | Douglas C. Wolf Syngenta Crop Protection |
Anna J. van der Zalm PETA Science Consortium International





Afternoon Session | 12:45 – 17:10 CEST

Welcome address by Akademie Fresenius and introduction by the Chairs

Tamara Coja, Austrian Agency for Health and Food Safety (AGES), Austria

Susanne Hougaard Bennekou, Danish Patient Safety Authority, Denmark

NAMs in general and examples for "Use of NAMs"

A framework for establishing scientific confidence in new approach methodologies

Anna J. van der Zalm, PETA Science Consortium International,

Characterising local acute irritation properties of the fungicides Captan and Folpet with new approach methods

Felix M. Kluxen, ADAMA Deutschland, Germany

Short break

NAMs in endocrine disruption assessments

Christiane Wiemann, BASF, Austria

Quantitative in vitro and in vivo extrapolation (QIVIVE) for predicting reduced anogenital distance produced by anti-androgenic pesticides in a rodent model for male reproductive disorders

Martin Scholze, Brunel University London, UK

Short break

An analysis of the limitations and uncertainties of in vivo developmental neurotoxicity testing and assessment to identify the potential for alternative approaches

Martin Paparella, Medical University of Innsbruck, Austria

Transforming the evaluation of agrochemicals

Douglas C. Wolf, Syngenta Crop Protection, USA



Online Training

Introduction: Operator, Resident, **Bystander, Worker Exposure Risk Assessment**

09 February - 10 February 2023, Online

www.akademie-fresenius.com/3337



Online Training

Genetic Toxicology within the Framework of the Plant Protection Regulation

26 April 2023, Online

www.akademie-fresenius.com/3338

Morning Session | 09:00 – 13:30 CEST

EFSA's work on NAMs

Overview of the EFSA NAMs case studies and the new NAMs4NANO project

Maria Chiara Astuto, European Food Safety Authority (EFSA), Italy

Case study NAMs and Tebufenpyrad – in a nutshell

Bertrand Desprez, French Agency for Food, Envrionmental and Occupational Health and Safety (ANSES), France

Short break

Development of integrated approaches to testing and assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment

Iris Mangas, EFSA Pesticide Peer Review (PREV) Unit, Italy

Development of AOPs for endocrine disruption properties

- Scientific part
- · How an AOP is developed
- Possible regulatory implications

Marina Marinovich, University of Milan, Italy

Short break

EFSA Guidance Document on Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals - use of NAMs

Christer Hogstrand, King's College London, UK (invited)

Development of EFSA Guidance on Read-Across and implementation of NAMs

Susanne Hougaard Bennekou, Danish Patient Safety Authority, Denmark

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!



Online Training

Absorption, Distribution, Metabolism and Excretion of PPP Toxicants

27 April 2023, Online

www.akademie-fresenius.com/3372



Online Conference

Assessment of Thyroid Disrupting Chemicals

1 and 2 February 2023, Online

www.akademie-fresenius.com/3246

Registration

By web www.akademie-fresenius.com/3277
By email registration@akademie-fresenius.com

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



Participation Fee: € 995.00 plus VAT

Representatives of an authority or a public university are eligible for a reduced fee of \in 595.00 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/3277



Do you have any questions?



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The Organisers

For more than 25 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 Cognos, 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
- Registration
- Marketing & distribution
- Human exposure & risk assessment
- Research & development
- Product stewardship & responsible care
- ✓ Human / consumer safety crop protection

Sectors taking part:

- Agrochemical industry
- Research institutes
- Authorities
- Professional associations
- Contract laboratories

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

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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.

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