

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 Occupational 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

Monday, 8 May 2023

Timings are in  
Central European Summer Time [CEST](#).

 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,  
Germany

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](http://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](http://www.akademie-fresenius.com/3338)

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Information available online at:  
[www.akademie-fresenius.com/3277](http://www.akademie-fresenius.com/3277)

 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, Environmental 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

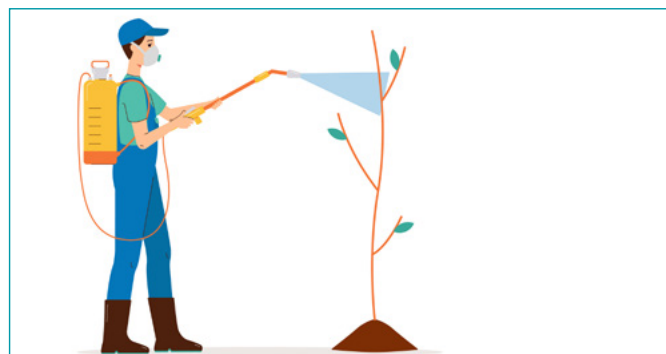
**Christer Hogstrand**, King's College London, UK (invited)

### 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!

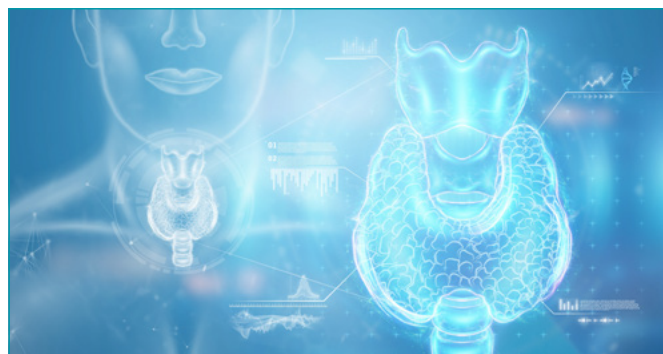


Online Training

### Absorption, Distribution, Metabolism and Excretion of PPP Toxicants

27 April 2023, Online

[www.akademie-fresenius.com/3372](http://www.akademie-fresenius.com/3372)



Online Conference

### Assessment of Thyroid Disrupting Chemicals

1 and 2 February 2023, Online

[www.akademie-fresenius.com/3246](http://www.akademie-fresenius.com/3246)

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# Registration

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By email [registration@akademie-fresenius.com](mailto:registration@akademie-fresenius.com)

## Participation Fee: € 995.00 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.

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 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.

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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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## 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

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