



2<sup>nd</sup> International Akademie Fresenius Conference

# Regulatory Toxicology of Active Substances in Plant Protection Products

+++ ONLINE CONFERENCE +++

16 and 17 March 2022

## Highlights

### Metabolites

- EFSA's Scientific Opinion on testing and interpretation of in vitro comparative metabolism studies
- OECD Guidance on residue definition – toxicological considerations
- Use and implementation of EFSA's templates for submission of in silico information on metabolites and impurities

### Cumulative assessment

- EFSA's Guidance on Scientific criteria for grouping chemicals into assessment groups (MixTox2)
- Cumulative assessment groups – industries' work

### Evaluation of pesticides

- Historical control data (HCD) and its use for evaluation of study results

### Genotoxicity

- EFSA's Guidance on aneugenicity assessment
- Industry perspective on changes in the Guidance on groundwater metabolites as regards genotoxicity

### New approach methodologies

- EFSA's Scientific Opinion on developmental neurotoxicity (DNT)
- EU-ToxRisk experience as regards chemical read-across
- EFSA's project on read-across and how to take read-across further into risk assessment



## The Experts

**Diane Benford** Vice-Chair of the EFSA Scientific Committee | **Susanne Hougaard Bennekou** Technical University of Denmark (DTU) | **Tamara Coja** Austrian Agency for Health and Food Safety (AGES) | **Sylvia Escher** Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM) | **George Kass** European Food Safety Authority (EFSA) | **Monika Kemény** BASF | **Kyriaki Machera** Benaki Phytopathological Institute (BPI) | **Stephanie Melching-Kollmuss** BASF | **Krista Meurer** BASF | **Martin Paparella** Medical University of Innsbruck | **Juan Parra Morte** European Food Safety Authority (EFSA) | **Olavi Pelkonen** University of Oulu

## Afternoon Session 12:45 – 16:45 CET

### Welcome address by Akademie Fresenius and introduction by the Chairs

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

**Susanne Hougaard Bennekou**, Technical University  
of Denmark (DTU), Denmark

## Metabolites

### EFSA Scientific Opinion on testing and interpretation of in vitro comparative metabolism studies

**Olavi Pelkonen**, University of Oulu, Finland

### OECD Guidance on residue definition – toxicological considerations

**Monika Kemény**, BASF, Germany

### EFSA templates for submission of in silico information on metabolites and impurities

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

## Cumulative assessment

### Guidance on Scientific criteria for grouping chemicals into assessment groups (MixTox2)

**Kyriaki Machera**, Benaki Phytopathological Institute (BPI),  
Greece

### Cumulative assessment groups – industries' work

- Relevant and stringent criteria for grouping of compounds
- Exposure-based prioritisation for retrospective and prospective cumulative risk assessments
- Views on aggregate cumulative assessments

**Stephanie Melching-Kollmuss**, BASF, Germany

### 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!



Information available online at:  
[www.akademie-fresenius.com/2968](http://www.akademie-fresenius.com/2968)

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 Morning Session 9:00 – 13:30 CET

## Evaluation of pesticides

### Historical control data (HCD) and its use for evaluation of studies results

- 40 years of discussions in the scientific community
- Coherent theoretical considerations and different practical implementations
- Effort to bring together relevant stakeholders and set the scene for common understanding - an EFSA project

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

## Genotoxicity

### EFSA guidance on aneugenicity assessment

**Diane Benford**, Vice-Chair of the EFSA Scientific Committee

### Industry perspective on changes in the Guidance on groundwater metabolites as regards genotoxicity

- Changes implemented in the revised guidance and their impact on metabolite assessment
- Where does the test strategy for groundwater metabolites deviate from other guidance?
- Do we still need an in vitro mammalian gene mutation assay as part of the test battery?

**Krista Meurer**, BASF, Germany

## New approach methodologies

### EFSA Scientific Opinion on developmental neurotoxicity (DNT)

**Martin Paparella**, Medical University of Innsbruck, Austria

### EU-ToxRisk experience as regards chemical read-across

- Use of mechanistic information from new approach methods to support similarity assessment within read-across approaches
- Testing strategy informed by adverse outcome pathways
- Derivation of a point of departure for risk assessment using IVIVE (in vitro to in vivo extrapolation) and PBK (physiologically based kinetic) modelling

**Sylvia Escher**, Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Germany

### EFSA's project on read-across using their pesticide database and how to take read-across further into risk assessment

**George Kass**, European Food Safety Authority (EFSA), Italy



International Akademie Fresenius Training  
**Risk Assessment of PECsoil in  
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2 March 2022, Online Training

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# Registration

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By email [registration@akademie-fresenius.com](mailto:registration@akademie-fresenius.com)  
By fax +49 231 75896-53

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## Participation Fee: € 895.00 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.

[www.akademie-fresenius.com/2968](http://www.akademie-fresenius.com/2968)

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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.

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

## Who will benefit from this conference?

Professionals working in the fields of:

- Toxicology
- Registration & authorisation
- Marketing & distribution
- Human exposure & risk assessment
- Research & development
- Product stewardship & responsible care
- Human/Consumer safety – crop protection

Sectors that should take part:

- Agrochemical industry
- Research institutes
- Regulatory 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. The price of the event documentation includes access to the secure Akademie Fresenius download area on our website. The secure access code will be dispatched around two weeks after the event and as soon as advance payment has been received.

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