

International Akademie Fresenius Conference

Novel Pesticides

Towards Sustainability in the Regulatory Framework of the EU

19 and 20 September 2024
in Dusseldorf/Germany

Highlights

Regulatory Update

- Update from the Commission – biologicals and other green technologies

Registering Novel Technologies

- Insights about registering novel technologies – perspectives from various industry players
- Registration of peptide-based insecticides derived from Spider Venom
- Registration of peptides as crop protection products: strategies and reflections
- Challenges and opportunities of registering RNA – a novel technology
- Competent Authority view on RNAi registrations: First-hand experiences and insights.
- Crop Life Europe on the assessment of innovative Biochemicals in the EU

Risk Assessment

- EFSA on scope, objectives, deliverables and timelines of the project 'Developing a stepwise approach for a fit for purpose risk assessment, in particular for low-concern active substances and uses'
- Julius Kühn Institute: Risk assessment for novel technologies, with a focus on RNAi
- A critical point of view: Assessing risks associated with novel pesticides



The Experts

Khalid Amari Julius Kühn Institute | **Marisé Borja** International Biocontrol Manufacturers Association (IBMA) | **Domenico Deserio** European Commission | **Rüdiger Hauschild** Applied Insect Sciences (APIS) | **Marija Horvat** Novonosis | **Patrick Kabouw** Novonosis | **Dimitrios Karpouzas** University of Thessaly | **Aude Kienzler** European Food Safety Authority (EFSA) | **Dominik Klinkenbuß** German Federal Office of Consumer Protection and Food Safety | **Anne Kortstee** Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) | **Peter Mc Cahon** Greenlight Bioscience | **Matt Orr** Vestaron | **Nina Ortiz** US Environmental Protection Agency | **Tess Renahan** PETA Science Consortium International | **Jacobijn van Etten** Dutch Board for the Authorisation of Plant Protection and Biocides (Ctgb) | **Eva Van Hende** Biotallys | **Michael Werner** Syngenta/CropLife Europe

Thursday, 19 September 2024

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

Morning Session | 09:30 – 13:05 CEST

09:00 On-site registration

09:30 Welcome Address by the Organisers and the Chairs

Patrick Kabouw, Novonosis, Denmark

Jacobijn van Etten, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

Regulatory Developments

09:40 **Biologicals and other Green Technologies: A Regulatory Update on Activities Besides the SUR**

Domenico Deserio, European Commission, Belgium (virtual presentation)

10:15 **Update from the IBMA: Peptides – Natural Substances at the Tip of a Knowledge Iceberg**

Marisé Borja, International Biocontrol Manufacturers Association (IBMA)

10:50 **CropLife Europe Contribution on the Assessment of Innovative Biochemicals in the EU**

- Proposition of a suitable data package to address EU Regulatory requirements for innovative biochemicals in the EU
- Why more clarity on data requirements is needed for biochemicals, outline of structure, key aspects of the contribution document
- Technical contribution as a starting point to develop a regulatory framework and fit for purpose data requirements for biochemicals in Europe, as already in place in other countries

Michael Werner, Syngenta/CropLife Europe, Switzerland

11:25 Coffee break

Registering Novel Technologies

11:55 **Navigating the Regulatory Maze: Challenges in Registering Proteins as Plant Protection Product**

- Locating Proteins within Regulation (EU) No 283/2013 and in Regulation (EU) No 284/2013
- Relevant industry insights from experience within the existing enzyme-specific legislative framework

Marija Horvat, Novonosis, Denmark

12:30 **Registration of Peptides as Crop Protection Products: Strategies and Reflections**

- The Biotalys platform
 - Principles of the current registration strategy in the EU and Feedback of authorities
 - Reflections on future strategies

Eva Van Hende, Biotalys, Belgium

13:05 Lunch Break

Afternoon Session | 14:05 – 17:30 CEST

14:05 **Registration of Peptide-based Insecticides derived from Spider Venom**

- History and origins of Vestaron's venom-based peptide technology
- Overview of regulatory data for Spear® insecticide
- Registration in North America
- Regulatory challenges and opportunities in the EU

Matt Orr, Vestaron, United States

14:40 **Challenges and Opportunities of Registering RNA – a Novel Technology**

- RNA profile and benefits
- Designing and developing an RNA product
- Limitations of current regulatory paradigms
- Precautionary Principle versus risk benefit approach

Peter Mc Cahon, Greenlight Bioscience, United States

15:15 Coffee break

15:45 **Challenges, Considerations and Current Status for dsRNA-based externally applied Pesticides for Plant Protection in the EU**

- Principles of the authorisation process of Plant Production Products (PPP) in the EU RNAi
- Challenges for the current risk assessment and management of PPP

Dominik Klinkenbuß Federal Office of Consumer Protection and Food Safety, Germany

16:20 **Towards Sustainability: Registering Innovative/ New Pesticides**

Nina Ortiz, US Environmental Protection Agency, United States (virtual presentation)

16:55 **Practical Experiences with Applications for New Plant Protection Products**

Anne Kortstee & Jacobijn van Etten, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

17:30 End of the first conference day

18:30 Evening event

 [Book now](#)



Information available online at:
www.akademie-fresenius.com/3548

Friday, 20 September 2024

 **Morning Session | 09:30 – 13:30 CEST**

09:30 Brief address by the Chairs

Patrick Kabouw, Novonosis, Denmark

Jacobijn van Etten, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

Risk Assessment

09:40 EFSA on Scope, Objectives, Deliverables and Timelines of the Project 'Developing a stepwise approach for a fit for purpose risk assessment, in particular for low-concern active substances and uses'

Aude Kinzler, European Food Safety (EFSA), Italy (virtual presentation)

10:05 Improving Risk Assessment of Low-Risk Pesticides: The RATION Project

Dimitrios Karpouzas, University of Thessaly, Greece

10:40 Modernising Regulatory Science: New Approach Methodologies for Biopesticides

- In silico and in vitro methods to assess acute toxicity under EU regulation
- Ongoing developments to tailor NAMs to microbial pesticides

Tess Renahan, PETA Science Consortium International, Germany

11:15 Coffee break



After the first conference day you are most welcome to attend our evening event for an unhurried evening of good food and leisure time. Please join us to continue the day's interesting discussions in a relaxed and comfortable atmosphere.

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11:45 Assessment of Novel Pesticides – Which Risks Need to be Assessed?

- Overview of potential hazards for human health and non-target organisms and the environment (microorganisms, natural substances, peptides and dsRNA)
- Evaluation of potential hazards and comparison to actual exposure through the use of the products based on the application technique
- Proposition of Methods to assess such risks – nurturing the idea to evaluate potential risk independently of existing data requirements and risk assessment schemes

Rüdiger Hauschild, Applied Insect Sciences (APIS), United Kingdom

12:20 RNA Interference in Plant Protection: Opportunities, Challenges, and Risk Assessment

- Introduction "Brief overview of RNAi"
- Efficiency of Exogenous dsRNA Application
- Challenges in dsRNA Application for plant protection
- Risk assessment of dsRNA-based pesticides

Khalid Amari, Julius Kühn Institute, Germany

12:55 Final Discussion

13:30 Lunch and end of the conference

 **Book now**



Information available online at:
www.akademie-fresenius.com/3548

Registration

By web www.akademie-fresenius.com/3548
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Participation Fee: € 1,795.00 plus VAT

Representatives of an authority or a public university are eligible for a reduced fee of € 895.00 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?



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The Organisers

For 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 should take part?

- ✓ Managing directors, managers, consultants and scientists working in the field of biological control
- ✓ Producers, distributors and downstream users of biologicals and pesticides that fall under low-risk category or were specifically developed to increase agricultural sustainability
- ✓ Technical Experts from research & development
- ✓ Risk assessors, toxicologists, ecotoxicologists, product Stewards, regulators

Sectors taking part:

- ✓ Agrochemical industry, biotech industry
- ✓ Research institutes, authorities
- ✓ Professional associations
- ✓ Contract laboratories/consultancies

Conference Venue

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We have reserved a limited number of rooms for our participants at reduced rates at the hotel. These rooms can be booked up to four weeks prior to the start of the event. Please book early and directly through the hotel quoting "Akademie Fresenius" as reference.

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.

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