Worker, Operator, Bystander and Resident Exposure and Risk Assessment

1 and 2 December 2016 in Mainz/Germany

Highlights

Regulatory issues
- Further developments of EFSA GD on exposure assessment – EFSA update
- EU Greenhouse Model
- Derivation of the acute acceptable operator exposure level (AAOEL)
- Generation of field data to refine the EFSA bystander/resident assessment
- EU Transfer Coefficient (TC)
- Operator exposure in China and the U.S.

Route of exposure
- A novel approach to test dislodgeable foliar residue for dermal absorption

Biomonitoring
- Results of the Institute of Occupational Medicine (IOM) resident biomonitoring study

Epidemiology
- Linking exposure and epidemiology
- Food Quality Protection Act (FQPA) uncertainty factor

Mitigation and management of risks
- Negligible exposure
- Operators, workers and personal protective equipment (PPE)
- Closed tractor cabins and closed application techniques

Speakers

Thursday, 1 December 2016

8.30  Registration and coffee

9.00  Welcome address by Akademie Fresenius and introduction by the Chairs
Alistair Morriss, Dow AgroSciences, and Neil A. Byron, Exponent, UK

Regulatory issues in the EU

9.10  Joint development of a European Greenhouse Model
• Database (e.g. exposure studies, data, scenarios and statistics)
• Predictive exposure model (e.g. exposure routes, calculations, tiered approach – work clothes and personal protective equipment)
• Examples using the developed Greenhouse exposure calculator
René Schreiber, Federal Institute for Risk Assessment (BfR), Germany

9.35  Derivation of the acute acceptable operator exposure level (AAOEL) – a regulator’s point of view
Marloes Busschers, Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), The Netherlands

10.00  ECPCA’s position on establishing the relevant acute endpoint for non-dietary risk assessment, i.e. the AAOEL
Luciano Merolla, Dow AgroSciences, UK

10.25  Panel discussion
10.45  Coffee break

11.15  Further developments of EFSA GD on exposure assessment
Frédérique Istace, European Food Safety Authority (EFSA), Italy

11.40  Questions and answers

11.50  A novel approach to test dislodgeable foliar residue for dermal absorption within OECD 428 test guideline
• Relevant dermal absorption for re-entry workers risk assessment
• Refinement of re-entry workers risk assessments with relevant dermal absorption values
Manoj Aggarwal, Dow AgroSciences, UK

12.15  Generation of an EU Transfer Coefficient associated with harvesting activities in vineyards
• Design and conduct of re-entry exposure studies in European vineyards
• Exposure of workers to dislodgeable foliar residues
• Provisional results and proposal for use in risk assessment
Heinrich Wicke, Bayer CropScience, Germany

12.40  Panel discussion
13.00  Lunch

14.30  Developments in resident and bystander exposure assessment
Clare Butler Ellis, Silsoe Spray Applications Unit, UK

14.55  Generation of field data to refine the EFSA bystander/resident assessment associated with airblast applications
Alistair Morriss, Dow AgroSciences, UK on behalf of ECPA

Biomonitoring

15.20  Biological monitoring of pesticide exposure in residents – results from UK study
Karen Galea, Institute of Occupational Medicine (IOM), UK

15.45  Panel discussion
16.15  Coffee break

Epidemiology

16.45  Linking exposure and epidemiology – industry perspective
Carol J. Burns, Burns Epidemiology Consulting, USA

17.10  Defining a reasonable certainty of no harm and the Food Quality Protection Act (FQPA) uncertainty factor: the congressional intent
• Certainty versus uncertainty
• Use of uncertainty factors
• Data quality requirements and Weight of Evidence
Curt Lunchick, Bayer, USA

17.35  The use of alternative risk assessment approaches in the US – chlorpyrifos case study
Jeffrey L. Dawson, U.S. Environmental Protection Agency (EPA), USA

18.00  Panel discussion
18.30  End of the first conference day

Get-Together on Wednesday, 30 November 2016
Will you arrive on Wednesday?
Come to the hotel bar at 8 p.m. and meet other participants and experts in a relaxed atmosphere.

The Programme
Friday, 2 December 2016

Chairs:
Alistair Morriss and Neil A. Byron

Regulatory issues around the globe

8.30  Development of an operator exposure model in China
Chuanjiang Tao, Ministry of Agriculture (ICAMA), China

8.55  Questions and answers

9.05  The development of the CropLife Principles of Regulation tool for operator exposure
• Use of the tool for exposure and risk assessment for handlers and applicators of PPP
• Global use of the tool, especially in developing countries
• Transparency of calculations and update with scenario specific data to fit local regulatory needs
Tharacad Ramanarayanan, Syngenta Crop Protection, USA

Mitigation and management of risks

9.30  Insight to the topic of negligible exposure – a manager’s point of view
Panagiotis Theodoris, Greece

9.55  Negligible exposure: an industry view
• Guidance from Commission
• Practical use of the guidance
• Key concerns on the applicability of the guidance
Martyn Griffiths, Bayer, France

10.20  Panel discussion

10.40  Coffee break

11.00  Operators, workers and personal protective equipment (PPE)
Thierry Mercier, French Agency for Food, Environmental and Occupational Health and Safety (ANSES), France

11.35  Non-dietary exposure assessment for PPPs and the respective risk mitigation measures considered in Greece
• Exposure assessment tools used for operator, worker, resident & bystander exposure assessment; comparison of the exposure outcomes using different models
• Refinement possibilities
• Risk mitigation measures considered in Greece
Agathi N. Charistou, Benaki Phytopathological Institute, Greece

12.00  Update on the standardisation of protective clothing requirements – view from Spain
• Experience in the development of EN/ISO standards in the field of protective clothing against pesticides
• Advantages of the harmonisation of requirements of protective clothing to protect against pesticides
Eva Cohen Gómez, National Institute of Safety and Hygiene at Work (INSHT), Spain

12.25  Short break

12.40  Closed systems, including closed tractor cabins and closed application techniques – view from authority
• Testing and approval of closed systems for filling PPP
• Testing of cabins (self-propelled sprayers and tractors) following EN 15696-1
• Consideration of closed systems in the authorisation procedure for PPP
Dirk Rautmann, Julius Kühn-Institute, Germany

13.05  Focus on closed systems, including closed tractor cabins and closed application techniques – view from industry
• Closed transfer systems during mixing and loading
• Closed systems during application of PPP
• Progress in the area of application technique and future requirements for safe applications of PPP
Reinhard Friesebleben, Bayer CropScience, Germany

13.30  Panel discussion
14.20  Lunch and end of the conference

Information available online at: www.akademie-fresenius.com/2339
The Experts

Manoj Aggarwal is a Senior Toxicologist at Dow AgroSciences in the UK with many years of industry experience as regulatory and risk assessor.

Carol J. Burns is President of Burns Epidemiology Consulting and an adjunct professor of epidemiology at the Central Michigan University College of Medicine, having previously worked in occupational epidemiology at the Dow Chemical Company for two decades.

Marloes Busschers is a Senior Toxicologist and Human Health Risk Assessor at the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) in the Netherlands.

Clare Butler Ellis is the Research Manager of Silsoe Spray Applications Unit. It became an independent R&D business in 2016, allowing it to continue the work it does for the agrochemical and agricultural engineering industries, as well as government, regulators and growers.

Neil A. Byron is working as a Senior Managing Scientist in Exponent UK’s Health Sciences Center for Chemical Regulation and Food Safety. Prior to joining Exponent he was with the UK’s CRD for 18 years.

Agathi N. Charistou is a Regulatory Toxicologist in the Laboratory of Toxicological Control of Pesticides in the Department of Pesticides Control at Benaki Phytopathological Institute in Greece.

Jeffrey L. Dawson is Acting Deputy Director at the U.S. EPA, Office of Pesticide Programmes, Health Effects Division and responsible for the development of risk assessments for non-dietary exposure to pesticides including workers and for all manner of residential exposures.

Eva Cohen Gómez is Head of the Technical Unit of Protective Clothing at the Protective Equipment Department of the National Centre for Protective Equipment and Work Conditions (CNMP) at the National Institute of Safety and Hygiene at Work (INSHT) in Seville.

Reinhard Friebelben is Head of the Global Application Technology at Bayer CropScience in Monheim. Since 1990 he has been working in various functions in the agrochemical industry. He has been Head of the German Phytomedical Society (DPG) working group “Application Technology” since 2000.

Karen Galea is Head of the Exposure Science Section of the Institute of Occupational Medicine (IOM) in the UK. She is responsible for a team of human exposure scientists and leads a wide variety of research projects, mainly focussed on exposure assessment relating to health risks.

Martyn Griffiths is EMEA Regulatory Strategy Manager at Bayer in Lyon. His involvement in crop protection started 26 years ago. He held a number of positions including responsibility for registrations in China, Taiwan and Korea. He is chairman of ECPA Regulatory Policy Team.

Frédérique Istance is an Officer in the Pesticide Unit of the European Food Safety Authority (EFSA) in Parma.

Curt Lunchick is the Product Safety Senior Pontificator and responsible for assessing occupational and residential exposure and risk at Bayer CropScience and Bayer Animal Health in North America. He is involved with the development of the North America Operator Exposure database.

Thierry Mercier is Deputy of the department at ANSES in charge of the evaluation and coordination of pesticides, biocides and fertilizers risk assessments since July 2010. Previously, he was Deputy Head of the Crops and Environment Department at AFSSA, and Regulatory Toxicologist at INRA.

Luciano Merolla is a Regulatory Toxicologist and Human Health Risk Assessor at Dow AgroSciences in UK. He has worked in the personal care, tobacco and agrochemical industries for the past 12 years as toxicologist and risk assessor.

Alistair Morriss is a Risk Assessor, in the Human Health Assessment team at Dow AgroSciences in UK since 2010. Prior to this he worked in contract research organisations for 8 years specialising in operator exposure studies as well as residue and environmental fate studies. He is Chairman of the ECPA OBEEG.

Tharacad Ramanarayanan is a Technical Leader at Syngenta, leading the Operator and Consumer risk assessment team for North America. He has 18 years of experience in human and environmental exposure and risk assessment. He is a member of CropLife International Operator Exposure group.

Dirk Rautmann is Deputy Head of the Institute for Application Techniques in Plan Protection at the Julius Kühn-Institute. Since 1987 he has been working on all aspects of plant protection equipment, drift and drift reduction, dust drift from sowing machines and seed treatment.

René Schreiber works as a Risk Assessor for evaluating the toxicology of PPP and performs risk assessments to determine safe use for operators, workers, residents and bystanders in a regulatory context at the BfR in Berlin.

Chuanjiang Tao has been working in the Institute for the Control of Agrochemicals at the Ministry of Agriculture (ICAMA) in Beijing since 1993, in the Residue Division, Health and Environment Division, and Health Division successively. His function is to review pesticide registration dossiers and to develop risk assessment tools.

Panagiotis Theodoris has an agronomy background.

Heinrich Wicke is an Occupational and Residential Exposure Expert for PPP at Bayer CropScience. He has a long standing global expertise in the non-dietary safety of PPP in different positions in the agrochemical industry and was involved in the development of exposure models and risk assessment approaches.
About

Who do you meet?

Groups that should take part:
Managing directors, boards of directors, managers, consultants and scientists in the fields of
- Research & development
- Human exposure & risk assessment
- Toxicology
- Registration
- Marketing & distribution
- Product stewardship & responsible care
- Human and consumer safety

Sectors that should take part:
- Agrochemical industry
- Research institutes
- Authorities
- Professional associations
- Contract laboratories

Do you have any questions?

Programme and conceptual design
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Trade Exhibition

Our conference provides you with the opportunity of presenting your company in a trade display. Present your products and services and reach out to your specific target groups. We would be happy to provide you with information on all the various options available – from displaying product information to an exhibition stand – with no further obligation on your part.

Use the attached fax reply sheet to request our information material. Or simply call us. We would be more than pleased to assist you personally.

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The Organiser

For over 20 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.

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**Registration**

By web [www.akademie-fresenius.com/2339](http://www.akademie-fresenius.com/2339)

By email registration@akademie-fresenius.com

By fax +49 231 75896-53

**Event Documentation**

Hotline +49 231 75896-50

Die Akademie Fresenius GmbH

Alter Hellweg 46, 44379 Dortmund

**Participation**

- I would like to take part in the 4th International Fresenius Conference „Worker, Operator, Bystander and Resident Exposure“, 1 to 2 December 2016 in Mainz/Germany. Fee: € 1,795.00 plus VAT.

- I am a representative of an authority or a public university and therefore eligible for a reduced fee of € 795.00 plus VAT per person (please provide evidence). The reduced fee cannot be combined with other rebates.

- I would like to take part in the **evening event on 1 December 2016** (included in the above price).

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### Terms of Participation and Purchase

The registration fee includes the event participation, event documentation, 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 conference documentation includes a hard copy of the documentation as well as an access code to the secure Akademie Fresenius download area. Both the documents and the secure access code will be dispatched around two weeks 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.

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**General Terms and Conditions**

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**Venue/Event Hotel**

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