



European
Commission



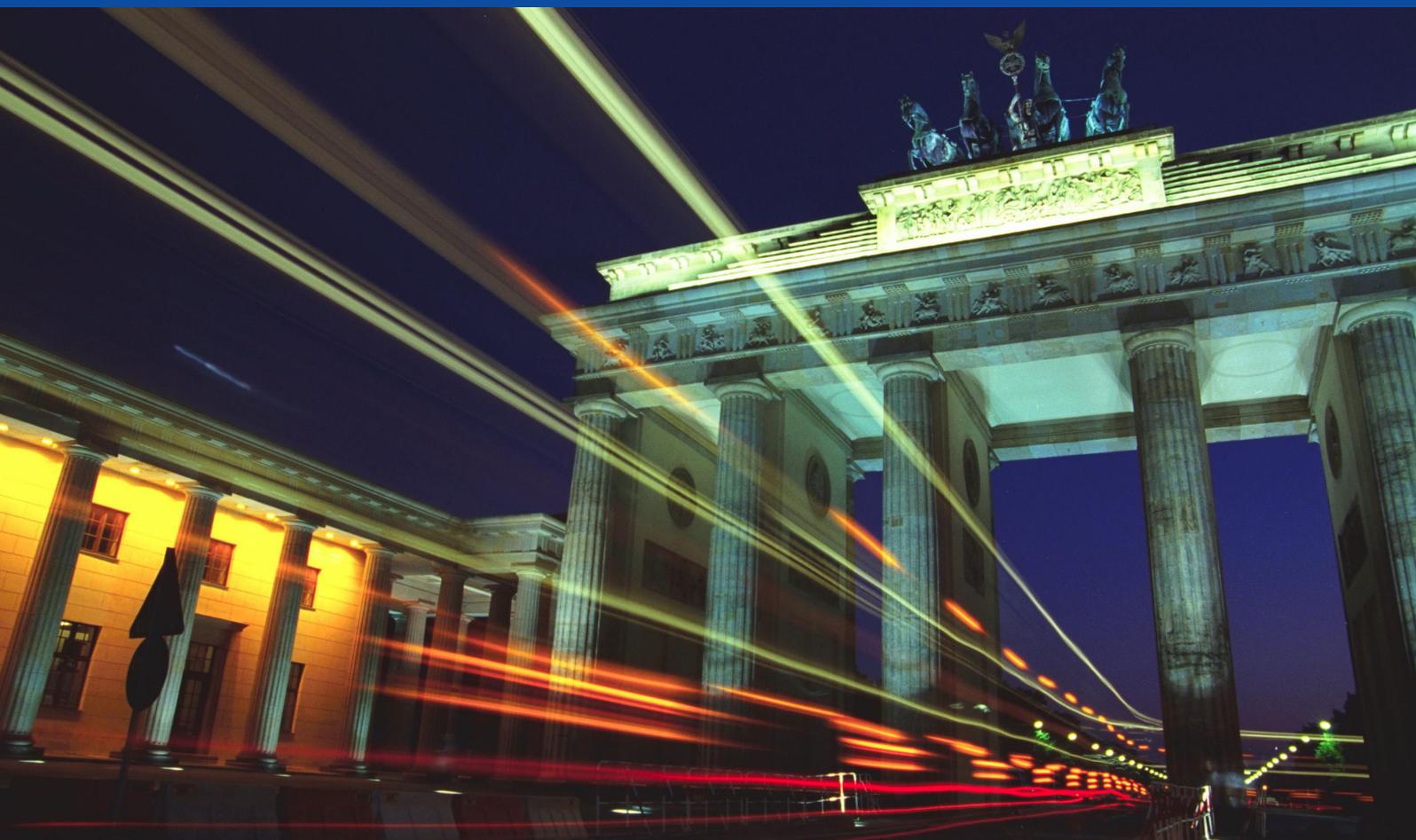
Federal Ministry
of Food
and Agriculture

Workshop

WHAT DOES THE FUTURE HOLD FOR HARMONISED HUMAN HEALTH RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS?

Berlin, 23-24 NOVEMBER 2017

Auditorium at the German Federal Institute for
Risk Assessment (BfR)





Dear Participant,

The German Federal Ministry of Food and Agriculture (BMEL) and the German Federal Institute for Risk Assessment (BfR) invite representatives of the European Commission (COM), the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the European Member States and stakeholders (industry associations, Non-governmental organisations, producer organisations) to discuss critical questions regarding the assessment of plant protection products. The workshop is held as a follow up of the dialogue event on the risk assessment of plant protection products organised by the EU Commission in 2015, where delegates of EFSA, ECHA, EU Member States and various stakeholder organisations discussed issues causing regularly debates in the risk assessment of plant protection products.

The topics were grouped in eight different panels. Results of the discussions were published by the COM and the BfR:

- http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/docs/dgs-consultations_working-groups_20150424_summary_en.pdf (in English)
- <http://www.bfr.bund.de/cm/343/eu-kommission-diskutiert-kritische-fragen-bei-der-bewertung-von-pflanzenschutzmittelwirkstoffen.pdf> (in German)

Several focal points were identified requiring extended discussions at an additional workshop organised by the BMEL.

Building on the successful dialogue process, the current workshop aims to intensify discussions among risk assessors, risk managers and stakeholders in order to understand current needs and explore possibilities to support the progress towards a harmonized human health risk assessment of plant protection products.



Format of the Workshop

Participation is by invitation and followed online registration only. Individual lectures are given in the scientific sessions. Subsequent panel discussions serve as platform for discussions. The results will be published on the BfR website. Expected participants will be representatives of the European Commission, from government, from international and national authorities and various stakeholders (industry associations, NGOs, producer organisations, universities).

Areas of Discussion

- **Understanding current needs regarding harmonised human health risk assessment of plant protection products**
- **How to realise an independent, valid and reliable evaluation of plant protection products**
- **Exploring possibilities to enhance the scientific dialogue between the different stakeholders and other experts**
- **Identifying the main challenges of implementing new concepts for human health risk assessment with regard to mixtures of plant protection products and metabolites**
- **Exploring possibilities to support the progress towards harmonised approaches for risk assessment**



Thursday – 23rd November 2017

12:30 pm **Registration**

01:00 pm **Welcome and Opening**
 European Commission –
 Prof. Dr. Ladislav Miko, Deputy Director-General responsible for the food chain – Directorate-General Health and Food Safety (SANTE)
 Federal Ministry of Food and Agriculture –
 Dr. Hermann Onko Aeikens, State Secretary German Federal Ministry of Food and Agriculture
 Federal Institute for Risk Assessment –
 Prof. Dr. Dr. Andreas Hensel, President of the German Federal Institute for Risk Assessment (BfR)

Human health risk assessment – How to realise an independent and reliable evaluation?

01:30 pm Independence of scientific data and risk assessments for decision making based on evidence – A Commission perspective
 Karin Nienstedt

01:50 pm Public availability and financing of studies – An industry perspective
 Euros Jones

02:10 pm Scientific publications in the regulatory practice – An NGO perspective
 Peter Clausing

02:30 pm Application of human epidemiological studies to pesticide risk assessment
 Antonio Hernández Jerez

02:50 pm Panel discussion

03:30 pm **Coffee break**



**Human health risk assessment –
Enhancement of the scientific dialogue between the experts
How to maintain a robust and objective scientific dialogue between government and stakeholder experts?**

04:00 pm An national authority perspective
[Jens Schubert](#)

04:20 pm An industry perspective
[Euros Jones](#)

04:40 pm An NGO perspective
[Angeliki Lyssimachou](#)

05:00 pm An authority perspective
[James Ramsay](#)

05:20 pm A SAPEA perspective

05:40 pm Panel discussion

06:30 pm ***"Get together" (Dinner)***



Friday – 24th November 2017

08:30 am Waking in

09:00 am ***Welcome and Introductory Remarks***

Human health risk assessment – Implementing of new concepts for mixtures

09:10 am Implementation of toxicological data from other legal provisions (e.g. REACH) – An industry perspective
[Christopher Dobe](#)

09:30 am Studies of pesticide toxicities from data on declared active substances and formulators - An university perspective
[Gilles-Eric Séralini](#)

09:50 am Data from alternative methodologies for cumulative risk assessment – An industry perspective
[Robert Landsiedel](#)

10:10 am Tools for a better understanding of cumulative interactions – An NGO perspective
[Martin Dermine](#)

10:30 am Application of the calculation method in regulatory risk assessment – An authority perspective
[Tamara Coja and Korinna Wend](#)

10:50 am Panel discussion

11:20 am ***Lunch break***



**Human health risk assessment –
Assessment of metabolites from pesticides**

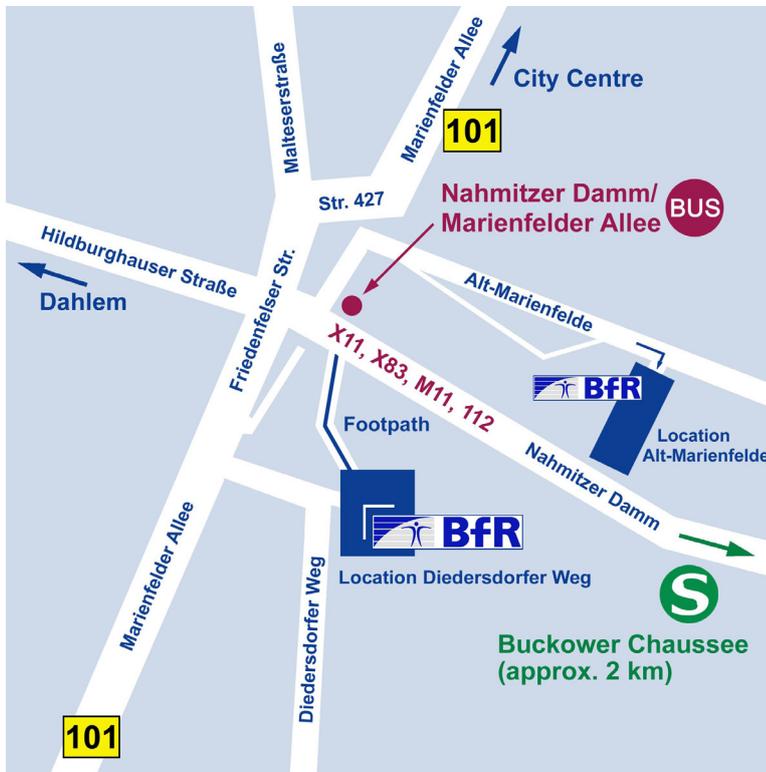
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| 12:10 pm | Application of the new EFSA Guidance on assessment of metabolites for dietary risk assessment for new submissions – An industry perspective Ivana Fegert |
| 12:30 pm | Grouping principles, assessment and testing of metabolites for the approval and re-approval of active substances – An authority perspective Jose Tarazona |
| 12:50 pm | Use of METAPATH in pesticide evaluation – An authority perspective Xavier Sarda |
| 01:10 pm | Need of further research on alternative tiered testing strategies – An NGO perspective Kristina Wagner |
| 01:30 pm | Panel discussion |
| 02:00 pm | Conclusion and Recommendations German Federal Institute for Risk Assessment Federal Ministry of Food and Agriculture European Commission |
| 02:30 pm | <i>End of workshop</i> |



Venue

Auditorium at the German Federal Institute for Risk Assessment (BfR)

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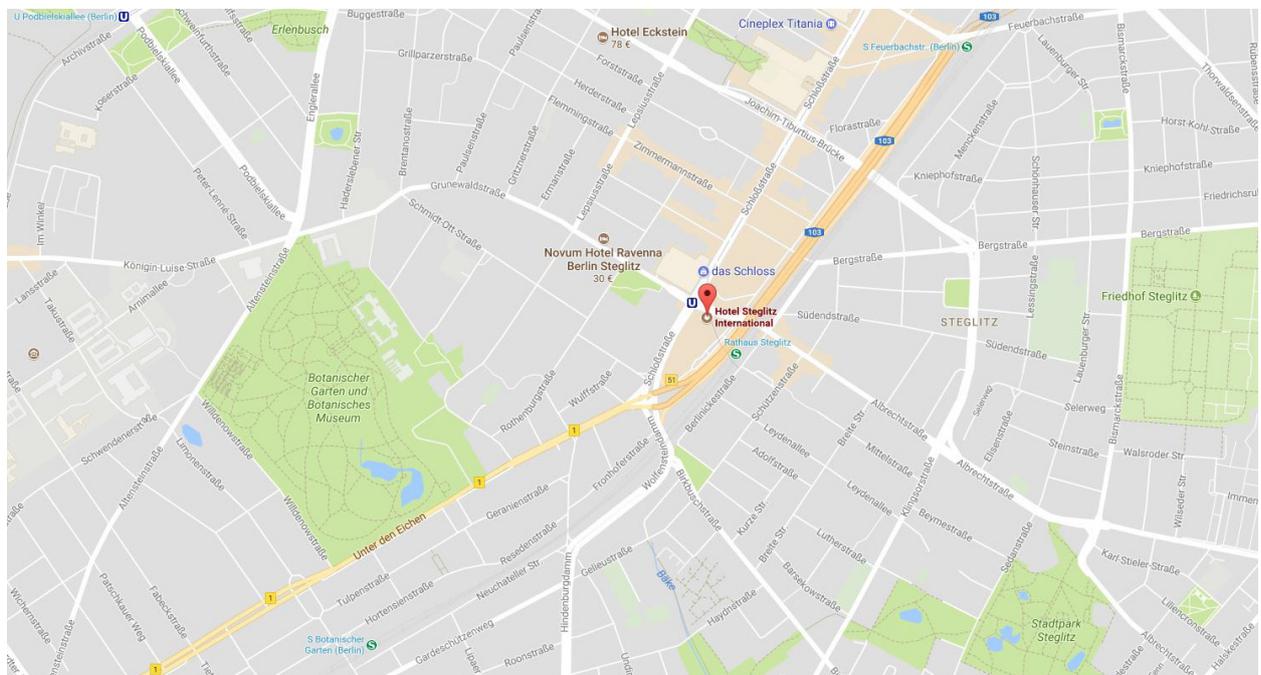
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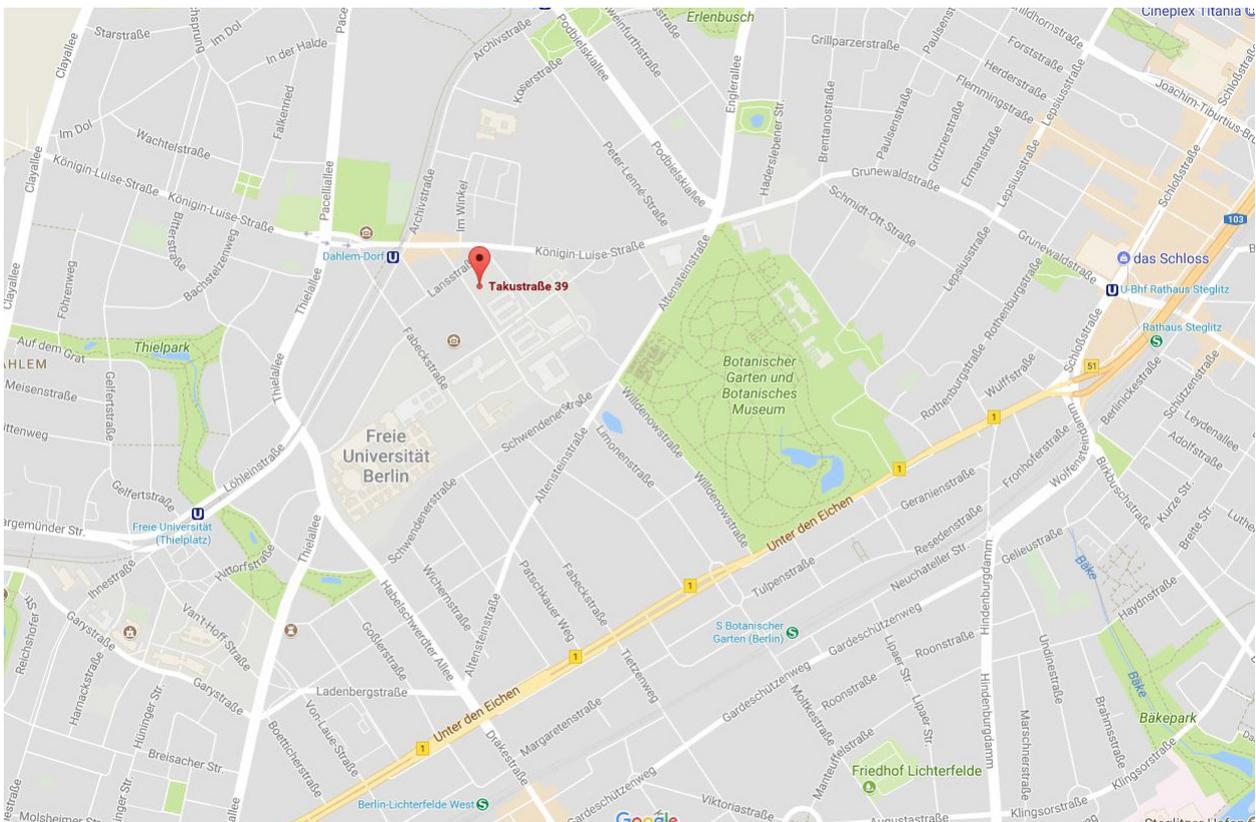
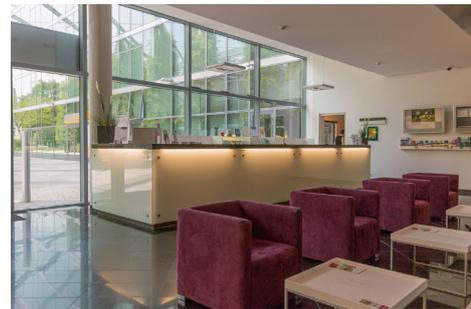
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Imprint

Publisher

Federal Ministry of Food and Agriculture (BMEL) Unit 512
53123 Bonn

Date

November 2017

Print

BMEL printing

Design

Federal Office for Agriculture and Food (BLE)
Unit 122 Management of Meetings and Conferences
Deichmanns Aue 29 I 53179 Bonn

Picture credits

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