

## Workshop on Harmonised Classification and Labelling (CLH) of active substances in Plant Protection Products (PPP)

The workshop deals with the cooperation at the European level in the assessment of human health hazards of active substances in PPP under the regulation (EC) no 1107/2009 and the harmonised classification and labelling of active substances under the regulation (EC) no 1272/2008.

### Programme

#### Tuesday, 12 April 2011

9.00 – 9.15

##### Welcome address

*Andreas Hensel, President of the Federal Institute for Risk Assessment (BfR)*

9.15 – 9.40

##### Goals and perspective of the workshop

*Roland Solecki, BfR*

##### Plenary session

*Chairs: Herman Fontier, European Food Safety Authority (EFSA) and Gabriele Schöning, European Chemicals Agency (ECHA)*

9.40 – 10.00

##### Introductory lecture: Legal aspects for approval, health cut-off criteria and classification from the PPP perspective

*Patrizia Pitton, European Commission (COM), DG SANCO*

10.00 – 10.20

##### Introductory lecture: EFSA-procedure and timelines in the active substance approval process according to regulation (EC) no 1107/2009

*Herman Fontier, EFSA*

10.20 – 10.40

##### Introductory lecture: Document formatting for dossiers and Draft Assessment Reports (DAR) according to regulation (EC) no 1107/2009

*Steve Dobson, Health and Safety Executive United Kingdom, Chemicals Regulation Directorate (CRD)*

10.40 – 11.00 *Coffee break*

11.00 – 11.30

##### Introductory lecture: Legal aspects and ECHA procedure on harmonisation of classification and labelling according to regulation (EC) no 1272/2008

*Gabriele Schöning, ECHA*

11.30 – 11.50

##### Introductory lecture: ECHA – practical experience with the processing of CLH dossiers under regulation (EC) no 1272/2008, especially for active substances in PPP

*Jose Tarazona, ECHA / Risk Assessment Committee (RAC)*

11.50 – 12.15

##### Discussion

12.15 – 12.30

##### Organisational remarks: Introduction of the outlines for the break out groups

*Vera Ritz, BfR*

12.30 – 13.30 *Lunch break*

13.30 – 15.30

##### First meeting of break out groups

15.30 – 16.00 *Coffee break*

16.00 – 18.00

##### Second meeting of break out groups

18.15

**Transfer to the hotels via bus shuttle**  
*(for details see below)*

20.00

**Joint dinner at restaurant “Alter Krug”**  
*(for details see below)*

#### Wednesday, 13 April 2011

9.00 – 9.30

##### Plenary session: Discussion of first results of the break out groups

*Chair: Patrizia Pitton, COM, and Jose Tarazona, ECHA/RAC*

09.30 – 11.00

##### Third meeting of break out groups

11.00 – 11.30 *Coffee break*

11.30 – 12.30

##### Plenary session: Presentation of the final results of the two Break out groups by chairs of each group and discussion of the results

*Chair: Patrizia Pitton, COM, and Jose Tarazona, ECHA/RAC*

12.30 – 13.45 *Lunch break*

13.45 – 14.50

##### Plenary session: Presentation of the final results

*Chairs of the break out groups*

14.50 – 15.00

##### Concluding remarks

*Rudolf Pfeil, BfR, and Roland Solecki, BfR*

## Break out groups

**Scope of break out group 1a + 1b:** streamlining and integration of the review procedures for active substances in PPP for approval under the regulation (EC) no 1107/2009 and for classification and labelling under the regulation (EC) no 1272/2008.

**Scope of break out group 2a +2b:** scientific and practical issues in the interpretation of carcinogenicity, mutagenicity and reproductive toxicity (CMR) studies and reporting regarding the criteria and practicalities in preparation of dossiers according to regulations (EC) no 1107/2009 and no 1272/2008.

For details please see the outline papers for the break out groups.

## Joint Dinner

On Tuesday, 12 April, a joint dinner for all workshop participants has been organized. Those who would like to take part are asked to pay 20 Euros for the buffet in advance on Tuesday morning at the registration counter.

The dinner will take place at the restaurant "Alter Krug" nearby both hotels (address: Königin-Luise-Straße 52, 14195 Berlin-Dahlem).

## Bus shuttle

A bus shuttle has been organized from the hotels "Seminaris Campus Hotel" and "Best Western Hotel Steglitz International" to the venue and from the venue to the hotels:

### 12 April 2011 – Hotels to BfR

Departure Seminaris Campus Hotel: 7.45  
Departure Steglitz International: 7.55  
Arrival at BfR: 8.30

### 12 April 2011 – BfR to hotels

Departure at BfR: 18.15  
Arrival at Steglitz International: 18.45  
Arrival at Seminaris Campus Hotel: 18.55

### 13 April 2011 – Hotels to BfR

Departure Seminaris Campus Hotel: 7.45  
Departure Steglitz International: 7.55  
Arrival at BfR: 8.30

## Venue



Federal Institute for Risk Assessment (BfR)  
Diedersdorfer Weg 1, 12277 Berlin

## Host/Organisation:

Federal Institute for Risk Assessment (BfR)  
Thielallee 88-92, 14195 Berlin  
Tel.: 030-18412-3232, Fax: 030-18412-2894,  
<http://www.bfr.bund.de>

# FEDERAL INSTITUTE FOR RISK ASSESSMENT

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Workshop  
12-13 April 2011