

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 4th meeting of the Working Group on the EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption

**Held on 10 (afternoon) - 11 (morning) November 2015, Parma
(Agreed on 30 November 2015)**

Participants

- **Working Group Members:**

Carsten Kneuer, Ian Dewhurst.

Peter Craig (10th afternoon) and Susanne Hougaard Bennekou (11th morning) have participated via teleconference.

- **Hearing Experts¹:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Arianna Chiusolo (chair), Daniele Court Marques, Federica Ruffo

AMU Unit: Gilles Guillot

- **Others:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies for absence were received by Harrie Buist, Andrea Terron, Peter Craig (11th morning) and Susanne Hougaard Bennekou (10th afternoon).

2. Adoption of agenda

The agenda was adopted without changes.

The agenda was adopted with an additional topic:

- Presentation to the ECPA Workshop (16-17 November).

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 3rd Working Group meeting held on 10 September 2015, Berlin.

The minutes of the 3rd Working Group meeting were agreed by written procedure on 25 September 2015.

5. Scientific topic(s) for discussion

5.1. EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption (EFSA-Q-2015-00169)

The status of development of the final comprehensive dataset on DA human *in vitro* studies from ECPA and BFR datasets was presented.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Missing data in the ECPA dataset were retrieved / recalculated from study reports. The dataset will be finalised after duplicates check and removal.

The outcome from a preliminary statistical analysis of data was presented. The protocol for statistical analysis to be applied to the final comprehensive dataset was discussed.

The status of the EFSA Scientific Report 'Assessment of new scientific studies on human in vitro dermal absorption' was discussed.

The WG agreed on the presentation for the ECPA workshop 'Understanding Formulation Design and Dermal Absorption: Technical, Scientific and Regulatory Perspectives' (16-17 November, The Netherlands).

6. Any Other Business

Not Applicable

7. Next meeting(s)

24 afternoon-25 morning February 2016 in Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 3rd meeting of the Working Group on the EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption

**Held on 10 September 2015, Berlin (Germany)
(Agreed on 25 September 2015)**

Participants

- **Working Group Members:**

Carsten Kneuer, Harrie Buist, Susanne Hougaard Bennekou.
Ian Dewhurst has participated via teleconference.

- **Hearing Experts¹:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Andrea Terron, Arianna Chiusolo (chair), Federica Ruffo.

AMU Unit: Gilles Guillot.

- **Others:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 2nd Working Group meeting held on 17 June 2015, Berlin.

The minutes of the 2nd Working Group meeting were agreed by written procedure on 26 June 2015.

5. Scientific topic(s) for discussion

5.1. EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption (EFSA-Q-2015-00169)

The status of development of the final comprehensive dataset on DA human *in vitro* studies from ECPA and BFR datasets was presented. Retrieval from study reports of data missing in the datasets is on-going.

The outcome from the quality check of data was presented and discussed. The WG agreed that submitted data are relevant for the revision of the current guidance/development of a new EFSA guidance on dermal absorption.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

The draft EFSA Scientific Report 'Assessment of new scientific studies on human in vitro dermal absorption' was reviewed and discussed.

6. Any Other Business

Not Applicable

7. Next meeting(s)

10th (afternoon)-11th (morning) November 2015 in Parma

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 2nd meeting of the Working Group on the EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption

**Held on 17 June 2015, Berlin (Germany)
(Agreed on 26 June 2015)**

Participants

- **Working Group Members:**

Carsten Kneuer, Gilles Guillot, Harrie Buist.

Ian Dewhurst and Susanne Hougaard Bennekou have participated via teleconference.

- **Hearing Experts¹:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

Pesticides Unit: Andrea Terron, Arianna Chiusolo (chair), Federica Ruffo

- **Others:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Korinna Wend (resigned from the WG).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 1st Working Group meeting held on 27 March 2015, Berlin.

The minutes of the 1st Working Group meeting were agreed by written procedure on 12 June 2015.

5. Scientific topic(s) for discussion

5.1. EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption (EFSA-Q-2015-00169)

The status of development of the final comprehensive dataset on DA human *in vitro* studies from ECPA and BFR datasets was presented and next steps agreed. It was evidenced that both submitted datasets are not completed and the WG agreed that missing data should be retrieved from the source (study reports) in order to finalise the comprehensive dataset.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

The outcome from a preliminary quality check of data was presented and discussed. The protocol for quality check to be applied to the datasets was agreed.

The structure of the EFSA Scientific Report 'Assessment of new scientific studies on human in vitro dermal absorption' was presented and it was agreed to draft the report for the next meeting.

6. Any Other Business

Not Applicable

7. Next meeting(s)

10th September 2015 in Berlin

Scientific Panel on Plant Protection Products and their Residues

Minutes of the 1st meeting of the EFSA Working Group on the EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption

**Held on 27th March 2015 in Berlin, BfR
(Agreed on 12/06/2015)**

Participants

- **Working Group Members:** Carsten Kneuer, Gilles Guillot, Ian Dewhurst (by teleconference), Susanne Hougaard Bennekou
- **EFSA:**
 - PRAS Unit: Andrea Terron, Arianna Chiusolo (chair).

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Korinna Wend.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the oral Declaration of interest at the beginning of this meeting.

4. Scientific topic(s) for discussion

EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption (EFSA-Q-2015-00169).

The following items were presented and discussed by the Working Group:

Activities, roles and responsibilities of EFSA, the Pesticide Unit and Working Group members.

Presentation of the terms of reference for the EC request to assess new scientific studies on dermal absorption submitted to EFSA and, if appropriate, to revise the guidance document on dermal absorption.

The current EFSA PPR Panel Scientific Opinion on Guidance on Dermal Absorption was presented in general principles and for the setting up of default values.

New human in vitro dermal absorption studies were presented as collected into the ECPA and BfR datasets.

Outcomes from the analysis of the ECPA dataset reported into published manuscripts were discussed.

The WG agreed with the necessity to develop a final comprehensive dataset (BfR and ECPA) before data evaluation.

5. Any other business

No other business was identified. Tasks were allocated.

6. Next Meeting

17th June 2015 in Berlin.