PESTICIDES PEER REVIEW (PREV) UNIT

5th Working Group meeting on the OPEX Guidance/Calculator update



24 Jun (9:00-13:00)- 27 Jun (10:00-13:00 / 14:00-17:00) 2024 MINUTES - Agreed on 10 Jul 2024

Location: Parma and web-conference

Attendees:

Working Group Members:

Tamara Coja, Peter Craig, Paul Hamey, Sabine Martin

Hearing Experts¹:

French Agency for Food, Environmental and Occupational Health & Safety (ANSES): Patrice Carpentier, Bertrand Desprez, Baptiste Reboulet

Bundesinstitut für Risikobewertung (BfR): Claudia Grosskopf, Enrico Peter, Tobias Willenbockel

Benaki Phytopathological Institute (BPI): Niki Arapaki, Despina Bournele, Agathi Charistou, Ioannis Theologidis, Kostantinos Kasiotis

Università degli Studi di Milano (UMIL): Ilaria Castelli, Luca Tosti

Università degli Studi di Torino (UNITO): Fabrizio Gioielli, Paolo Marucco

 $_{\odot}$ $\,$ European Commission and/or Member States representatives: Not Applicable

o EFSA:

Pesticide Peer Review (PREV) Unit: Arianna Chiusolo (chair), Frederique Istace Environment, Plants and Ecotoxicology (PLANTS) Unit: Varvara Gouliarmou Methodology and Scientific Support (MESE) Unit: Josè Cortinas, Efisio Solazzo

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 Independence2 and the Decision of the Executive Director on Competing Interest Management3, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Hearing Experts

A technical hearing was organised with the beneficiaries (consortium ANSES, BfR, BPI, UNIMI, UNITO) of the grant GP/EFSA/PREV/2022/02- Evaluation of new evidence on non-dietary exposure

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

Meeting minutes – 24/27 Jun 2024 5th Working Group meeting on the OPEX Guidance/ Calculator update



to plant protection products'. The members of the consortium were invited to support the Working Group by presenting the status of the activities and answering questions as needed by the Working Group.

5. Scientific topics for discussion

On day-1 (24 Jun), the Working Group discussed Interim Report 3 (including outcomes from evidence synthesis) on seed treatment and sowing evidence (Work Package 1), as well as Interim Report 1 on Residents and Bystanders evidence (Work Package 2) drafted by the beneficiaries of the grant (GP/EFSA/PREV/2022/02). Consolidated feedback was captured during the meeting and shared with the beneficiaries during the technical hearing on day-2 (27 Jun), when main elements of the report were discussed. Next steps for the project were agreed.

In addition, the Working Group discussed on day-1 (24 Jun) available evidence on the Closed Transfer System Operator Exposure Study. In the end, the Working Group agreed on amendments needed to the online tool.

6. Any Other Business

None

7. Next meeting

The next meeting will be held on 5 Jul (1-4PM) as web conference.

PESTICIDES PEER REVIEW (PREV) UNIT

4th Working Group meeting on the OPEX Guidance/Calculator update



3 (9:00-12:00)- 5 (10:00-13:00 14:00-17:00) Apr 2024 MINUTES - Agreed on 18 Apr 2024

Location: Parma and web-conference

Attendees:

o Working Group Members:

Tamara Coja, Peter Craig, Paul Hamey, Sabine Martin

Hearing Experts¹:

French Agency for Food, Environmental and Occupational Health & Safety (ANSES): Patrice Carpentier, Bertrand Desprez, Baptiste Reboulet

Bundesinstitut für Risikobewertung (BfR): Claudia Grosskopf, Enrico Peter, Tobias Willenbockel

Benaki Phytopathological Institute (BPI): Niki Arapaki, Despina Bournele, Agathi Charistou, Vasileia Laskari, Kyriaki Machera, Ioannis Theologidis

Università degli Studi di Milano (UMIL): Ilaria Castelli, Luca Tosti

Università degli Studi di Torino (UNITO): Fabrizio Gioielli, Paolo Marucco

 $_{\odot}$ $\,$ European Commission and/or Member States representatives: Not Applicable

o EFSA:

Pesticide Peer Review (PREV) Unit: Arianna Chiusolo (chair), Frederique Istace Environment, Plants and Ecotoxicology (PLANTS) Unit: Varvara Gouliarmou Methodology and Scientific Support (MESE) Unit: Josè Cortinas, Efisio Solazzo

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 3rd Working Group meeting held on 9 and 11 January 2024, via web-conference

The minutes of the 3rd Working Group meeting were agreed by written procedure on 23 January 2024.

4. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

5. Hearing Expert (s)

A technical hearing was organised with the beneficiaries (consortium ANSES, BfR, BPI, UNIMI, UNITO) of the grant GP/EFSA/PREV/2022/02- Evaluation of new evidence on non-dietary exposure to plant protection products'. The members of the consortium were invited to support the Working Group by presenting the status of the activities and answering questions as needed by the Working Group.

Scientific topic(s) for discussion

Draft guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (<u>EFSA-Q-2023-00403</u>).

On day-1 (3 Apr), the Working Group discussed Interim Report 2 (including outcomes from evidence appraisal) on seed treatment and sowing evidence (Work Package 1), as well as Protocol on Residents and Bystanders evidence (Work Package 2) drafted by the beneficiaries of the grant (GP/EFSA/PREV/2022/02). Consolidated feedback was captured during the meeting and shared with the beneficiaries during the technical hearing on day-2 (5 Apr), when main elements of the report were discussed. Next steps for the project were agreed.

In addition, the Working Group discussed on day-1 (3 Apr) the evidence submitted to EFSA with the Closed Transfer System Operator Exposure Study. In the end, the Working Group discussed amendments needed to the online tool.

7. Any Other Business

None

8. Next meeting

The next meeting will be held on 25 Jun (9:00-12:00 and 13:00-16:00) and 27 Jun 2024 (10:00-13:00 and 14:00-17:00) as web conference.

PESTICIDES PEER REVIEW (PREV) UNIT

3rd Working Group meeting on the OPEX Guidance/ Calculator update



9 -11 January 2024 9:00-13:00 MINUTES – Agreed on 23 Jan 2023

Location: Teleconference

Attendees:

Working Group Members:
 Tamara Coja, Peter Craig, Paul Hamey, Sabine Martin

Hearing Experts¹:

<u>French Agency for Food, Environmental and Occupational Health & Safety (ANSES)</u>: Patrice Carpentier, Bertrand Desprez

Bundesinstitut für Risikobewertung (BfR): Claudia Grosskopf, Enrico Peter, Tobias Willenbockel

<u>Benaki Phytopathological Institute (BPI)</u>: Niki Arapaki, Despina Bournele, Agathi Charistou, Vasileia Laskari, Kyriaki Machera, Ioannis Theologidis

Università degli Studi di Milano (UNIMI): Ilaria Castelli, Luca Tosti

<u>Università degli Studi di Torino (UNITO)</u>: Fabrizio Gioielli, Paolo Marucco

 $_{\odot}$ $\,$ European Commission and/or Member States representatives: Not Applicable

o EFSA:

Pesticide Peer Review (PREV) Unit: Arianna Chiusolo (chair), Frederique Istace Environment, Plants and Ecotoxicology (PLANTS) Unit: Varvara Gouliarmou Methodology and Scientific Support (MESE) Unit: Josè Cortinas, Efisio Solazzo

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

MEETING MINUTES – 09 and 11 January 2024 3rd Working Group meeting on OPEX Guidance/calculator update



4. Hearing Expert (s)

A technical hearing was organised with the beneficiaries (consortium ANSES, BfR, BPI, UNIMI, UNITO) of the grant GP/EFSA/PREV/2022/02- Evaluation of new evidence on non-dietary exposure to plant protection products'. The members of the consortium were invited to support the Working Group by presenting the status of the activities and answering questions as needed by the Working Group.

5. Scientific topic(s) for discussion

On day-1 (9 Jan), the Working Group discussed the Interim Report 1 (including outcomes from study selection and data extraction together with a draft appraisal) on seed treatment and seed sowing evidence (Work Package 1), drafted by the beneficiaries of the grant GP/EFSA/PREV/2022/02. Consolidated feedback was captured during the meeting and shared with the beneficiaries during the technical hearing on day-2 (11 Jan), when main elements of the report were discussed. Next steps for the project were agreed.

In addition, on day-1 (9 Jan) the Working Group discussed the evidence submitted to EFSA with the Closed Transfer System Operator Exposure Study. In the end, the Working Group also discussed amendments needed to the online tool for calculations.

6. Any Other Business

None

7. Next meeting

The next meeting will be held on 3 April (9:00-12:00 and 13:00-15:00) and 5 Apr 2024 (10:00-13:00 and 14:00-17:00) as web conference.

PESTICIDES PEER REVIEW UNIT

2nd Working Group meeting on the OPEX Guidance/ Calculator update



11 - 13 October 2023 09:00-13:00 - 09:00-13:00 MINUTES - Agreed on 20 Oct 2023

Location: Teleconference

Attendees:

Working Group Members:

Tamara Coja, Peter Craig, Paul Hamey (day-1 only), Sabine Martin (day-1 only)

Hearing Experts¹:

<u>French Agency for Food, Environmental and Occupational Health & Safety (ANSES)</u>: Patrice Carpentier, Bertrand Desprez, Baptiste Reboulet, Ahmed-Chaouki Zerouala

Bundesinstitut für Risikobewertung (BfR): Claudia Grosskopf, Rene Schreiber

<u>Benaki Phytopathological Institute (BPI)</u>: Agathi Charistou, Ioannis Theologidis, Kostantinos Kasiotis, Kyriaki Machera, Niki Arapaki

<u>Università degli Studi di Milano (UNIMI)</u>: Ilaria Castelli, Luca Tosti

<u>Università degli Studi di Torino (UNITO)</u>: Fabrizio Gioielli, Paolo Marucco

- European Commission and/or Member States representatives:
 Not Applicable
- o EFSA:

Pesticide Peer Review (PREV) Unit: Arianna Chiusolo (chair), Frederique Istace

Environment, plants and ecotoxicology (PLANTS) Unit: Varvara Gouliarmou

Methodology and Scientific Support (MESE) Unit: Josè Cortinas, Efisio Solazzo

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received from Paul Hamey and Sabine Martin for day-2 of the meeting (13 Oct 2023).

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: https://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

MEETING MINUTES – 11 and 13 October 2023 2nd Working Group meeting on OPEX Guidance/calculator update



4. Hearing Expert (s)

A technical hearing was organised with the beneficiaries (consortium ANSES, BfR, BPI, UNIMI, UNITO) of the grant GP/EFSA/PREV/2022/02- Evaluation of new evidence on non-dietary exposure to plant protection products'. The members of the consortium were invited to support the Working Group by presenting the status of the activities and answering questions as needed by the Working Group.

5. Scientific topic(s) for discussion

On day-1 (11 Oct), the Working Group discussed the protocol for the analysis of the SeedTropex⁴ evidence (Work Package 1), drafted by the beneficiaries of the grant (GP/EFSA/PREV/2022/02. Consolidated feedback was captured during the meeting and shared with the beneficiaries during the technical hearing on day-2 (13 Oct), when main elements of the protocol were discussed. Next steps for protocol finalization were agreed.

6. Any Other Business

The Working Group was informed that, in addition to the 3 priorities identified at the stakeholders' workshop⁵, and as agreed with Commission, the raw data submitted to EFSA with the Closed Transfer System Operator Exposure Study will be assessed within the update of the OPEX Guidance and Calculator.

7. Next meeting

The next meeting will be held on 9 Jan (9:00 - 13:00) and 11 Jan 2024 (9:00-13:00) as web conference.

⁴ Exposure Model for Seed Treatment and Seed Sowing

https://www.efsa.europa.eu/en/events/stakeholder-workshop-next-update-efsa-guidance-non-dietary-exposure-pesticides

PESTICIDES PEER REVIEW UNIT

1st Working Group meeting on the OPEX Guidance/ Calculator update



29 - 30 August 2023 14:00-18:00 - 09:00-13:00 MINUTES - Agreed on 15 Sep 2023

Location: Parma and teleconference

Attendees:

o Working Group Members:

Tamara Coja, Peter Craig, Paul Hamey, Sabine Martin

Hearing Experts¹:

<u>French Agency for Food, Environmental and Occupational Health & Safety (ANSES)</u>: Patrice Carpentier, Bertrand Desprez, Baptiste Reboulet, Ahmed-Chaouki Zerouala

Bundesinstitut für Risikobewertung (BfR): Claudia Grosskopf, Rene Schreiber

<u>Benaki Phytopathological Institute (BPI)</u>: Agathi Charistou, Despina Bournele, Ioannis Theologidis, Kyriaki Machera, Niki Arapaki, Vasileia Laskari

Università degli Studi di Milano (UNIMI): Francesca Metruccio, Luca Tosti

Università degli Studi di Torino (UNITO): Paolo Marucco

 $_{\odot}$ $\,$ European Commission and/or Member States representatives: Not Applicable

o EFSA:

Pesticide Peer Review (PREV) Unit: Arianna Chiusolo (chair), Frederique Istace Methodology and Scientific Support (MESE) Unit: Josè Cortinas, Efisio Solazzo

Finance (FIN) Unit: Laura Perati

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. At the beginning of the meeting, Paul Hamey and Sabine Martin declared they have provided general feedback to the SeedTropex Task Force during the development of the model, as part of the experts employment (UK CRD and BfR, respectively) tasks, therefore no Conflicts of Interest was identified.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: https://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

MEETING MINUTES – 29-30 August 2023 1st Working Group meeting on OPEX Guidance/calculator update



4. Hearing Expert (s)

A technical hearing was organised with the beneficiaries (consortium ANSES, BfR, BPI, UNIMI, UNITO) of the grant GP/EFSA/PREV/2022/02- Evaluation of new evidence on non-dietary exposure to plant protection products'. The members of the consortium were invited to support the Working Group by presenting the status of the activities and answering questions as needed by the Working Group.

5. Scientific topic(s) for discussion

On day-1 (29 Aug), the Working Group discussed the background information for the second update of the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (OPEX) and related Calculator (EFSA, 2022). Identified priorities for the update of the OPEX Guidance and Calculator were the following:

- 1. SeedTropex (Exposure Model for Seed Treatment and Seed Sowing),
- 2. Resident and Bystander exposure,
- 3. Worker exposure, DFR (Dislodgeable Foliar Residue), DT50 (time required for 50% dissipation of the initial concentration).

The Working Group agreed on the identified priorities and clarified that also TC (Transfer Coefficient) values should be collected and evaluated under the priority 3, if relevant data are available.

The Working Group was informed that a grant (GP/EFSA/PREV/2022/02) with a consortium of ART. 36 Organisations has been implemented with the aim to evaluate new evidence on Non-Dietary Exposure (NDE) made available to EFSA. The 3 priorities have been organised into 3 Work Packages (WPs) planned to be developed with a modular approach.

The Working Group was informed about the data and information submitted to EFSA through the NDE Functional Mailbox in relation to the 3 WPs. The provided evidence will be analysed in view of updating the approaches for Operators, Workers, Residents and Bystanders in the OPEX Guidance and Calculator.

At the beginning of the meeting on day-2 (30 Aug), the EFSA Procurement Team presented an overview on the best practices for grants. During the technical hearing with the beneficiaries of the grant (GP/EFSA/PREV/2022/02), the Working Group was updated on the project development. Also, a preliminary version of the protocol for analysis of evidence for the WP1 (SeedTropex) was presented and discussed.

In the end, the calendar of meetings was agreed.

6. Any Other Business

None.

7. Next meeting

The next meeting will be held on 11 Oct 2023 (9:00 – 13:00) and 13 Oct 2023 (9:00-13:00) as web conference.