SCIENTIFIC PANEL ON Glyphosate 41st Working Group meeting on Ecotoxicology

ersa European FOOD SAFETY AUTHORITY

27 March 2023 10:00-13:00 MINUTES - Agreed on 12 April 2023

Location: Webconference

Attendees:

Working Group Members:Paul van den Brink, Theo Brock

Hearing Experts¹:
 Not Applicable

o European Commission and/or Member States representatives:

EC: Not Applicable

o EFSA:

Rachel Sharp (Chair for all but iv(b)), Alessio Ippolito (Chair for iv(b)) and Simone Rizzuto

Others:Not Applicable

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. 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 Management^{3,} 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.

IV. Scientific topic(s) for discussion

(a) Alvarado-Suárez GB, Silva-Briano M, Arzate-Cárdenas MA, Carbajal-Hernández AL, Yáñez-Rivera B, Rico-Martínez R. Feeding behavior of early life stages of the zebrafish Danio rerio is altered by exposure to glyphosate. Environ Sci Pollut Res Int. 2022 Dec;29(56):85172-85184. doi: 10.1007/s11356-022-21790-x. Epub 2022 Jul 6. PMID: 35794329.

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

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The WG was asked to provide their opinion on the reliability of the study and consider how the results should be considered in the context of a risk assessment performed in accordance with EFSA PPR Panel (2013)⁴.

The bioaccumulation experiments presented severe drawbacks (no kinetic of bioaccumulation - only one sample in time without proof of steady-state being achieved, BCF values based on dry weight, no normalisation for lipid content etc.). The derived BCF values are not considered reliable, but the study is an additional line of evidence confirming the low bioaccumulation potential of glyphosate.

Another experiment compared survival of four groups in which fish larvae of 8 days post fertilisation were fed with rotifers. A LOEC = 0.8 mg/L can be derived from the study, which would in principle challenge the currently derived NOEC of 1 mg/L. Nonetheless, a more in-depth evaluation of the experiment revealed significant issues due to the experimental methodology and other aspectes related to the risk assessment. Specifically, tested concentrations were not measured in the test medium despite an important dilution took place in one go, as it may be inferred from the description of the test setup. Uncertainties are also related to the atypical experimental setup (microplate test) and on the appropriateness of the diet being used in the experiment.

The main conclusion is that, due to the aforementioned issues, the study should not be used for regulatory risk assessment.

However, the experimental design was novel and raises some interesting points on the potential impact of pesticides on the fish diet, which would benefit of further academic research, as a general point for toxicity testing.

(b) C. Pelosi, C. Bertrand, V. Bretagnolle, M. Coeurdassier, O. Delhomme, M. Deschamps, S. Gaba, M. Millet, S. Nélieu, C. Fritsch, Glyphosate, AMPA and glufosinate in soils and earthworms in a French arable landscape, Chemosphere, Volume 301, 2022, 134672, ISSN 0045-6535, https://doi.org/10.1016/j.chemosphere.2022.134672.

The WG was asked to provide their opinion on the reliability of the measured residue values, the calculated BAF values and, if reliable, to consider a plausible explanation for the findings. The measured residue levels in earthworms are considered reliable, however, since the study was a monitoring study, the residue values cannot be linked to the representative uses under assessment. However, several issues were identified regarding the reliability of the calculated BAF values. Specifically:

- Since the study was a field monitoring study, it is not possible to understand if the steady state concentration in the worms was reached (which is a requirement in test guidelines for BCF or BAF studies).
- For the BAF dry weight calculation, experimentally derived BAF is always preferred since the steady state is always reached and controlled.
- The calculation of BAF set as LoD/2 in case of <LOD may represent an issue since a large fraction of soil samples were <LOD values. It is also noted that when the value was between LOQ and LOD, the LOD value was used (which is a worst-case approach).
- It appears that the highest BAF value is achieved when the LOD for earthworms is divided by the half LOD for the soil. It is noted that the authors did not report using the LOD for

⁴ EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. doi:10.2903/j.efsa.2013.3290

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earthworms. However, this suggests that the highest BAF values were an artefact of these assumptions.

- In some areas the median BAF concentration was below the LOQ.

Overall, the BAF values, due to the identified methodological limitations, are not considered as reliable for regulatory assessment.

V. Any Other Business

None.

VI. Next meeting

None are planned.

SCIENTIFIC PANEL ON Glyphosate 40th Working Group meeting on Ecotoxicology

efsa EUROPEAN FOOD SAFETY ALITHOUSTY

15 March 2023 09:00-11:00 / 14:00-16:00 MINUTES - Agreed on 21 March 2023

Location: Webconference

Attendees:

Working Group Members:Paul van den Brink, Theo Brock

Hearing Experts¹:

Not Applicable

o European Commission and/or Member States representatives:

EC: Not Applicable

o EFSA:

Rachel Sharp (chair), Alessio Ippolito and Simone Rizzuto

Others:Not Applicable

I. Welcome and apologies for absence

The Chair welcomed the participants.

Paul van den Brink attended the meeting in the morning and Theo Brock attended the meeting in the afternoon. Alessio Ippolito did not attend the afternoon meeting.

II. Adoption of agenda

The agenda was adopted without changes.

III. 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 Management^{3,} 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.

IV. Scientific topic(s) for discussion

The WG was provided with two studies which they will be asked to evaluate:

(i) Alvarado-Suárez GB, Silva-Briano M, Arzate-Cárdenas MA, Carbajal-Hernández AL, Yáñez-Rivera B, Rico-Martínez R. Feeding behavior of early life stages of the zebrafish Danio rerio is altered by exposure to glyphosate. Environ Sci Pollut Res Int. 2022

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 – 15 March 2023 40th Working Group meeting on Glyphosate



Dec;29(56):85172-85184. doi: 10.1007/s11356-022-21790-x. Epub 2022 Jul 6. PMID: 35794329.

(ii) C. Pelosi, C. Bertrand, V. Bretagnolle, M. Coeurdassier, O. Delhomme, M. Deschamps, S. Gaba, M. Millet, S. Nélieu, C. Fritsch, Glyphosate, AMPA and glufosinate in soils and earthworms in a French arable landscape, Chemosphere, Volume 301, 2022, 134672, ISSN 0045-6535, https://doi.org/10.1016/j.chemosphere.2022.134672.

For (i) the WG is asked to evaluate the reliability of the study and consider how the results should be considered in the context of a risk assessment performed in accordance with EFSA PPR Panel (2013)⁴.

For (ii) the WG is asked to evaluate the reliability of the measured residue values, the calculated BAF values and, if reliable, to consider a plausible explanation for the findings.

The initial evaluation of the studies was briefly discussed, and several aspects were highlighted for further consideration.

It was agreed that the WG members would evaluate the studies and the assessment of the WG will be delivered orally at the next WG meeting.

V. Any Other Business

None.

VI. Next meeting

The next meeting will be held on 27th March 2023 via web conference.

⁴ EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. doi:10.2903/j.efsa.2013.3290

EFSA WORKIGN GROUP ON GLYPHOSATE RESIDUES

Working Group meeting on GLYPHOSATE RESIDUES



23 February 2023 9:00-11:30 MINUTES – Agreed on 13 March 2023

Location: EFSA - Parma (Meeting Room 00/02)/Webconference

Attendees:

o Working Group Members:

Kalliopi KOKKINAKI

Hearing Experts¹:

Not Applicable

o European Commission and/or Member States representatives:

EC: Not Applicable

o EFSA: J. Oriol Magrans, Anne Theobald, Andrea Mioc, Anja Friel.

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. 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 Management^{3,} 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.

IV. Scientific topic(s) for discussion

a. Conclusion on glyphosate. (EFSA-0-2020-00140)

The WG discussed the residue trial available in the dossier of glyphosate as presented by the RMS in the updated RAR after the Peer Review Experts' Teleconference (TC) 83.

The criteria used by the RMS to select the reliable residue trials on basis the residue stability in samples was discussed. Residue trials fulfilling the stability criteria demonstrated and agreed in the Experts 'Teleconference were identified as basis of the EFSA conclusion.

Actions for the meeting participants and preparatory works of the conclusion were agreed.

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

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





PREV Unit PPR Panel

MINUTES OF THE 38TH MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

Residues

Held on 15 November 2022 (teleconference)

Participants

Working Group Members:

Kalliopi KOKKINAKI, Olavi PELKONEN,

Hearing Experts:

Not applicable

■ European Commission and/or Member States representatives:

Not applicable

EFSA:

Andrea MIOČ, Anne THEOBALD, Samira JARRAH, J. Oriol MAGRANS (chair of teleconference).





The Chair welcomed the participants. Olavi apologized as needed to leave the meeting at 11:30. Samira apologized for not being able to attend the meeting due to personal reasons of force majeure.

2. Introduction

The chair, J. Oriol Magrans, informed that the purpose of the meeting was the preparation of the Expert Consultation on the Residues section of Glyphosate TC 83, to be held in Parma between the 28th of December and the 2nd of December 2022. The way the expert consultation operates was summarily explained.

3. Revision of the background information to be presented in the Peer Review Meeting Report

The group went through the Template of the Peer Review Meeting Report and discussed the information drafted by EFSA for the background section. Issues potentially requiring special consideration by the meeting were identified as the interlinking issues and the time estimated for discussion of each expert consultation point. The presenter for each expert consultation point was also identified.

4. AOB

The experts agreed to continue in touch during the days before the meeting. Further background information provided by the RMS or comments by MSs are expected to be received one week in advance to the meeting and would be shared in the working group as appropriate.





PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 37th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

ECOTOXICOLOGY - Microbiome

Held on 10 November 2022 (Parma, Italy)

(Agreed on 11 November 2022)

Participants

■ Working Group Members:

Diana Di Gioia

Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Peer Review Unit: Fernando Álvarez, Maria Arena, Domenica Auteri, Franco Ferilli (Chair), Simone Rizzuto, Rachel Sharp, Csaba Szentes





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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

In preparation for the upcoming Pesticide Peer Review Teleconference 82, the working group discussed the relevance and reliability of peer reviewed publications dealing with the effects of glyphosate on the microbiome of non-target organisms and on soil microbiota that were available within the peer review for glyphosate renewal.

5. Next meeting(s)

To be confirmed.

 $^{^{1}\ \}underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf}}$

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





THE PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 36TH MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

ENVIRONMENTAL FATE AND BEHAVIOUR

Held on 8th November 2022 (teleconference)

(Agreed on 14th November 2022)

Participants

■ Working Group Members:

Claudia Autengruber Joannis Kandris Sonia Ullucci

Hearing Experts¹:

Not Applicable

European Commission and/or Member States representatives:

Not Applicable

EFSA:

Pesticides Peer Review Unit: Chris Lythgo, Gabriella Fait, Laia Herrero Nogareda, Roberta Lava, Laura Padovani and Mark Egsmose

Others:

Not Applicable

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

The Chair welcomed the participants.

No apologies were received.

2. Adoption of agenda

The agenda was adopted with minor 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 Management^{3,} 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. Agreement of the minutes of the 1st Working Group meeting

The minutes of the 1st Working Group meeting were agreed by written procedure on 21st October 2022 and published.

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion

- 6.1. The WG had a discussion on views on the groundwater monitoring information in preparation of the Pesticide Peer Review TC 81, 14 to 21 November 2022 on the environmental fate and behaviour of glyphosate.
 - 6.2. The WG had a discussion on views on the surface water and sediment monitoring information presented in the RAR in preparation of the Pesticide Peer Review TC 81, 14 to 21 November 2022 on the environmental fate and behaviour of glyphosate.
 - 6.3. The WG had a discussion on views on the drinking water monitoring information presented in the RAR in preparation of the Pesticide Peer Review TC 81, 14 to 21 November 2022 on the environmental fate and behaviour of glyphosate.
- 6.4. The WG had a discussion on views on the air monitoring information presented in the RAR in preparation of the Pesticide Peer Review TC 81, 14 to 21 November 2022 on the environmental fate and behaviour of glyphosate.

6.5. **Any Other Business**

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

None

7. Next meeting(s)

No further meetings are scheduled for this subgroup.





PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 35TH MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

Ecotoxicology

Held on 8th November 2022

(Agreed on 19th November 2022)

Participants

■ Working Group Members:

Not Applicable.

Hearing Experts:

Andreas Focks

■ European Commission and/or Member States representatives:

Not Applicable.

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp (Chair), Alessio Ippolito, Alberto Linguadoca.





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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the hearing expert invited to the present meeting. No additional conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Discussion of the Applicants' (GRG) submitted documents and the evaluation of the RMS (AGG)

The hearing expert was asked questions specifically related to Ctgb (2019). It was noted that the assessment of the Ctgb was considering a less diverse GAP relative to the representative uses under assessment. It was further noted that some relevant remarks are inlcuded in the current GAP table (i.e., related to the percentage of cropped area to be treated and the specified risk mitigation for using 75% drift reducing nozzles).

The hearing expert was also requested to clarify the concern raised regarding the use of 21-day time-weighted average toxicity values and approach used by the applicant to estimate the hazard likelihood in the effect model. This was noted to be a key issue for further discussion.

4.2. Tasks and deadlines

No tasks were identified.

5. AOB

None.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





6. Next meeting

No additional meetings anticipated.





PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 34th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

ECOTOXICOLOGY - Biodiversity

Held on 7 November 2022 (teleconference)

(Agreed on 11 November 2022)

Participants

■ Working Group Members:

Theo Brock, Paul Van den Brink

Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

EFSA:

Pesticides Peer Review Unit: Fernando Álvarez, Domenica Auteri (Chair), Rachel Sharp, Csaba Szentes





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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

In preparation for the upcoming Pesticide Peer Review Teleconference (PPR TC) 82, the Working Group discussed (i) the approach followed by the applicant to address indirect effects of glyphosate on biodiversity, including the risk mitigation measures proposed by the applicant, and (ii) the evaluation of the revised biodivesity assessment done by the Rapporteur Member State (Assessment Group on Glyphosate) as reported in the updated RAR.

5. Next meeting

To be confirmed.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 33RD MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT Non-dietary exposure

Held on 28 October 2022 (teleconference)

(Agreed on 09 November 2022)

Participants

Working Group Members:

Paul Hamey

EFSA:

Pesticides Peer Review Unit: Frederique Istace (chair)

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management², 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. Scientific topic(s) for discussion

4.1. Exposure estimates

The non-dietary exposure estimates for operators, workers, bystanders and residents (as presented in the revised RAR of 30th September 2022) were discussed in detail for the different representative uses (10) supported for the renewal of glyphosate.

5. Next meeting(s)

Not applicable any more since the next step is the discussion by the experts in the Pesticide Peer Review TC 80 (14-25 November 2022).

¹ 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





Pesticide Peer Review UNIT

MINUTES OF THE 32nd MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

GENOTOXICITY

Held on 21 October 2022 (teleconference)

(Agreed on 25 October 2022)

Participants

Working Group Members:

Christiane Vleminckx

EFSA:

Juan Manuel Parra Morte (Chair), Danièle Court Marques, Marco Binaglia

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

Juan explained the main skeleton of the draft main document and related tables on the preliminary assessment on DNA damage. The main document and its tables will be an annex to the background of the experts' meeting report. The document will be a preliminary EFSA position on DNA damage with the aim to help the discussion and will not represent the final view of EFSA on genotoxicity and/or DNA damage.

A discussion was held on the preliminary assessment done by Christiane on the draft overview tables, for which additional clarifications will be added by Christiane and Juan. Christiane will finalise the draft document and its tables and send them back to Juan for final revision before sharing with Member States.

Juan clarified the type of information that will be included as background information on other genotoxicity experts' consultation points (other than experts' consultation on DNA damage).

5. Next meeting(s)

Peer Review Experts' Meeting in November-December 2022.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





Pesticide Peer Review Unit

MINUTES OF THE 31ST MEETING OF THE WORKING GROUP ON THE GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

EPIDEMIOLOGICAL STUDIES AND NEUROTOXICITY

Held on 20 October 2022 (teleconference)

(Agreed on 9 November 2022)

Participants

Working Group external Members:

Antonio Hernandez Jerez

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

Federica Crivellente (Chair), Juan Parra Morte, Daniele Court Marques

Others:

Not Applicable





The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes at the beginning of the meeting.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², 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. Scientific topic(s) for discussion

4.1 **Assessment of epidemiological studies**

The WG discussed the outcome of the assessment of epidemiological studies on carcinogenicity, neurotoxicity, intoxication/respiratory reproductive toxicity and others (e.g. oxidative stress, etc.). Differences between the assessment provided by the RMS and by the WG were discussed; such differences will be further discussed for a selected number of studies during the experts' meeting on glyphosate.

Assessment of neurotoxicity studies

The WG discussed the outcome of the assessment of neurotoxicity studies (in vivo, in vitro together with the epidemiological evidence mentioned under 4.1). Differences between the assessment provided by the RMS and by the WG were discussed; such differences will be further discussed for a selected number of studies during the experts' meeting on glyphosate.

5. Next Meeting(s)

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





Not applicable





Pesticide Peer Review UNIT

MINUTES OF THE 30TH MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - ADME

Held on 17 October 2022 (teleconference)

(Agreed on 4 of November)

Participants

Working Group Members:

Olavi Pelkonen

EFSA:

PREV Unit: Marco Binaglia (Chair), Martina Panzarea

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

A discussion was held on the additional information requested during the stop-of-the-clock period on ADME.

The next steps and tasks allocation in preparation of the experts' meetings were presented by EFSA and discussed with the expert.

5. Next meeting(s)

None.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





THE PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 29th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

Environmental fate and behaviour

Held On 12th October 2022 (teleconference)

(Agreed on 21st October 2022)

Participants

Working Group Members:

Claudia Autengruber Joannis Kandris Sonia Ullucci

Hearing Experts¹:

Not Applicable

European Commission and/or Member States representatives:

Not Applicable

EFSA:

Pesticides Peer Review Unit: Chris Lythgo, Gabriella Fait, Laia Herrero Nogareda, Roberta Lava, Laura Padovani and Mark Egsmose

Others:

Not Applicable

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

The Chair welcomed the participants.

No apologies were received.

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 Management^{3,} 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. Agreement of the minutes of the (n-1)th Working Group meeting

This was the first WG meeting

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion

- 6.1. Outline of the available monitoring data as assessed in the amended RAR. A presentation concerning the outline of the available monitoring data as assessed in the amended RAR was provided. The outline included monitoring data from the environmental compartments air, groundwater, drinking water, surface water and sediment.
- 6.2. Scientific Check key comments relating to monitoring data and further information requests. During the Scientific Check in addition to the comments from the peer-review also public comments were received. Some Data requirements identified, important open points and issues to be considered in a future Experts' consultation in relation to environmental monitoring data were discussed during the WG meeting.
- 6.3. WG discussion on task distribution and use of collaboration tools. Following an exchange in the WG tasks were distributed to the WG members. The WG members will present their considerations and relevant issues identified on environmental monitoring of glyphosate for discussion in the next WG meeting.

6.4. **Any Other Business**

None

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

7. Next meeting(s)

The next WG meeting is scheduled for 8^{th} November 2022.





Pesticide Peer Review UNIT

MINUTES OF THE 28th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - Microbiome

Held on 10 October 2022 (teleconference)

(Agreed on 13 October 2022)

Participants

Working Group Members:

Lorena Ruiz, Giovanni Savoini and Diana Di Gioia

Observer:

None

EFSA:

PREV Unit: Frederique Istace and Anna Lanzoni (Chair).

The Chair welcomed the participants. No apologies were received.

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

The Working Group (WG) finalised the reliability and relevance assessment of the studies under its remit (investigating possible effects of glyphosate on microbiome/microbiota in humans and domestics animals) and discussed the reporting approach. Tasks were allocated to WG members and deadlines agreed.

The WG advice will be considered further in the Peer Review Process of glyphosate.

5. Next meeting(s)

None.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





Pesticide Peer Review UNIT

MINUTES OF THE 27th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - Immunotoxicity

Held on 6 October 2022 (teleconference)

(Agreed on 26 of October)

Participants

Working Group Members:

Emanuela Corsini

EFSA:

PREV Unit: Marco Binaglia (Chair), Daniele Court Marques, Anna Lanzoni, Frederique Istace, Martina Panzarea

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

A discussion was held on the additional information requested during the stop-of-the-clock period on immunotoxicity endpoint.

The next steps and tasks allocation in preparation of the experts' meetings were presented by EFSA and discussed with the expert.

5. Next meeting(s)

None.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 26TH MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

ECOTOXICOLOGY - MODELLING

Held on 4th October 2022 (teleconference)

(Agreed on 17th October 2022)

Participants

- Working Group Members: Not Applicable
- Hearing Experts:
 Andreas Focks
- European Commission and/or Member States representatives:Not Applicable.
- EFSA:

Pesticides Peer Review Unit: Rachel Sharp (Chair), Alessio Ippolito, Alberto Linguadoca.

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 the Decision of the Executive Director on Competing Interest Management, 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.

Certain interests were declared orally by one member before the beginning of the meeting. For further details on the outcome of the screening of the Oral declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

4. Scientific topic(s) for discussion

4.1. Discussion of the Applicants' (GRG) submitted documents and the evaluation of the RMS (AGG)

The GRGs submission and the assessment of the AGG was briefly summarised. It was noted that the AGG assessment included a link to a second evaluation performed by the Dutch National Authority for pesticides, Ctgb, in the context of a national authorisation of a product containing glyphosate (Ctgb, 2019¹). The assessment is available to Member States on CIRCABC. Therefore, the Ctgb assessment is considered as a supporting document to the RAR.

The hearing expert was asked questions specifically related to Ctgb (2019).

i) It was requested that the expert explained how the evaluation was performed and whether the EFSA PPR Panel Opinion on Good Modelling Practice (EFSA PPR Panel, 2014²) was followed.

It was confirmed that the applicant has provided an assessment of the modelling in accordance with the EFSA PPR Panel (2014). Consequently, the evaluation also used the recommendations of EFSA PPR Panel (2014).

ii) It was requested that the expert summarised the conclusion of the assessment and explained what were the critical issues that were identified for the model and modelling.

It was explained that overall, the Ctgb concluded that the results of the modelling could not be used in the context of the national authorisation of the product for which it had been submitted.

4.2. Tasks and deadlines

No tasks were identified.

5. AOB

None.

¹ The Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), 2019. Final REGISTRATION REPORT, Appendix to CEU Core Part B9, Evaluation of the eVole model (summaries A 2.1.2.2.3-7 (reports 1 to 5) in B9). Available on CIRBABC: https://circabc.europa.eu/ui/welcome

² EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2014. Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. EFSA Journal 2014;12(3):3589, 92 pp. doi:10.2903/j.efsa.2014.3589 Available online: www.efsa.europa.eu/efsajournal





6. Next meeting

7th November.

Annex I

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

<u>CONFLICT OF INTEREST:</u> With regard to this meeting, Mr. Andreas Focks indicated that in the updated RAR, the AGG has included a link to an evaluation that was performed by the Dutch National Authority for pesticides, Ctgb, in the context of a national authorisation of a product containing glyphosate. Mr Focks explained that he contributed to this evaluation and that this evaluation assessed the exact documents that have been submitted by the Applicants (GRG) for the AIR VI renewal of Glyphosate. Therefore, since the Ctgb evaluation is considered as a supporting document to the updated RAR it was considered not appropriate for Mr Focks to peer review an evaluation to which he originally contributed to.

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI). This results in the change of the status of Mr Focks in the Working Group to hearing expert.

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





MINUTES OF THE 25th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

ECOTOXICOLOGY - Biodiversity

Held on 28 September 2022 (teleconference)

(Agreed on 14 October 2022)

Participants

Working Group Members:

Theo Brock, Paul Van den Brink

Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

EFSA:

Pesticides Peer Review Unit: Fernando Álvarez, Domenica Auteri (Chair), Rachel Sharp, Csaba Szentes





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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

The WG discussed the additional information submitted by the applicant to address indirect effects of glyphosate on biodiversity, following a request from EFSA during the commenting phase. The WG discussed the extent to which the revised biodiversity addressed all considerations made by EFSA. The WG noted that direct effects on the target weeds (including the impact on the seed bank), nontarget plants, non-target arthropods and bees were not quantified. The WG also discussed the risk mitigation measures proposed by the applicant. The WG agreed to prepare a discussion paper which can serve to facilitate the discussion on biodiversity at the Pesticide Peer Review experts' meeting in November. This document will be finalised at the next meeting.

5. Next meeting

7 November 2022.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





Pesticide Peer Review UNIT

MINUTES OF THE 24th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - Genotoxicity

Held on 26 September 2022 (teleconference)

(Agreed on 27 September 2022)

Participants

Working Group Members:

Christiane Vleminckx

EFSA:

Juan Manuel Parra Morte (Chair), Danièle Court Marques, Martina Panzarea

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

A discussion was held on the preliminary assessment done by Christiane on some genotoxicity studies, for which additional clarifications will be added by Christiane to the overview table. Juan asked for support to Christiane to assess some additional genotoxicity studies for the next WG meeting.

Juan and Martina clarified to the group how bone marrow exposure was assessed, in line with the comments provided by EFSA in the reporting table.

As regards next steps Juan clarified that once the revised assessment report is available, Juan will start drafting the background document for the experts' meeting, then the draft will be revised by Christine and discussed during the next WG meeting before sending it to the experts attending the Peer Review Experts' meeting.

5. Next meeting(s)

21st October 2022 (9.30 to 16.30).

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





MINUTES OF THE 23rd MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - Microbiome

Held on 19 September 2022 (teleconference)

(Agreed on 23 September 2022)

Participants

Working Group Members:

Lorena Ruiz, Giovanni Savoini and Diana Di Gioia

Observer:

None

EFSA:

PREV Unit: Franco Ferilli, Frederique Istace and Anna Lanzoni (Chair).

The Chair welcomed the participants. No apologies were received.

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

The Working Group (WG) discussed the reliability and relevance of the studies under its remit (investigating glyphosate and microbiome/microbiota in humans and domestics animals). Tasks were allocated to WG members, including the finalisation of the reliability and relevance assessment of the studies and reporting.

Further discussion is needed.

The WG advice will be considered further in the Peer Review Process of glyphosate.

5. Next meeting(s)

10 October 2022 (tele meeting).

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





MINUTES OF THE 22nd MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

ECOTOXICOLOGY - Microbiome

Held on 14 September 2022 (teleconference)

(Agreed on 16 September 2022)

Participants

Working Group Members:

Diana Di Gioia

Hearing Experts:

Not Applicable

European Commission and/or Member States representatives:

Not Applicable

EFSA:

Pesticides Peer Review Unit: Fernando Álvarez, Domenica Auteri, Franco Ferilli (Chair), Csaba Szentes.





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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

The WG discussed on the assessment of relevance and reliability of the peer reviewed publications dealing with the effects of glyphosate on the microbiome of non-target organisms and on soil microbiota that were identified in the systematic literature search or received during the public consultation.

5. Scientific topic(s) for discussion

10 November 2022.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





MINUTES OF THE 21st MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - BIOMONITORING DATA

Held on 9 September 2022 (teleconference)

(Agreed on 16 September 2022)

Participants

- Working Group Members:
 Antonio HERNÁNDEZ-JEREZ, Olavi PELKONEN, Paul HAMEY
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Frederique Istace (Chair), Danièle Court-Marques

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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.

Certain interests were declared orally by one member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

4. Scientific topic(s) for discussion

The experts discussed the assessment of the relevance of the study results, and the first considerations for the risk assessment based on biomonitoring data for glyphosate. An overview table will be developed to show the outcome of this risk assessment, including a description of the related uncertainties.

5. Next meeting(s)

To be determined.

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





ANNEX I

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

<u>CONFLICT OF INTEREST</u>: With regard to this meeting, Mr Paul HAMEY declared the following interest: he was employed in the agency who performed the urine analyses for some biomonitoring studies (even though he was in a separate division of the agency). In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI).

Therefore, it was decided by the group that Paul would not be involved in the assessment of these specific studies.





MINUTES OF THE 20th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - EPIDEMIOLOGICAL STUDIES

Held on 5 September 2022 (teleconference)

(Agreed on 19 September 2022)

Participants

- Working Group Members: Antonio Hernandez Jerez
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Federica Crivellente (Chair), Juan Parra Morte, Daniele Court Marques

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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. Scientific topic(s) for discussion

The WG discussed the assessment of epidemiological studies (on carcinogenicity, genotoxicity, neurotoxicity, etc.) based on OHAT criteria and following the recommendations of the 2017 PPR Panel Opinion.

5. Next meeting(s)

October 20th, 2022

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





MINUTES OF THE 19th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - BIOMONITORING DATA

Held on 27 July 2022 (teleconference)

(Agreed on 12 August 2022)

Participants

- Working Group Members:
 Antonio HERNÁNDEZ-JEREZ, Olavi PELKONEN, Paul HAMEY
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Frederique Istace (Chair), Marco Binaglia

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

¹ As defined in Article 15 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:

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 Management^{3,} 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.

Certain interests were declared orally by one member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

4. Scientific topic(s) for discussion

A discussion was held on the assessment of the reliability of the biomonitoring data submitted for glyphosate based on criteria agreed by the working group. Criteria for the assessment of the relevance of the study results were also briefly discussed.

5. Next meeting(s)

To be determined

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

Annex I

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

<u>CONFLICT OF INTEREST</u>: With regard to this meeting, Mr Paul HAMEY declared the following interest: he was employed in the agency who performed the urine analyses for some biomonitoring studies (even though he was in a separate division of the agency). In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI).

Therefore, it was decided by the group that Paul would not be involved in the assessment of these specific studies.





Pesticide Peer Review UNIT

MINUTES OF THE 18th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - Microbiome

Held on 4 July 2022 (teleconference)

(Agreed on 8 July 2022)

Participants

Working Group Members:

Diana Di Gioia, Lorena Ruiz and Giovanni Savoini

EFSA:

PREV Unit: Fernando Alvarez, Franco Ferilli, Frederique Istace and Anna Lanzoni (Chair).

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

A discussion was held on the comments received during the public consultation potential effects of glyphosate on microbiome.

The next steps and tasks allocation in preparation of the experts' meetings were presented by EFSA and discussed with the experts.

The Working Group (WG) advice will be considered further in the Peer Review Process of glyphosate.

5. Next meeting(s)

September. The meeting date(s) will be defined via email with the experts.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





Pesticide Peer Review UNIT

MINUTES OF THE 17th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - Immunotoxicity

Held on 16 June 2022 (teleconference)

(Agreed on 7 of July)

Participants

Working Group Members:

Emanuela Corsini

EFSA:

PREV Unit: Marco Binaglia (Chair), Daniele Court Marques, Anna Lanzoni, Frederique Istace, Martina Panzarea

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

A discussion was held on the comments received during the public consultation on immunotoxicity potential of glyphosate.

The next steps and tasks allocation in preparation of the experts' meetings were presented by EFSA and discussed with the expert.

The Working Group (WG) advice will be considered further in the Peer Review Process of glyphosate.

5. Next meeting(s)

None. Meeting plan will be decided and shared with the expert by email.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





MINUTES OF THE 16th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW – RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - ADME

Held on 03 June 2022 (teleconference)

(Agreed on 23 June 2022)

Participants

Working Group Members:

Olavi Pelkonen

EFSA:

PREV Unit: Juan Manuel Parra Morte (Chair), Martina Panzarea

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

A discussion was held on the overview of the comments on absorption, distribution, metabolism, and excretion (ADME) data provided during the public consultation.

The next steps and tasks allocation were presented by EFSA and discussed with the expert.

5. Next meeting(s)

To be decided.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf





MINUTES OF THE 15th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - BIOMONITORING DATA

Held on 1 March 2022 (teleconference)

(Agreed on 11 March 2022)

Participants

- Working Group Members:
 Antonio HERNÁNDEZ-JEREZ, Olavi PELKONEN, Paul HAMEY
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Frederique Istace (Chair), Federica Crivellente, Martina Panzarea

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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.

Certain interests were declared orally by one member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

4. Scientific topic(s) for discussion

A discussion was held on the overview of the comments on biomonitoring data provided during the public consultation.

5. Next meeting(s)

To be determined.

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





Annex II

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

<u>CONFLICT OF INTEREST:</u> With regard to this meeting, Mr Paul HAMEY declared the following interest: he was employed in the agency who performed the urine analyses for some biomonitoring studies (even though he was in a separate division of the agency). In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI).

Therefore, it was decided by the group that Paul would not be involved in the assessment of these specific studies.





MINUTES OF THE 14th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - GENOTOXICITY

Held on 18 February 2022 (teleconference)

(Agreed on 25 February 2022)

Participants

- Working Group Members: Christiane Vleminckx
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Juan Manuel Parra Morte (Chair), Danièle Court Marques, Martina Panzarea

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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. Scientific topic(s) for discussion

A discussion was held on the overview of the comments on genotoxicity during the public consultation.

5. Next meeting (s)

To be determined.

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





MINUTES OF THE 13th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

RESIDUES

Held on 25 January 2022 (teleconference)

(Agreed on 11 February 2022)

Participants

- Working Group Members: Kalliopi Kokkinaki, Olavi Pelkonen
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Plant Health and Pesticide Residues Unit: Samira Jarrah, Anne Theobald, J. Oriol Magrans (chair of teleconference)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

The Chair welcomed the participants. No absences

2. Introduction of the objectives and purpose of the meeting

The chair presented the purpose of the meeting. The purpose of the meeting was to agree on the proposals for the column 4 of the reporting tables, focusing on the points needing experts' consultation and data requirements.

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 Management^{3,} 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. Review and agreement on the follow up actions to be proposed in the column 4 of the section 3 of the Reporting Table of Glyphosate. Comments on other sections relevant to section 3 to be considered as appropriate for cross reference

The proposals for column 4 were discussed and agreed by the working group.

5. AOB

No further issues were discussed in this meeting.

6. Next meeting

To be agreed once the experts' consultation dates are fixed. A preparatory meeting of the WG will take place before the experts' consultation for its preparation.

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





MINUTES OF THE 12th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

RESIDUES

Held on 17 January 2022 (teleconference)

(Agreed on 17 January 2022)

Participants

- Working Group Members: Kalliopi Kokkinaki, Olavi Pekonen
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Plant Health and Pesticide Residues Unit: Samira Jarrah, Anne Theobald, J. Oriol Magrans (chair of teleconference)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

The Chair welcomed the participants. No absences.

2. Introduction of the objectives and purpose of the meeting

The chair presented the purpose of the meeting. Essentially, the purpose of the meeting was to explain the procedure and give guidelines on how to fill column 4 of the reporting tables and agree among the WG members on how to proceed with this task.

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 Management^{3,} 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. Basic guidance for the completion of the column 4 of the Reporting table

S.J. presented the instructions and guidance on how the column 4 of the Reporting Table. This column collects the proposed follow up of the comments over the peer review process. Basic options for a given comment is to be considered Addressed or require a follow up action Open Point (RMS), Data requirement (applicant) or Experts consultation (MSs experts and EFSA). For a given comment several follow up actions may be needed (Eg. Data requirement plus Experts'consultation).

5. Overall overview of comments to the residue section of glyphosate B

A.T. Presented and overview of the comments in the RT, which include comments made by EFSA, MSs, other EU organizations and public. The need to cross reference comments related to the a given scientific issue within the section and across the different sections was emphasized. AT presented a excel sheet prepared to facilitate this task.

6. Planning and task allocation for the completion of the Column 4 of the residues section of the Reporting Table for glyphosate.

WG members agreed to address comments according their expertise following the same distribution of subsections already agreed for the scientific check. As a first step, the proposals of the RMS will be transferred to column 4. WG members will comment on this proposal or propose changes on them. Following advice received, an expert consultation will be proposed for each subsection. The final proposal for each row on the table will be agreed during next meeting the 25th of January. Exchange among the WG members will be done using the standard means of e-mail and Teams chat and phone calls.

7. AOB

No further issues were discussed in this meeting.

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

8. Next meeting

Date/Time: 25 January 2022 from 11:00 – 13:00 (morning session) and from 14:00-18:00 (afternoon session)





MINUTES OF THE 11th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

ECOTOXICOLOGY

Held on 14 January 2022 (teleconference)

(Agreed on 26 January 2022)

Participants

- Working Group Members:
 Theo Brock, Paul Van den Brink
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Domenica Auteri (Chair), Rachel Sharp, Csaba Szentes, Alessio Ippolito

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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. Scientific topic(s) for discussion

The comments to the section Residues of the Glyphosate RAR, already drafted by the different WG members were reviewed and amended or confirmed. The comments to the section Residues of the Glyphosate RAR, already drafted by the different WG members were reviewed and amended or confirmed.

4.1. Discussion on the biodiversity assessment

The WG discussed the approach proposed by the applicant, and included in the RAR, for the assessment of biodiversity and indirect effects. It was agreed that the data/information should be collected in a systematic manner and it was recommended that this is part of the request to the applicant. The importance of the indirect effect resulting from the removal of pest species including the impact on the seed bank was acknowledged. Furthermore, it was noted that the extent to which the general protection goals for the direct assessment for non-target organisms covers their role in trophic food chains is not explicit. The WG noted that the consideration of the direct effects on terrestrial invertebrates was fundamental to the assessment of indirect effects. The complexities of the biodiversity assessment were acknowledged and the WG suggested that the assessment could be done for some representative scenarios.

The Working Group (WG) advice will be considered further in the Peer Review Process of glyphosate.

4.2. Tasks and deadlines

EFSA will be tasked to complete the next step of the peer review process during January.

5. AOB

Not applicable.

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





MINUTES OF THE 10th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

RESIDUES

Held on 19 November 2021 (teleconference)

(Agreed on 7 December 2021)

Participants

- Working Group Members:Kalliopi Kokkinaki, Olavi Pelkonen (absent)
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Residues Unit: Samira Jarrah, Anne Theobald, J. Oriol Magrans (chair of teleconference)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

The Chair welcomed the participants. Olavi apologized for not being able to attend the meeting.

2. Introduction of the objectives and purpose of the meeting

The chair presented the purpose of the meeting. Essentially, the purpose of the meeting was to confirm of the comments made by EFSA to the RAR of glyphosate in relation to the section of Residues.

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 Management^{3,} 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. Discussion and confirmation of the comments proposed for the residues section

The comments to the section Residues of the Glyphosate RAR, already drafted by the different WG members were reviewed and amended or confirmed. The comments to the section Residues of the Glyphosate RAR, already drafted by the different WG members were reviewed and amended or confirmed.

5. Any other business

No further issues were discussed in this meeting. The need and time frame of further meetings to prepare next peer review phases and will agree by written procedure.

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





MINUTES OF THE 9th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - SUPPLEMENTARY STUDIES INCLUDING IMMUNOTOXICITY

Held on 17 November 2021 (teleconference)

(Agreed on 6 December 2021)

Participants

- Working Group Members: Emanuela Corsini
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Manuela Tiramani (chair), Danièle Court Marques, Martina Panzarea

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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. Scientific topic(s) for discussion

4.1. Supplementary studies including immunotoxicity

A discussion was held on the EFSA comments to volume 3CA, B.6.9 of the RAR on glyphosate regarding supplementary studies, including immunotoxicity. The Working Group (WG) advice will be considered further in the Peer Review Process of glyphosate.

5. Any other business

An overview of the procedure after the commenting phase was presented. The involvement of the expert in the further steps was discussed.

6. Next meeting(s)

None. Meeting plan for 2022 will be decided and shared with the expert by email.

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





MINUTES OF THE 8th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - GENOTOXICITY

Held on 17 November 2021 (teleconference)

(Agreed on 17 November 2021)

Participants

- Working Group Members: Christiane Vleminckx
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Juan Parra Morte (chair), Danièle Court Marques

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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. Scientific topic(s) for discussion

A discussion was held on the EFSA comments to volume 3, B.6.4 and volume 1 of the RAR on glyphosate regarding in vitro and in vivo DNA damage studies.

5. Next meeting(s)

To be determined.

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





MINUTES OF THE 7th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - ADME

Held on 12 November 2021 (teleconference)

(Agreed on 24 November 2021)

Participants

- Working Group Members: Olavi Pelkonen
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Manuela Tiramani (chair), Juan Parra, Frederique Istace, Martina Panzarea

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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. Scientific topic(s) for discussion

The available data on absorption, distribution, metabolism, and excretion (ADME) for glyphosate were discussed. Specific questions (e.g. on bioavailability/absorption, distribution, metabolism, potential formation of reactive metabolites) were raised by EFSA staff to the expert. The Working Group (WG) advice will be considered further in the Peer Review Process.

5. Next meeting(s)

None. Meeting plan for 2022 will be decided and shared with the expert.

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





MINUTES OF THE 6th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - NON-DIETARY EXPOSURE

Held on 12 November 2021 (teleconference)

(Agreed on 12 November 2021)

Participants

- Working Group Members: Paul Hamey
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Frederique Istace (chair)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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. Scientific topic(s) for discussion

4.1. Exposure estimates

The exposure estimates for operators, workers, bystanders and residents were discussed in detail for the different representative uses (10) supported for glyphosate.

5. Next meeting(s)

To be determined.

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





MINUTES OF THE 5th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - NEUROTOXICITY AND EPIDEMIOLOGICAL STUDIES

Held on 11 November 2021 (teleconference)

(Agreed on 17 November 2021)

Participants

- Working Group Members: Antonio Hernandez Jerez
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Federica Crivellente (Chair), Frederique Istace, Juan Parra Morte, Daniele Court Marques

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

The Chair welcomed the participants. Apologies were received from Juan Parra Morte and Daniele Court Marques.

2. Adoption of agenda

The agenda was adopted without changes at the beginning of the meeting.

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 Management^{3,} 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. Scientific topic(s) for discussion

4.1 Biomonitoring data

The assessment of exposure to glyphosate from biomonitoring studies was discussed together with the further need of some considerations versus the non-dietary exposure predicted by the EFSA calculator for the representative uses.

4.2 Neurotoxicity studies

An overall discussion on the neurotoxicity data package available was performed by taking into consideration also the studies available on the effect of glyphosate on microbiota and possibly affecting neurotoxicity endpoints.

4.3 Medical data and epidemiological studies

An overall discussion on the medical data and epidemiological studies (including epidemiological evidences on genotoxicity and carcinogenicity) available was performed.

5. Next meeting(s)

To be determined.

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





MINUTES OF THE 4th MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - CARCINOGENICITY

Held on 10 November 2021 (teleconference)

(Agreed on 10 November 2021)

Participants

- Working Group Members: Christiane Vleminckx
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Pesticide Peer Review Unit: Danièle Court Marques (chair)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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 Management^{3,} 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. Scientific topic(s) for discussion

A discussion was held on the EFSA comments to volume 3, B.6.5 and volume 1 of the RAR on glyphosate regarding carcinogenicity studies in rats and mice and open literature on statistical analysis and mode of action (DNA methylation, lipid accumulation, tumorigenesis promotion, monoclonal gammopathy and oxidative stress).

5. Next meeting(s)

17 November (9:30–11:30) for the genotoxicity assessment.

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





MINUTES OF THE 3rd MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - NON-DIETARY EXPOSURE

Held on 28 October 2021 (teleconference)

Agreed on 28 October 2021

Participants

■ Working Group Members: Paul Hamey

■ EFSA: PREV Unit: Frederique Istace (chair of teleconference)





The Chair welcomed the participants.

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², 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. Scientific topic(s) for discussion

4.1. Representative uses

The table of representative uses (Vol.1 and List of End Points) was discussed in comparison with the critical uses assessed in Vol.3, B.6 CP.

4.2. Exposure estimates

The proposed exposure estimates by the RMS were considered for the different scenarios available.

5. Next meeting (s)

The next meeting will be held on 11th November 2021 (10:00-12:00 am).

¹ 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





MINUTES OF THE 2nd MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

RESIDUES

Held on 26 October 2021 (teleconference)

Agreed on 28 October 2021

Participants

- Working Group Members: Kalliopi Kokkinaki, Olavi Pelkonen.
- EFSA: Samira Jarrah, Anne Theobald, J. Oriol Magrans (chair of teleconference)





The Chair welcomed the participants.

2. Introduction round the table

Working group members introduced themselves and detailed their relevant background.

3. "Kick off presentation". Milestones of glyphosate renewal peer review.

J. Oriol Magrans presented the renewal risk assessment process of Glyphosate and the different phases of the peer review of the Risk Assessment Report prepared by the RMS. Time framework for the main milestones in this process were also presented.

4. Scientific check induction presentation.

Samira Jarrah presented in detail the first phase of the peer review (scientific check comments). Issues that need to be checked or commented and the criteria generally used by EFSA were introduced. Information on the background documents in the RAR and relevant guidance and guidelines were also presented.

5. WG discussion on task distribution and use of collaboration tools of the terms of reference

Working group members agreed on how to proceed and collaborate during the scientific check phase of glyphosate peer review. It was agreed to distribute the revision of the different chapters in the residues section of the RAR according WG members expertise. Members will work independently using the shared documents and with $ad\ hoc$ exchanges and communications. The final list of comments will be agreed in a meeting on the 19^{th} of November.

6. AOB

The date for next meeting was identified:

-19th of November Morning: 8:30 - 11:00 h; 13:30 - 16:30 h (CET Time Zone).

The meeting will take place via web-conference.





MINUTES OF THE 1st MEETING OF THE WORKING GROUP ON GLYPHOSATE PEER REVIEW - RENEWAL ASSESSMENT

MAMMALIAN TOXICOLOGY - CARCINOGENICITY

Held on 14 October 2021 (teleconference)

(Agreed on 28 October 2021)

Participants

- Working Group Members: Christiane Vleminckx
- EFSA: Pesticide Peer Review Unit (PREV): Danièle Court Marques (chair), Juan Parra (last half hour)

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic(s) for discussion

A presentation of the WG members and procedures to be followed by the peer review of glyphosate were presented, with focus on the carcinogenicity chapters and the task expected for the scientific check, deadline 22 November. It was agreed that Christiane will also review the genotoxic potential of glyphosate and glyphosate-based formulations, regarding a potential (oxidative) DNA damage, Comet assays (*in vitro* and *in vivo*).

5. Next meeting(s)

10 November (9:30-11:30) for the carcinogenicity assessment

17 November (9:30-11:30) for the genotoxicity assessment

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf