



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 32nd MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on the 18th and 19th of October 2022

(Agreed on 3rd November 2022)

Participants

- Working Group Members:
Theo Brock (TB) (Chair),
Emily McVey (EM)
- European Commission and/or Member States representatives:
Not Applicable.
- EFSA:
Pesticides Peer Review Unit: Rachel Sharp (RS), Maria Arena (MA), Gabriella Fait (GF)
- Hearing Experts:
None.



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Cleaning the final comments in the draft guidance document

The final comments remaining in the draft guidance document were discussed and cleaned. The final decision on the appropriate methodology for calculations of concentrations in puddles was also discussed and agreed.

5. AOB

None.

6. Next meeting

No more WG meetings are planned.



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 31st MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on the 17th and 18th of October 2022

(Agreed on 3rd November 2022)

Participants

- Working Group Members:
Theo Brock (TB) (Chair),
Emily McVey (EM)
- European Commission and/or Member States representatives:
Not Applicable.
- EFSA:
Pesticides Peer Review Unit: Rachel Sharp (RS), Alessio Ippolito (AI), José Cortiñas Abrahantes (JC)
- Contractor on behalf of EFSA:
Dagmar Bemelmans (only from 11:00 on the 18th October)
- Hearing Experts:
Stefano Ubbiali (ICPS, IT), Erik Amos Pedersen (EPA, DK), Christina Mordziol (UBA, DE), Steven Kragten (CropLife Europe), Manousos Foudoulakis (CropLife Europe), Anna-Lena Lindgren (KEMI, SE), Mathilde Zorn (Ctgb, NL, connected via TEAMS), Olivia Wilfling (AGES, AT).



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Feedback from the participants on the draft bird and mammal WebApp

Before the meeting, the participants were given access to the WebApp and asked to test it for its usability and correctness using four case studies. Written feedback from the hearing experts were submitted and shared with the other participants to the meeting. During the meeting, EFSA presented each page of the WebApp which was then followed by a discussion with the meeting participants to collect their views and feedback. Several important issues were identified (e.g., an incorrect MAF values for single applications was being used). Furthermore, multiple recommendations for improvements to the tool in terms of usability were discussed. A particularly clear recommendation was to combine the output spreadsheets and reduce the number that was produced by the tool. The users also reported some functioning issues with the tool. The experts also provided positive feedback on the info page and asked whether additional examples could be included. EFSA explained that the feedback obtained during the meeting, and in the submitted written comments, will be prioritised and the most important issues addressed before the tool is published. It was further explained that a manual will be available to accompany the WebApp.

5. AOB

None.

6. Next meeting

The next WG meeting is scheduled for the 18th (PM) and 19th (AM) October.



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 30th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on the 4th of July 2022

(Agreed on 18th July 2022)

Participants

- Working Group Members:
 - Theo Brock (TB)
 - Emily McVey (EM)
 - Ana Lopez Anita (AL)
 - Pierre-François Chaton (PFC)
 - Alf Aagaard (AA)
 - Phillipe Berny (PB)
- European Commission and/or Member States representatives:
 - Not Applicable.
- EFSA:
 - Pesticides Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA), Alessio Ippolito (AI), Gabriella Fait (GF)
- Contractor on behalf of EFSA:
 - Dagmar Bemelmans (agenda item 4.2 only)

1. Welcome and apologies for absence



The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Feedback from the WG on the implementation of the screening and Tier 1 methodology into the calculator tool

The WG discussed the feedback that they collated whilst testing the calculator using the case studies. There were some bugs in the previous version of the tool which meant that some aspects of the tool could not be checked. In general, the WG considered that the tool was useful, but some simple changes could make the tool more intuitive for first-time users. Several other recommendations for improvement and corrections were identified. It was also recommended that the information page is used to explain the functionality of the tool but the tool itself should remain as simple as possible meaning it must be used in conjunction with the guidance document.

4.2. Demonstration and use of Tier 2 and 3

The Tier 2 and Tier 3 exposure refinements within the tool were demonstrated to the WG. It was discussed whether, for the Tier 2 refinement of DT50 and RUDs this should be applied automatically to the food item or whether a user should enter it for each generic model species and growth stage. Structurally the latter was simpler for the tool development and is more 'open' for the user. It was acknowledged that the downside is that it takes longer for the user to input the refinements. It was suggested that when a focal species is used the user is also asked to label the geographical areas for which the focal species is relevant. It was also requested for it to be possible to have several focal species per feeding guild. It was also discussed and agreed how the refinements should be reported in so that it can be easily seen which parameters have been refined.

5. AOB

The summary of the spray-drift values was presented. It was agreed that the document should be circulated to the WG for comment.

6. Next meeting

The next meeting is planned for October, 17-18



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 29th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 13 June 2022

(Agreed on 29 June 2022)

Participants

- Working Group Members:
 - Emily McVey (EM)
 - Ana Lopez Anita (AL)
 - Pierre-François Chaton (PFC)
 - Alf Aagaard (AA)
 - Phillipe Berny (PB)
- European Commission and/or Member States representatives:
 - Not Applicable.
- EFSA:
 - Pesticides Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA), Alberto Linguadoca (ALB)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.



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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Method for calculation of PEC puddle

On the basis of the comments that were received, the WG discussed which approach was most suitable for calculating the concentration in puddles. It was agreed that Appendix R and the text in the GD should be updated/

4.2. Updated text on BMD

The updated text on BMD was discussed. Further amendments were agreed which will be integrated into the guidance document.

4.3. Updated text on use of literature data when selecting focal species

The updated text was discussed and agreed.

4.4. Revised text for additive toxicity

The updated text was discussed and agreed.

4.5. Updated text on MDD

The updated text was discussed and agreed.

4.6. Fmet in metabolite risk assessment

The WG discussed proposed solutions and agreed on the final exposure assessment for metabolites in plants.

4.7. Outstanding comment

The remaining comments for were discussed. Deadlines were agreed for the WG to address the remaining comments and make the final amendments to the guidance document.

5. AOB

None.

6. Next meeting

The next tele-meeting will be in July



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 28th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 31 May 2022 (teleconference)

(Agreed on 14 June 2022)

Participants

- Working Group Members:
Theo Brock (TB)
Emily McVey (EM)
- European Commission and/or Member States representatives:
Not Applicable.
- EFSA:
Pesticides Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA), Alberto Linguadoca (ALB)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Finalisation of comments in Chapter 5, 6 and 7

The remaining comments for Chapters 5, 6 and 7 were discussed and changes were made in the relevant sections.

5. AOB

None

6. Next meeting

The next tele-meeting will be in June.



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 27th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 8 April 2022 (teleconference)

(Agreed on 20 April 2022)

Participants

■ Working Group Members:

Theo Brock (TB)

Emily McVey (EM)

Ana Lopez Anita (AL)

■ European Commission and/or Member States representatives:

Not Applicable.

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA), Alberto Linguadoca (ALB), Alessio Ippolito (AI), Gabriella Fait (GF)



PESTICIDES PEER REVIEW UNIT

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Residue decline – Appendix O

The remaining comments on Appendix O were discussed and addressed by the WG.

4.2. Other exposure issues

The WG discussed and agreed several issues relating to the exposure assessment. The definition of the off-crop area where the risk assessment for small mammals is needed was discussed. It was agreed to ensure that the guidance clearly indicates the 'evaluation area/zone'. This should be reflected in the problem formulation section. Related to this, the comments received on the deposition value in the off-crop area were discussed. It was acknowledged that in reality the deposition value is variable, but the chosen value was considered to be a reasonable estimation for the risk assessment for small mammals since their presence is also reliant on the availability of sufficient plant coverage. For consistency reasons, it was also agreed to reflect that an off-crop risk assessment may be needed in the case of seed treatments when agreed dust-drift deposition values are available. Several additional comments related to the exposure assessment for seed treatments were discussed and agreed.

5. AOB

None.

6. Next meeting

The next tele-meeting will be in May.



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 26th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on the 14th of March 2022

(Agreed on 30th March 2022)

Participants

- Working Group Members:
Theo Brock (TB)
Emily McVey (EM)
Pierre-François Chaton (PFC)
- European Commission and/or Member States representatives:
Not Applicable.
- EFSA:
Pesticides Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA), Alberto Linguadoca (ALB)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Follow-up actions – Ecological field studies

The working group discuss the comments on the field studies (focal species, PT, PD and field-effect studies). The clarifications which were sought at the previous WG meeting with the hearing experts were also discussed. The WG agreed the sections of the draft guidance which will be modified.

The WG was also informed of some additional comments on Section 6 and 7 which were not submitted during the public consultation owing to a technical issue related to the new EFSA tool. Given the circumstances, as an exceptional case, the WG are asked to also address these comments.

4.2. Update on the revision of the EFSA Scientific Committee Guidance Document on benchmark dose modelling

The working group were presented a summary of the revised EFSA Scientific Committee Guidance Document on benchmark dose modelling.

5. AOB

None.

6. Next meeting

The next tele-meeting will be in April.



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 25th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on the 18th of February 2022

(Agreed on 9th March 2022)

Participants

■ Working Group Members:

Theo Brock (TB)

Emily McVey (EM)

Ana Lopez Anita (AL)

Pierre-François Chaton (PFC)

Alf Aagaard (AA)

Phillipe Berny (PB)

■ Hearing Experts:

Maria Benito (Agenda items 4.2 to 4.8 only)

Ralf Dittrich (Agenda items 4.2 to 4.8 only)

Jan-Dieter Ludwigs (RIFCON) (Agenda items 4.2 to 4.8 only)

Tina Grimm (RIFCON) (Agenda items 4.2 to 4.8 only)

■ European Commission and/or Member States representatives:

Not Applicable.

■ EFSA:

Pesticides Peer Review Unit: Maria Arena (MA) (Chair), Rachel Sharp (RS), Alberto Linguadoca (ALB)



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Discussions of questions to be raised

The WG discussed the questions which were to be asked to the hearing experts.

4.2. Background and introduction

The Chair welcomed the hearing experts and introduced the meeting. It was explained that the purpose of the meeting was to ask for clarifications and further explanations on the comments the experts submitted during the public consultation specifically related to bird and mammal field studies. Prior to the meeting the Working Group had identified the need for further explanations and as such developed a number of questions. Those were asked and orally replied by hearing experts during the meeting.

4.3. General issues for field studies

The WG posed several questions in response to the comments received in the public consultation regarding the text in the draft guidance document related to characterising the landscape. It was specifically asked whether the list of examples of parameters which could be used to characterise the landscape for birds and mammals could be realistically measured. The hearing experts indicated that these parameters could be measured but, in their opinion, the specific parameters measured should depend on the study objective and species of interest. It was also indicated that it would be more reasonable to indicate which parameters, and to what level of detail, should be measured for each study type. The hearing experts expressed concern that providing examples without clear instructions can lead to variable interpretations.

It was indicated that discussion with Member-State Competent Authorities has been useful to reach the final decision on site selection. The hearing experts suggested that such discussions should be encouraged.



It was also discussed whether food availability could be measured in field studies. The hearing experts indicated simple assessments could be done relatively easily but, to obtain detailed data, extensive assessments would be needed.

Regarding the characterisation of the agronomic conditions/practices undertaken during the study, it was questioned what type of data are normally obtained and what other types of information could be collected. The hearing experts noted that the type of information collected depends on the study objective and specific conditions of the study. It was suggested that the type and quantity of data needed to be collected should be balanced with the study objective and how the study will be used for risk assessment. It was also reflected that under GLP, study directors should record anything which 'may influence the outcome of the study'.

Methods for deriving a reasonable number of field sites was also discussed. The hearing experts again reflected that this is dependent on the study type. It was suggested that the results of PT studies usually are more consistent whereas for studies used to define focal species a higher number of sites was needed since there was greater spatial variability.

4.4. Focal Species

It was questioned whether there are any additional methodologies or types of observations that could be done in order to define appropriate focal species. One of the hearing experts suggested that focal species could be pre-defined without the performance of additional field studies using existing data and expert knowledge. However, given the number of crops and locations the guidance document needs to cover, it was noted that this would be an extensive task and data is lacking. It was suggested that other methods such as assessing the frequency of foraging could be an alternative to the assessment of time on the field. It was also suggested that additional clarity is included in the guidance document for the definition of a vulnerable species used to define focal species. It was also suggested the ratio between the number of sightings in the off-field relative to the in-field area can be used to understand which birds forage more in-field and would be a good candidate as a focal species. It was also suggested that the definition of focal species could be enhanced by performing a dedicated literature review to substantiate the field studies and to reduce the chances of needing to consider additional focal species identified by the RMS. It was also reflected that it is more helpful to precisely indicate what data are expected to be collected.

It was also questioned whether any additional considerations should be done for focal species field studies to ensure that migratory species are appropriately captured. The hearing experts replied indicating that migratory species should be appropriately covered assuming the study was performed at the correct time of year and location. There is good data for migratory routes and therefore it is relatively simple to understand whether the conditions of the study capture migratory species.

4.5. PT field studies

It was questioned whether the experts had recommendations for characterising the conditions for PT field studies above those already discussed under point 4.2, above. The hearing experts responded indicating that the approach given in the draft guidance document for minor uses, whereby the percentage of the crop of interest in the landscape should be above a defined value, was a logical recommendation. It was suggested that this could be extended to all crops. It was also suggested that it would be feasible to provide specific data on the development of the crop in the general study area, in order to prove that the PT values were obtained in a landscape with availability of the crop/BBCH stage of interest.



It was also noted that thermal imaging can be useful for small mammal species who visit the field edges.

The hearing experts reflected that the site selection for the field work was critical and, often, compromises had to be made. Again, the hearing experts considered that discussion with the MS competent authorities is useful for the site selection.

It was questioned whether and how individuals with a PT value of 0 could be used for deriving a realistic worse-case PT value for the risk assessment. The hearing experts suggested that the criteria given in EFSA (2009) could be maintained and individuals who are caught on the crop can be considered as active on the crop and could be included in the calculation of PT. It was further noted by the hearing experts that the treatment of 'non-consumers' caught in the crops did not seem to be harmonised between risk assessors.

The WG also sought clarification on the comments received regarding the independence of PT values from repeated sessions of the same individuals. One of the hearing experts indicated that they were the author of a study which was due to be published in the scientific literature in the near future. It was explained that this paper makes proposals to address this issue and makes suggestions of how the data can be applied in risk assessments according to EFSA (2009).

4.6. PD field studies

The Working Group asked whether the hearing experts could elaborate on the comments made during the public consultation. Specifically, it was requested if the hearing experts could explain whether there are additional methodologies which can be used to assess the dietary composition and how can be it ensured that the data are relevant for the assessment. It was explained that animals are caught on the crop of interest, but it is still not reassured that animal had been foraging in the treated area prior to the assessment. Methods such as DNA sequencing could be useful for identification of the food items, but it is not able to address the concern of whether the animal had been foraging in the crop of interest. The hearing experts noted that they had successfully overcome this issue for some species of small mammal by observing the location of the animals for a period of time before the assessment. It was not considered feasible to be able to accurately identify food items an animal is taking using video recordings for most crop scenarios (e.g., bare soil is an exception).

4.7. Effect field studies

For the comments received on the section of the guidance document describing the effect field studies the working group asked the hearing experts for clarification and examples of using the confidence interval approach for assessing the statistical power of regulatory field studies. It was reflected that, for some species, obtaining sufficient sample sizes was problematic and that there was a number of ethical considerations. One hearing expert noted that there are other statistical approaches which could be more appropriate for studies attempting to demonstrate the absence of an effect. It was also explained that they have run model simulations with data from other ecological studies (such a PT) with removing individuals to demonstrate the ability of the statistical method to show an effect.

Further clarifications were sought on the comments received suggesting nest monitoring as a useful approach to consider long-term effects in avian field studies. It was suggested that nest survival can be monitored and compared to untreated control and pre-application survival. The Working Group asked whether the hearing experts had considered if such methodology would be suitable for precocial species. It was replied that chicks could be marked and monitored but the suitability would depend on the endpoint of interest.



4.8. Additional methodologies

The hearing experts explained the advantages of using enclosure studies for some small mammal species. It was further reflected that study protocols were not always provided to the Member State Competent Authority at the time of submission of the dossier and it was suggested that these may help address some of the concerns of the evaluators. It was also suggested that it may be useful to discuss protocols with the Member State Competent Authorities prior to performing the study.

5. AOB

None.

6. Next meeting

The next tele-meeting will be in March 2022.



PESTICIDE PEER REVIEW UNIT

PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 24th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 17 January 2022 (teleconference)

(Agreed on 31 January 2022)

Participants

- Working Group Members:
 - Theo Brock (TB)
 - Emily McVey (EM)
 - Ana Lopez Anita (AL)
 - Pierre-François Chaton (PFC)
 - Alf Aagaard (AA)
 - Phillipe Berny (PB)
- European Commission and/or Member States representatives:
 - Not Applicable.
- EFSA:
 - Pesticide Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA)



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Uncertainty analysis

The WG discussed the draft uncertainty analysis for the Tier 1 risk assessment for sprays. Several suggestions for improvement and simplification were agreed. It was agreed to provide a more detailed consideration to those parameters which are more frequently refined in the higher tier steps.

4.2. Questions for hearing experts

Comments were received during the public consultation related to conducting and interpreting field studies. The WG noted that several of these comments would benefit from clarifications which could be done by inviting the commentor to a WG meeting as hearing expert. Consequently, the WG developed and discussed questions which could be raised for these specific points.

4.3. Recent issues which should be clarified in the GD

Several questions had been raised during the peer review of active substances which were considered relevant to the guidance document. These included the body weight of the GMS for mammals who consume potato tubers, ecological refinements for seed treatments, the averaging period for time-weighted average concentrations for seed treatments and the additive risk assessments for toxic metabolites and parent substances. These issues were discussed, and it was agreed that they need to be clarified in the revised guidance document.

4.4. Tasks and deadlines

The next tasks and deadlines were discussed and agreed.



5. AOB

Not applicable.

6. Next meeting

The next tele-meeting will be in February.



PESTICIDE PEER REVIEW UNIT

PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 23rd MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 29 November 2021 (teleconference)

(Agreed on 14 December 2021)

Participants

■ Working Group Members:

Theo Brock (TB)

Emily McVey (EM)

Ana Lopez Anita (AL)

Pierre-François Chaton (PFC)

Alf Aagaard (AA)

Phillipe Berny (PB)

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA), Gabriella Fait (GF)



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Comments from public consultation

The WG discussed the key issues identified in the comments received from the public consultation. Several topics were discussed in detail considering the comments received. In particular the WG identified some comments on the field study methodology for which further clarification would be needed. It was proposed that for these specific points of clarification the expert who provided the comment could be requested to attend a future WG meeting as a hearing expert. It was agreed that the WG would identify the relevant comments and develop the questions which will be asked to the hearing expert(s). These questions should be shared with the WG and discussed in the January meeting.

The strategy for responding to the comments and for updating the draft guidance in response to the comments was discussed. It was agreed that EFSA will allocate a suggested expert to each comment.

4.2. Uncertainty analysis of the Tier 1 methodology

As previously discussed, the WG will provide an assessment of the uncertainty of the tier 1 risk assessment methodology. Primarily the purpose of this is to provide information to risk assessors for the uncertainty analysis for higher tier assessments. It was also reflected that it may be useful to risk managers when considering the regulatory status of the guidance document. It was recognised that, for a number of parameters, e.g., RUD values, the level of uncertainty depends on the quantity of data available or whether a surrogate value had been used. Owing to the vast range of parameters, it was considered not practical to provide a complete uncertainty analysis for the tier 1. Therefore, for the parameters which have a variable amount of uncertainty the WG should just provide the background information so that it can be easily comprehended by the risk assessor when needed. It was agreed to draft the uncertainty analysis for spray applications for the January meeting.

4.3. Tasks and deadlines



The next tasks and deadlines were discussed and agreed.

5. AOB

The meeting dates for 2022 were agreed.

6. Next meeting

The next tele-meeting will be in January.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 22nd MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 13 and 14 September 2021 (teleconference)

(Agreed on 28 September 2021)

Participants

■ Working Group Members:

Theo Brock (TB)

Emily McVey (EM)

Ana Lopez Anita (AL)

Pierre-François Chaton (PFC)

Alf Aagaard (AA)

■ European Commission and/or Member States representatives:

Not Applicable.

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA), Gabriella Fait (GF), Laura Villamar (agenda item 4.6 only), Alberto Linguadoca (agenda item 4.4).



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the only change being the order of the discussion.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Additive RA document

The updated document was discussed, and the comments addressed. It was agreed to restructure the flow of the text for the guidance document by putting the decision scheme at the start of the section. The equation for 'combiTER' was also clarified.

4.2. Uncertainty and WoE

The updated document was discussed. Some text was modified, and the content was agreed by the WG.

4.3. Tier 1 formulae

It was agreed that it would be better for the user of the guidance document if the FIR calculations were included in the main section. The structure and updated formulae were agreed by the WG.

4.4. Residue per Unit Dose (RUD) values in fruit

An analysis of the data submitted by CropLife Europe was presented. Several questions were raised and discussed. It was agreed to group the data according to the crop groups which will be used for the tier 1 assessment. The analysis was agreed but it was decided that the data should be merged with those values in Lahr et al. (2018). It was therefore agreed that updated calculations of the geometric mean and 90th percentile values were needed. It was also agreed that the analysis should be reflected in the Appendix on deriving RUD values.

4.5. Selection of parameters for screening indicator model species



The background document and underlying equations were presented. The WG agreed on the parameters to be selected for the indicator model species.

4.6. Evaluation Tool for residue decline studies

The higher tier evaluation tool was presented, and the comments addressed. It was agreed that this tool will be included in the guidance document.

4.7. Structure of the Guidance Document and flow

The WG made some modifications to the structure of the document. Comments were discussed and resolved. It was agreed that EFSA will continue to clean the document and consult the members of the WG where necessary.

4.8. Tasks and deadlines

The next tasks and deadlines were discussed and agreed. The WG was asked to provide final comments by 17th September.

5. AOB

A proposal was discussed for surrogate crops for consideration of the tier 1 generic model species for those crops which were not already. Some changes were made based on previous experiences and the crop/plant structure. It was agreed that these would be reflected in the guidance document. The Appendix on GMS will need to be updated accordingly.

6. Next meeting

The next tele-meeting will be in November.



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 21st MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on the 16th of July 2021

(Agreed on 29th July 2021)

Participants

- Working Group Members:
Theo Brock (TB)
Emily McVey (EM)
Ana Lopez Anita (AL)
Pierre-François Chaton (PFC)
Alf Aagaard (AA)
- European Commission and/or Member States representatives:
Not Applicable.
- EFSA:
Pesticides Peer Review Unit: Maria Arena (MA) (Chair), Rachel Sharp (RS), Gabriella Fait (GF)

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the only change being the order of the discussion.



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, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. Additive RA document

The document was discussed, and the questions raised addressed. It was agreed that the text will be simplified as far as possible. Further actions were identified on the approach to estimate combined exposure. It was agreed that a revised document would be distributed for comment to the WG.

4.2. Granules

The document was discussed, and the remaining questions were resolved.

4.3. Seedling dilution factor

The document was discussed, and the comments were addressed. It was agreed that, owing to the relatively small data set used for the analysis, it would be more appropriate to take a worst-case value for the 21-day ftWA. The dilution factor was agreed. Follow up actions were identified and the document, which will be an Appendix to the GD, will be updated accordingly.

4.4. Avoidance

The document was discussed, and the comments were addressed. It was agreed that, once cleaned, the document could be considered as final.

4.5. Uncertainty

The document was discussed, and the comments were addressed. The general approach was agreed, and it was agreed that the document should be updated on the basis of the discussions.

4.6. Draft GD

The draft GD was discussed with regard to the structure and flow of the document. Several sections were identified as needing to be moved to an Appendix. Furthermore, it was considered that it would be preferential to move the higher tier effects sections to after the tier 1 assessment. The need for the additional Tier 0 was also rediscussed and it was agreed to revise the approach.

4.7. Tasks and deadlines

The next tasks and deadlines were discussed and agreed.



5. AOB

A proposal for how to use the information in the Tier 3 database was discussed. The WG noted some inconsistencies and agreed for the document to be updated on the basis of the discussion. A revised document will be circulated to the WG.

6. Next meeting

The next tele-meeting will be in September.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 20th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on the 21st and the 22nd of June 2021 (teleconference)

(Agreed on 7th July 2021)

Participants

■ Working Group Members:

Theo Brock (TB)

Emily McVey (EM)

Phillipe Berny (PB)

Ana Lopez Anita (AL)

Pierre-François Chaton (PFC)

Alf Aagaard (AA)

■ European Commission and/or Member States representatives:

Not Applicable.

■ EFSA:

Pesticide Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA), Gabriella Fait (GF), Alberto Linguadoca (ALB), Alessio Ippolito (AI)) (agenda item 17), Laura Villamar (LV) (agenda item 17), Anne Theobald (AT) (agenda item 16)



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the only change being the planned timing of Agenda items 4, 13 and 16.

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

4. Scientific topic(s) for discussion

4.1. Follow-up on actions from previous WG meeting

The actions were discussed and addressed.

4.2. Introduction to field studies and focal species text

The documents were discussed, and the questions raised addressed. It was agreed that any generic information which is relevant for any type of ecological field study should be moved to the introduction section. It was agreed that further explanation needed to be provided for the number of study sites required.

4.3. Higher tier – effect field studies and evaluation tool for effect field studies

The document and evaluation tool spreadsheet were discussed. It was agreed that the WG should provide further comments on the section on nest monitoring section.

Regarding the evaluation tool, it was agreed that EFSA should ensure that the instructions tab and evaluation tab are appropriate and harmonised.

4.4. PD

The document was discussed, and the comments were addressed. It was agreed that some aspects of the document will be moved to the introduction section for field studies.

4.5. Population models

The document was discussed, and the comments were addressed. It was agreed that a revised document would be distributed for comment to the WG.

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



4.6. Seed availability

The document was discussed, and the comments were addressed. It was agreed that a revised document would be distributed for comment to the WG.

4.7. Dehusking

The document was discussed, and the comments were addressed. It was agreed that a revised document would be distributed for comment to the WG.

4.8. MAF x TWA tier 1

The document was discussed, and comments addressed. It was agreed to reflect the 21 day averaging period in the section on uncertainty.

4.9. Extrapolation factor for mammals

The document was discussed, and comments addressed. The background document will be used as an appendix to the guidance document. The section in the effect assessment will be updated with the agreed extrapolation factors for mammals.

4.10. Migratory bird text

The paragraph was discussed, and the comments were addressed.

4.11. Water scoping document

The document was discussed, and the comments were addressed. It was agreed that the scoping assessment did not negate the need for considering the puddle scenario in the risk assessment. Therefore, the suggested text for the guidance document will be used.

4.12. Metabolites

The document was discussed, and comments addressed. It was agreed to ensure that the terminology used for metabolites triggering further assessment should be harmonised with other guidance documents. The proposed scheme was agreed and the text will be used for the guidance document.

4.13. DT50 refinement and evaluation tool

The document was discussed, and the comments were addressed. It was agreed to add to the document to ensure that it also properly covered dissipation on treated seed.

4.14. Tasks and deadlines

The next tasks and deadlines were discussed and agreed.

5. AOB

Remaining questions on the previously discussed documents on refinement of PT and secondary poisoning were discussed and addressed. The concern regarding the feasibility of considering the avian breeding season was also addressed and the text amended. A discussion also took place on the background to the risk assessment for granular products. It was agreed that the section on granular products should be shared with the WG prior to the next meeting.

6. Next meeting

The tele-next meeting will be in July.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 19th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 19 and 20 April 2021

(Agreed on 5 May 2021)

Participants

■ Working Group Members:

Theo Brock (TB)

Emily McVey (EM)

Phillipe Berny (PB)

Ana Lopez Anita (AL)

Pierre-François Chaton (PFC)

Alf Aagaard (AA)

■ European Commission and/or Member States representatives:

Not Applicable.

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp (RS), Maria Arena (MA) (Chair) Gabriella Fait (GF), Alberto Linguadoca (ALB), Nusrat NOOR (NN), Monica del Aguila (MO)



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 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. Follow-up on actions from previous WG meeting

The actions from the last WG meeting were discussed and closed.

4.2. Update from Tier 1 exposure parameters

The Working Group (WG) discussed the relevant document for RUD and plant DT50. Some RUD values were updated. It was noted that still little data is available on RUDs on seeds. Regarding default DT50 values in plants, the WG discussed the available data and decided to align with the WG on the revision of the Bee GD.

4.3. Update on secondary poisoning

The WG discussed the proposed risk assessment for secondary poisoning to fish-eating, benthic invertebrates eating and earthworm eating birds and mammals. Particularly, the pertinent PEC that should be used to estimate the final daily residues in the relevant organism (i.e. fish, worm, benthic invertebrate). Another point of discussion was the type of information that should trigger spiked sediment bioaccumulation tests with benthic invertebrates. Concerns were raised that exposure through benthic invertebrates might be overlooked by having as a trigger bioaccumulation in fish tests. The WG further noted that an approach based on PECpore water would be the most appropriated to conduct a risk assessment for earthworm-eating birds and mammals but the model to calculate this value has not been implemented yet. Therefore, it was suggested to include both the pore water approach and the dry soil approach in the GD.

4.4. Exposure via water (including PEC pore water)

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



Appendix K and a document regarding drip irrigation were presented and discussed by the WG. The relevant crop groups for the leaf scenario under Appendix K were discussed and agreed upon. Care was taken with crop morphologies that could or could not be relevant for this scenario. Furthermore, the WG reflected on the exposure of birds to drip irrigation. The working group discussed the relevance of this scenario considering climate change and how it should be addressed in the risk assessment.

4.5. Text for tier 1 seed treatments – focused on changes/comments.

Following the previous meetings, a paragraph was included in this document regarding seedlings. The WG discussed this paragraph. Furthermore, a deviation between the soil and the Birds and Mammals GD was noted regarding maize seed size definition (is defined as a small seed in the soil GD and as a large seed in the B&M GD). The WG decided that the Bird and Mammals GD definition is more appropriated considering that only medium size birds will feed on maize seed and decide to reflect on the deviation with the soil GD.

4.6. Critical appraisal sheet – ecological studies

An excel file with reliability and relevance criteria to guide the risk assessors in assessing higher tier ecological studies was developed by the WG experts and was further discussed during the meeting. This excel tool will be further amended based on the WG discussion.

4.7. PT

During the meeting, the WG considered including few additional clarifications on the general recommendations and guidance on PT, PD, and focal species field studies in the GD document. Experts also agreed on the data required for the studies where at least one study was considered based on the eco-regions but not the EU zones. Therefore, they decided to include appropriate definitions in the glossary section to avoid further confusion. It was also decided in the meeting that the refinement of the PT studies (90th percentile) will be done only by the consumer species.

4.8. Tasks and deadlines

The next tasks and deadlines were discussed and agreed.

5. AOB

None.

6. Next meeting

The tele-next meeting will be in June.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 18th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 18 March 2021 (teleconference)

(Agreed on 6 April 2021)

Participants

■ Working Group Members:

Theo Brock (TB)

Emily McVey (EM)

Ana Lopez Anita (AL)

Pierre-François Chaton (PFC)

Alf Aagaard (AA)

■ European Commission and/or Member States representatives:

Not Applicable.

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp (RS), Maria Arena (MA) (Chair), Gabriella Fait (GF), Alberto Linguadoca (ALB), Mirza Nusrat NOOR (NN), Monica DEL AGUILA (MO)



1. Welcome and apologies for absence

The Chair welcomed the participants. The Working Group Member Phillipe Berny was not present in this meeting.

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. Follow-up on actions from previous WG meeting

The actions from the last WG meeting were discussed. Outstanding actions were transferred to the next meeting.

4.2. Update from Tier 1 exposure parameters

This agenda item was postponed to the next meeting.

4.3. Text for tier 1 exposure sprays and seed treatments – focused on changes/comments.

The Tier 1 exposure sprays and seed treatment documents were presented and discussed. As previously agreed by the WG, an off-field exposure scenario is necessary for small mammals. The WG noted that for cases where this scenario fails, the risk will have to be addressed by mitigation measurements. Furthermore, the updated equation for Tier 1 exposure assessment for products applied as seed treatments was presented and discussed. Finally, the WG agreed on a generic nomenclature to refer to the different terminologies in the Guidance and the supportive documents.

4.4. Generic Model Species (GMS) Appendix – clean remaining comments and finalise

This section was discussed, and comments were addressed directly in the document. It was agreed to change the terminology of ground-dwelling and foliage-dwelling arthropods to ground and foliage

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



invertebrates. Regarding the GMS species for earthworms-eating birds and mammals, the WG noted that small species only feed on earthworms when there are out on the surface (e.g. after rainy days) and therefore they might not be a good representative for a 100% worm diet. Furthermore, the WG considered possible default values for bananas and pineapple. Finally, the WG reflected that care needs to be taken when considering spray-drift buffer zones.

4.5. Granules - proposal

A short introduction was given on the topic. A proposal will be further developed.

4.6. Tier 3 PT

Comments in this section were addressed directly in the document. The WG discussed how to ensure that the PT studies represent a realistic worst case. It was reflected that care must be taken if a high amount of pesticides has been applied or if machinery (i.e. for applying pesticide or fertilizers) is used during the study.

4.7. Water intake

This agenda item was postponed to the next meeting.

4.8. Update on secondary poisoning

An update was given on the risk of secondary poisoning of birds and mammals feeding on aquatic invertebrates. It was pointed out that in aquatic invertebrates the exposure can be through sediment and water but probably the invertebrates living in the sediment will represent the worst-case exposure. Nevertheless, it was proposed to introduce a step on the risk assessment to ensure that the worst-case is chosen. Further considerations on the use of PEC_{pore} water for this scenario were discussed and actions were given to draft a proposal. Finally, the WG explored the possibility of developing a Tier 3 step for this scenario.

4.9. Update on plant DT50 refinement

This agenda item was postponed to the next meeting.

4.10. Next tasks and deadlines

The next tasks and deadlines were discussed and agreed.

5. AOB

None.

6. Next meeting

The next WG meeting will be in April.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 17th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 18 and 19 February 2021 (teleconference)

(Agreed on 8 March 2021)

Participants

- Working Group Members:
 - Theo Brock (TB) (chair)
 - Emily McVey (EM)
 - Phillipe Berny (PB)
 - Ana Lopez Anita (AL)
 - Pierre-François Chaton (PFC)
 - Alf Aagaard (AA)
- Hearing Experts:
 - Vanessa Mazerolles and Claire Blondel (agenda item 4.3 only)
- European Commission and/or Member States representatives:
 - Not Applicable.
- EFSA:
 - Pesticides Peer Review Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA) Gabriella Fait (GF), Alberto Linguadoca (ALB)



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 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. Follow-up on actions from previous WG meeting

The actions from the last WG meeting were discussed and closed.

4.2. Update from Tier 1 exposure parameters

The WG discussed the approaches for multiple application factors (MAF) and time-weighted average (TWA). It was agreed that a probabilistic approach for exposure would not be followed and that the tier 1 assessment should maintained a deterministic approach. For tier 2 refinements it was agreed that the guidance should be written in a way that did not prevent such approaches being used. Following the discussions, actions were identified for the finalisation of this section of the guidance and the associated appendices.

4.3. Presentation from contractors on the outcome of procurement extracting information from the ecological parameter data base

The hearing experts gave a presentation summarising the outcome of their task which was to extract and summarise the ecological parameters from the EFSA database collected by Lahr et al. 2018³. It was noted that key issue for using the ecological data presented is that, often, a wide range of growth stages were given without clarity of whether the data are relevant for all the growth stages i.e. for focal species studies – whether the bird or mammal was present throughout the monitoring period. Another point for consideration was whether improvements on the methodology for performing such studies would be made in this version of the guidance. It was furthermore noted, that information was

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

³ Lahr J, Krämer W, Mazerolles V, Poulsen V, Jölli D, Müller M, McVey E, Wassenberg J, Derkx R, Brouwer A, Deneer D, Beltman W, Lammertsma D, Jansman H, Buij R, 2018. Data collection for the estimation of ecological data (specific focal species, time spent in treated areas collecting food, composition of diet), residue level and residue decline on food items to be used in the risk assessment for birds and mammals. EFSA supporting publication 2018:EN-1513. 155 pp.



provided from studies undertaken in the Central and Southern zone. It was agreed that care must be taken to ensure that any recommendations to use this data are aligned with the tier 3 recommendations in the revised guidance. This was considered to be of particular importance for mammals.

4.4. Tier 3 higher tier ecological refinement. Identification of key issues to be addressed.

The WG briefly discussed the approach to identification of focal species and how the tier 1 risk assessment should inform the higher tier assessment. It was noted that there has been an issue in the past where the study author of focal species studies had put omnivorous animals into specific feeding guilds. It was agreed that the concept of generic model species and feeding guilds must be clearly explained and that care needs to be taken to avoid focal species being inappropriately excluded from higher tier assessments. Actions were identified to further develop the appendix for focal species identification.

The methodology for defining the proportion of diet obtained in the treated area was also discussed and actions were identified to further develop the appendix for focal species identification.

4.5. Tier 2 higher tier refinement. Identification of key issues to be addressed.

Refinement of degradation of substances in plant foliage was discussed and it was agreed to draft this section before proceeding to the other matrices. This should be discussed at the next WG meeting.

4.6. Secondary poisoning assessment.

It was noted that the need for an assessment of the potential for biomagnification has been replaced by the assessment of PBT (persistence, bioaccumulation, toxicity) in Regulation 1107/2009⁴. Nevertheless, the PBT criteria is only applicable to active substances. Therefore, it was agreed that some brief guidance should be given to how to approach such assessment for metabolites.

For the assessment of fish-eating birds and mammals, the WG agreed that there is a need to consider the appropriateness of the model species assumed for the tier 1 assessment. It was also noted that further clarification of the use of the time-weighted average exposure estimates and the appropriate averaging period should be given. A concern was raised as to whether the fish-eating bird/mammal assessment is sufficiently protective of other aquatic food chains. Actions were identified to consider this in more detail.

For the earthworm-eating bird and mammal assessment, the WG agreed that the appropriateness of the parameters for the model species assumed in the tier 1 assessment should be checked. It was agreed that a single methodology should be recommended for the exposure assessment. It was discussed whether the pore water approach could now be followed since the EFSA (2017)⁵ provides methodology for calculating the pore water concentrations. Actions were identified for revising this section of the guidance.

⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁵ EFSA (European Food Safety Authority), 2017. EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2017;15(10):4982, 115 pp.<https://doi.org/10.2903/j.efsa.2017.4982>



4.7. Exposure via residues in contaminated water

It was noted that a comment was received in the public consultation questioning the need for the puddle scenario for the risk assessment for bird and mammals from consumption of contaminated water given that this assessment very rarely indicates a risk. It was agreed to perform a scoping type assessment to assess the need to maintain such a scenario. However, for such an assessment it would be necessary to check the appropriateness of the methodology for the exposure assessment.

For the leaf axil scenario actions were agreed to revise this section of the guidance document.

A concern was raised regarding the use of drip-irrigation water containing pesticides in dry conditions. It was agreed to seek for evidence and, if appropriate, reflect this in the guidance for consideration.

4.8. Update on mammal tier 1 parameters

The background document for the selection of the tier 1 parameters for the mammal generic model species was discussed and actions for finalisation were identified.

4.9. Update on avian tier 1 parameters

The few remaining questions in the background document for the selection of the tier 1 parameters for the mammal generic model species were discussed and actions for finalisation were identified.

4.10. Tasks and deadlines

The next tasks and deadlines were discussed and agreed.

5. AOB

None.

6. Next meeting

The next tele-meeting will be in March.



PESTICIDES PEER REVIEW UNIT

MINUTES OF THE 16th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 25 and 26 January 2021 (teleconference)

(Agreed on 10 February 2021)

Participants

- Working Group Members:
 - Theo Brock (TB) (chair)
 - Emily McVey (EM)
 - Phillipe Berny (PB)
 - Ana Lopez Anita (AL)
 - Pierre-François Chaton (PFC)
- Hearing Experts:
 - Not Applicable
- European Commission and/or Member States representatives:
 - Not Applicable
- EFSA:
 - Pesticide Peer Review Unit: Rachel Sharp (RS), Maria Arena (MA) Gabriella Fait (GF)



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 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. Problem formulation, approach to tiered risk assessment and risk assessment strategy

The draft section on problem formulation was discussed. Comments were addressed directly in the document. It was agreed to include a paragraph to help risk assessors formulate the problem formulation for application methodologies which are not covered by the current guidance document.

The document on the tiered approach to risk assessment was finalised. The draft text for the risk assessment strategy for was discussed and comments addressed in the document.

4.2. Applications to crop stubbles

The background paper was presented and discussed, and it was clear that there are uses of pesticide products on crop stubbles and that they can be made throughout the year. Consequently, it was agreed to include this as a use in the revised guidance document. The 'bare soil scenario' included in the current version of the guidance document was noted to have caused problems for Member States risk assessors as it was assumed not to have weeds. It was agreed to have separate scenario for 'bare fallow' and also pre-emergent-field crops (i.e. BBCH – 10). It was discussed whether weeds would be present in pre-emergent field crops, however, the evidence presented indicated that, in some cases, weeds will be present. Therefore, it was agreed to assume in the tier 1 (which needs to account for all a wide range of situations) that weeds can be present. Member States may exclude the presence of weeds in a tier 2 risk assessment accounting for the specific situations in their Member State.

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



4.3. Exposure chapter and tier 1

The document on crop interception values was presented and discussed. Some comments were addressed directly in the document. Furthermore, it was agreed to use the same criteria, as already included in EFSA (2009), for when crop interception to weeds was relevant. It was noted that in some cases, data were lacking, and a surrogate crop interception value was considered. It was questioned if a tier 2 assessment, where more appropriate data are provided, is an option for refinement. It was agreed that this should be discussed with the fate and behaviour experts and the approach harmonised between the guidance documents.

The document containing the available revised residue values was finalised. It was agreed that this document should be developed into an appendix to the guidance document.

The draft text for the determination of the exposure estimate for spray applications and for seed treatments was discussed. Comments were addressed directly in the document. It was agreed that the text should be finalised and moved into the draft document.

The remaining questions in the background document on the tier 1 parameters for birds were discussed and addressed. It was agreed that the text for the appendix should be updated. The spreadsheet containing the tier 1 parameters for birds needs to be completed.

The mammal generic model species were also discussed. It was noted that the literature review had been performed but some tasks were remaining. It was also noted that there are many mammal species which do not enter into the field owing to the lack of crop cover. A concern was raised that if a risk assessment excludes certain generic model species then exposure in the field margin is relevant. It was acknowledged that, for all generic model species, there is the potential for exposure from residues in the field margin. However, normally, relative to in-field exposure, the exposure is considered to be negligible, except when in-field exposure is excluded for mammals. It was agreed that the finalisation of the tier 1 parameters for mammals was a priority.

5. AOB

The next tasks and deadlines were discussed and agreed.

6. Next meeting

The next tele-meeting will be in February.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 15th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 26 and 27 November 2020

(Agreed on 14 December 2020)

Participants

- Working Group Members:
 - Theo Brock (TB)
 - Emily McVey (EM)
 - Phillipe Berny (PB)
 - Ana Lopez Anita (AL)
 - Pierre-François Chaton (PFC)
- Hearing Experts:
 - Not Applicable
- European Commission and/or Member States representatives:
 - Not Applicable
- EFSA:
 - Pesticides Peer Review Unit: Rachel Sharp (RS) (chair), Maria Arena (MA) Gabriella Fait (GF)



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 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. Discussion on the proposals on the generic model species for birds

The background paper on the herbivorous bird generic model species was discussed. Specifically, there was a detailed discussion on the appropriate selection of the body weight for the feeding guild. It was noted that the species included in this feeding guild are not uniformly distributed in Europe and, in some cases, only present for some periods of the year. It was agreed to provide further consideration for the need for medium herbivorous birds. Furthermore, a concern was raised regarding the assumed dietary proportions for omnivorous birds during the winter months as there is evidence that some birds will switch to a predominantly herbivorous diet during the winter. This will be further considered for the omnivorous bird feeding guild. It was agreed to finalise the background document.

The background paper on insectivorous birds was discussed and the body weights for the generic model species for each crop group were agreed. It was noted that birds feeding on flying insects are assumed to be covered by those feeding on foliar-dwelling insects. However, this must be reflected in the section for focal species selection.

The background paper on frugivorous birds was discussed and the body weights for the generic model species for each crop group were agreed.

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



4.2. Discussion on the proposals on the generic model species mammals

The background paper on mammals was presented and the body weights for the generic model species were discussed. It was agreed that further evidence would be collected to support the proposed bodyweights for mammals.

4.3. Finalisation hazard sections

The available documents for the hazard section were discussed. It was agreed to share the text on benchmark dose modelling with EFSA colleagues from the Scientific Committee to ensure consistency. The sections on biological relevance, information from literature, endpoint selection and long-term mammal endpoint were briefly discussed. These sections should be finalised by the end of the year. It was noted that the section for the extrapolated endpoints in the case of low acute toxicity substances needs to be considered by the WG at the next meeting.

4.4. Protection goal document

The section on protection goals was discussed and finalised.

4.5. Approach to Tiered Risk Assessment

The text on the approach to tiered risk assessment was discussed in detail. It was noted that the screening step according to the EFSA (2009) guidance document did not meet the definition in the proposed text. It was agreed for EFSA to further reflect on this and propose a solution so that there is consistency between EFSA Guidance Document but information given from the current format of the screening step is not lost. It was agreed that following the generic text there will need to be some further text detailing how the approach is applied to the risk assessment for birds and mammals.

5. AOB

Crop groups forestry and ornamentals:

The proposed crop groups forestry and various ornamentals were discussed. It was noted that the selection of appropriate risk assessment parameters for ornamental crops can be problematic for risk assessors as ornamentals can cover such a wide variety of plants and growing practices. It was noted that the use of the BBCH growth stages only provides limited information as the plant structure can vary widely. In principle the proposed groupings were agreed but it was suggested that there was further differentiation for bulb ornamentals as these are considered to be more comparable to onions relative to other ornamental plants. Some other ornamentals can be better grouped with other crops



for the purposes of the risk assessment, due to similarities in crop structure and interception at various growth stages. For forestry uses, the generic model species will need to be specific for these uses.

Feedback and discussion on the ECPA database for fruit residue values:

Feedback was given to the WG regarding the discussions with the hearing expert from ECPA who attended the 14th WG meeting. At this meeting the questions raised regarding the ECPA residue database on fruits were discussed. The hearing expert provided some clarifications. However, the hearing expert informed the WG that the study authors/references were not included in the current version of the database and to add them would take a notable amount of time as there were multiple companies who provided data. It was noted that without the study references it cannot be ensured that there is no overlap of the data included in the database owned by EFSA <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1513>. The hearing expert also informed the WG that information as to whether the study has been evaluated by a Member State Competent Authorities or EFSA were not collected when compiling the database. Raw data had not been provided.

The WG considered that these issues are fundamental for transparency and ensuring the quality of the assessment as well as for an independent evaluation of the data. The WG acknowledged that the database is extensive, and the requested information could take time to gather. However, if the aforementioned issues cannot be resolved, then was considered that it would be inappropriate to use the data as presented. It was suggested that the fruit items, gourds and berries, could be prioritised as for these matrices few data are available in the database owned by EFSA <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1513>. The WG noted that it would be prudent to write the guidance in such a way would allow new, reliable and fully evaluated data to be used to improve residue values.

Tasks, deadlines and meeting dates 2021 were discussed and agreed.

6. Next meeting

The next tele-meeting will be in January.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 14th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 24 November 2020 (teleconference)

(Agreed on 4 December 2020)

Participants

- Working Group Members:
Not applicable.
- Hearing Experts:
Jorge Hahne (JH) (ECPA)
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Rachel Sharp (RS) (Chair), Maria Arena (MA) Gabriella Fait (GF)



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

Not applicable as no Working Group members were invited for the meeting.

Hearing Experts submit an ADoI in advance of a meeting to which they are invited. No DoI screening, assessment or validation is performed for ADoIs submitted by Hearing Experts.

4. Scientific topic(s) for discussion

4.1. Questions from the WG on the ECPA

The European Crop Protection Association (ECPA) had previously submitted to EFSA a data base summarising residue values in fruit. The database was welcomed by the WG; however, during the consideration, a number of questions were raised for which it was decided to invite a representative from ECPA for discussion. The questions were discussed in turn:

1. The excel file is dated 02/2019, is this the last version?

JH explained that there is an updated version submitted to EFSA in October 2019 which included some minor changes. Furthermore, JH noted that the data has been included in a publication Schabacker et al., 2020¹.

2. The actual name of the active substances, the study authors, and the year would be needed in order to avoid duplication of data and for allowing the WG to do an independent evaluation of any new data included compared to the database owned by EFSA <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1513>.

JH explained that some of this information was not currently included in the database. It was noted that this information could be added; however, to do so would take a substantial amount of time. It was acknowledged that avoiding the duplication of values in the database is essential for the appropriate combination of the ECPA data base and those included in the database collected in Lahr et al., 2018².

¹ Schabacke J, Hahne J, Ludwigs J, Vallon M, Foudoulakis M, Murfitt R, Ristau K, 2020. Residue levels of pesticides on fruits for use in wildlife risk assessment. Integrated Environmental Assessment and Management 2020:1–10

² Lahr J, Krämer W, Mazerolles V, Poulsen V, Jölli D, Müller M, McVey E, Wassenberg J, Derkx R, Brouwer A, Deneer D, Beltman W, Lammertsma D, Jansman H, Buij R, 2018. Data collection for the estimation of ecological data (specific focal



3. Some selection criteria are reported in the excel file, such as: GLP-studies conducted in EU during the last 20 years, trials evaluated by EU member state authorities, trials with one or more applications considered. However, it should be clarified whether other quality criteria were used for the selection of the studies.

JH explained that quality criteria were applied to the data included in the database. The studies would have been deemed valid according to the test guideline used for performing the study. It was questioned whether it was possible to link each of the studies to an evaluation by a Member State Competent Authority. However, this was not possible with the database in the manner it was compiled.

4. For the group 'grapes' and 'large fruits from orchards' only trials with 1 application are considered. Is this correct?

JH confirmed that this was correct.

5. For the groups 'other berries', 'gourds', 'small fruits from orchards, and 'strawberries' studies with one or more applications are considered and the residue values after the last application taken for the evaluation. Is this correct?

JH confirmed that this was correct.

6. Which matrices were analysed (e.g.: whole fruit, peel, fruit without peel, flesh after stoning)?

JH could only confirm the matrix for the data provided by Bayer. These were:

Citrus: whole fruit

Melon: whole fruit

Stone fruit: whole fruit

Grapes: either single berries or bunch of grapes (did not make a difference, therefore both were included)

7. Does the column 'crop' correspond to the matrix analysed?

It was confirmed that this is correct. If the crop is mentioned, then this indicates the matrix.

8. Which is the meaning of the column 'indication'?

This column refers to the type of pesticide (I= insecticide, F = fungicide).

9. For some data for cucumber and melon it is specified that data are related to the whole fruit, and then it is not clear which matrix was analysed for the other data.



JH conformed that, for the data submitted by Bayer, the data refer to the whole fruit. It was acknowledged that some of the naming in the database was inconsistent owing to the multiple contributors.

10. Does the column 'RUD' only reflect values at DALT0?

JH indicates that it can also refer to the highest measured residue after the last application.

JH provided an analysis of Residue per Unit Dose (RUD) values derived according to the data in Lahr et al., 2018. It was noted that the data was relatively aligned with those derived using the ECPA database but not with the values in the EFSA (2009) Guidance Document. It was noted that the RUD values derived had excluded non-GLP data included in Lahr et al., 2018. However, it was noted that this approach will not be followed by the WG who consider that non-GLP data, meeting the appropriate, quality criteria will be used for deriving RUD values.

It was explained that the WG will further consider the ECPA database for residues in fruit on the basis of the feedback provided at the meeting.

5. AOB

Not applicable.

6. Next meeting

The next tele-meeting of the WG will be 26/27th of November.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 13th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 19 October 2020

(Agreed on 2 November 2020)

Participants

■ Working Group Members:

Theo Brock (TB)

Emily McVey (EM)

Phillipe Berny (PB)

Ana Lopez Anita (AL)

Alf Aargard (AA)

Pierre-François Chaton (PFC)

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp (RS) (chair), Maria Arena (MA) Gabriella Fait (GF)



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 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. Planning and timelines

The planning and timelines were presented and discussed.

4.2. Structure and contents

The structure and overview of the guidance document was discussed and agreed. Several suggestions were integrated into the document.

5. AOB

None.

6. Next meeting

The next tele-meeting will be on 26 and 27 November 2020.

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 12th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 15 September 2020 (teleconference)

(Agreed on 2 October 2020)

Participants

- Working Group Members:
 - Theo Brock (chair)
 - Emily McVey
 - Phillipe Berny
 - Ana Lopez Anita
 - Pierre-François Chaton
 - Alf Aagaard
- Hearing Experts:
 - Not Applicable
- European Commission and/or Member States representatives:
 - Not Applicable
- EFSA:
 - Pesticide Peer Review Unit (PREV): Rachel Sharp (RS), Maria Arena (MA) Gabriella Fait (GF)



1. Welcome and apologies for absence

The Chair welcomed the participants. It was reported that Joe Crocker had informed EFSA that he was resigning from the WG. The Chair and WG wished to thank Joe for the work and knowledge he had already contributed.

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. Update from EFSA on planning

Considering the complexity of the project, including the on-going debate on SPG, EFSA requested for the WG reanalyse the priorities and to discuss in the next WG meeting. The current planning of the activities will be revised if needed.

4.2. Update from the hazard assessment subgroup

The WG members discussed the available background documents. It was agreed to finalise these documents as a priority. Several additional sections were identified to need to be drafted. The responsibility for these were allocated to WG members.

4.3. Update from the bird subgroup

The WG members discussed the available background document. It was considered that this document would be useful to be included in the clarified guidance document and the diet of the generic model species updated accordingly.

4.4. Update from the mammal subgroup

The WG discussed the progress of the sub-tasks for the risk assessment for mammals.

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



4.5. Update on the tier 1 residue values

The questions for a hearing expert were presented and explained.

4.6. Allocations of tasks and deadlines

Tasks were not identified but will be subsequently discussed when the new planning is finalised.

5. AOB

None.

6. Next meeting

The next tele-meeting will be in October.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 11th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 6 and 7 July 2020 (teleconference)

(Agreed on 17 July 2020)

Participants

■ Working Group Members:

Theo Brock (chair)

Emily McVey

Phillipe Berny

Joe Crocker

Ana Lopez Anita

Pierre-François Chaton

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticide Peer Review Unit: Rachel Sharp, Maria Arena, Gabriella Fait, Fernando Álvarez (for part of the discussion under agenda item 4.2 only)



1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alf Aagaard who could not attend the WG meeting.

The Chair also welcomed a new WG member, Pierre-François Chaton who is an experienced risk assessor working in the ANSES, the French competent authority for pesticide risk assessment.

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. Update from the hazard assessment subgroup

The WG members discussed the available background document which had been circulated for comment prior to the teleconference. It was agreed to finalise these documents as a priority. Several additional sections were identified which need to be drafted. The responsibility for these were allocated to WG members.

4.2. Update from the bird subgroup

The WG members discussed the available background document which had been circulated for comment prior to the teleconference. Several the questions raised in the document were addressed. It was agreed to update the document based on the discussions.

4.3. Update from the mammal subgroup

The WG discussed the progress of the sub-tasks for the risk assessment for mammals. Several topics were identified to need data collection.

4.4. Update on the tier 1 residue values

An update was given to the WG on the RUD values. Several questions were identified relating to the ECPA data base for residues in fruits. It was therefore agreed to invite a hearing expert to address

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



some of the identified questions. An update on crop interception values was also given but not discussed; it was agreed that these should be discussed at the next WG meeting.

4.5. Follow-up discussion on granular products – feedback from SEU

This item was not discussed and will be rescheduled for discussion at the next WG meeting.

4.6. Allocations of tasks and deadlines

Tasks and related deadlines were identified and allocated.

5. AOB

None.

6. Next meeting

The next tele-meeting will be in September.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 10th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 31 March, 3 April and 21 April 2020 (teleconference)

(Agreed on 30 April 2020)

Participants

■ Working Group Members:

Theo Brock (chair)

Emily McVey

Alf Aagaard

Phillipe Berny

Joe Crocker

Ana Lopez Anita

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticide Peer Review Unit: Rachel Sharp, Maria Arena (31 March and 21 April only), Gabriella Fait (3 April and 21 April only)



1. Welcome and apologies for absence

This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

The Chair welcomed the participants. The Chair informed the participants that Mark Clook is resigning from the Working Group.

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. TWA criteria (discussed on the 31 March)

The WG members discussed the available background document which had been circulated for comment prior to the teleconference. Several the questions raised in the document were addressed. It was agreed to update the document based on the discussions.

4.2. FIR/bw impact analysis (discussed on the 31 March)

The WG discussed the available background documents detailing the impact in the exposure estimate if smaller bodyweight values are used. It was agreed that further information needs to be sought before making a final decision on the body-weight values for the generic model species used in the tier 1 risk assessment.

4.3. Tier 1 Residue per Unit Dose (RUD) values for foliar sprays (discussed on the 3 April)

The WG discussed the RUD values calculated in the background document. Several issues were discussed and the WG made recommendations for how to address such issues. It was noted that data were lacking for several matrices and it was agreed to try and find additional data if available. The WG noted that if only few data were available then this should be acknowledged in the guidance document as an uncertainty. It was agreed to discuss the RUD values again after the recommendations by the WG are addressed.

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



4.4. Presence of insects in crops (discussed on the 21 April)

The WG discussed the data collected about the presence of pest insects in crops. Those data, if considered appropriate, might be used as surrogate for estimating for which crop and at which growth stage a scenario for insectivorous birds is relevant.

4.5. Granule risk assessment parameters (discussed on the 21 April)

A survey will be developed and administered to Member States to collect information about granular application. This information will be used to understand how to better revise the risk assessment for granules currently available.

4.6. TWA in risk assessment (discussed on the 21 April)

The WG discussed the appropriateness of the use of Time Weighted Average (TWA) based on the different types of endpoints for birds and mammals.

4.7. Follow up discussion on the RUD values (discussed on the 21 April)

The WG discussed the available database for the estimation of RUD values for different matrices.

4.8. Allocations of tasks and deadlines

Tasks and related deadlines were identified and allocated.

5. Any Other Business

The WG was informed that ECPA submitted information on initial residues in fruits. The WG agreed that the data will be checked and evaluated.

6. Next meeting

The next Tele-meeting will be in June.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 9th MEETING OF THE WORKING GROUP ON THE REVISION OF EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 10/11 February 2020

(Agreed on 25 February 2020)

Participants

■ Working Group Members:

Theo Brock (chair)
Emily McVey
Alf Aagaard
Phillipe Berny
Joe Crocker
Ana Lopez Anita

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp, Maria Arena, Gabriella Fait

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Mark Clook.



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. Update on the development of the tier 1

The WG members discussed the workplan for revising the Tier 1 for spray applications and seed treatments for both birds and mammals. The tier 1 for granules was only briefly considered due to time constraints. All the activities, including gaps and areas needing clarifications or revisions, were identified and the methodologies for proceeding agreed. A number of background documents are already available. Timelines and priorities were set and agreed.

4.2. Update on the revision of the Hazard characterisation section

The WG discussed the progress on the revision of the hazard characterisation chapter. Many sections have already been drafted. The follow-up actions for finalising the chapter were discussed and timelines agreed.

5. Any Other Business

None.

6. Next meeting(s)

30th to 31st March 2020.

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



Secretarial notes from 9th WG meeting 10/11 February 2020

Notes were made directly in the background document:

<https://dms.efsa.europa.eu/otcs/llisapi.dll?func=ll&objaction=overview&objid=22972952>

ACTIONS

Priority issues:

Criteria and appropriateness of TWA – Emily

RUDs – EFSA

Occurrence of foliar insects

Efficacy/PPP authorisation of insecticides – Emily, Ana and Alf, Rachel

Look at NTA field studies – EFSA

Impact of BW and FIR – Joe for birds (step 1), Joe with support from Emily for Mammals

Template for the GD – hazard and tier 1. EFSA

PLAN OF ACTION:

Priority tasks to be done by WG as discussed above.

Template to be provided by EFSA – background section can be in note form and bullet points. Where text from the old guidance will be maintained – this should be copied in. The structure of the tier 1 can be included.

Second priority is to finalise the hazard section. Following this the WG can critically evaluate the proposed text and comment.

Protocol planning document:

- Hazard and tier 1 spray and seed treatment to be circulated to WG 20th Feb, comments (including whether additional sub-questions are needed) 2 weeks later
- Tier 1 granules, water intake and secondary poisoning to be circulated 20th Feb, comments (including whether additional sub-questions are needed) 2 weeks later
- Share granules examples
- Tier 2 protocol to be developed and circulated.

Next meeting – criteria for discussion, impact analysis for the FIR and bw, RUD values, occurrence of arthropods

TC – in April to discuss protocol for other tier 1 scenarios and then the tier 2.



PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 8th MEETING OF THE WORKING GROUP ON THE REVISION EFSA (2009) GUIDANCE DOCUMENT 'RISK ASSESSMENT FOR BIRDS AND MAMMALS'

Held on 19 November 2019 (Teleconference)

(Agreed on 3 December 2019)

Participants

- Working Group Members:
 - Theo Brock (chair)
 - Emily McVey
 - Alf Aagaard
 - Phillipe Berny
 - Joe Crocker
 - Ana Lopez Anita
- Hearing Experts:
 - Not Applicable
- European Commission and/or Member States representatives:
 - Not Applicable
- EFSA:
 - Pesticide Peer Review Unit: Rachel Sharp



1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Mark Clook.

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. Update the development of the tier 1 generic focal species

The WG members discussed the available background document (for birds) which had been circulated for comment prior to the teleconference. A number of the questions raised in the document were addressed. The methodology for checking and selecting the tier 1 generic focal species was agreed and it was also identified where further data need to be obtained. A discussion also took place regarding the body-weight values and mixed diet proportions for the generic focal species. It was agreed that these needed to be checked to ensure that the assumptions of the tier 1 generic focal species are protective of all birds in the feeding guild feeding within the crop. It was also agreed that information will be provided in the guidance to reflect which generic focal species are represented of EU Red List species.

It was agreed to update the document based on the discussions and initiate data gathering. On the basis of the discussions, the background document already available for mammals should also be updated and recirculated for comment.

4.2. Update on citizen science

The WG discussed the use of citizen science in the risk assessment. It was agreed that this is a promising area and could be a good source of data. Several issues were noted with the currently available data (e.g. granularity, information on the crop where the animal was sighted). It was agreed to further consider the use of citizen science data noting that it is unlikely that it will be suitable for use in the short-term.

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



5. Any Other Business

None.

6. Next meeting(s)

10th to 11th February 2020.

PPR / Pesticide Peer Review Unit

Minutes of the 7th Meeting of the Working Group on the revision EFSA (2009) Guidance Document 'Risk Assessment for Birds and Mammals'

Held on 9 - 10 September 2019, Parma

(Agreed on 20 September 2019)

Participants

■ Working Group Members:

Theo Brock (Chair)

Emily McVey

Alf Aagaard

Phillipe Berny

Joe Crocker

Ana Lopez Anita

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp



1. Welcome and apologies for absence

The Chair welcomed the participants. It was explained that Mark Clook could not attend the meeting or work on the guidance document until the 31st of October.

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. Indirect effects

The section on the assessment of indirect effects of pesticides was discussed and the comments in the document addressed. The Working Group agreed with the proposed conclusion that to properly address indirect effects in ERA a holistic approach, beyond the scope of Regulation 1107/2009, needs to be undertaken. It was agreed to make clear recommendations for the steps to be taken in the short-term (e.g. to consider when developing protection goals for non-target arthropods, soil organisms and non-target terrestrial plants) and long-term (e.g. landscape level and holistic approach). It was also agreed to try and identify any actions which could be taken to reduce the impact of indirect effects. It was also discussed whether a separate risk assessment scheme for pesticides used in an integrated pest management strategy should be developed (e.g. targeted spot applications). It was agreed to further consider whether this is feasible.

4.2. Recommendations for action following the publication of the PPR Panel scientific statement on the coverage of bats by the current pesticide risk assessment for birds and mammals

The background paper containing the proposals for how to integrate bat species to the risk assessment was discussed. With regard to the lack of data to exclude the higher sensitivity of bats relative to the test species was acknowledged but it was also noted that this issue is not exclusive to bat species but is also true for all wild mammals. It was agreed that this is a key uncertainty that should be reflected.

It was noted that the concern for risk via dermal exposure is also not exclusive to bats. It was agreed that the most appropriate way forward was to consider dermal exposure to birds and mammals in general. Therefore, it was agreed to firstly assess whether use could be made of

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



already available models (e.g. the US EPA Terrestrial Investigation Model³). If it is seen that there is potential for such models to be used, then an evaluation of the model against the criteria given in EFSA PPR Panel (2014)⁴ would be needed. It was also agreed to consider whether the acute dermal toxicity data submitted for the purposes of the toxicology assessment could be used as a screening to negate the need for a more detailed risk assessment.

The Working Group noted that it would also be prudent to consider whether and how to specify mitigation that could exclude exposure to bats (e.g. to ensure that applications do not coincide with bat foraging activity).

For the risk assessment to bats via dietary exposure, it was expected that there will need to be three tier 1 generic focal species covering different feeding strategies of bats.

4.3. Progress and focussed discussions on Work Package 5: Ecological information

The working group discussed the available background document for indicator species, tier 1 generic focal species and specific focal species. It was noted that the indicator species used at the screening step assumed a single food item and, in some cases, resulted in a more conservative than any of the tier 1 generic focal species. It was also questioned whether there was a benefit to performing a screening level assessment with indicator species as few substances were screened out with this methodology. It was therefore agreed to remove the screening step from the risk assessment methodology but if comments were received in the final public consultation then it would be reinstated.

The methodology for checking the currently selected tier 1 generic focal species was discussed and agreed that it should be developed further. It was noted that information on pest species can be informative for understanding the type of species which are relevant. It was agreed also to prioritise updating the Appendix on selecting specific focal species.

The Working Group discussed the appropriateness of using known pest species (e.g. common voles) as specific focal species. The Working Group acknowledged the apparent contradiction but, for numerous reasons, agreed that it would not be appropriate to exclude such species in the risk assessment. It was agreed that these reasons need to be clearly explained in the guidance document.

4.4. Degradation and TWA

The background document was discussed which outlined the discrepancy between the tier 1 risk assessment methodology in EFSA (2009)⁵, where degradation was accounted for, and that in EFSA (2013)⁶, where it is necessary to demonstrate that several criteria are met before degradation is accounted for in the exposure estimation. The reason for not accounting for degradation in the first instance is that there is a concern that long-term effects can be a result of short-term exposure. The Working Group discussed and acknowledged this discrepancy. It was noted that the 21-day averaging period for the time-weighted average factor (which accounts for the degradation of the

³ Available at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#tim>

⁴ 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

⁵ European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

⁶ 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, 268 pp. doi:10.2903/j.efsa.2013.3290



substance) has never been justified. The Working Group also noted that vertebrate testing should be avoided and that expecting applicants to demonstrate that there are no long-term effects from short-term exposure could open the door for additional studies. It was agreed to further consider this point at the next meeting.

4.5. Selection of endpoint for mammals

The document was discussed and agreed. It was considered better to move the descriptions of the studies to an appendix and leave the description of the endpoints together with a decision-making scheme in the main section of the guidance document.

4.6. Risk assessment for seed treatments

The exploratory risk assessment for dust-drift depositing on to the food items for birds and mammals in the field margin was discussed. It was agreed that the exposure values may need to be updated pending on the latest data and knowledge before the final publication of the guidance document. Based on the calculations presented, it was agreed that this route of exposure is not likely to pose a significant risk to birds and mammals. A sentence should be added to note that, in some exceptional circumstances, a risk assessment may be needed but this will be the exception rather than the norm.

The tier 1 assumptions were also discussed, and several recommendations were made for further consideration.

The paper on assessing the number of seeds on the soil surface following drilling and the foraging area needed to reach the toxicity endpoint divided by the assessment factor (the regulatory acceptable dose) was discussed. For several reasons, it was noted that it will be difficult to give clear guidance on deciphering the foraging area and using this information in a risk assessment e.g. landscape characteristics and ecological characteristics. It was also suggested that, for the acute assessment, it may be more appropriate to consider the exposure from a single feeding bout rather than the exposure for an entire day. EFSA (2009) already includes a section on a 'meal-size approach' but it was not commonly applied to risk assessment. It was noted that it will be necessary to clearly define what is a feeding bout and that it is not the equivalent to the number of seeds taken in a single visit. It was agreed that this suggestion should be considered further and discussed at a follow-up meeting.

The paper on dehusking was discussed and the comments addressed. It was agreed that, it should be made clear in the guidance that if dehusking is accounted for in a refined risk assessment, then a second specific non-dehusking species should also be considered in the risk assessment.

4.7. Allocation of tasks, deadlines and need for additional expertise

It was agreed to postpone the planned meeting in November to January 2020 to allow the Working Group to finalise the current tasks. The priorities for each member of the Working Group were summarised and agreed.



5. Any Other Business

No further points were discussed.

6. Next meeting(s)

Teleconference 19th November (PM)

PPR / Pesticide Peer Review Unit

Minutes of the 6th Meeting of the Working Group on the revision EFSA (2009) Guidance Document 'Risk Assessment for Birds and Mammals'

Held on 3 July 2019 (Teleconference)

(Agreed on 15 July 2019)

Participants

■ Working Group Members:

Theo Brock (Chair)

Emily McVey

Phillipe Berny

Joe Crocker

Ana Lopez Anita

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp



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 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. Update from the discussions with the hearing expert for uncertainty

An update from the discussions held at the 5th working group meeting (26th and 27th June) on integrating the uncertainty into the guidance document was given. It was explained that one of the key elements is to ensure that the risk assessment methodology is calibrated against the management objective (the specific protection goal). It was explained that in the absence of suitable robust field data or population modelling then a solution could be to perform a series of Expert Knowledge Elicitation (EKE) exercises. Performing such EKE sessions would add to the time and resources needed for the update of the guidance document and therefore this will be further considered by EFSA.

4.2. Comments endpoints for selection of endpoints from toxicology studies

An update on the discussions held at the 5th working group meeting (26th and 27th June) on the selection of endpoints for the risk assessment for wild mammals was given. It was agreed that any further comments on the document should be made available as soon as possible. Further discussions were also had on the way to consider effects at the organ level and carcinogenicity studies. The WG members who were not present at the 5th working group meeting agreed with the conclusions of the 5th working group meeting. It was agreed that the document should be finalised in the autumn.

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



4.3. Update from Work Package 5: ecological information

An update on the discussions and agreements made at the 5th working group meeting (26th and 27th June) on the ecological parameters was given. In particular the approaches to developing the methodology for the selection of the tier 1 generic focal species was explained. It was agreed that the methodology should also be applicable for selecting the tier 1 focal species for the seed treatment and seedling scenarios. It was noted that there should be consistency in the tier 1 generic focal species needed for the seedling scenario and for equivalent growth stages for the assessment of foliar sprays. It was agreed to add the selection of the tier 1 generic focal species for seed treatment and seedling scenarios to the list for checking. The tasks identified for the working group to check the current tier 1 generic focal species were agreed. It was noted that it is planned that the tasks should be completed for discussion in the November meeting.

4.4. Task allocation

A summary of the key tasks already identified was given. Further tasks and deadlines were discussed and agreed.

5. Any Other Business

None.

6. Next meeting(s)

9th - 10th September, Parma

PPR / Pesticide Peer Review Unit

Minutes of the 5th Meeting of the Working Group on the revision EFSA (2009) Guidance Document 'Risk Assessment for Birds and Mammals'

Held on 26 - 27 June 2019

(Agreed on 15 July 2019)

Participants

■ Working Group Members:

Theo Brock (Chair)

Emily McVey

Alf Aagaard

Joe Crocker

Mark Clook

■ Hearing Experts:

Andy Hart

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticides Peer Review Unit: Rachel Sharp for the entire meeting and Gabriella Fait, Alessio Ippolito, Csaba Szentes, Frederique Istace, Silvia Messinetti, Katri Saari



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 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. Integrating uncertainty discussion with hearing expert – part 1

A presentation was delivered outlining the background and needs for integrating the assessment of uncertainty into the revised Guidance document. One of the key points was that there was an uncertainty analysis performed on the risk assessment methodology already included in the current version of the guidance document. The guidance also includes the recommendation that an uncertainty analysis is performed as part of the overall risk characterisation for individual substances. Nevertheless, the uptake of including an explicit assessment of the uncertainties was low with only a few Member States routinely performing such assessments. The presentation also described several questions posed to the hearing expert on uncertainty which had been formulated by the WG. It was explained that, in order to perform an uncertainty analysis of the standard procedure (approximately equivalent to the tier 1 risk assessment), in line with the recommendations of EFSA Scientific Committee (2018), the risk assessment methodology needs to be appropriately calibrated against the management objective (i.e. the specific protection goal). Ideally, this calibration would be based on data on actual effects in the field (as for the acute birds calibration in the existing guidance) or population modelling of effects. In the absence of such data or modelling then it is possible to perform a series of Expert Knowledge Elicitation (EKE) exercises (EFSA 2014). These EKE exercises would aim to elicit structured judgements from a group of carefully selected experts to assess how well the risk assessment methodology addresses the management objective, including accounting for the uncertainties involved. If necessary, the procedure can be an iterative process where the risk assessment methodology and associated assumptions are adjusted until the EKE exercise reaches a positive conclusion. Once a properly calibrated risk assessment methodology was available then risk assessments following the standard procedure would not need an assessment of the uncertainties for individual substances. If, however,

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



risk assessments deviated from those standard procedures (e.g. in the case of higher tier assessments, or if the first tier assessment was affected by non-standard uncertainties) then there would need to be a consideration of the uncertainties and whether the risk assessment, together with the associated uncertainties, were able to still reach the management objective.

4.2. Ecological endpoints for mammals

The WG discussed the comments received on the available document. The WG discussed on the approach to setting the ecotoxicologically relevant endpoint when effects on the organ are observed. It was suggested to focus on those endpoints which are directly relevant for the population but also reflect on those which are indirectly relevant e.g. as part of an uncertainty analysis. It was suggested that this approach would make the selection of the relevant endpoint as simpler and more consistent. It was agreed to provide guidance for considering when there are major effects on the organs which would be considered as relevant for the assessment of wild mammals.

4.3. Progress and focussed discussions on Work Package 5: Ecological information

A presentation outlining the key tasks for the experts involved in this work package was delivered. The WG agreed to maintain the general concept of performing a screening, tier 1 and higher tier assessment for an indicator, generic focal species and specific focal species, respectively. It was also agreed to remove the examples given for the tier 1 generic focal species as this has led to the misuse of these as specific focal species. It was agreed to develop an approach for the selection of the tier 1 generic focal species. This methodology should be then used to check the appropriateness of the current assumptions and to propose the appropriate generic focal species for any new crop scenarios. The allocation of the experts responsible for checking the generic focal species will be done once the methodology is agreed by the WG. It was also agreed that the assumptions for the diet will also be checked by the allocated experts. No concerns have been highlighted regarding the methodology used for Food Intake Rate (FIR) and therefore it was agreed just to add further information on the food items which are not sufficiently covered.

The WG also discussed the principles of using shortcut values in the tier 1 risk assessment. It was noted that the feedback on these was variable. It was agreed to ensure that the parameters used in the determination of the shortcut values are described in sufficient detail to ensure that the assumptions are transparent. It was also agreed to consider the feasibility of using Monte Carlo simulations for deriving the shortcut values.

The issue of long-term effects from short-term exposure was raised. It was noted that the approach in the EFSA (2009)³, where degradation is accounted for in the tier 1 long-term risk assessment as default, differs to the approach in the EFSA PPR Panel (2013)⁴. It was agreed that this should be discussed again at the next WG meeting and a background paper developed.

³ European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

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, 268 pp. doi:10.2903/j.efsa.2013.3290.



The possibility of developing tier 2 scenarios was also discussed. The WG experts noted that this is dependent on the availability of data to make such proposals. It was agreed that the first step is to summarise the information in the available data bases.

The issue of how to consider endangered species in the guidance was discussed. It was agreed to include a section in the guidance on this issue.

The data collection exercise for the juvenile and chick scenario was discussed and it was agreed that two experts would consider this issue further.

The need to determine whether there is exposure during the breeding season was raised during the public consultation. It was noted that Regulation (EC) No. 283/2013⁵ states that an avian reproduction study for birds is not necessary if an applicant demonstrates that there will not be exposure during the breeding season. However, no methodology for excluding exposure is available. The WG noted that there are several sources of information available to indicate the presence of breeding birds but a concern was raised of whether the granularity of the data would be sufficient. It was agreed, in line with the Regulation (EC) No. 283/2013, the default assumption should be that there is exposure hence an assessment is required. It was agreed to consider methodology for excluding exposure further.

4.4. Integrating uncertainty discussion with hearing expert – part 2

The WG expressed the view that it would be good to have examples of how EKE can be used to calibrate and assess the uncertainty of a risk assessment methodology similar to that included in the EFSA (2009) guidance document. No suitable examples are yet available, but it was noted that the approach is consistent with EFSA (2009) where the acute risk assessment for birds was calibrated using field data and an uncertainty assessment was performed using informal expert judgement, rather than a formal EKE process. A similar expert judgement approach was used to calibrate the acute risk assessment for mammals and the long-term risk assessments, although in those cases little or no field data were available and instead the calibration relied on expert assessment of whether the risk assessment methodology was likely to reach the protection goal defined in the guidance document. The feasibility of performing an example EKE exercise using an illustrative specific protection goal was discussed but it was explained that, in order to produce a meaningful example, preparatory work would need to be done. The steps needed to perform a calibration exercise using EKE were discussed in detail (following figure 12 of EFSA Scientific Committee (2018)⁶. It was noted that steps A-C and I in Figure 12 are part of the normal work of developing a guidance document. Step C is the fundamental step of ensuring that the management objective (specific protection goal) is sufficiently well defined. It was acknowledged that the definition of the specific protection goal is the responsibility of the risk managers and is currently being progressed by the Commission. Steps D-H are additional work required for calibration. The hearing expert emphasised that the way these were addressed could be scaled to fit within the time and resources available. The key steps are D (planning the approach) and E (the EKE process).

⁵ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Text with EEA relevance). <https://publications.europa.eu/en/publication-detail/-/publication/dc94d73e-2c9f-4a52-bbe1-c816eb499760>

⁶ EFSA (European Food Safety Authority) Scientific Committee, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Nøtveit H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Younes M, Craig P, Hart A, Von Goetz N, Koutsoumanis K, Mortensen A, Ossendorp B, Martino L, Merten C, Mosbach-Schulz O and Hardy A, 2018. Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):5123, 39 pp. <https://doi.org/10.2903/j.efsa.2018.5123>



The WG expressed concern that conducting case-specific uncertainty analysis for pesticides requiring higher-tier assessment could impose a large burden on assessors. It was explained that uncertainty analysis can always be scaled to the resources available: at minimum, when reaching a conclusion on a higher tier assessment in their normal way, assessors would also express their degree of certainty about the conclusion. To prepare them for this, assessors would need brief (1-2 hour) training in probability judgements, but this could be provided remotely by e-learning. Once trained, they could complete a minimal uncertainty analysis for an individual assessment in a few minutes. More refined uncertainty analysis could be considered in critical cases where more effort was justified.

Following the discussion with the hearing expert the WG considered the next steps for calibration and integrating the uncertainty assessment into the guidance document. It was acknowledged that, owing to the wide scope of the EFSA (2009) guidance document and the complexity of the risk assessment, if a calibration exercise was to be performed as described then this would add additional time and resources to the planned work. The WG also noted that it would be useful to have an exchange of views with the risk managers on this before. The WG expressed the view that having a properly calibrated risk assessment is desirable and therefore it was agreed for EFSA to discuss further with the Commission.

5. Any Other Business

No further points were discussed.

6. Next meeting(s)

Teleconference 3rd July (AM)

PPR / Pesticide Peer Review Unit

Minutes of the 4th Meeting of the Working Group on the revision EFSA (2009) Guidance Document 'Risk Assessment for Birds and Mammals'

Held on 15 May 2019 (Teleconference)

(Agreed on 29 May 2019)

Participants

- Working Group Members:
 - Theo Brock (Chair)
 - Emily McVey
 - Alf Aagaard
 - Phillipe Berny
 - Joe Crocker
 - Ana Lopez Anita
 - Mark Clook
- Hearing Experts:
 - Not Applicable
- European Commission and/or Member States representatives:
 - Not Applicable
- EFSA:
 - Pesticide Peer Review Unit: Rachel Sharp, Gabriella Fait



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 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. Agreement of the minutes of the 3rd Working Group meeting held on 26 – 28, March, 2019, Ede

The minutes of the 3rd Working Group meeting were agreed by written procedure on 15 April 2019³.

5. Update on project planning, prioritisation and actions from previous meeting

A detailed discussion took place where the tasks were allocated to separate 'work packages'. The experts responsible for the work package were allocated. The prioritisation of tasks was discussed and agreed. It was agreed that the allocated experts would start drafting the prioritised sections. Appropriate methods for gathering and appraising evidence were discussed e.g. following EFSA (2015)⁴. It was agreed that for the new topics to be considered a scoping review of the literature could be performed in order to ascertain the extent of the information and identify the appropriate manner to consider further.

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

³ <http://www.efsa.europa.eu/sites/default/files/wqs/pesticides/wq-Birds-Mammals.pdf>

⁴ EFSA (European Food Safety Authority), 2015. Scientific report on Principles and process for dealing with data and evidence in scientific assessments. EFSA Journal 2015;13(5):4121, 35 pp. doi:10.2903/j.efsa.2015.4121



6. Scientific topic(s) for discussion

6.1. Background document on uncertainty

The comments received on the background paper on uncertainty were discussed. It was agreed that the paper would be further developed and should be made available to the WG and the hearing expert 2 weeks before the next WG meeting.

6.2. Action plan for dermal and inhalation

Discussed under agenda item 5.

6.3. Juvenile scenario

Discussed under agenda item 5.

6.4. Update on progression of allocated sections

Discussed under agenda item 5.

7. Any Other Business

None.

8. Next meeting(s)

26th - 27th June, Parma

PPR / Pesticide Peer Review Unit

Minutes of the 3rd Meeting of the Working Group on the revision EFSA (2009) Guidance Document 'Risk Assessment for Birds and Mammals'

Held on 26 - 28 March 2019, Ede

(Agreed on 15 April 2019)

Participants

■ Working Group Members:

Theo Brock (Chair)

Emily McVey

Alf Aagaard

Phillipe Berny

Joe Crocker

Ana Lopez Anita

Mark Clook

■ Hearing Experts:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

Pesticide Peer Review Unit: Rachel Sharp, Gabriella Fait



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 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. Agreement of the minutes of the 2nd Working Group meeting held on 28-29 February 2019, Parma

The minutes of the 2nd Working Group meeting were agreed by written procedure on 8th February 2019.³

5. Scientific topic(s) for discussion

5.1. Update on ongoing actions

The working group was updated on the progress of the on-going activities. In particular, the importance of gathering information on available higher tier effect studies and population modelling was noted. It was noted that, in the long-term, having a suite of agreed population models for key focal/vulnerable species would most likely be the most appropriate way forward. It was acknowledged that this will not be possible in the timescale of the current project. Nevertheless, the recommendations made should be open for the possibilities of using population models. The WG discussed the need for additional expertise in higher tier effect studies, population models and statisticians. This expertise may be achieved by using hearing experts.

The WG were informed that the ICPS (Italy) have developed a draft guidance document for assessing the exposure and risks to non-target organisms in rice (in-draft not published). It was noted that it would be sensible not to duplicate their efforts and to integrate their proposals where possible.

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

³ <http://www.efsa.europa.eu/en/pesticides/working-groups>



5.2. Update and discussion on protection goals

The WG were informed of on-going activities on the development of protection goal methodology by DG SANTE at the Commission. It was noted that these activities may impact on the possibility to deliver the revised guidance document according to the current timelines. Nevertheless, it was agreed useful to finalise the document already drafted on protection goals. The comments made on the draft document by the WG members were discussed and resolved during the meeting.

5.3. Uncertainty

A background presentation was delivered which highlighted the importance, and need, for considering uncertainty in risk assessments under the current legislation for pesticides. There is also a need to provide an uncertainty analysis within the revised guidance document on the ability of the proposed methodology to meet the agreed protection goals. It was noted that the need for an uncertainty analysis was already included in the current version of the guidance document but the uptake from risk assessors was low. It was therefore agreed to try to understand the reasons for the low uptake and to address these in the revised guidance document. As previously agreed, a hearing expert on uncertainty in risk assessment will be invited to a future WG meeting. It was agreed that appropriate background documents will need to be available in time for the discussions with the hearing expert.

5.4. Relevance of endpoints (eggshell thinning example)

An update was given on the assessment of the methodology used to derive an ecologically relevant endpoint; eggshell thinning was used as an example. A suggested approach for challenging the level at which ecological relevance is assumed was discussed. The WG agreed with the analysis as presented and the suggested approach for challenging ecological relevance. It was agreed that this section should be developed further and included in the revised guidance document.

5.5. Selection of long-term endpoints (BMD)

The WG discussed the available EFSA external scientific report (Azimonti et al., 2015⁴) where BMD values were compared to statistically derived NOEL values. It was noted that, for the examples in the report, where the BMD could be determined, the lower limit of the BMD₁₀ value was lower than the NOEL value in 34% of cases. It was noted that the lower limit of the BMD₁₀ was the endpoint conventionally derived in toxicology and it would seem logical to be consistent. It was agreed to explain what uncertainty is addressed by using BMD. It was also noted that, in Azimonti et al., 2015, there were several cases where the BMD value could not be derived for birds; the reasons for this was questioned. The WG agreed that any recommendations for the use of the BMD values should not result in rejecting additional studies for this reason only (i.e. to ensure that the recommendations do not lead to additional vertebrate testing). It was agreed to further develop this section of the guidance document.

⁴ Azimonti et al., 2015. Comparison of NOEC values to EC₁₀/EC₂₀ values, including confidence intervals, in aquatic and terrestrial ecotoxicological risk assessment. EFSA supporting publication 2015:EN-906.274pp



5.6. Seed treatment section – progress and questions

The draft text written for performing the tier 1 risk assessment for pesticides which are used as seed treatments was discussed. It was noted that currently a SANCO guidance document on risk assessments for seed treatments is being drafted (in-draft not published). It was agreed to ensure consistency between the two documents where possible (e.g. definition of small and large seeds).

It was noted that exposure to birds and mammals is dependent on the availability of seeds which, in turn, is dependent on several parameters including the type of machinery used to drill the seeds. It was questioned whether the drilling machinery is specified in the Good Agricultural Practice (GAP) tables and treated seed labels. It was agreed that, where possible, the risk assessment methodology should account for the way the seeds will be sown. In unclear cases then the tier 1 risk assessment will have to include the worst-case conditions (i.e. broadcast sowing). It was agreed to try and develop methodology for performing studies to derive the number of seeds remaining on the soil surface which could then be accounted for in the risk assessment.

The WG discussed the likely routes of exposure to birds and mammals from pesticides applied as seed treatments. It was agreed that, if minor routes of exposure are to be excluded from the risk assessment, then this will need to be supported by evidence. The WG discussed the appropriateness of accounting for residue decline in the long-term risk assessments. It was agreed that this discussion was also relevant for other types of pesticide formulations (e.g. those applied as foliar sprays) and therefore should be considered together at a later date.

The WG discussed the risk assessment for birds and mammals consuming seedlings. It was agreed to further consider whether the birds and mammals consume only the vegetative part or whether the root and seed case are also consumed. This should be clarified in the revised guidance document. With regard to the selection of generic focal species for the tier 1 risk assessment, the WG agreed that this should be based on evidence from field studies. Overall, it was agreed to further develop this section based on the recommendations of the WG.

5.7. Indirect effects

The WG discussed the information available regarding risk assessments covering indirect effects of pesticides. The WG agreed that a review of indirect effects should be included in the revised guidance. It was noted that the UBA (Germany) had recently introduced methods to address indirect effects and the overall protection of biodiversity; it was suggested to seek further details and to consider in the revised guidance. It was also agreed to include a consideration of possible mitigation methods and their effectiveness.

5.8. Update on the RUD data base

An update on the progress made on the data bases for residues was given.

5.9. Update on the bat statement and assessment of dermal/inhalation exposure

A presentation was given on the key findings of the PPR Panel statement on whether bat species are sufficiently covered by the current risk assessment. The statement is current in the final stages of being drafted but is not yet publicly available. The WG discussed and agreed that a background paper needs to be developed for further consideration by the WG.



5.10. Update on draft sections

With regard to the consideration of historical control data for endpoint setting, an update on the analysis of the Valverde-Garcia et al 2018 paper was given. It was noted that this is a crosscutting issue relevant also for toxicology. It was suggested that it would be better to consider the use of historical control data, together with toxicologists, outside the guidance document for birds and mammals. The WG expressed concern that this may not be available in the short-term and therefore it would be better to give some considerations in the revised guidance. It was agreed to develop this section further.

The experts updated the WG on the progress of allocated chapters but no detailed discussions took place.

5.11. Identification of actions and sections for drafting

It was agreed to develop the already allocated sections further before making further allocations. It was agreed for EFSA to share the summary of on-going tasks.

6. Any Other Business

The WG was informed of two additional documents submitted by the European Crop Protection Association (ECPA). The WG agreed to consider these when drafting the relevant sections.

7. Next meeting(s)

Teleconference 15th May (AM).

Pesticides Unit

Minutes of the 2nd meeting of the Working Group on the revision EFSA (2009) Guidance Document 'Risk assessment for Birds and Mammals'

Held on 28-29 January, Parma, Italy

(Agreed on 8th February 2018)

Participants

- **Working Group Members:**

Theo Brock (chair)

Emily McVey

Alf Aagaard

Phillipe Berny

Joe Crocker

Ana Lopez Anita

Mark Clook

- **Hearing Experts:**

Not Applicable

- **EFSA:**

Pesticides Unit: Rachel Sharp, Gabriella Fait, Katri Saari, Silvia Messinetti

- **Others:**

Not Applicable

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 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. Agreement of the minutes of the 1st Working Group meeting held on 26-27 November, 2018, Parma

The minutes of the 1st WG meeting were agreed by written procedure on 10 December 2018.

5. Scientific topic(s) for discussion

5.1. Update on actions from the previous meeting

The status of the list of actions from the 1st WG meeting (November 2018) was briefly discussed.

5.2. Presentation and discussion on uncertainty

A presentation was delivered outlining the importance of assessing uncertainty both for the methodology that will be developed within the

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

guidance document and for individual assessments performed using the guidance document. The WG agreed that uncertainty was an integral aspect of the risk assessment and should be considered in the guidance document. It was noted that the need for an uncertainty assessment was already included in the 2009 version of the guidance document but the uptake from risk assessors and risk managers in the Member States was low. The reasons for this should be reflected upon and considered in future recommendations. It was agreed to invite a hearing expert with expertise in addressing uncertainty in risk assessment to a WG meeting. The precise questions to be asked and discussed with the hearing expert were agreed to be developed before the meeting.

5.3. Update and discussion on protection goals

The draft document on protection goals was discussed and comments were addressed. It was agreed that the document will be reviewed and circulated to the WG for further consideration. For the proposed specific protection goals, both exposure and effects assessment goals need to be defined.

The WG also discussed indirect effects of pesticides to birds and mammals. It was agreed to develop a background paper and to discuss at a future meeting.

In the context of calibrating the risk assessment methodology against the protection goals, it was agreed to collate available effects field studies for long-term effects and population models. If such data has been peer reviewed by EFSA and MS then the comments received should also be collected.

5.4. Bench mark dose modelling (BMD) approach to endpoint setting

The WG discussed the use of benchmark dose (BMD) modelling to set endpoints from long-term and reproductive studies which currently derive a NOEL value. The WG agreed that the BMD approach was a more appropriate method for setting long-term endpoints and can address some of the uncertainty with the setting of endpoints. Furthermore, it would help with ensuring consistency between substances. However, it was acknowledged that use of BMD for all long-term/reproductive endpoints for birds and mammals would be a change from the status quo and therefore would need clear justification. Concerns regarding the potential increase in workload for Member State risk assessors relative to the potential benefits were also raised. It was agreed to consider the

feasibility and benefit of recommending the BMD approach for setting endpoints.

5.5. Relevance of toxicity endpoints

A presentation of the studies, and endpoints derived from such studies, currently requested as part of the toxicology assessment for pesticides under Regulations 283/2013³ and 284/2014⁴ was given. It was noted that the current risk assessment for wild mammals uses endpoints based on parameters which are considered to be related to the reproductive success. The WG discussed whether additional chronic parameters should also be considered. It was noted that the duration of some of the studies performed for the human health assessment are long and may result in effects which are not relevant for wild mammals. It was further noted that there is a disparity between the endpoints used for risk assessment (based on individuals) and the current protection goal (for the population in long-term ERA). Consequently, there needs to be a judgement on which parameters on individuals are likely to translate to population level effects. It was agreed that any additional endpoints which are introduced should be accompanied by a justification and an estimate of the regulatory impact of introducing such parameters.

The WG acknowledged there was a discrepancy for the level of assessment requested for setting the endpoint for mammals relative to that for birds where only a single one generation study is available. The WG acknowledged that this is an issue and should be considered when assessing the ability of the risk assessment to address the protection goals. It was noted that test guidelines for more comprehensive studies in birds were not available nor were requested according to Regulations (EU) No. 283/2013³ and No. 284/2014⁴.

The WG discussed the use of historical control data for setting endpoints. The EFSA (2009) guidance document provides some information on the use of historical control data but further detail may be beneficial. It was highlighted that this issue was discussed in a recent paper by Valverde-Garcia et al. (2018)⁵. The WG noted that in general the historical control data should not be used to replace the concurrent control. The WG acknowledged that, owing to the low number replicates used for the avian reproduction studies, a high variability in control data is observed. It was agreed to include a consideration in the guidance document on the use of historical control data.

³ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32013R0283>

⁴ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32013R0284>

⁵ Valverde-Garcia et al. (2018), *Regulatory Toxicology and Pharmacology* 92 (2018) 295–302.
<https://doi.org/10.1016/j.yrtph.2017.12.004>

5.6. Documents provided by industry and other stakeholders

The WG discussed the availability of documents submitted by stakeholders. In particular several documents had been received from the European Crop Protection Association (ECPA). The WG agreed that these should be considered when developing the relevant sections. The WG also noted that a consultancy recently published a document with suggestions for improvements to field studies. Where useful the WG may refer to this document as grey literature.

5.7. Update on progress on allocated sections

The WG was updated with the status of allocated sections.

5.8. Continuation of brainstorming for sections not discussed in the November meeting

Not discussed.

5.9. Allocation of further sections

Additional tasks were allocated to the members of the WG.

6. Any Other Business

Not applicable.

7. Next meeting(s)

26-28 March, 2019, Ctgb, the Netherlands.

Pesticides Unit

Minutes of the 1st meeting of the Working Group on the revision of EFSA (2009) Guidance Document 'Risk assessment for Birds and Mammals'

Held on 26-27 November, Parma, Italy

(Agreed on 10 December 2018)

Participants

- **Working Group Members:**

Theodorus Brock (chair), Alf Aagaard, Phillipe Berny, Mark Clook (via teleconference), Joe Crocker, Ana Lopez Anita, Emily McVey

- **Hearing Experts:**

Not Applicable

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

Karin Nienstedt (DG SANTE.DDG2.E.4.002- via teleconference)
Sofie Hofkens (DG SANTE.DDG2.E.4.002- via teleconference)
Zsuzsanna Koenig (DG SANTE.DDG2.E.4.002 - via teleconference)

- **EFSA:**

Pesticides Unit: Rachel Sharp, Maria Arena, Domenica Auteri, Gabriella Fait

- **Others:**

Not Applicable

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 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 topics for discussion

4.1. Background and scope of the revision including the mandate and terms of reference³

The mandate and terms of reference were discussed. An overview was given of the regulatory framework for pesticides and the key aspects related to the hazard and risk assessments for birds and mammals. It was noted that, according to Regulation 1107/2009⁴, vertebrate testing should be minimised as far as possible.

4.2. Discussion on developing specific protection goals

An overview of the methods for developing specific protection goals (SPGs) was given. The WG members discussed the protection goals as outlined in the EFSA (2009)⁵ guidance document and agreed that they would need to be brought in line with the EFSA PPR (2010)⁶ Opinion on the development of SPGs. It was also agreed that exposure assessment goals (EAGs) would also need to be developed.

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

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00555>

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107>

⁵ <https://www.efsa.europa.eu/en/efsajournal/pub/1438>

⁶ <https://www.efsa.europa.eu/en/efsajournal/pub/1821>

The agreement of the SPG and (several aspects of) the EAG is for risk managers to decide. Therefore, it was noted that an open and iterative discussion with risk managers would be needed at an early stage of the development of the guidance document.

4.3. Available background documents

The WG discussed a number of background documents which will be considered as part of the development of the revised guidance. The WG members agreed that the comments received from the public consultation should be taken in to account during the revision. The WG members discussed whether the outcome of the ongoing PPR Panel statement on whether bat species are sufficiently covered by the current risk assessment methodology, would be considered during the revision of the guidance document.

4.4. Recently published literature

The WG members briefly discussed several papers which were already known to them which are relevant and should be considered as part of the revised guidance. It was also agreed that EFSA will perform a literature review capturing all relevant publications since the development of the last guidance document, noting that a number of them will have already been captured and considered as part of the data collection procurement (EFSA-Q-2015-0021)⁷.

4.5. Additional documents from ECPA

The WG was informed that ECPA had indicated that they had a number of studies and position papers which they would be willing to make available to the WG for consideration. It was agreed to request these papers together with the raw data.

4.6. Outline and structure of new guidance including new chapters

The preliminary proposed structure of the guidance was discussed and ideas were shared for the content of several of the chapters (background, introduction, SPGs and EAGs, risk assessment approach, effect assessment, tier 1 exposure assessment, tier 1 risk assessment).

⁷ <https://www.efsa.europa.eu/en/supporting/pub/en-1513>

Methodology for higher tier risk assessment is to be discussed at a later stage.

4.7. Allocation of tasks and chapters and timeline for deliver the first draft

The allocation of the lead authors for several chapters and subchapters was agreed.

4.8. Identification of information needed and additional expertise if required

It was agreed that EFSA will perform a literature review capturing all relevant publications since the development of the last guidance document noting that a number of them will have already been captured and considered as part of the data collection procurement (EFSA-Q-2015-0021). It was also agreed that EFSA will provide a review of information available for exposure via dermal and inhalation exposure. It was briefly discussed whether the need for additional expertise could already be identified. It was noted that specific expertise in characterising uncertainty is needed at an early stage of the drafting. It was suggested EFSA should discuss with risk managers to understand what their expectation is for integrating an analysis of uncertainty in to the risk assessment methodology.

5. Next meeting

28-29 January, 2019, EFSA.