



PPR / Pesticide Peer Review Unit

Minutes of the 4th WG meeting of the Working Group on setting of health based reference values for metabolites of the active substance terbuthylazine

Held on 1 March 2019 via Teleconference

(Agreed on 25 March 2019)

Participants

- **Working Group Members:**

Tamara Coja (Chair)
Olavi Pelkonen
Thomas Kuhl
Anneli Widenfalk

- **Hearing Experts:**

Not Applicable

- **EFSA:**

Pesticide Peer Review Unit & Pesticide Residue Unit: Dimitra Kardassi, Rositsa Serafimova, Anja Friel

- **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 2nd Working Group meeting held on 23 January 2019, via teleconference.

The minutes of the 3rd WG meeting held on 23 January 2019, via teleconference, were agreed.

5. Scientific topic(s) for discussion

5.1. Finalisation of the drafting of the Scientific Opinion

The draft scientific opinion was amended following comments of the EFSA Journal mainly of editorial nature. EFSA informed that on a bilateral TC that took place the same day between EFSA-SANTE, SANTE asked the PPR Panel WG to present the exposure calculations for all European scenarios and not only the two worst case scenarios. The draft opinion was revised to present additional exposure calculations for metabolites LM3 and LM6.

The opinion will be presented for adoption in April PPR Panel meeting.

6. Future meeting dates, teleconferences and physical meetings

No other meetings are foreseen.

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

PPR / Pesticide Unit

Minutes of the 3rd WG meeting of the Working Group on setting of health based reference values for metabolites of the active substance terbuthylazine

Held on 23 January 2019 via Teleconference

(Agreed on 12 February 2019)

Participants

- **Working Group Members:**

Tamara Coja (Chair)

Olavi Pelkonen

Thomas Kuhl

Anneli Widenfalk

- **Hearing Experts:**

Not Applicable

- **EFSA:**

Pesticide Peer Review Unit & Pesticide Residue Unit: Dimitra Kardassi, Rositsa Serafimova, Anja Friel

- **Others:**

Not Applicable

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4. Agreement of the minutes of the 2nd Working Group meeting held on 10 January 2019, Parma.

The minutes of the 2nd WG meeting held on 10 January 2019, in Parma, were agreed.

5. Scientific topic(s) for discussion

5.1. Presentation and drafting of the Scientific Opinion

The draft scientific opinion was updated during the meeting with the purpose to be distributed to the PPR Panel for written commenting after the PPR Plenary meeting in February 2019.

The presentation of the draft opinion in the PPR Plenary meeting was also discussed and agreed. The draft scientific opinion will be presented with a particular focus on the terms of reference as interpreted by the WG and the methodology followed to define the health based values. Also, particular attention will be paid to the uncertainty factors considered.

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

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

The draft scientific opinion will be scheduled for adoption by the Panel in the April Plenary meeting.

6. Future meeting dates, teleconferences and physical meetings

4th meeting date was agreed by all experts:

- 1 March 2019 (Teleconference)

PPR / Pesticide Unit

Minutes of the 2nd WG meeting of the Working Group on setting of health based reference values for metabolites of the active substance terbuthylazine

Held on 10-11 January 2019, Parma (Italy)

(Agreed on 23 January 2019)

Participants

- **Working Group Members:**

Tamara Coja (Chair), Thomas Kuhl (via teleconference), Olavi Pelkonen, Anneli Widenfalk

- **Hearing Experts:**

Not Applicable

- **EFSA:**

Pesticide Peer Review Unit & Pesticide Residue Unit: Dimitra Kardassi, Rositsa Serafimova, Frederique Istace, Anja Friel

- **Others:**

Not Applicable

1. Welcome and apologies for absence

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4. Agreement of the minutes of the 1st Working Group meeting held on 11-12 December 2018, Parma.

The minutes of the 1st WG meeting were agreed by written procedure on 18 December 2018.

5. Scientific topic for discussion

5.1. Presentation and drafting of the Scientific Opinion³

The methodologies and approaches used were discussed. The OECD QSAR Toolbox 4.2 was proposed to estimate chemical similarities (LM2-LM6 and terbuthylazine and characterised metabolites MT1, MT13 and MT14) to support read-across.

Where no RV could be derived application of TTC approach was investigated.

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²

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³ Link to the EFSA's register of questions
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00950>

According to Commission request, for those metabolites for which RV can be set, EFSA should calculate the consumer exposure – this is not part of PPR Panel mandate and is not further assessed in the Scientific Opinion. Exposure calculations where TTC approach may be used were discussed. Uncertainties in the assessment were identified. Investigation of other potential sources of exposure and literature data were presented.

6. Future meeting dates, teleconferences and physical meetings

3rd meeting date was agreed by all experts:

- 23 January 2019, TC

PPR / Pesticide Unit

Minutes of the 1st WG meeting of the Working Group on setting of health based reference values for metabolites of the active substance terbuthylazine

Held on 11-12 December 2018, Parma (Italy)

(Agreed on 18 December 2018)

Participants

- **Working Group Members:**

Tamara Coja (Chair), Thomas Kuhl, Olavi Pelkonen, Anneli Widenfalk (via teleconference)

- **Hearing Experts:**

Not Applicable

- **EFSA:**

Pesticide Unit: Dimitra Kardassi, Frederique Istace, Rositsa Serafimova

- **Others:**

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4. Scientific topics for discussion

4.1. Presentation and clarification of mandate³

The mandate was presented and clarifications were given in accordance to the acceptance letter. The Panel on Plant Protection Products and their Residues were asked to establish health based reference values for the LM metabolites (LM2, LM3, LM4, LM5 and LM6) based on the available evidence, unless the evidence is not considered sufficient to do so. The Panel is also requested to specify any uncertainties associated with the values derived and how such uncertainties could be further addressed in the future.

More specific the Commission asked the Panel on Plant Protection Products and their Residues to:

- Assess the available evidence;
- Consider the data gaps identified in the EFSA Conclusion and whether they could be addressed in light of the current state of 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

³Link to the EFSA's register of questions- Question Number EFSA-Q-2018-00950, Mandate Number M-2018-0188 <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00950>

art on read-across and other alternative in silico and non-testing methods and tools;

- Specify any uncertainties and how these could be further addressed, for example, in case additional safety factors are required;
- Based on these assessments, to establish health based reference values for the LM metabolites (LM2, LM3, LM4, LM5 and LM6) of terbuthylazine.

Furthermore, in case the Panel establishes reference values, EFSA is requested to update the risk assessment for consumers to take into account exposure to the LM metabolites using the reference values established by the Panel in accordance with this mandate. This activity is requested under Article 31 of Regulation (EC) No 178/2002 with a deadline of 3 months from the time the Opinion of the PPR Panel is published in the EFSA Journal. Member States should be provided with an opportunity to submit comments on such an assessment (since it will be an EFSA Output).

It was clarified that though the use of the Guidance on the residue definition is not explicitly said in the mandate, in the acceptance letter it is clearly stated that the mandate is accepted acknowledging that the reassessment will be done following the guidance of the PPR Panel (Guidance on the residue definition), which represents a different methodology than that used in the previous EFSA assessment. The experts agree that the Guidance on the residue definition should be used for the re-assessment.

4.2. Structure of the document and sharing of writing tasks

The main chapters of the document were agreed on the basis of the terms of references. Writing tasks were distributed between experts on the basis of their expertise.

5. Future meeting dates, teleconferences and physical meetings

2nd meeting dates were agreed by all experts:

- 10-11 January 2019

Next meeting dates were proposed, but they will be agreed upon at a later stage.

3rd WG meeting: 23 January 2019, TC

4th WG meeting: 13-14 February 2019, EFSA Parma

5th WG meeting: 14 March, TC