SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS **AND THEIR RESIDUES**

11th Working Group meeting on azole-resistant *Aspergillus* risk factors, prevention and control



25 September 2024 09:00-13:00 MINUTES - Agreed on 10 October 2024

Location: Online

Attendees:

- Working Group Members: Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Sijmen SCHOUSTRA, Frank SCHREIBER, Paul VERWEIJ
- Hearing Experts¹: Not applicable
- European Commission and/or Member States representatives: Not applicable
- o EFSA: Dimitra KARDASSI (PREV), Alexandra PITI (PREV), Pietro STELLA (BIOHAW)²
- o Others: Not applicable

Welcome and apologies for absence Ι.

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members III.

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management, 4 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.

Agreement of the minutes of the 10th Working Group IV. meeting held on 13-14 June 2024 in Parma (physical)

The minutes of the 10th Working Group meeting were agreed by written procedure on 26 June 2024.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf ² Attended the discussion on agenda item VI(e).

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



V. Actions from previous meeting(s) and update from EFSA

The state of play on the actions from the previous meeting(s) was reviewed. In addition, progress on the other ToRs of this joint mandate was shared with the Working Group.

VI. Scientific topic(s) for discussion (EFSA-Q-2022-00040)

a. Reviewing Annex E - discussing pending points and concluding on them

The Working Group reviewed Annex E and agreed on tasks and actions to have the text of the different sections finalised.

VII. Next steps

Next steps and actions were assigned and agreed throughout the meeting to finalise the text of Annex E.

VIII. Any other business & date of next meeting

No further points were mentioned, and no additional meetings are planned.

IX. Closure of the meeting

The Chair thanked the active participation of the Working Group members in the preparation of the scientific output and closed the meeting.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

10th Working Group meeting on azole-resistant Aspergillus – risk factors, prevention and control



13-14 June 2024 13:00-17:00 / 09:00-13:00 MINUTES - Agreed on 26 June 2024

Location: Physical meeting on EFSA premises (Parma)

Attendees:

- Working Group Members: Tamara COJA (Chair), Thomas KUHL, Sijmen SCHOUSTRA, Frank SCHREIBER, Paul VERWEIJ, Henrik Elvang JENSEN
- Hearing Experts¹: Not applicable
- o European Commission and/or Member States representatives: Not applicable
- o EFSA: Dimitra KARDASSI (PREV), Alexandra PITI (PREV), Pietro STELLA (BIOHAW)², Andras SZORADI (PREV)
- Others: Not applicable

Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members III.

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management, 4 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.

Agreement of the minutes of the 9th Working Group IV. meeting held on 17 April 2024, online

The minutes of the 9th Working Group meeting were agreed by written procedure on 29 April 2024.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf ² Attended the discussion on agenda item VI(e).

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



V. Actions from previous meeting(s) and update from EFSA

The state of play on the actions from the previous meeting(s) was reviewed. In addition, progress on the other ToRs of this joint mandate was shared with the Working Group.

VI. Scientific topic(s) for discussion (EFSA-Q-2022-00040)

a. Aerial dispersal of (resistant) A. fumigatus - latest developments

Sijmen SCHOUSTRA presented the preliminary findings of a study on aerial dispersal of *A. fumigatus*.

b. Update and final remarks on the work on pesticides (ToR 5)

Thomas KUHL presented the final version of the heatmap that will be included in the pesticides section of Annex E. The Working Group agreed on minor changes to improve the readability of the heatmap.

c. Update and final remarks on the work on biocides (ToR 5)

Frank SCHREIBER gave a status update on the results of his calculations in the biocides area. Minor changes in the visual representation were discussed and agreed.

d. Discussion on ToR 6 (based on the outcomes of ToR 5)

The Working Group discussed the risk mitigation measures recommended as part of ToR 6.

e. Publication of the methodology developed as part of ToR 5 in a peer-reviewed scientific journal

It was agreed that the ToR 5 methodology may be submitted for publication in a peer-reviewed scientific journal, but only after the scientific report from this joint mandate has been published and provided the principle is agreed by the EU agencies involved in the joint mandate.

f. Reviewing Annex E

The Working Group reviewed Annex E and agreed on tasks to have the text of the different sections finalised.

VII. Next steps

Next steps and actions were assigned and agreed throughout the meeting.

VIII. Any other business & date of next meeting

The next Working Group meeting will take place as an online meeting on 25 September 2024.

IX. Closure of the meeting





17 April 2024 09:00-13:00 MINUTES - Agreed on 29 April 2024

Location: Online

Attendees:

Working Group Members: Tamara COJA (Chair), Thomas KUHL, Sijmen SCHOUSTRA, Frank SCHREIBER, Paul VERWEIJ

 Hearing Experts¹: Not applicable

- European Commission and/or Member States representatives: Not applicable
- o EFSA: Dimitra KARDASSI (PREV), Alexandra PITI (PREV), Pietro STELLA (BIOHAW), Andras SZORADI (PREV)
- o Others: Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apology for absence was received from Henrik Elvang JENSEN, who could not join the meeting.

Adoption of agenda II.

The agenda was adopted without changes.

III. **Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http:/

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

MEETING MINUTES – 17 April 2024 9th Working Group meeting on azole-resistant *Aspergillus*



IV. Agreement of the minutes of the 8th Working Group meeting held on 18-19 March 2024, in Parma

The minutes of the 8th Working Group meeting were agreed by written procedure on 5 April 2024.

V. Actions from previous meeting(s) and update from EFSA

The state of play on the actions from the previous meeting(s) was reviewed. In addition, a brief update was given on the progress of other ToRs and the last Interagency meeting.

VI. Scientific topic(s) for discussion (EFSA-Q-2022-00040)

a. Heatmaps for identification of possible hotspots/visualisation of potential risks

Thomas KUHL presented a draft heatmap to facilitate the identification of possible hotspots and visualisation of potential risks in the pesticides area. In principle, the Working Group agreed with the draft heatmap, and some suggestions were made on how the final version could be improved both from a content and visual point of view.

b. Progress on the work on biocides

Frank SCHREIBER gave a status update on progress made with his calculations in the biocides area. Annex E will be updated with his most recent findings.

c. Annex E – discussing specific points and list of appendices

The Working Group clarified and agreed on the list of appendices that would be annexed to the final report.

d. Initiating discussion on ToR 6 based on the outcomes of ToR 5

The Working Group members agreed on how ToR 6 on risk mitigation measures should be drafted and captured in Annex E. ToR 6 will be discussed and finalised during the next Working Group meeting.

VII. Next steps

Next steps and actions were assigned and agreed throughout the meeting.

VIII. Any other business & date of next meeting

The next Working Group meeting will take place as a physical meeting on 13-14 June 2024 at EFSA premises (Parma).

IX. Closure of the meeting





18-19 March 2024 13:00-17:00 / 9:00-13:00 MINUTES - Agreed on 05 April 2024

Location: Physical, Parma, EFSA

Attendees:

Working Group Members: Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Sijmen SCHOUSTRA, Frank SCHREIBER¹, Paul VERWEIJ

- Hearing Experts²: Not applicable
- European Commission and/or Member States representatives: Teresa LETTIERI (JRC)
- o EFSA: Dimitra KARDASSI (PREV), Alexandra PITI (PREV), Pietro STELLA (BIOHAW), Andras SZORADI (PREV)
- o Others: Not applicable

Welcome and apologies for absence

The Chair welcomed the participants. Apology for absence was received from Frank SCHREIBER, who could not join the second day of the meeting.

II. Adoption of agenda

The agenda was adopted without changes.

Declarations of Interest of Working Groups members III.

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management, 4 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.

Attended only the first day of the meeting.
As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http:/

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

MEETING MINUTES – 18-19 March 2024 8th Working Group meeting on azole-resistant *Aspergillus*



IV. Actions from previous meeting & reporting back from other ToRs

The state of play on the actions from the previous meeting was reviewed. Update was given on the progress of ToR7 and the link with the work under ToR5.

V. Methodology for the selection of relevant azoles for further assessment

After a fruitful discussion, the Working Group members agreed on the methodology for the selection of relevant azoles for further assessment.

VI. Progress on the work on VMPs

Henrik Elvang JENSEN gave an update on the work on VMPs, as well as the related uncertainties.

VII. Progress on the work on pesticides

Thomas KUHL gave a status update on progress made along with a proposal for finalising the methodology.

VIII. Progress on the work on biocides

Frank SCHREIBER gave a status update on progress made along with the uncertainties he encountered while writing the chapter on azole biocides.

IX. Closure of the 1st day of the meeting

The Chair thanked the constructive and fruitful debate and suggested to continue the reflection and discussion the next day.

X. Data gaps & uncertainties

The Working Group clarified and amended the proposed data gaps.

XI. Discussing drafted sections in Annex E

The Working Group revisited the structure of the report to be delivered and discussed how to address the questions posed in the problem formulation.

XII. Next steps

Next steps and actions were assigned and agreed throughout the meeting.

XIII. Any other business & date of next meeting

The next Working Group meeting will take place as an online meeting on 17 April 2024.

XIV. Closure of the meeting





31 January 2024 13:00-17:00 MINUTES - Agreed on 9 February 2024

Location: Webconference

Attendees:

Working Group Members:
 Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Frank SCHREIBER, Paul VERWEIJ,
 Sijmen SCHOUSTRA

Hearing Experts¹:
 Not applicable

o EFSA:

Dimitra KARDASSI (PREV), Alexandra PITI (PREV), Andras SZORADI (PREV)

Others:Not Applicable

Welcome and apologies for absence

The Chair welcomed the participants. No apology for absence was received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Actions from previous meeting

The state of play on the actions from the previous meeting was reviewed.

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

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



V. Presentation of appropriate PNEC values and assessment factor for resistance selection in A. fumigatus

Paul VERWEIJ gave a presentation on the progress made with respect to identifying what would be the most appropriate assessment factor to use when calculating PNEC values.

VI. Progress on the work on pesticides

Thomas KUHL gave a status update on the progress made with respect to the azole pesticides considered under ToR5.

VII. Progress on the work on biocides

Frank SCHREIBER gave a status update on the progress made with respect to the azole biocides considered under ToR5.

VIII. Progress on the work on VMPs

Henrik JENSEN gave a status update on his contribution for VMPs under ToR5.

IX. Comparison of highest residue values with PNECs – summary and discussion

The most appropriate assessment factors to use when calculating PNEC values was discussed and agreed. In the area of pesticides, the next step will be to compare the highest residue values with the PNEC values.

X. Next steps

Next steps and actions were assigned and agreed throughout the meeting.

XI. Any other business & date of next meeting

The next Working Group meeting will take place as a physical meeting on 18-19 March 2024.

XII. Closure of the meeting





12-13 December 2023 13:00-17:00 / 9:00-13:00 MINUTES - Agreed on 21 December 2023

Location: Webconference

Attendees:

Working Group Members: Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Frank SCHREIBER, Paul VERWEIJ

Hearing Experts¹: Not applicable

- European Commission and/or Member States representatives: Isabella Sanseverino (JRC), Teresa Lettieri (JRC)
- EFSA: Dimitra KARDASSI (PREV), Alexandra PITI (PREV), Pietro STELLA (BIOHAW), Andras SZORADI (PREV)
- Others: Not Applicable

Welcome and apologies for absence 1.

The Chair welcomed the participants. Apology for absence received from Sijmen SCHOUSTRA.

Adoption of agenda II.

The agenda was adopted with the change that Paul VERWEIJ wished to present his work on PNEC calculations. The presentation was allotted to the JRC timeslot.

Declarations of Interest of Working Groups members III.

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Actions from previous meeting

The state of play on the actions from the previous meeting was reviewed.

As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://

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



V. Activity of azoles and non-azole substances against A. fumigatus in clinical and environmental samples – experiments performed by the JRC

JRC presented the outcome of the experiments they have performed on some substances. The discussion focused on how the results can be considered for the work undertaken in this Working Group for ToR5.

VI. Debriefing from other ToRs and meetings with relevance to ToRs 5&6

EFSA reported back from the different meetings they have attended in relation to this joint mandate. Information relevant to ToRs 5&6 was shared and discussed.

VII. Progress on the work on pesticides

Thomas KUHL gave a status update on the progress made with respect to the azole pesticides considered under ToR5.

VIII. Progress on the work on biocides

Frank SCHREIBER gave a status update on the progress made with respect to the azole biocides considered under ToR5.

IX. Feedback on conclusions reached for VMPs under ToR1

Henrik JENSEN gave a status update on the conclusions reached for VMPs under ToR1 and how this impacts the assessment under ToR5.

X. Closure of the 1st day of the meeting

The Chair thanked the group for the constructive and fruitful debate and suggested to continue the reflection and discussion the next day.

XI. How to record uncertainties, data gaps & research needs?

Based on past EFSA outputs, the Chair presented some options on how to capture identified uncertainties, data gaps & research needs in the final report from this Working Group. As an outcome of the discussion a format was agreed on how best to present this information in the final report.

XII. 'Heat Map' for visualising results – an idea

The Chair presented an example of a possible 'heat map' for visualising complex results in a simplified manner.

XIII. Discussing drafted sections in Annex E

The Working Group reviewed some sections of the draft report. Roles and responsibilities for drafting the missing sections were agreed.

MEETING MINUTES – 12-13 December 2023 6th Working Group meeting on azole-resistant *Aspergillus*



XIV. Next steps

Next steps and actions were assigned and agreed throughout the meeting.

XV. Any other business & date of next meeting

The next Working Group meeting will take place as an online meeting on 31 January 2024, and the one after as a physical meeting on 18-19 March 2024.

XVI. Closure of the meeting





6-7 November 2023 13:00-17:00 / 9:00-13:00 MINUTES - Agreed on 14 November 2023

Location: EFSA - Parma (Meeting Room M03)

Attendees:

- Working Group Members:
 Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Sijmen SCHOUSTRA,
 Frank SCHREIBER, Paul VERWEIJ
- Hearing Experts¹: Not applicable
- $_{\odot}$ $\,$ European Commission and/or Member States representatives: Not applicable
- EFSA:
 Dimitra KARDASSI (PREV), Pietro STELLA (BIOHAW), Andras SZORADI (PREV)
- Others:Not Applicable

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Tamara COJA (Chair) declared that she simply resubmitted her previous ADoI to EFSA and that no new interest was declared.

IV. Actions from previous meeting

The state of play on the actions from the previous meeting was reviewed.

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

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

MEETING MINUTES – 6-7 November 2023 5th Working Group meeting on azole-resistant *Aspergillus*



V. Debriefing from the ToR4 meeting held on 25 October 2023

EFSA reported back from the ToR4 meeting held on 25 October 2023 with relevance to ToRs 5&6. It was agreed that EFSA will act as a bridge between the ECDC Expert Panel on ToR4 and the EFSA Working Group on ToRs 5&6.

VI. Debriefing from the ASPAR_KR workshop held on 1-3 November 2023

Sijmen SCHOUSTRA reported back from the ASPAR_KR workshop held on 1-3 November 2023 in Wageningen, with specific focus on new information/research on hotspots linked to azole-resistant *Aspergillus fumigatus*.

VII. Normalisation of data on the use of azole pesticides (based on AgbioInvestor summary)

EFSA presented the outcome of the normalisation of data (as received from AgbioInvestor) on the use of azole pesticides and how it compares with the normalised sales data on azole pesticides (as collected under ToR1). It was also discussed in which context to best use this data/information.

VIII. Questions from the Working Group on the 3-year survey in Denmark (based on progress reports)

Based on the progress reports received from the Danish Ministry of Environment on a 3-year survey in Denmark (titled: Investigations for environmental hotspots and application practices for azole resistant *Aspergillus fumigatus*), the Working Group reviewed the list of questions to be shared with Prof. Maiken Cavling Arendrup. The intention is to invite Prof. Arendrup (as a Hearing Expert) to the December 2023 meeting of this Working Group to present the conclusions and recommendations of this Danish survey.

IX. Progress on the work on pesticides

Thomas KUHL gave a status update on progress made along with the assumptions he made while running the methodology agreed for azole pesticides.

X. Progress on the work on biocides

Frank SCHREIBER gave a status update on progress made along with the uncertainties he encountered while further defining the methodology for azole biocides.

XI. Closure of the 1st day of the meeting

The Chair thanked the constructive and fruitful debate and suggested to continue the reflection and discussion the next day.

XII. Discussing drafted sections in Annex E

The Working Group revisited the structure/skeleton of the report to be delivered and made some modifications to the overall structure & headings of the report. Roles and responsibilities for drafting the missing sections were agreed.

MEETING MINUTES – 6-7 November 2023 5th Working Group meeting on azole-resistant *Aspergillus*



XIII. Next Steps

Next steps and actions were assigned and agreed throughout the meeting.

XIV. Any other business & date of next meeting

The next Working Group meeting will take place as an online meeting on 12-13 December 2023, and the one after also as an online meeting on 31 January 2024.

XV. Closure of the meeting





9-10 October 2023 13:00-17:00 / 14:00-18:00 MINUTES - Agreed on 16 October 2023

Location: Webconference

Attendees:

- Working Group Members:
 Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Sijmen SCHOUSTRA,
 Frank SCHREIBER, Paul VERWEIJ
- Hearing Experts¹: Not applicable
- $_{\odot}$ $\,$ European Commission and/or Member States representatives: Not applicable
- EFSA:
 Dimitra KARDASSI (PREV), Andras SZORADI (PREV)
- Others:Not Applicable

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologise were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Dr. Tamara COJA (Chair) declared that she simply resubmitted her previous ADoI to EFSA and that no new interest was declared.

IV. Actions from previous meeting

The state of play on the actions from the previous meeting was reviewed.

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

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

MEETING MINUTES – 9-10 October 2023 4th Working Group meeting on azole-resistant *Aspergillus*



V. Presenting MIC50 values identified from literature

An introductory presentation on how MIC (Minimum Inhibitory Concentration) testing is done and which definitions are being used was provided. The MIC50 values identify from literature for a series of azole substances was discussed.

VI. Presenting an overview of the progress reports from the Danish authorities in connection with the 3-year survey in Denmark

EFSA presented a summary of the information received from the Danish Ministry of Environment in connection with a 3-year survey in Denmark. The final survey report is expected to be available in December 2023.

VII. Proposed methodology to be followed for biocides

A methodology (similar to the one developed for pesticides) was presented and discussed. At the end of the discussion the Working Group agreed to test the methodology with a handful of biocide products.

VIII. Proposed methodology to be followed for VMP

For the time being the Working Group agreed not to go ahead with the development of a dedicated methodology for VMP. The rational for that will be explained in the final report. Nevertheless, the Working Group also agreed to revisit this point in case new information/evidence suggest that there is a need for such methodology.

IX. Progress on the agreed methodology to be followed for pesticides

The list of active substances to be considered for the first steps of the methodology has been agreed. It was discussed that only data from uses submitted, evaluated and published can be taken into account.

X. Closure of the 1st day of the meeting

The Chair thanked the constructive and fruitful debate and suggested to continue the reflection and discussion the next day.

XI. Outcome of ToR1 (normalisation of sales data for PPP)

EFSA presented the normalised sales data on pesticides. It was also discussed in which context to best use this data/information.

XII. Data on the use of azole pesticides (AgbioInvestor summary)

EFSA presented additional information/data shared by AgbioInvestor/Kynetec on use of azoles in crop protection. It was agreed to seek for additional information data on some of the non-crop categories.

MEETING MINUTES – 9-10 October 2023 4th Working Group meeting on azole-resistant *Aspergillus*



XIII. Problem formulation for ToR5 and ToR6 – discussion on the drafted sections

Working Group members revisited the structure/skeleton of the final report. The content elaboration for the various sections to be drafted were assigned to the different Working Group members.

XIV. Next Steps

Next steps and actions were assigned and agreed throughout the meeting.

XV. Any other business & date of next meeting

The next Working Group meeting will take place as a physical meeting at EFSA premises on 6-7 November 2023, and the one after as an online meeting on 12-13 December 2023.

XVI. Closure of the meeting





14-15 September 2023 13:00-17:00 / 9:00-13:00 MINUTES - Agreed on 22 September 2023

Location: Webconference

Attendees:

o Working Group Members:

Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Sijmen SCHOUSTRA, Frank SCHREIBER, Paul VERWEIJ

Hearing Experts¹:

Not applicable

- $_{\odot}$ $\,$ European Commission and/or Member States representatives: Not applicable
- o EFSA:

Dimitra KARDASSI (PREV), Pietro STELLA (BIOHAW), Andras SZORADI (PREV)

Others:Not Applicable

Welcome and apologies for absence

The Chair welcomed the participants. No apologise were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

IV. Actions from previous meeting

The state of play on the actions from the previous meeting was reviewed.

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

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

MEETING MINUTES – 14-15 September 2023 3rd Working Group meeting on azole-resistant Aspergillus



V. Update on new literature search and relevant parameters: discuss outcome

After a brief recap on the search methodology/protocol, the high-level findings of the new literature search were presented and discussed in the Working Group.

VI. Outcome of ToR1 - Data on sales (collected by ECHA) and uses of selected compounds (collected by CropLife Europe) and proposal for categorisation of crops (undertaken by the Working Group)

EFSA presented the updated information collected under ToR1 and the high-level data received from CropLife Europe on use of azoles in horticulture. The Chair then presented a proposal for the categorisation of crops (incl. other crops) from the ToR1 survey linked to pesticides. The discussion focused on how these different data streams can be used to address the ToRs of this Working Group.

The Working Group also discussed whether starting at crop level or at substance level would be the best point of departure and if any criteria can be defined to exclude a particular crop or substance from the overall assessment.

VII. Closure of the 1st day of the meeting

The Chair thanked the constructive and fruitful debate and suggested to continue the reflection and discussion the next day.

VIII. Outcome of the evaluations of stability/metabolism data of azoles on the target crops (Article 12 evaluations)

A methodology for the use of azole residue data for *Aspergillus fumigatus* hotspot assessment was presented and discussed. At the end of the discussion the Working Group agreed to start the assessment at substance, rather than at crop/commodity level and only thereafter to consider the crop/commodity dimension along with other factors and considerations.

IX. Problem formulation for ToR5 and ToR6 – discussion on the drafted sections

Working Group members briefly revisited the problem formulation questions and all members were encouraged to provide their suggested changes/revisions on the formulated questions. The content elaboration for the various sections to be drafted were assigned to the different Working Group members.

X. Feedback from Experts' Panel meeting risk assessment (under ToR 4)

The feedback from the meeting was provided under agenda item 2. The Working Group will provide input to ECDC on environmental hotspots to support their work under ToR4.

MEETING MINUTES – 14-15 September 2023 3rd Working Group meeting on azole-resistant Aspergillus



XI. Next Steps

Next steps and actions were assigned and agreed throughout the meeting.

XII. Any other business & date of next meeting

The next Working Group meeting is scheduled to take place as an online meeting on 9-10 October 2023. It was also agreed to have the subsequent meeting as a physical meeting at EFSA premises on 6-7 November 2023.

XIII. Closure of the meeting





14-15 June 2023 13:00-17:00 / 9:00-13:00 MINUTES - Agreed on 23 June 2023

Location: EFSA - Parma (Meeting Room M04 / M08)

Attendees:

o Working Group Members:

Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Sijmen SCHOUSTRA, Frank SCHREIBER, Paul VERWEIJ

Hearing Experts¹:

Jane GILBERT (Carbon Clarity), Laurent OGER (CropLife Europe), Helge SIEROTZKI (Syngenta)

European Commission and/or Member States representatives:
 Teresa LETTIERI (DG JRC), Mark WILLIAMS (DG SANTE)

o ECHA:

Ales FRONTINI

o EFSA:

Dimitra KARDASSI (PREV), Pietro STELLA (BIOHAW) Andras SZORADI (PREV)

Others:Not Applicable

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologise were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

IV. Actions from previous meeting

Relevant actions from the previous meeting were completed.

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

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



V. Update from ToR1 ('Use azole fungicides'): reporting on data collection, overview of responses and next step

ECHA, as ToR 1 Coordinator, was invited to the Working Group meeting (for this agenda item only) to present the data collected from Members States on azole fungicides, other than as human medicines. The discussion focused on how the collected data can be best used and integrated into the work of this Working Group that is linked to ToR 5 (Risk factors) and ToR 6 (Prevention and Control) of the interagency mandate on azole-resistant *Aspergillus*⁴.

VI. Research to prevent/minimise the development of environmental resistance from the use of azole fungicides

Hearing Experts from CropLife Europe and Syngenta were invited to the Working Group meeting (for this agenda item only) to present the industry view on azole-resistance, along with the activities they have initiated to prevent/minimise the development of azole-resistant *Aspergillus fumigatus* in the environment. In addition, they replied to specific questions from the Working Group during the meeting.

VII. Discussion on the drafted sections

The structure of the Scientific Report was presented and the problem formulation (i.e. questions to be answered) was reviewed and refined by the Working Group.

VIII. & IX. Conclusions from the first day & closure of the meeting

The Chair concluded that further reflection is needed on how the information presented by ECHA can be considered. It was also clarified that should there be a need to report the views of the hearing experts in the final report then this will be clearly distinguished from the opinion of the Working Group.

X. Composting practices and their possible impact on azoles-resistant *Aspergillus* development

A Hearing Expert from Carbon Clarity was invited to the Working Group meeting (for this agenda item only) to answer specific questions from the Working Group on composting practices and their possible impact on azoles-resistance *Aspergillus* development.

XI. Data on azole concentrations in surface and ground waters

The JRC was invited to the Working Group meeting (for this agenda item only) to present their monitoring work on azole concentrations in surface and ground waters under the EU Water Framework Directive. The discussion focused on how the collected data can be used and integrated into the work of this Working Group that is linked to ToR 5 (Risk factors) and ToR 6 (Prevention and Control) of the interagency mandate on azole-resistant *Aspergillus*.

⁴ https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00040

MEETING MINUTES – 14-15 June 2023 2nd Working Group meeting on azole-resistant *Aspergillus*



XII. Discussion on the drafted sections (continued)

The discussion continued on the relevance of the different data streams presented and how they could be used and integrated into the work of this Working Group.

XIII. Next Steps

The planning for the next steps was shared and discussed and tasks were allocated to the Working Group members.

XIV. Any other business

The next Working Group meeting is scheduled to take place on 14-15 September 2023 as an online meeting. It was also agreed to have the subsequent meeting sometime in October 2023.

XV. Closure of the meeting



1st Working Group meeting on azole-resistant Aspergillus risk factors, prevention and control



24 April 2023 13:00-17:00 MINUTES - Agreed on 5 May 2023

Location: Webconference

Attendees:

o Working Group Members:

Tamara COJA (Chair), Henrik Elvang JENSEN, Thomas KUHL, Frank SCHREIBER

Hearing Experts¹:

Not Applicable

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

Dimitra KARDASSI (PREV), Pietro STELLA (BIOHAW) Andras SZORADI (PREV)

Others:Not Applicable

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologise were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

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

IV. Brief introduction from participants

As it was the first meeting of the Working Group, meeting participants briefly introduced themselves.

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

anttp://www.ersa.europa.eu/sites/default/files/corporate publications/files/policy independence.pdf

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

MEETING MINUTES - 24 April 2023 1st Working Group meeting on azole-resistant Aspergillus



V. Interagency mandate on azole-resistant Aspergillus

EFSA introduced the interagency mandate from the European Commission to develop a Scientific Report on the impact of the azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus spp.* The background information and the terms of references (ToRs) were presented to the experts. The interdependence amongst the different ToRs was highlighted. It was clarified that the present Working Group was established to address ToR 5 (Risk factors) and ToR 6 (Prevention and Control) of the interagency mandate (find specific ToRs below). The ToRs 5 and 6 were presented and discussed. The Working group was informed about the completed and ongoing work from the other ToRs and how those deliverables will facilitate the discussion in the Working Group in addressing ToRs 5 and 6.

ToR 5 (Risk factors):

Review the drivers/selection dynamics behind the development of environmental resistance in Aspergillus (in so called "hotspots"), in particular identification of: i) specific types of uses, ii) individual classes of substances, iii) use conditions that lead to the development of environmental resistance (including conditions during storage and processing of (waste) materials with azole residues); providing, if possible, an indication of the selection risk from different uses and the contribution of sectoral uses of azoles. Experimental work should be considered in order to provide additional information on this point.

ToR 6 (Prevention and Control):

Identify measures that could be implemented with respect to the use of azole fungicides and storage/processing of (waste) materials with azole residues and metabolites to prevent or minimise the development of environmental resistance or minimise the spread of resistant Aspergillus into patients.

The discussion focused on the following elements:

- i) problem formulation and methodology to be followed to address ToRs 5 and 6;
- ii) the input/deliverables needed to address ToRs 5 and 6;
- iii) conditions favouring the growth of *Aspergillus fumigatus* in the environment and factors contributing to the development of azole-resistant *Aspergillus fumigatus* in the environment:
- iv) definition of hotspots and identification of potential hotspots that favour the development of azole-resistant *Aspergillus fumigatus* in the environment;
- v) collaboration space for exchanging and working on documents.

The structure of the Scientific Report was presented and tasks were allocated to the Working Group members. The planning for the next steps was shared and discussed with the Working Group.

VI. Next meeting

The next Working Group meeting is scheduled to take place on 14-15 June 2023, in Parma.

⁴ https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00040

MEETING MINUTES - 24 April 2023 1st Working Group meeting on azole-resistant Aspergillus



Annex

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

With regard to this meeting, Dr. Tamara COJA (Chair) declared the following interest: Project Coordinator (on behalf of the Austrian Agency for Health and Food Safety (AGES) as beneficiary) of an EFSA grant (GP/EFSA/FDP/2022/02) on GLP criteria covering different regulatory areas within EFSA's remit. It was noted that the EFSA grant falls outside the scope/remit of this Working Group. In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

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

⁶ http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf