



PESTICIDE PEER REVIEW UNIT

## PESTICIDE PEER REVIEW UNIT

### MINUTES OF THE 7<sup>TH</sup> MEETING OF THE WORKING GROUP ON *PSEUDOMONAS CHLORORAPHIS* STRAIN MA 342

**Held on 8 September 2020 (via teleconference)**

**(Agreed on 23 September 2020)**

#### Participants

- Working Group Members:  
Anneli WIDENFALK, Tamara COJA, Lieve HERMAN.
- Hearing expert:  
Not applicable.
- European Commission and/or Member States representatives:  
Not applicable.
- EFSA:  
Pesticide Residues Unit (PRES): J. Oriol MAGRANS (chair of teleconference).



## 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. Revision of comments and suggestions by Panel members and reviewers.

The comments and suggestions provided by the Panel Members and Panel Reviewers to the draft statement were discussed and addressed as appropriate. Abstract, Summary and sections 4 to 8 of the draft statement were mainly considered in this meeting.

## 5. Preparation of presentation to the Panel.

A first draft of the presentation for the 107<sup>th</sup> PPR Panel plenary meeting was shared and discussed. Comments from the WG were collected.

**Action:** Oriol and Anneli to finalise the presentation and share it with WG members before the Panel Plenary. Deadline: Friday 11th September.

## 6. AOB WG

**Action:** Oriol to have a last check of the Statement for typos and complete the administrative front cover. Deadline: Friday 11<sup>th</sup> September.

## 7. WG Farewell

WG members celebrated the finalisation of their task in drafting the statement with a virtual toast.

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<sup>1</sup> [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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## PESTICIDE PEER REVIEW UNIT

### MINUTES OF THE 6<sup>TH</sup> MEETING OF THE WORKING GROUP ON *PSEUDOMONAS CHLORORAPHIS* STRAIN MA 342

**Held on 1 September 2020 (via teleconference)**

**(Agreed on 3 September 2020)**

#### Participants

- Working Group Members:  
Anneli WIDENFALK, Tamara COJA, Lieve HERMAN.
- Hearing expert:  
Not applicable.
- European Commission and/or Member States representatives:  
Not applicable.
- EFSA:  
Pesticide Residues Unit: J. Oriol MAGRANS (chair of teleconference).



## 1. Welcome and apologies for absence

The Chair welcomed the participants. Lieve HERMAN apologizes for having to leave the meeting earlier due to inescapable commitment (by 12:30).

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. Revision of comments and suggestions by Panel members and reviewers.

The comments and suggestions provided by the Panel Members and Panel Reviewers to the draft statement were discussed and addressed as appropriate. Abstract, Summary and sections 1 to 3 of the draft statement were considered in this meeting.

## 5. AOB

### **Actions:**

**All** to revise the document considering possible final editorial changes and typos. To consider comments received for sections 4. Uncertainties, 5. Conclusions and 6. Recommendations in preparation for the next meeting.

## 6. Next WG meeting

The meeting confirmed the date for next (final) WG meeting:

Teleconference 7: 8<sup>th</sup> of September (Half day, morning 9:00 – 13:00).

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<sup>1</sup> [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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



PESTICIDE PEER REVIEW UNIT

## PESTICIDE PEER REVIEW UNIT

### MINUTES OF THE 5<sup>TH</sup> MEETING OF THE WORKING GROUP ON *PSEUDOMONAS CHLORORAPHIS* STRAIN MA 342

**Held on 25 June 2020 (via teleconference)**

**(Agreed on 8 July 2020)**

#### Participants

- Working Group Members:  
Anneli WIDENFALK, Tamara COJA, Lieve HERMAN.
- Hearing expert:  
Not applicable.
- European Commission and/or Member States representatives:  
Not applicable.
- EFSA:  
Pesticide Residues Unit: J. Oriol MAGRANS (chair of teleconference).
- 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. Revision and finalization of the statement. 3.1 Taxonomic identification.

The statement section on 3.1 Taxonomic identification was discussed. Comments and changes were addressed and agreed.

## 5. Revision and finalization of the statement. 3.2.1 Microorganism translocation and internalization.

The statement section on 3.2.1 Microorganism translocation and internalization. Comments and changes were addressed and agreed.

## 6. Revision and finalization of the statement. 3.2.2. Metabolite DDR.

The statement section on 3.2.2. Metabolite DDR. Comments and changes were addressed and agreed.

## 7. Revision and finalization of the statement. 4.Uncertainties. 5.Conclusions. 6.Recommendations.

The statement section on 4. Uncertainties. 5.Conclusions. 6.Recommendations. Main points under these concluding sections were discussed. It was agreed to draft them and to agree through a written procedure until the 10<sup>th</sup> of July.

## 8. AOB Next WG meeting

**Actions: Oriol** to prepare written first draft of sections 4. Uncertainties. 5.Conclusions. 6.Recommendations and clean the draft by accepting or rejecting changes as appropriate. **Deadline 1<sup>st</sup> July.**

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<sup>1</sup> [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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



**All** to revise and agree by written procedure on the final draft of the statement before sharing with the Panel and the Reviewers, paying special attention to sections 4. Uncertainties. 5. Conclusions. 6. Recommendations. **Deadline 10<sup>th</sup> of July.**

## 9. Next WG meeting

The meeting agreed for efficiency reasons to split next full day meeting originally envisaged for 1<sup>st</sup> of September in two days half meeting as follows:

Teleconference 6: 1st of September (Half day, morning 9:00 – 13:00).

Teleconference 7: 8<sup>th</sup> of September (Half day, morning 9:00 – 13:00).



PESTICIDE PEER REVIEW UNIT

## PESTICIDE PEER REVIEW UNIT

### MINUTES OF THE 4TH MEETING OF THE WORKING GROUP ON PSEUDOMONAS CHLORORAPHIS STRAIN MA 342

**Held on 28 May 2020 (via teleconference)**

**(Agreed on 5 June 2020)**

#### Participants

- Working Group Members:  
Anneli WIDENFALK, Tamara COJA, Lieve HERMAN.
- Hearing expert: (nominated by the RMS, the Netherlands):  
Esther De Jong
- European Commission and/or Member States representatives:  
Not applicable
- EFSA:  
Pesticide Residues Unit: J. Oriol MAGRANS (chair of teleconference).
- Others:  
Not applicable





## 1. Welcome and apologies for absence

The Chair welcomed the participants. Esther De Jong was welcomed and thanked for having accepted to support the working group 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. Welcome of the RMS hearing expert and presentation of the WG members and the mandate.

Anneli presented the mandate to the hearing expert, members of the working group were introduced to her and she was thanked for the support.

## 5. Presentation by the hearing expert of the assessment of *P. chlororaphis* done by the RMS.

The hearing expert confirmed that the position of the RMS was reflected in the RAR and summarized in the position paper that was presented as attachment to the mandate. Therefore, it was agreed to proceed with the examination of the questions prepared by the WG.

## 6. Questions and discussion of the issues proposed by the WG.

### List of questions shared with the hearing expert in advance to the meeting.

1. *In the position paper it is concluded that no translocation was found and that *P. chlororaphis* has only been found in the first primary leaf and in concentrations lower than in the roots and that it is not found on plant parts at distances more than 5 cm from the seeds. It is also stated that the population of *P. chlororaphis* will increase around the seed embryo, reach a plateau and decline completely within a period of 14 weeks (p16 RAR). Can you provide the references of studies in the dossier supporting these statements? Can you also consider the references Anonymous (1993), McInroy and Kloepper (1995), and Snyder et al. 1998 in respect to this issue?*

<sup>1</sup> [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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



2. *In the position paper it is stated that the Scientific Committee on Plants concluded that because *P. chlororaphis* MA342 applied to seeds does not continue to colonise the emerging plant, the number of *P. chlororaphis* associated with the harvested grain as well as the concentration of any metabolites would be very low. Can you identify the reference of the study in the dossier on which this conclusion of the SCP was based? The panel working group has found Anonymous (1997), where indeed no colonisation has been seen, but where also no beneficial effects were reported. So it is not clear if in this experiment the *P. chlororaphis* were successfully applied for root colonisation. In relation to the greenhouse experiments, the report (Hokeberg et al., 2000, Response from applicant to questions raised by the Rapporteur, p. 18, nr. 4.18) stated the following observation: 'Poor root colonisation was observed on seedlings grown at both 6 and 14°C also observed in pilot experiments in which barley seeds were grown in greenhouse at 20°C. What is the relevance of results based on experiments without colonisation of the root system?*
3. *In the position paper it is stated that DDR is only produced during growth of *P. chlororaphis* MA342. Can you provide the reference of a study in the dossier supporting this statement? Can you also indicate when DDR would not be produced in relation to the growth cycle of *P. chlororaphis*?*
4. *In the position paper it is stated that the production of DDR is only expected to occur in direct interaction with the target pathogen which could trigger their production. DDR is only produced when required for survival, as their production is always a matter of cost and energy. Can you give the references on which this statement is based? Where can we find the related information in the dossier?*
5. *In the RAR it is stated that under laboratory conditions *P. chlororaphis* MA342 is able to produce the metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR). DDR is also found in the technical material batches at the end of the fermentation process at levels between 2.5 – 30 µg / mL. This is however contradictory to the statement above, as plant pathogens are not expected to be present under the conditions of production of *P. chlororaphis* MA342. How can the presence of DDR be explained in this case?*
6. *Is there any study in the dossier investigating the production of metabolite DDR in soil under different conditions (e.g. in presence and absence of target pathogen)?*
7. *Is there any study in the dossier investigating the uptake of DDR from soils and or its translocation from roots to other plant parts?*
8. *In the RAR it is stated that metabolite DDR is also produced by other microorganisms (by up to 2 % of soil rhizosphere microorganisms referring to a personal communication quoted in Ugglä (not dated)). Is there any further confirmation of this statement in the dossier? Is there any measurement or estimation of background levels of DDR in non *P. chlororaphis* MA342 treated soils?*
9. *In the RAR, it was concluded that DDR has a rather short half-life. However, this conclusion was based on the study by Eriksson (2000 e) which was a study on hydrolysis as a function of pH (and temperature) in a bacterial suspension. Could you please share your thoughts regarding how reliable these data are to support the conclusion that there will be a rapid degradation also under environmentally realistic conditions and in the soil or in the treated crops? Is there in the dossier any study investigating the transformation products of DDR?*



10. *In the more recent study on the determination of DDR in treated crops (Aversa, 2015), levels of DDR on wheat seeds after foliar application were determined. Although this was a GLP study, the focus was to validate the analytical method used, and detailed information regarding the field trial part (treatment, application rate and type, time of sampling etc) is missing. Additionally, only two samples from treated wheat were analyzed, both indicating that the content of DDR in these samples was <LOQ (1 µg/kg). Could you please reflect on the reliability of this study in relation to seed treatment with *P. chlororaphis*? Is there any information regarding the colonisation ability of *P. chlororaphis* in the plants and the efficacy of the treatment? Considering that the samples came from efficacy trials this information should be available and reported to validate the results.*

## Discussion

The different questions were addressed in detail by the hearing expert and discussed by the WG. Hearing expert provided insights on the RMS interpretation of the information available in the dossier and identified the key issues addressed by each particular study. Limitations of studies and information gaps identified by the WG were also discussed. During this meeting, it was confirmed that the WG group had identified all the studies in the dossier relevant to address the questions in the mandate.

It was agreed with the hearing expert that in case she finds some other information in the dossier relevant to the mandate, she could communicate this to the WG before the 12<sup>th</sup> of June, to allow the panel to consider it in the statement.

Two specific clarification were asked to the hearing expert in relation to Anonymous (1998) and Tombolini (1999) and the personal communication by Tombolini, which needed further consideration by her. It was agreed that the request for clarifications will be formulated in writing and that the hearing expert will provide the answer also within the deadline of the 12<sup>th</sup> of June.

Esther De Jong, the hearing expert, left the meeting at this point.

## 7. AOB

The preparation of the panel meeting of 10<sup>th</sup> and 11<sup>th</sup> of June was discussed. It was agreed that in the meeting two presentations will be used:

- 1) A general presentation (to be presented by Anneli) on the progress of the works of the working group and the next steps planned. The progress in relation with the translocation of the microorganism and the metabolite DDR will be summarized in the presentation, but the actual text in the statement with respect to these points will not be presented or discussed in the panel meeting. The panel will be requested to identify the reviewers and will be informed on the written procedure to revise the draft statement over summer period.
- 2) A specific presentation (already prepared by Tamara) on the outcome of the consultation to the SC WG on genotoxicity with respect to metabolite DDR. For this presentation the text already drafted in the conclusion with respect to this point, which is in advanced drafting state, will be shared with the panel members.

## Actions:

Lieve to prepare written questions for the clarifications requested to the hearing expert.<sup>3</sup>

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<sup>3</sup> At the time of written these minutes the questions had already been agreed and sent to the hearing expert for her consideration.



Esther (hearing expert) to provide answer to the clarifications requested and any other information in relation to the dossier that may be relevant for the WG statement. Deadline 12<sup>th</sup> of June.

Oriol to prepare the notes and minutes of WG meeting 4. Deadline 5<sup>th</sup> of June

Oriol and Anneli to prepare the presentation 1) of the panel. Deadline 5<sup>th</sup> of June

All to update the statement considering the consultation with the hearing expert giving it a *close to* finalized form. Also include draft of conclusions and recommendations. This version will be discussed and finalized during the meeting of the 25<sup>th</sup> of June and then shared with the panel for written consultation. Deadline 19<sup>th</sup> June.

## 8. Next WG meeting

The dates for next meetings were confirmed:

Teleconference 5: 25<sup>th</sup> of June (Morning).

Teleconference 6: 1<sup>st</sup> of September (Full day).\*

\*Initially planned as a physical meeting has been changed to a teleconference since physical meetings have been suspended in EFSA for the whole year 2020 as part of the measures to mitigate COVID 19 spread.



PESTICIDE PEER REVIEW UNIT

## PESTICIDE PEER REVIEW UNIT

### MINUTES OF THE 3<sup>RD</sup> MEETING OF THE WORKING GROUP ON PSEUDOMONAS CHLORORAPHIS STRAIN MA 342

**Held on 27 April 2020 (via tele-web conference)**

**(Agreed on 30 April 2020)**

#### Participants

- Working Group Members:  
Anneli WIDENFALK, Tamara COJA, Lieve HERMAN.
- Hearing Experts:  
Not applicable
- European Commission and/or Member States representatives:  
Not applicable
- EFSA:  
Pesticide Residues Unit: J. Oriol MAGRANS (chair of teleconference).
- Others:  
Not applicable



## 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. Tamara Coja had previously informed the chair of her late arrival to the meeting (9:30) due to conflicting unavoidable commitments.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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 (at the time of entering the meeting for Tamara Coja, 9:30).

## 4. Statement drafting, microorganism life cycle and transposition.

WG members have continued working in the draft the statement.

WG agreed on the current text drafted for the "Interpretation of the terms of reference" and "Data and methodologies". Further revisions of these sections may be needed once the statement is close to finalization.

WG agreed on the justification drafted in relation to the need to examine the information in the dossier concerning the taxonomic classification of the microorganism.

Studies in the dossier that contain information or investigated the translocation and proliferation of the microorganism in the plants have been identified and conclusions that can be derived from them are summarized in the statement and put in relation with the state of the art.

Conclusions and consequences for the risk assessment were discussed. Final conclusion on this issue needs to await the consultation with the hearing expert from RMS. WG group will formulate the relevant questions for the hearing expert by the 13<sup>th</sup> of May.

## 5. Statement drafting, DDR metabolite formation, fate and transposition.

Information available in the dossier addressing the production of the metabolite DDR by *P.chlororaphis* M342 and its degradation was discussed by the WG. RMS hearing expert will be consulted in relation

<sup>1</sup> [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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



to these and other possible information in the dossier related to the production and degradation of the metabolite DDR.

Studies investigating the levels of DDR in barley plants, its representativeness and reliability were also discussed.

WG group will formulate the relevant questions for the hearing expert by the 13<sup>th</sup> of May.

## 6. Statement drafting, DDR metabolite genotoxicity.

The SC WG on genotoxicity provided a new assessment of the two available genotoxicity studies essentially confirming the findings of the peer review. The conclusion of this SC WG has been summarized and transferred to the draft statement.

WG agreed that this part of the assessment can be presented in detail in the next plenary of the panel the 10-11<sup>th</sup> of June.

## 7. Preparation of questions for the RMS hearing expert.

Some possible questions to be addressed to the RMS's hearing expert were identified. These questions consist of request for clarifications on statements of RMS in the RAR and the RMS position paper attached by the European Commission to the mandate. Statements in RMS position paper are only to be considered if referring to information contained in the dossier (not to new studies). The WG agree to finalize the formulation of the questions in writing (deadline: 13<sup>th</sup> of May). The WG also propose to explore the organization of an additional meeting at the end of May for the consultation of the hearing expert.

## 8. Tasks identification and allocation

EFSA (Oriol): To consult internally on the possibility of organising an additional meeting on the 28<sup>th</sup> of May and initiate the procedure for the invitation of the RMS's hearing expert (deadline: 30<sup>th</sup> of April).

All to prepare and agree the questions for the hearing expert (deadline: 13<sup>th</sup> of May).

All to update the draft statement as appropriate according the discussed items (deadline: 21<sup>st</sup> of May).

## 9. Next WG meeting

The dates for next meetings were confirmed, an additional meeting was proposed:

Teleconference 3b: 28<sup>th</sup> of May (Morning). Additional meeting proposed, pending of approval by EFSA.\*

Teleconference 3c: 25<sup>th</sup> of June (Morning).

Physical meeting: 1<sup>st</sup> of September (Full day).

**\*Post meeting note:** The organization of this additional meeting has already been agreed at the time of publishing these minutes.



## PESTICIDE PEER REVIEW UNIT

### MINUTES OF THE 2<sup>ND</sup> MEETING OF THE WORKING GROUP ON PSEUDOMONAS CLORORAPHIS STRAIN MA 342

**Held on 8 and 14 April 2020 (via tele-web conference)**

**(Agreed on 21 April 2020)**

#### Participants

- Working Group Members:  
Anneli WIDENFALK, Tamara COJA, Lieve HERMAN.
- Hearing Experts:  
Not applicable
- European Commission and/or Member States representatives:  
Not applicable
- EFSA:  
PRES Unit: J. Oriol MAGRANS (chair of teleconference).
- Others:  
Not applicable





## DAY 1- 8 APRIL 2020

### 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.

### 2. Adoption of agenda

The agenda was adopted without changes.

### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. Drafting of the statement, general issues.

WG members have been already working in the draft statement. The draft statement can be found in EFSA DMS.

### 5. Drafting of the statement, Interpretation of the terms of reference.

The Terms of the Reference in the statement should be presented in the statement as provided by the requestor (EC in this case). Clarifications and general issues related to the Terms of Reference are to be presented by the Panel in the Interpretation of the Terms of Reference section of the statement.

### 6. Update / feedback from the BIOHAZARD panel on QPS

In the previous meeting, the WG noted that *Pseudomonas chlororaphis* is discussed in an opinion of the EFSA Biohazards Panel (2015) and it is not considered a QPS. The WG previously discussed on the need for a possible confirmation / update on the status of *Pseudomonas chlororaphis* MA342 with respect to QPS criteria. After internal considerations by EFSA, the EFSA Biohazards Panel will update the QPS statement on *P. chlororaphis*. This update is expected to be available by June 2020.

### 7. Drafting of the statement, taxonomic identification

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<sup>1</sup> [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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



EFSA conclusion did not identify any issue with respect to the identity of the microorganism. The *P. chlororaphis* strain MA342 has been deposited in 1994 in the NCIMB collection, Sweden under the deposition number NCIMB 40616 (certificate of deposition in the dossier).

However, there is no data available in the dossier confirming the identity of the strain designed as *P. chlororaphis* MA342 as belonging to the species *P. chlororaphis*. The microorganism was characterized according the methodology and knowledge available at the time of the first authorization. No updated identification according the state of the art is available in the renewal dossier. This is a source of uncertainty in relation to the relevance of data of papers referring to only the species, not mentioning the specific strain MA 342. This uncertainty will be presented as appropriate in the statement where relevant.

## **8. Drafting of the statement, Assessment of degradation and translocation. Microorganism**

Data available with respect to the translocation of the microorganism had been reviewed and conclusions were presented to the group and drafted in the statement.

### **DAY 2 – 14 APRIL 2020**

## **9. Welcome apologies for absence and declaration of interest**

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. No interests were declared orally by the members at the beginning of the second session of this meeting

## **10. Drafting of the statement, Assessment of degradation and translocation. Metabolite DDR degradation**

Different aspects in relation to the information of metabolite DDR available in the dossier was considered by the WG.

-The main study addressing the degradation of DDR in the dossier is the study: "Decomposition of DDR in bacterial suspension supernatant at different pH and temperature" (Eriksson 2000). Aspects of this study were discussed, in relation to standard requirements and the [OECD 111 test guideline](#) (hydrolysis as a function of pH).

Other issues that were considered in relation to the metabolite DDR are:

-Whether information in the dossier allows to determine possible natural background levels and the origin of the claim that a certain percentage of other soil microorganisms produce it.

-Whether information in the dossier allow to assess if DDR can be formed and taken up from soil by the plants.

-Whether information in the dossier allow to determine levels of DDR in edible parts of plants (peas and cereals) after seed treatment. Quality and reliability of the residue trials available and analytical method and LOQ of DDR in edible plant parts in the studies presented in the dossier.

-Potential implications of the existence of other sources of exposure to DDR with respect to the risk assessment (e.g. in relation to the applicability of the TTC approach for consumers risk assessment).



- Possible effects of cooking and other processing on the degradation of DDR before consumption.
- Identification of uncertainties and possible conclusion recommendations.

### **11. Update / Feedback from the SC WG on genotoxicity**

SC WG Genotoxicity meeting held on 19-20 March, 2020 agreed providing feedback on the aneugenicity of DDR. The WG was informed that the SC WG genotoxicity will be discussing the issue of the aneugenicity of metabolite DDR on a meeting the 15th of April. The result of their discussions will be provided to the WG and incorporated into the statement for further discussion and agreement next WG meeting.

### **12. Drafting of the statement, Assessment of degradation and translocation. Metabolite DDR Genotoxicity**

Further discussion on the genotoxic properties of metabolite DDR were postponed waiting for the feedback of the SC WG genotoxicity (see point 11).

### **13. Drafting of the statement, Conclusions**

Some conclusions were suggested along the discussion of the different sections of the statement. However, it was found still premature to agree or formulate them.

### **14. Drafting of the statement, Recommendations**

Some recommendations were suggested along the discussion of the different sections of the statement. However, it was found still premature to agree or formulate them.

### **15. Tasks identifications, allocation**

EFSA to search and provide some studies referenced in the RAR but not found in the folders with the selected relevant studies in the dossier (deadline: 17<sup>th</sup> of April).

All to update the draft statement according to discussed items (deadline: 24<sup>th</sup> of April).

The possibility of inviting a RMS expert as a hearing expert for one of next WG meeting was considered.

### **16. Next WG meetings**

The dates for next meeting were confirmed:

- Teleconference IIa: 27th of April (Morning).
- Teleconference IIb: 25th of June (Morning).
- Physical meeting: 1st of September (Full day).



PESTICIDE PEER REVIEW UNIT

## PESTICIDE PEER REVIEW UNIT

### MINUTES OF THE 1<sup>ST</sup> MEETING OF THE WORKING GROUP ON PSEUDOMONAS CLORORAPHIS STRAIN MA 342

**Held on 27 February 2020, (via tele-web conference)**

**(Agreed on 09 March 2020)**

#### Participants

- Working Group Members:  
Anneli WIDENFALK, Tamara COJA, Lieve HERMAN
- Hearing Experts:  
Not Applicable
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
PRES Unit: J. Oriol MAGRANS (chair of teleconference); PREV Unit: Arianna CHIUSOLO.
- 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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. Presentation of the mandate, background information and project planning.

The new mandate: "*Request for a scientific advice on the translocation potential by *Pseudomonas chlororaphis* MA342 in plants after seed treatment of cereals and peas and, if applicable, for a revision of the assessment of the risk to humans*" from the European Commission to EFSA's PPR Panel was presented to the WG members.

EC ask for the statement to be provided by 30th of September 2020.

## 5. Interpretation of the terms of reference

### **Items discussed**

The motivations and justification for the acceptance of the mandate and the regulatory framework of plant protection products was discussed.

EFSA will incorporate the studies found in the applicant dossier in a dedicated folder accessible by the WG members.

### **General issues**

The WG will elaborate a justification of acceptance in relation of the conflicting appraisals of studies in the dossier.

The WG will need to consider the quality of studies presented by the applicant, since a number of the studies in the dossier have not been performed under GLP. Regulation already foresees a derogation of the requirement of GLP status for studies supporting microorganisms.

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<sup>1</sup> [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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



The WG noted that *Pseudomonas Chlororaphis* is discussed in an opinion of the EFSA Biohazards Panel (2015) and it is not considered a QPS. The WG discussed on the need for a possible confirmation / update on the status of *Pseudomonas chlororaphis* MA342 with respect to QPS criteria.

### **Translocation of the microorganism and metabolite DDR to edible parts of the plants**

Studies in the dossier will be examined and assessed by the WG.

### **Auneugenicity of metabolite DDR**

The dossier contains two studies addressing genotoxicity (aeneugenicity) of metabolite DDR.

The WG noted that the Scientific Committee Standing Working Group on genotoxicity is currently finalising a draft guidance document on auneugenicity for public consultation.

The WG decided to request feedback from the SC SWG on Genotoxicity with respect to the auneugenicity of metabolite DDR. The issue will be presented to the SC WG Genotoxicity to be held the 19-20 March, 2020.

## **6. Structure of the output**

The structure of the output was discussed and agreed.

## **7. Tasks identification and allocation**

- EFSA will incorporate in DMS folders accessible to the WG members the studies found in the applicant's dossier. **Deadline:** 02/03/2020
- EFSA to introduce the Terms of Reference as provided by the requester in the draft statement. **Deadline:** 27/03/2020
- WG experts to develop criteria for assessment of reliability of the studies. Deadline: week 2 to 6 / 03 / 2020.
- EFSA and WG experts to draft the Interpretation of the Terms of Reference in the draft statement. **Deadline:** 27/03/2020.
- The issue of the auneugenicity of metabolite DDR will be presented to the SC WG Genotoxicity to be held the 19-20 March, 2020. **Deadline:** week 2 to 6 / 03 / 2020
- Request to the Biohazard Panel QPS Working Group for a confirmation /update on the status of *Pseudomonas chlororaphis* MA342. **Deadline:** week 2 to 6 / 03 / 2020



## 8. Next meetings

The dates for next meeting were identified and agreed:

Physical meeting: 2nd of April (Full day)\*

Teleconference IIa: 27th of April (Morning)

Teleconference IIb: 25th of June (Morning)

Physical meeting: 1st of September (Full day).

**\*Post meeting note:** The Italian government issued a new decree on the 08/03/2020 outlining the new measures put in place, across the Lombardy region and the provinces of Modena, Parma, Piacenza, Reggio nell'Emilia, Rimini, Pesaro e Urbino, Venezia, Padova, Treviso, Asti, Vercelli, Novara, Verbano Cusio Ossola e Alessandria, and also across the rest of the country, to contrast and contain the spread of COVID-19 virus. These measures will apply from today 08/03/2020 to Friday 03/04/2020.

Amongst other measures, the decree orders to absolutely avoid any movement in and out of the designated territories, as well as within such territories, with the exception of movements justified by irrevocable work needs or emergency situations. The decree also outlines the suspension of schools, universities, creches, public gatherings etc. until 03/04/2020.

Consequently, the meeting of the WG foreseen for the 2<sup>nd</sup> of April as a physical meeting will take place in the form of a teleconference.