



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 11<sup>th</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held on 5 October 2020 by teleconference**

**(Agreed on 13 October 2020)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford  
Thorhallur Halldorsson  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Maria Chiara Astuto  
FIP Unit: Katharina Volk
- Others:  
Not Applicable

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<sup>1</sup> As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
[http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/expertselection.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf)

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Bernard Bottex, Anna Castoldi, Arianna Chiusolo, and Andrea Terron.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Scientific topic(s) for discussion

### 4.1 Assessment of NMDR<sup>4</sup>

The WG members revised the different Sections of the draft Scientific Opinion in line with the comments received from the WG on BPA and the Scientific Committee. The members discussed the proposed ameliorations and the agreed text was integrated accordingly.

The WG members proceeded with the delivery of the tasks allocated in the last meeting. The members evaluated the new articles on BPA and reviewed the second part of the probabilistic analysis results. After discussion, the new content was agreed and integrated into the main text of the draft Scientific Opinion. All the details will be reported in the dedicated Annexes. Lastly, the text for the Section on the Conclusions was proposed and the main elements agreed.

Finally, the WG agreed on the next steps, and additional tasks were agreed between the WG members. The document will be presented for endorsement for public consultation at the November Scientific Committee plenary meeting. All the comments received will be used for the finalisation of the Scientific Opinion.

## 5. Any Other Business

### 5.1 Not Applicable

## 6. Next meeting(s)

The next WG meeting dates will be decided later.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 10<sup>th</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held on 4 September 2020 by teleconference**

**(Agreed on 15 September 2020)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford  
Thorhallur Halldorsson  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Maria Chiara Astuto
- Others:  
Not Applicable

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<sup>1</sup> 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>.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Bernard Bottex, Anna Castoldi, Arianna Chiusolo, Andrea Terron, and Katharina Volk.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Scientific topic(s) for discussion

### 4.1 Assessment of NMDR<sup>4</sup>

The WG members revised the different Sections of the draft Scientific Opinion. The document was amended in line with the comments provided by the members. The WG reviewed the first part of the probabilistic analysis results. New content was proposed and agreed upon. A draft version of the document was prepared for submission to the September Scientific Committee plenary meeting. Finally, the WG agreed on the next steps, and additional tasks were distributed among the WG members.

## 5. Any Other Business

### 5.1 Not Applicable

## 6. Next meeting(s)

The next meeting is scheduled for 5 October 2020, by teleconference.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 9<sup>th</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held on 6 July 2020 by teleconference**

**(Agreed on 16 July 2020)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford  
Thorhallur Halldorsson  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Bernard Bottex (absent), Maria Chiara Astuto  
PREV Unit: Andrea Terron (absent) and Arianna Chiusolo (absent)  
FIP Unit: Anna Federica Castoldi and Katharina Volk
- Others:  
Not Applicable

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<sup>1</sup> 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>.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron, Arianna Chiusolo, and Bernard Bottex.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Scientific topic(s) for discussion

### 4.1 Assessment of NMDR<sup>4</sup>

The WG revised the content of the different Sections of the draft Scientific Opinion. The document was amended following the proposals on new text, figures, and tables provided by the members. A new structure of the document was discussed and agreed upon. The WG proceeded with the review of the Annexes dedicated to the assessment of the non-monotonic dose-response (NMDR) observed for BPA and phthalates. A new Annex should be produced on the details of the probabilistic assessment. Based on the new achievements, a new draft version of the document will be produced and then shared with the members, for further revision and refinement. The WG members agreed on the work plan and additional tasks were distributed.

## 5. Any Other Business

### 5.1 Not Applicable

## 6. Next meeting(s)

The next meeting is scheduled for 4 September 2020, by teleconference.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 8<sup>th</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held on 20-21 May 2020 by teleconference**

**(Agreed on 5 June 2020)**

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.

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford  
Thorhallur Halldorsson  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Bernard Bottex (absent), Maria Chiara Astuto  
PREV Unit: Andrea Terron (absent) and Arianna Chiusolo (absent)  
FIP Unit: Anna Federica Castoldi (absent)
- Others:

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<sup>1</sup> 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>.

Not Applicable

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron, Arianna Chiusolo, Anna Federica Castoldi, and Bernard Bottex.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Scientific topic(s) for discussion

### 4.1 Assessment of NMDR<sup>4</sup>

The WG reviewed the new evidence for non-monotonic dose-response for phthalates. Based on this information, a new text was proposed and discussed by the members. The WG proceeded with the review of additional experimental studies on the non-monotonic dose-response for BPA, supported by the statistical evaluation. The considerations from the assessment of NMDRs for phthalates and BPA will be addressed in a dedicated Annex. The WG continued the revision of the draft Scientific Opinion. The structure and the related content were revised according to comments from the members. Lastly, the WG agreed on the work plan and additional tasks were distributed.

## 5. Any Other Business

### 5.1 Not Applicable

## 6. Next meeting(s)

The next meeting is scheduled for 6 July 2020, by teleconference.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>





SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 7<sup>th</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held on 29 April 2020 by teleconference**

**(Agreed on 7 May 2020)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford (absent)  
Thorhallur Halldorsson  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin (absent)
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Bernard Bottex (absent), Maria Chiara Astuto  
PREV Unit: Andrea Terron and Arianna Chiusolo (absent)  
FIP Unit: Anna Federica Castoldi (absent)
- Others:  
Not Applicable

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<sup>1</sup> 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>.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron, Arianna Chiusolo, Anna Federica Castoldi, Bernard Bottex, Diane Benford and Laurent Bodin.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Scientific topic(s) for discussion

### 4.1 Assessment of NMDR<sup>4</sup>

The WG addressed the comments from the Scientific Committee plenary meeting and agreed on the adoption of the proposed ameliorations. The members proceeded with the analysis of the evidence of non-monotonic dose-response for BPA. Lastly, the WG members discussed the next steps and additional tasks were distributed.

## 5. Any Other Business

### 5.1 Not Applicable

## 6. Next meeting(s)

The next meeting is scheduled for 20-21 May 2020 by teleconference.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 6<sup>th</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held on 8 April 2020 by teleconference**

**(Agreed on 21 April 2020)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford  
Thorhallur Halldorsson  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Bernard Bottex (absent), Maria Chiara Astuto  
PREV Unit: Andrea Terron and Arianna Chiusolo (absent)  
FIP Unit: Anna Federica Castoldi
- Others:  
Not Applicable

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<sup>1</sup> 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>.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron, Arianna Chiusolo and Bernard Bottex.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Scientific topic(s) for discussion

### 4.1 Assessment of NMDR<sup>4</sup>

The WG revised the different Sections of the draft Scientific Opinion according to the comments provided by the members. In addition, key elements to be presented at the April Scientific Committee plenary meeting were agreed upon. Additional tasks were allocated among the WG members.

## 5. Any Other Business

### 5.1 Not Applicable

## 6. Next meeting(s)

The next meeting has been tentatively scheduled for 20-21 May 2020 by teleconference.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 5<sup>th</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held on 26-27 March 2020 by teleconference**

**(Agreed on 6 April 2020)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford  
Thorhallur Halldorsson  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Bernard Bottex (absent), Maria Chiara Astuto  
PREV Unit: Andrea Terron (absent)  
FIP Unit: Anna Federica Castoldi (absent)
- Others:  
Not Applicable

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<sup>1</sup> 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>.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron, Bernard Bottex and Anna Federica Castoldi.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Scientific topic(s) for discussion

### 5.1. Assessment of NMDR<sup>4</sup>

The members presented the results of the tasks allocated in the previous meeting and revised the additional evidence for BPA and phthalates. During the review, the WG members reflected on possible implications of the observed non-monotonic dose-response relations for the current risk assessment practices (in accordance with the Terms of References). The WG members discussed the draft Scientific Opinion and agreed on large parts of the text. In addition, key elements to be presented at the April Scientific Committee plenary meeting were agreed upon. The WG members agreed on next steps, and additional tasks have been allocated.

## 5. Any Other Business

### 5.1. Not Applicable

## 6. Next meeting(s)

The next meeting has been scheduled for the 8<sup>th</sup> April 2020 by teleconference.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 4th MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held in Parma on 17-18 February 2020**

**(Agreed on 26 February 2020)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford (by teleconference)  
Thorhallur Halldorsson  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin (by teleconference)
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Bernard Bottex (absent), Maria Chiara Astuto  
PREV Unit: Andrea Terron (absent)  
FIP Unit: Anna Federica Castoldi (present on 17)
- Others:  
Not Applicable

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<sup>1</sup> 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>.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron and Bernard Bottex.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Scientific topic(s) for discussion

### 5.1. Assessment of NMDR<sup>4</sup>

The WG analysed additional experimental studies in order to evaluate the biological plausibility of non-monotonic behaviours of the response claimed in the scientific papers. During the assessment, the WG members also focused on the relevance of these effects in relation to the current risk assessment practices (in accordance with the Terms of References). Additional tasks have been allocated among the WG members.

## 5. Any Other Business

### 5.1. Not Applicable

## 6. Next meeting(s)

Tentatively, a meeting has been scheduled for 26 March (afternoon) and 27 March (morning) 2020, to be confirmed.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>





SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 3rd MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held in Parma on 5 December 2019**

**(Agreed on 18 December 2019)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford (by teleconference)  
Thorhallur Halldorsson  
Josef Schlatter
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Jose Tarazona, Maria Chiara Astuto  
PREV Unit: Andrea Terron  
FIP Unit: Anna Federica Castoldi
- Others:  
Not Applicable

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from the hearing expert Laurent Bodin and the EFSA staff Arianna Chiusolo and Bernard Bottex.

## 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. Hearing Expert (s)

Dr Laurent Bodin sent apologies.

## 5. Scientific topic(s) for discussion

### 5.1. Assessment of NMDR<sup>3</sup>

The WG analysed the details of selected publications mentioned in the external report, focusing on the biological plausibility, and relevance for the risk assessment, of the endpoints showing potentially non-monotonic dose responses in the statistical/visual analysis. The structure of the information to be extracted from each publication for these detailed assessments was confirmed. This activity will continue with the incorporation of additional studies, covering also some recent publications not mentioned in the external report.

In line with the Terms of Reference, EFSA presented, for information, available databases compiling the endpoints mostly used for setting ADIs and other Health Based Guidance Values (HBGV) in EFSA scientific assessments.

Additional tasks were agreed and distributed among the WG members.

## 6. Any Other Business

### 6.1. Not Applicable

## 7. Next meeting(s)

Tentatively, a meeting has been scheduled for 17 February (afternoon) and 18 February (morning) 2020, to be confirmed.

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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)

<sup>3</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 2<sup>nd</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held by teleconference on 23 October 2019**

**(Agreed on 05 November 2019)**

#### Participants

- Working Group Members:
  - Maged Younes (Chair)
  - Diane Benford
  - Thorhallur Halldorsson
  - Josef Schlatter
- Hearing Experts<sup>1</sup>:
  - Laurent Bodin
- European Commission and/or Member States representatives:
  - Not Applicable
- EFSA:
  - SCER Unit: Bernard Bottex, Jose Tarazona
  - PREV Unit: Arianna Chiusolo
- Others:
  - Not Applicable

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<sup>1</sup> 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>.

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Andrea Terron.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Hearing Expert (s)

Dr Laurent Bodin was invited for supporting the WG in the assessment of the external report and ANSES probabilistic assessments and to provide clarifications on the methodology and the results of the statistical analysis.

## 5. Scientific topic(s) for discussion

### 5.1. Assessment of NMDR<sup>4</sup>

The WG analysed the first contributions resulting from the task distribution agreed at the first meeting.

During the discussion, the basic elements for the introduction were agreed. Additional tasks were agreed and distributed among the WG members.

A tentative date for the next meeting was agreed pending final confirmation.

## 6. Any Other Business

### 6.1. Not Applicable

## 7. Next meeting(s)

Tentatively, a meeting has been scheduled for 5 December 2019, to be confirmed.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>



SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 1<sup>ST</sup> MEETING OF THE WORKING GROUP ON NON-MONOTONIC DOSE RESPONSES

**Held on 11 September 2019, Parma**

**(Agreed on 23 September 2019)**

#### Participants

- Working Group Members:  
Maged Younes (Chair)  
Diane Benford  
Josef Schlatter
- Hearing Experts<sup>1</sup>:  
Laurent Bodin has participated via teleconference
- European Commission and/or Member States representatives:  
Not Applicable
- EFSA:  
SCER Unit: Bernard Bottex, Jose Tarazona  
PREV Unit: Arianna Chiusolo  
Not Applicable
- Others:  
Not Applicable

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.

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<sup>1</sup> 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>.

Apologies were received from Thorhallur Halldorsson and Andrea Terron.

## 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>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</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. Hearing Expert (s)

Dr Laurent Bodin was invited to present the external report and ANSES probabilistic assessments and to provide clarifications on the methodology and the results of the statistical analysis.

## 5. Scientific topic(s) for discussion

### 5.1. Assessment of NMDR<sup>4</sup>

The WG analysed the Terms of Reference and considered that they were clear and feasible within the proposed timeline.

Following a presentation by the Hearing Expert of the external report and the additional probabilistic assessment, covering both the methodology and the key results, the available information was examined.

During the discussion, a set of elements to be considered and included in the scientific opinion were identified. The first tasks were agreed and distributed among the WG members.

A tentative date for the next meeting, to be held by teleconference, was agreed pending final confirmation.

## 6. Any Other Business

### 6.1. Not Applicable

## 7. Next meeting(s)

Tentatively, a teleconference has been scheduled for 23 October 2019, to be confirmed.

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<sup>2</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>3</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)

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00530>