

26 January 2024  
09:00-11:50 hours

**Location:** Teleconference

**Attendees:**

- Working Group Members:  
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukuła-Koch, Kirsten Pilegaard
- Hearing Experts:  
Josef Schlatter
- European Commission representatives:  
Fruzsina Nyemecz<sup>1</sup>
- EFSA:  
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Victor Bunea, George Kass  
FEEDCO Unit: Paola Manini  
MESE Unit: Jean Lou Dorne, Alicia Paini
- Others:  
Observers from the European Medicines Agency: Jorge Rodrigues, Karin Erika Svedlund

## **I. Welcome and apologies for absence**

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Castenmiller.

## **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 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.

## **IV. Scientific topic(s) for discussion**

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<sup>1</sup> From 10.45 onwards

<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)



The sixth Working Group (WG) meeting was dedicated to the presentation of the data received through the call for data and the outcome of the systematic reviews which were conducted in relation to the following mandates:

- Safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C. Presl) (EFSA-Q-2022-00804)
- Safety in use of plant preparations containing berberine (EFSA-Q-2022-00803)
- Safety in use of plant preparations containing hydroxycitric acid and of isolated hydroxycitric acid (EFSA-Q-2022-00805)

The WG was also presented with an overview about the status of the evaluation of data submitted on botanical species containing hydroxyanthracene derivatives submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006 for safety evaluation of substances placed under Union scrutiny in Part C of Annex III (EFSA-Q-2022-00790). The evaluation is carried out by the cross-cutting WG on Genotoxicity of the EFSA Scientific Committee.

## **V. Any Other Business**

## **VI. Next meeting**

The next meeting will be held on 13th February 2024, via teleconference.

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16 October 2023  
14:00-17:00 hours

**Location:** Teleconference

**Attendees:**

- Working Group Members:  
Alexandre Maciuk (WG Chair), Carlo Bicchi, Jacqueline Castenmiller, Josef Rasinger, Wirginia Kukuła-Koch
- Hearing Experts:  
Jacqueline Wiesner, Josef Schlatter, Kirsten Pilegaard
- EFSA:  
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Victor Bunea
- Others:  
FEEDCO Unit: Paola Manini  
MESE Unit: Jean Lou CM Dorne<sup>1</sup>

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

## **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 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.

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 Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

## **IV. Scientific topic(s) for discussion**

The fifth Working Group (WG) meeting was dedicated to the introduction of TKplate tool and the WG was informed about the ongoing work on hydroxyanthracene derivatives (HADs).

### **a. Presentation of TKPlate tool: An open access Platform for toxicokinetic and toxicodynamic modelling of chemicals**

The TKPlate tool was presented and commented on by the members of the WG.

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<sup>1</sup> Present only for the first agenda point.

<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)



**b. HYDROXYANTHRACENE DERIVATIVES (HADS): FILES FOR THE SAFETY OF SUBSTANCES LISTED IN ANNEX III, PART C OF REGULATION 1925/2006**

New data related to botanical species containing Hydroxyanthracene derivatives (HADs) have been presented and commented by the WG, pursuant to Article 8(4) of Regulation (EC) No 1925/2006 for safety evaluation of substances placed under Union scrutiny in Part C of Annex III.

**V. Any Other Business**

The WG agreed on the meeting dates for the next year.

**VI. Next meeting**

The next meeting will be held on 26<sup>th</sup> January 2024, via web conference.

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## Annex

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

With regard to this meeting, Alexandre Maciuk declared the following interests: Member of scientific advisory entities (Association Française de Normalisation, European pharmacopoeia) and a research funding project on plant-derived vaccine adjuvants. In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

With regard to this meeting, Wirginia Kukuła-Koch declared the following interests: a public funded research project and a patent related emodin glucoside. In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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.

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<sup>4</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>5</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>6</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>7</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)

12 and 14 June 2023

14:00-17:00 hours (day 1) / 09:00-13:00 hours (day 2)

**Location:** Webconference

**Attendees:**

- Working Group Members:  
Alexandre Maciuk (WG Chair), Carlo Bicchi, Jacqueline Castenmiller, Josef Rasinger
- Hearing Experts<sup>1</sup>:  
Jacqueline Wiesner<sup>2</sup>, Josef Schlatter<sup>2</sup>
- EFSA:  
NIF Unit: Ariane Titz, Lucia Fabiani, Leng Heng<sup>3</sup>, Leonard Matijević, Pedro das Neves Ferreira, Roanne Saad, Thibault Fiolet
- Others:  
KNOW Unit: Bernard Bottex  
FEEDCO Unit: Paola Manini<sup>2</sup>, Yvette Dirven<sup>2</sup>

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

## **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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</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.

## **IV. Scientific topic(s) for discussion**

The fourth Working Group (WG) meeting was dedicated to discussing the comments received from the public consultation on the draft protocols, taking place between 12<sup>th</sup> May and 11<sup>th</sup> June (see following).

- a. Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine ([EFSA-Q-2022-00803](#))**

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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>

<sup>2</sup> Participation only on the 2nd day of the meeting in relation to EFSA-Q-2022-00804

<sup>3</sup> Participation only on the 1st day of the meeting in relation to EFSA-Q-2022-00803 and EFSA-Q-2022-00805

<sup>4</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>5</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)



**b. Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid ([EFSA-Q-2022-00805](#))**

The WG was presented with, and discussed the comments submitted by the interested parties during the public consultation, regarding both protocols. The appropriate changes were applied in the documents, and the answers to be included in the technical report were agreed by the WG members.

The meeting proceeded with a discussion on methodological aspects of the call for data which will address some of the risk assessment sub-questions.

**c. Scientific Opinion on the evaluation of the safety of use of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung ([EFSA-Q-2022-00804](#))**

The second day of the WG was fully dedicated to review the comments from the public consultation on the protocol for the assessment of the safety of preparations of fruits of bitter and sweet fennel.

The approach to the call for data to be launched was also reviewed.

## **V. Any Other Business**

None.

## **VI. Next meeting**

The next meeting will be held on 11<sup>th</sup> September 2023, via web conference.

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13 and 21 April 2023

09:00-13:00 hours (day 1) / 09:00-13:00 hours (day 2)

**Location:** Webconference

**Attendees:**

- Working Group Members:  
Alexandre Maciuk (WG Chair), Carlo Bicchi, Wirginia Kukula-Koch, Josef Rasinger
- Hearing Experts<sup>1</sup>:  
Josef Schlatter<sup>2</sup>
- EFSA:  
NIF Unit: Pedro das Neves Ferreira<sup>3</sup>, Lucia Fabiani, Thibault Fiolet, George Kass<sup>2</sup>, Leonard Matijević<sup>3</sup>, Roanne Saad, Ariane Titz
- Others:  
KNOW Unit: Bernard Bottex<sup>3</sup>  
MESE Unit: José Ángel Ruiz Gómez<sup>2</sup>  
FEEDCO Unit: Paola Manini<sup>2</sup>, Yvette Dirven<sup>2</sup>

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

## **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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</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.

## **IV. Scientific topic(s) for discussion**

The third Working Group (WG) meeting resumed the discussion of the draft protocols for the assessments to be carried out on the mandates received from the European Commission (see following).

### **a. Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine. ([EFSA-Q-2022-00803](#))**

<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>

<sup>2</sup> Participation only on the 2<sup>nd</sup> day of the meeting in relation to EFSA-Q-2022-00804

<sup>3</sup> Participation only on the 1<sup>st</sup> day of the meeting in relation to EFSA-Q-2022-00803 and EFSA-Q-2022-00805

<sup>4</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>5</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)





**b. Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid. ([EFSA-Q-2022-00805](#))**

The WG resumed the discussion on the two draft protocols, taking into account the feedback received from the NDA Panel during its meeting on 30 March 2023. For the protocol related to the assessment of the safety of plant preparations containing berberine, the assessment of the exposure to berberine was rediscussed and some amendments were proposed. Specific discussions took place on the evidence needs for answering the risk assessment questions for both protocols. The draft protocols will be submitted to the NDA Panel for endorsement for public consultation during its meeting on 27 April 2023.

**c. Scientific Opinion on the evaluation of the safety of use of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung ([EFSA-Q-2022-00804](#))**

The WG resumed the discussion on the draft protocol, taking into account the feedback received from the NDA Panel during its meeting on 30 March 2023. The discussion of the WG focused mainly on the exposure assessment to be carried out, followed by the ADME of estragole, the risk characterization and the evidence needs for answering the risk assessment questions. The draft protocol will be submitted to the NDA Panel for endorsement for public consultation during its meeting on 27 April 2023.

## **V. Any Other Business**

None.

## **VI. Next meeting**

The next meeting will be held on 12<sup>th</sup> of June 2023, via web conference.

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6 and 7 March, 2023

14:00-17:00 hours (day 1) / 09:00-13:00 hours (day 2)

**Location:** Webconference

**Attendees:**

- Working Group Members:  
Alexander Maciuk (WG Chair), Wirginia Kukula-Koch, Carlo Bicchi, Jacqueline Castenmiller
- Hearing Experts<sup>1</sup>:  
Jacqueline Wiesner<sup>2</sup>, Josef Rasinger
- EFSA:  
NIF Unit: Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Pedro das Neves Ferreira, Roanne Saad
- Others:  
KNOW Unit: Bernard Bottex<sup>2</sup>  
MESE Unit: José Ángel Ruiz Gómez<sup>2</sup>  
ED Office: George Kass  
FEEDCO Unit: Paola Manini<sup>2</sup>, Yvette Dirven<sup>2</sup>

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

## **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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</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.

## **IV. Scientific topic(s) for discussion**

The second Working Group (WG) meeting resumed the discussion of the draft protocols for the assessments to be carried out on the mandates received from the European Commission (see following).

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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>

<sup>2</sup> Participation only on the 1<sup>st</sup> day of the meeting in relation to EFSA-Q-2022-00804 (fennel fruit preparations)

<sup>3</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>4</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)



**a. Scientific Opinion on the evaluation of the safety of use of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung ([EFSA-Q-2022-00804](#))**

The WG was updated with the feedback received in the 132<sup>nd</sup> NDA plenary meeting and presented with a new version of the draft protocol for the assessment of the safety of preparations of fruits of bitter and sweet fennel. The discussion of the WG focused on the exposure assessment to be carried out, and the evidence needs for answering the risk assessment questions.

**b. Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine. ([EFSA-Q-2022-00803](#))**

**c. Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid. ([EFSA-Q-2022-00805](#))**

The WG was presented with, and discussed, the endpoints to be taken under consideration in both Scientific Opinions, based on scoping searches of potential adverse health effects. Following, the evidence needs and the research methodologies to be used for answering the assessment sub-questions were defined.

## **V. Any Other Business**

None.

## **VI. Next meeting**

The next meeting will be held on 26<sup>th</sup> of April 2023, via web conference.

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# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 1<sup>st</sup> Working Group meeting on substances other than vitamins and minerals (Art. 8(2) of Regulation (EC) No 1925/2006)



13 and 17 February 2023

09:00-12:30 hours (day 1) / 13:30-16:30 hours (day 2)

**Location:** Webconference

### **Attendees:**

- Working Group Members:  
Alexander Maciuk (WG Chair), Wirginia Kukula-Koch, Carlo Bicchi, Jacqueline Castenmiller
- Hearing Experts<sup>1</sup>:  
Jacqueline Wiesner<sup>2</sup>, Josef Rasinger
- European Commission and/or Member States representatives:  
EC: Carolin Bendadani, Fruzsina Nyemecz<sup>2</sup>
- European Medicines Agency:  
Wieland Peschel<sup>2</sup>
- EFSA:  
NIF Unit: Leng Heng, Ariane Titz, Lucia Fabiani, Leonard Matijević, Thibault Fiolet, Pedro das Neves Ferreira, Roanne Saad
- Others:  
KNOW Unit: Bernard Bottex<sup>2</sup>  
MESE Unit: José Ángel Ruiz Gómez<sup>2</sup>  
ED Office: George Kass  
FEEDCO Unit: Paola Manini<sup>2</sup>, Yvette Dirven<sup>2</sup>

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

## **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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</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.

## **IV. Scientific topic(s) for discussion**

<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>

<sup>2</sup> Participation only on the 2<sup>nd</sup> day of the meeting in relation to EFSA-Q-2022-00804 (fennel fruit preparations)

<sup>3</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>4</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 first Working Group (WG) was dedicated to the discussion of the draft protocols for the assessments to be carried out on the mandates received from the European Commission (see following). WG members were informed about the background of the mandates. The Secretariat presented to WG members the EFSA framework for the use of protocols in scientific assessment.

- a. **Scientific Opinion on the evaluation of the safety in use of plant preparations containing berberine. ([EFSA-Q-2022-00803](#))**
- b. **Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid and isolated hydroxycitric acid. ([EFSA-Q-2022-00805](#))**

The WG discussed the first drafts of the protocols, addressing the following elements: problem formulation, target population and definition of the exposure of interest. Discussions took also place on the relevant endpoints to be included in the opinion.

- c. **Scientific Opinion on the evaluation of the safety of use of preparations from the fruits of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung ([EFSA-Q-2022-00804](#))**

The second day of the WG meeting was dedicated to reviewing the first draft of the protocol for the assessment of the safety of preparations of fruits of bitter and sweet fennel. The discussion of the WG focused on previous assessments of fennel fruit preparations and on how to conduct the exposure assessment.

## V. Any Other Business

None.

## VI. Next meeting

The next meeting will be held on 6<sup>th</sup> and 7<sup>th</sup> March 2023, via web conference.

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