5th Working Group meeting on Thebaine and Oripavine

8 December 2025 14:00-18:00 MINUTES - Agreed on 8 December 2025



Location: Webconference

Attendees:

o Working Group Members:

Birgit Dusemund, Antonio Hernández-Jerez, Tim Hofer, Jean-Charles Leblanc

Hearing Experts¹:

Margherita Bignami, Emilio Benfenati

Applicants participating in a technical hearing²:

Not applicable

o European Commission and/or Member States representatives:

Frans Verstraete

o EFSA:

FEEDCO Unit: Anna Christodoulidou, Lydia Alarcón Asensio

MESE Unit: Zsuzsanna Horvath

Others:Not applicable

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 Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s with Risk Assessment". No conflicts of interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the Working Group members at the beginning of these meetings.

As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf

² As defined in the "EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products": https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6472

³ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf

MEETING MINUTES - 8 December 2025 5th Working Group meeting on Thebaine and Oripavine



IV. Agreement of the minutes of the 4th Working Group meeting held on 28 October 2025, via web-conference

The minutes of the 4th Working Group meeting were agreed during the meeting on 28 October 2025.

V. Scientific topic(s) for discussion

 Discussion of the EFSA scientific opinion on the risk for public health related to the presence of thebaine and oripavine in poppy seeds and derived products (<u>EFSA-Q-2024-00400</u>)

The WG discussed the occurrence data from 2018 in comparison to the data from previous years on thebaine and oripavine. The approach to follow for the occurrence and dietary exposure scenarios were agreed on by the WG. The QSAR data for genotoxicity was presented and interpretation of the results was discussed. The sections on Toxicokinetics, Animal toxicity, Human toxicity and Mode of Action were discussed. The list of pending tasks for next meeting was agreed on.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 21 January 2026, via web conference.

4th Working Group meeting on Thebaine and Oripavine

28 October 2025 14:00-18:00 MINUTES - Agreed on 28 October 2025



Location: Webconference

Attendees:

o Working Group Members:

Birgit Dusemund, Antonio Hernández-Jerez, Tim Hofer, Jean Charles Leblanc

Hearing Experts¹:

Emilio Benfenati

Applicants participating in a technical hearing²:

Not applicable

o European Commission and/or Member States representatives:

EFSA:

FEEDCO Unit: Anna Christodoulidou, Lydia Alarcón Asensio

MESE Unit: Zsuzsanna Horvath

Others:Not applicable

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 Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s with Risk Assessment". No conflicts of interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the Working Group members at the beginning of these meetings.

¹ As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf

² As defined in the "EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products": https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6472

³ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf

MEETING MINUTES - 28 October 2025 4th Working Group meeting on Thebaine and Oripavine



IV. Agreement of the minutes of the 3rd Working Group meeting held on 24 September 2025, via web-conference

The minutes of the 3rd Working Group meeting were agreed during the meeting on 24 September 2025.

V. Scientific topic(s) for discussion

a. Discussion of the EFSA scientific opinion on the risk for public health related to the presence of thebaine and oripavine in poppy seeds and derived products (<u>EFSA-Q-2024-00400</u>)

The WG discussed the occurrence data and the exposure approaches followed in the 2011 and 2018 EFSA Opinions on poppy alkaloids. The findings were compared to the available thebaine and oripavine occurrence data from the last 10 years and a way forward for the exposure assessment was discussed. The QSAR report was presented to the WG and the use of further computational models was discussed. The sections on Toxicokinetics, Animal toxicity, Developmental and reproductive toxicity, Neurotoxicity, Genotoxicity and Human toxicity were discussed. The list of pending tasks for next meeting was agreed.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 8 December 2025, via web conference.

3rd Working Group meeting on Thebaine and Oripavine

24 September 2025 9:00-16:00 MINUTES - Agreed on 24 September 2025



Location: Webconference

Attendees:

o Working Group Members:

Birgit Dusemund, Antonio Hernández-Jerez¹, Tim Hofer², Jean Charles Leblanc

Hearing Experts³:
 Margherita Bignami

Applicants participating in a technical hearing⁴:

Not applicable

o European Commission and/or Member States representatives:

EC: Frans Verstraete

EFSA:

FEEDCO Unit: Anna Christodoulidou, Lydia Alarcón Asensio

MESE Unit: Zsuzsanna Horvath

Others:Not applicable

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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s with Risk Assessment". No conflicts of interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the Working Group members at the beginning of these meetings.

¹ Absent from 9:30 to 10:30

² Present form 13:30 to 16:00

³ As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf

⁴ As defined in the "EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products": https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6472

 $^{^{5}\ \}underline{\text{https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf}$

⁶ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf

MEETING MINUTES - 24 September 2025 3rd Working Group meeting on Thebaine and Oripavine



IV. Agreement of the minutes of the 2nd Working Group meeting held on 10 June 2025, via web-conference

The minutes of the 2nd Working Group meeting were agreed during the meeting on 10 June 2025.

V. Scientific topic(s) for discussion

 Discussion of the EFSA scientific opinion on the risk for public health related to the presence of thebaine and oripavine in poppy seeds and derived products (<u>EFSA-Q-2024-00400</u>)

The WG discussed the changes made to the draft protocol sent for publication. The occurrence data available in the EFSA Scientific Datawarehouse (SDWH) on thebaine and oripavine in poppy seeds and other products for the last 10 years was presented. The strategy for data cleaning and the exposure approach were discussed. The animal toxicity studies, in particular acute toxicity, were discussed as well as MoA and biomonitoring data in humans. Toxicokinetic studies mainly on the distribution and metabolism of thebaine and oripavine were reviewed. The list of pending tasks for next meeting was agreed.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 28 October 2025, via web conference.

2nd Working Group meeting on Thebaine and Oripavine

10 June 2025 9:00-13:00 MINUTES - Agreed on 10 June 2025



Location: Webconference

Attendees:

o Working Group Members:

Birgit Dusemund, Antonio Hernández-Jerez, Tim Hofer

Hearing Experts¹:

Not Applicable

European Commission and/or Member States representatives:

EC: not present

o EFSA:

CONTAM Unit: Anna Christodoulidou, Lydia Alarcón Asensio

MESE Unit: Zsuzsanna Horvath

Others:Not applicable

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jean-Charles Leblanc

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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

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

MEETING MINUTES – 10 June 2025 2nd Working Group meeting on Thebaine and Oripavine



IV. Agreement of the minutes of the 1st Working Group meeting held on 9 April 2025, in via web-conference

The minutes of the 1st Working Group meeting were agreed by written procedure on 5 March 2025.

V. Scientific topic(s) for discussion

a. Discussion of the EFSA scientific opinion on the risk for public health related to the presence of thebaine and oripavine in poppy seeds and derived products (EFSA-Q-2024-00400)

The WG reviewed the Draft Protocol and made changes to better suit the requirements of this Opinion. Considerations of the assessment questions and eligibility criteria for the selection of toxicity studies were discussed. An overview of the selected literature was presented and the currently available toxicological and occurrence data was discussed by the WG. An extraction of the occurrence data on thebaine and oripavine available to EFSA from the last 10 years was presented. A first analysis of the amount of submitted data, critical food categories and distribution of the data was provided. Tasks were allocated.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 24 September 2025 via webconference.

1st Working Group meeting on Thebaine and Oripavine

9 April 2025 9:00-13:00 MINUTES - Agreed on 5 May 2025



Location: Webconference

Attendees:

o Working Group Members:

Birgit Dusemund, Antonio Hernández-Jerez, Tim Hofer, Jean-Carles Leblanc

Hearing Experts¹:

Not Applicable

European Commission and/or Member States representatives:

EC: not present

o EFSA:

CONTAM Unit: Anna Christodoulidou, Lydia Alarcón Asensio

MESE Unit: Zsuzsanna Horvath

Others:Not applicable

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 Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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

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

MEETING MINUTES - 9 April 2025 1st Working Group meeting on Thebaine and Oripavine



IV. Agreement of the minutes of the 1st Working Group meeting held on 9 April 2025, in via web-conference

The minutes of the 1st Working Group meeting were agreed by written procedure on 5 March 2025.

V. Scientific topic(s) for discussion

a. Discussion of the EFSA scientific opinion on the risk for public health related to the presence of thebaine and oripavine in poppy seeds and derived products (EFSA-Q-2024-00200)

The members of the Working Group were introduced to the collaborative way of work and discussed the mandate and the interpretation of the terms of reference. The WG agreed on upcoming meeting dates as well as the work plan that will be followed to draft this Opinion. A first discussion on the Draft Protocol was performed as well as a discussion on the structure of the draft Opinion on the risk for public health related to the presence of thebaine and oripavine in poppy seeds and derived products.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 10 June 2025 via webconference.