

7th meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

**Location** : EFSA. Parma, Italy.

**Attendees:**

- **Working group members:** Avelino Alvarez Ordoñez (Chair), Amie Adkin, Olivier Andreoletti, John Griffin, Romolo Nonno, Marion Simmons.
- **EFSA:** Angel Ortiz Pelaez. Barbara Lanfranchi from RANDSTAD participated under the contract CP/IHUF2060/374

## **I. Welcome and apologies**

- The Chair welcomed the participants. No apologies received.

## **II. Adoption of the agenda**

- The agenda was adopted without changes.

## **III. Approval of the minutes of the 6<sup>th</sup> Working Group meeting held on 9 February 2024<sup>1</sup>**

- The minutes of the 6<sup>th</sup> Working Group meeting held on 9 February 2024 were agreed by written procedure on 15 February 2024.

## **IV. Declarations of Interest of Working Groups members**

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

## **V. Scientific topic(s) for discussion<sup>2</sup>**

- The experimental data of BSE infectivity in sheep for the ovine model was reviewed. Then the results of the bovine and ovine models with the final parameterization were discussed. The approach to assessment question 5 (human exposure to gelatine containing BSE infectivity) and assessment question 6 (probability of new case generated in cattle and small ruminants due to exposure to gelatine containing BSE infectivity) were thoroughly discussed and a course of action agreed to produce

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<sup>1</sup> <https://www.efsa.europa.eu/sites/default/files/2022-11/pigpap.pdf>

<sup>2</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00059>

29<sup>th</sup> February 2024 13:30 – 17:30h CET

1<sup>st</sup> March 2024 8:30 – 12:30h CET

## MINUTES

7th meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins



answers to the terms of reference. Finally, the draft opinion was reviewed, with a new layout agreed that allows a better flow and readability. New sections will be populated by the next meeting together with the revision of the sections already drafted.

- The schedule of the next meetings is as follows:
  - 8<sup>th</sup> WG meeting: Monday 6 April 2024. Half-day web-meeting 10:00-14:00h CET
  - 9<sup>th</sup> WG meeting: Monday 15 April 2024. Half-day web-meeting 10:00-14:00h CET
  - 10<sup>th</sup> WG meeting: Tuesday 7 May 2024. Half-day web-meeting 10:00-14:00h CET.

## VI. AOB

- There was no other business. The chair thanked the participants and closed the meeting.

6th meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

**Location:** Web-meeting

**Attendees:**

- **Working group members:** Avelino Alvarez Ordoñez (Chair), Amie Adkin, Olivier Andreoletti, John Griffin, Romolo Nonno, Marion Simmons.
- **EFSA:** Angel Ortiz Pelaez. Barbara Lanfranchi from RANDSTAD participated under the contract CP/IHUF2060/374

## **I. Welcome and apologies**

- The Chair welcomed the participants. No apologies received.

## **II. Adoption of the agenda**

- The agenda was adopted without changes.

## **III. Approval of the minutes of the 5<sup>th</sup> Working Group meeting held on 15 January 2024<sup>1</sup>**

- The minutes of the 5<sup>th</sup> Working Group meeting held on 15 January 2024 were agreed by written procedure on 19 January 2024.

## **IV. Declarations of Interest of Working Groups members**

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

## **V. Scientific topic(s) for discussion<sup>2</sup>**

- The models were reviewed, mainly the sheep verison with decisions made on the parameterization. The approach to assessment question AQ6 was thoroughly discussed, and how to estimate the probability of a new case of BSE in a host species. Finally, AQ5 was the third topic of the agenda addressed by the working group. There is already a description of the risk pathways for exposure of humans to gelatine,

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6th meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

- based on different uses, with the oral and parenteral routes being the most likely routes of exposure.
- There was not much time left to discuss the structure and content of the draft opinion although some actions were agreed to amend existing sections or draft new sections.
- The schedule of the next meetings is as follows:
  - 8<sup>th</sup> WG meeting: Monday 6 April 2024. Half-day web-meeting 10:00-14:00h CET
  - 9<sup>th</sup> WG meeting: Monday 15 April 2024. Half-day web-meeting 10:00-14:00h CET
  - 10<sup>th</sup> WG meeting: Tuesday 7 May 2024. Half-day web-meeting 10:00-14:00h CET.

## **VI. AOB**

- There was no other business. The Chair thanked the participants and closed the meeting.

5th meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

**Location:** Web-meeting

**Attendees:**

- **Working group members:** Avelino Alvarez Ordoñez (Chair), Amie Adkin, Olivier Andreoletti, John Griffin, Romolo Nonno, Marion Simmons.
- **EFSA:** Angel Ortiz Pelaez. Barbara Lanfranchi from RANDSTAD participated under the contract CP/IHUF2060/374

## **I. Welcome and apologies**

- The Chair welcomed the participants. No apologies received.

## **II. Adoption of the agenda**

- The agenda was adopted without changes.

## **III. Approval of the minutes of the 4<sup>th</sup> Working Group meeting held on 11 December 2023<sup>1</sup>**

- The minutes of the 4<sup>th</sup> Working Group meeting held on 11 December 2023 were agreed by written procedure on 15 December 2023.

## **IV. Declarations of Interest of Working Groups members**

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

## **V. Scientific topic(s) for discussion<sup>2</sup>**

- The main approach on how to transfer the estimation of exposure of BSE infectivity into risk and probability of new cases of BSE generated were discussed, based on various proposals by working group members. In line with such decision, the draft protocol was discussed and the final draft agreed, pending a minor modification in

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<sup>2</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00059>



5th meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

- one assessment question. It will be submitted to the BIOHAZ Panel for approval in the plenary of 24-25 January 2024.
- Then the models were reviewed. The bovine model will be amended to accommodate the calculation of the probability of new cases of BSE in animal species and the ovine model was presented for the first time. The approach for humans will be only the exposure assessment, as agreed with the requestor. It was acknowledged that for the ovine model there are less data available and more assumptions will have to be made. Finally, the structure of the draft opinion was revised and a number of actions were agreed to draft or amend new or existing sections.
- The schedule of the next meetings is as follows:
  - 6<sup>th</sup> WG meeting: Friday 9 February 2024. Half-day web-meeting 10:00-14:00h CET
  - 7<sup>th</sup> WG meeting: 29 February 2024 13:30-17:30h CET – 1 March 2024 08:30-12:30h CET. Physical meeting in Parma.

## **VI. AOB**

- There was no other business. The Chair thanked the participants and closed the meeting.

4th meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

**Location:** Web-meeting

**Attendees:**

- **Working group members:** Avelino Alvarez Ordoñez (Chair), Amie Adkin, Olivier Andreoletti, John Griffin, Romolo Nonno, Marion Simmons.
- **EFSA:** Angel Ortiz Pelaez

## **I. Welcome and apologies**

- The Chair welcomed the participants. No apologies received.

## **II. Adoption of the agenda**

- The agenda was adopted without changes.

## **III. Approval of the minutes of the 3<sup>rd</sup> Working Group meeting held on 24 November 2023<sup>1</sup>**

- The minutes of the 3<sup>rd</sup> Working Group meeting held on 24 November 2023 were agreed by written procedure on 30 November 2023.

## **IV. Declarations of Interest of Working Groups members**

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

## **V. Scientific topic(s) for discussion<sup>2</sup>**

- The draft protocol was discussed and a modification of the assessment questions was agreed. Changes in the evidence and methodology sections of the protocol will be added a posteriori. The protocol triggered discussion on the definition of risk and how it would be estimated for animals species and humans. The protocol will be submitted to the January 2024 plenary of the BIOHAZ Panel for approval by . The model for bovine infectivity was then reviewed with the preliminary outputs of the model

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<sup>1</sup> <https://www.efsa.europa.eu/sites/default/files/2022-11/pigpap.pdf>

<sup>2</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00059>



4th meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

presented. The structure and parameterization were approved by the working group. The initial structure of the ovine version was also presented but there is a need for more accurate data to populate the model. The state of the draft opinion was reviewed and a number of new sections will be drafted following the decisions made during the meeting. The working group agreed to pursue the presentation of the opinion for adoption to the BIOHAZ Panel in June 2024, before the end of the mandate.

- The schedule of the next meetings is as follows:
  - 5<sup>th</sup> WG meeting: Monday 15 January 2024. Half-day web-meeting 10:00-14:00h CET
  - 6<sup>th</sup> WG meeting: A doodle poll will be circulated to fix the date of a half-day web-meeting in early February 2024.

## **VI. AOB**

- There was no other business. The Chair thanked the participants and closed the meeting.

3rd meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

**Location:** Web-meeting

**Attendees:**

- **Working group members:** Avelino Alvarez Ordoñez (Chair), Amie Adkin, Olivier Andreoletti, John Griffin, Romolo Nonno, Marion Simmons.
- **EFSA:** Angel Ortiz Pelaez

## **I. Welcome and apologies**

- The Chair welcomed the participants. No apologies received.

## **II. Adoption of the agenda**

- The agenda was adopted without changes.

## **III. Approval of the minutes of the 2<sup>nd</sup> Working Group meeting held on 9-10 October 2023<sup>1</sup>**

- The minutes of the 2<sup>nd</sup> Working Group meeting held on 9-10 October 2023 were agreed by written procedure on 16 October 2023.

## **IV. Declarations of Interest of Working Groups members**

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

## **V. Scientific topic(s) for discussion<sup>2</sup>**

- The new data and information provided by the industry as well as the extra clarification requested to the European Commission were reviewed by the working group. The framework of the quantitative risk assessment using a probabilistic model was presented for the first time and discussed in depth. The input parameters and assumptions were agreed for the initial model for bovine animals in a scenario of no TSE restrictions. New and unpublished data on BSE infectivity in sheep were

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<sup>1</sup> <https://www.efsa.europa.eu/sites/default/files/2022-11/pigpap.pdf>

<sup>2</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00059>



3rd meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

presented and discussed. It was agreed to use such data to develop an alternative model to estimate BSE infectivity in gelatine produced with sheep and goat bones. The protocol was reviewed but it could not be finalised. It will be done in the next meeting.

- The schedule of the next meetings remains as agreed in the 2<sup>nd</sup> meeting::
  - 4<sup>th</sup> WG meeting: Monday 11 December 2023 Half-day web-meeting 10:00-14:00h CET
  - 5<sup>th</sup> WG meeting: Monday 15 January 2024. Half-day web-meeting 10:00-14:00h CET
  - 6<sup>th</sup> WG meeting: Physical meeting lunch to lunch. Thursday 29 February 2024 13:30-17:30h CET/ Friday 1 March 2024 08:30-12:30h CET.
- The calendar for other meetings for 2024 will be discussed based on the decision of the date for submission of the opinion for adoption.

## **VI. AOB**

- There was no other business. The Chair thanked the participants and closed the meeting.

2nd meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

**Location:** Physical. EFSA HQ. Parma, Italy

**Attendees:**

- **Working group members:** Avelino Alvarez Ordoñez (Chair), Amie Adkin, Olivier Andreoletti, John Griffin, Romolo Nonno, Marion Simmons.
- **EFSA:** Angel Ortiz Pelaez

## **I. Welcome and apologies**

- The Chair welcomed the participants. No apologies received.

## **II. Adoption of the agenda**

- The agenda was adopted without changes.

## **III. Approval of the minutes of the 1<sup>st</sup> Working Group meeting held on 17 July 2023<sup>1</sup>**

- The minutes of the 1<sup>st</sup> Working Group meeting held on 17 July 2023 were agreed by written procedure on 21 July 2023.

## **IV. Declarations of Interest of Working Groups members**

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

## **V. Scientific topic(s) for discussion<sup>2</sup>**

- The clarifications requested from the European Commission on the scope of the BSE risk to be assessed, the source and type of materials to be used and the restrictions of use of collagen and gelatine under the ABP regulations, were reviewed by the WG as well as the replies by the industry on gelatine production in Europe. Following preliminary decisions on the approaches, a number of assessment questions were drafted in the protocol template to break down the terms of reference.

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<sup>1</sup> <https://www.efsa.europa.eu/sites/default/files/2022-11/pigpaw.pdf>

<sup>2</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00059>

9 October 2023– 13:30-17:30h CET

10 October 2023 08:30 -12:30h CET

## MINUTES

2nd meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins



- The model developed in 2019-2020 was reviewed. It was decided to develop a variation of that model initially for cattle to be expanded at a later stage for small ruminantes. Data needs were agreed for the model. Work plan and calendar of meetings were also agreed.

## VI. Next meetings

- The schedule of the next meetings was agreed as follows:
  - 4<sup>th</sup> WG meeting: Monday 11 December 2023 Half-day web-meeting 10:00-14:00h CET
  - 5<sup>th</sup> WG meeting: Monday 15 January 2024. Half-day web-meeting 10:00-14:00h CET
  - 6<sup>th</sup> WG meeting: Thursday 29 February 2024 13:30-17:30h CET/ Friday 1 March 2024 08:30-12:30h CET. Physical meeting lunch to lunch.
- The calendar for other meetings for 2024 will be discussed based on the decision of the date for submission of the opinion for adoption.

## VII. AOB

- There was no other business. The Chair thanked the participants and closed the meeting.

1st meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins

**Location:** Web-meeting

**Attendees:**

- **Working group members:** Avelino Alvarez Ordoñez (Chair), Amie Adkin, Olivier Andreoletti, John Griffin, Romolo Nonno, Marion Simmons.
- **EFSA:** Kateryna Chuzhakina, Angel Ortiz Pelaez

## I. Welcome and apologies

- The Chair welcomed the participants. No apologies received.

## II. Adoption of the agenda

- The agenda was adopted without changes.

## III. Declarations of Interest of Working Groups members

- In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, 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.
- 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>

- After the introductions of the members of the working group, EFSA presented administrative and logistic aspects of the management of the working group, the work plan, the background of the mandate and the terms of reference. The chair led an initial brainstorming session about the mandate and the terms of reference. A revision of previous work done by EFSA in this area was conducted. After discussion, it was agreed to request the European Commission clarification about the scope of the BSE risk to be assessed, the source and type of materials to be used and the restrictions of use of collagen and gelatine under the ABP regulations. It was also agreed to retrieve information provided by the industry in 2020 with the view to update it.

## V. Next meetings

- The schedule of the next meetings for 2023 was agreed as follows:

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<sup>1</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00059>

## MINUTES – 17 JULY 2023 09:30-13:30h CET

1st meeting of the working group on the request for a scientific opinion on the potential BSE risk posed by ruminant collagen and gelatine other than derived from hides and skins



- 2<sup>nd</sup> WG meeting: physical meeting in Parma at EFSA HQ. Monday 9 October 2023: 13:30-17:30h CET and Tuesday 10 October 2023 8:30-12:30h CET
- 3<sup>rd</sup> WG meeting: web-conference Friday 24 November 2023 9:30-13:30h CET

- The calendar of meetings for 2024 will be discussed in the next meeting.

## VI. AOB

- There was no other business. The Chair thanked the participants and closed the meeting.