

GMO Unit

Minutes of the 4th meeting of the Working Group on integration/non-integration of a DNA plasmid

**Held on 13 December 2016 (tele)
(Agreed on 19 December 2016)**

Participants

- **Working Group Members:**

Ross Houston, Fabien Nogué, Simon Moxon

- **Hearing Experts¹:**

Stephen Spencer (Veterinary Medicines Directorate)

- **EFSA:**

GMO Unit: Nikoletta Papadopoulou, Matthew Ramon, Elisabeth Waigmann (chair)

- **Others:**

EMA observer: Martin Ilott

EC: Panagiotis Daskaleros, Ilaria Ciabatti

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 3rd EFSA Working Group held on 22 November 2016

The minutes of the 3rd Working Group meeting held on 22 November 2016 in Parma were agreed by written procedure on 29 November 2016.

5. Scientific topic(s) for discussion

5.1. M-2016-0103 ([EFSA-Q-2016-00320](#))

The WG members discussed and finalized the EFSA statement.

6. Next meeting(s)

n/a

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

GMO Unit

Minutes of the 3rd meeting of the Working Group on integration/non-integration of a DNA plasmid

**Held on 22 November 2016, Parma (Italy)
(Agreed on 29 November 2016)**

Participants

- **Working Group Members:**

Ross Houston, Fabien Nogué, Simon Moxon

- **Hearing Experts¹:**

Stephen Spencer (Veterinary Medicines Directorate)

- **EFSA:**

GMO Unit: Nikoletta Papadopoulou, Matthew Ramon, Elisabeth Waigmann (chair)

- **Others:**

EMA observer: Martin Ilott

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 2nd EFSA Working Group held on 20 October 2016

The minutes of the 2nd Working Group meeting held on 20 October 2016 in Parma were agreed by written procedure on 16 November 2016

5. Scientific topic(s) for discussion

5.1. M-2016-0103 ([EFSA-Q-2016-00320](#))

The WG members discussed the data received in the frame of the mandate and the draft scientific opinion.

6. Next meeting(s)

n/a

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

GMO Unit

Minutes of the 2nd meeting of the Working Group on integration/non-integration of a DNA plasmid

Held on 20 October 2016, Parma (Italy)

(Agreed on 16 November 2016)

Participants

- **Working Group Members:**

Fabien Nogué

Ross Houston and Simon Moxon have participated via teleconference

- **Hearing Experts¹:**

Stephen Spencer (Veterinary Medicines Directorate)

Ginny Jones, Marc Molkenboer, Lincoln Tubbs (Elanco)

- **European Commission:**

Kaja Kantorska

- **EFSA:**

GMO Unit: Nikoletta Papadopoulou, Matthew Ramon, Elisabeth Waigmann (chair)

ALPHA Unit: Frank Verdonck

- **Others:**

EMA observer: Martin Ilott

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 1st EFSA Working Group held on 27 September 2016

The minutes of the 1st Working Group meeting held on 27 September 2016 in Parma were agreed by written procedure on 6 October 2016

5. Scientific topic(s) for discussion

5.1. M-2016-0103 ([EFSA-Q-2016-00320](#))

The Applicant was invited to join the meeting and provide clarifications on questions raised by the WG. In addition, the WG members discussed the draft scientific opinion.

6. Next meeting(s)

22 November 2016, Parma

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

GMO Unit

Minutes of the 1st meeting of the Working Group on integration/non-integration of a DNA plasmid

Held on 27 September 2016, Parma (Italy)

(Agreed on 06 October 2016)

Participants

- **Working Group Members:**

Ross Houston and Simon Moxon

- **Hearing Experts¹:**

Stephen Spencer

- **European Commission and/or Member States representatives:**

none

- **EFSA:**

GMO Unit: Nikoletta Papadopoulou, Matthew Ramon, Elisabeth Waigmann (chair)

- **Others:**

EMA observer: Martin Ilott

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Fabien Nogu .

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

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 and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topic(s) for discussion

4.1. M-2016-0103 ([EFSA-Q-2016-00320](#))

The Working Group discussed the data received in the frame of this mandate. Further discussion and clarification from the applicant is needed.

5. Next meeting(s)

20 October 2016, Parma

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>