

# Scientific Panel on Genetically Modified Organisms (GMO) Minutes of the 7<sup>th</sup> meeting of the GMO Working group on a Technical Note on sequencing quality

**Held on 27 April 2018, Parma  
(Agreed on 10 May 2018)**

## Participants

- **Working Group Members:**

Josep Casacuberta, Huw Jones, Simon Moxon, Fabien Nogué (tele) and Korbinian Schneeberger

- **Hearing Experts<sup>1</sup>:**

none

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

EC: Hans Moons

- **EFSA:**

GMO Unit: Silvia Federici, Nikoletta Papadopoulou, Matthew Ramon and Claudia Paoletti

- **Others:**

EURL-GMFF observers: Cristian Savini and Mauro Petrillo

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

## 2. Adoption of agenda

The agenda was adopted without changes.

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<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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 Mandate to develop a technical note to the applicants on, and checking of, the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified (GM) event, and generational stability and integrity**

**[\(EFSA-Q-2017-00706\)](#)**

The Working Group further discussed the concept of read depth when NGS is used for molecular characterisation of the events in the GM plant. The outline and content of the annexes to the Technical note were discussed. The WG will proceed with the finalisation of the Technical note.

### **5. Next meeting(s)**

22 May 2018, TELE/WEB (optional)

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

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

# Scientific Panel on Genetically Modified Organisms (GMO) Minutes of the 6<sup>th</sup> meeting of the GMO Working group on a Technical Note on sequencing quality

**Held on 13 April 2018, TELE/WEB  
(Agreed on 20 April 2018)**

## **Participants**

- **Working Group Members:**

Josep Casacuberta, Huw Jones, Simon Moxon, Fabien Nogué and Korbinian Schneeberger

- **Hearing Experts<sup>1</sup>:**

none

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

EC: Hans Moons

- **EFSA:**

GMO Unit: Silvia Federici and Nikoletta Papadopoulou

- **Others:**

EURL-GMFF observers: Cristian Savini

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

The Chair welcomed the participants. Apologies were received from Mauro Petrillo (EURL-GMFF)

## **2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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 Mandate to develop a technical note to the applicants on, and checking of, the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified (GM) event, and generational stability and integrity**

**[\(EFSA-Q-2017-00706\)](#)**

The Working Group further discussed the requirements to demonstrate genetic stability of events in the GM plant in case a sequencing strategy is used. The outline and content of the annex to the Technical note was discussed. Further discussion on the Technical note is needed.

### **5. Next meeting(s)**

27 April 2018, Parma

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

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

# Scientific Panel on Genetically Modified Organisms (GMO) Minutes of the 5<sup>th</sup> meeting of the GMO Working group on a Technical Note on sequencing quality

**Held on 23 March 2018, Parma  
(Agreed on 03 April 2018)**

## **Participants**

- **Working Group Members:**

Josep Casacuberta, Huw Jones, Simon Moxon and Fabien Nogué (tele) and Korbinian Schneeberger (tele)

- **Hearing Experts<sup>1</sup>:**

Bin Cong – Pioneer (tele), Petra Kostolaniova - EuropaBio (tele) and Andre Silvanovich – Monsanto – for Agenda item 4.1.3

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

EC: Hans Moons

- **EFSA:**

GMO Unit: Silvia Federici, Claudia Paoletti, Nikoletta Papadopoulou, Matthew Ramon

- **Others:**

EURL-GMFF observers: Mauro Petrillo and Cristian Savini

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

The Chair welcomed the participants. No apologies were received.

## **2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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 Mandate to develop a technical note to the applicants on, and checking of, the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified (GM) event, and generational stability and integrity**

#### **(EFSA-O-2017-00706)**

- 4.1.1 The Working Group discussed the requirements to demonstrate genetic stability and integrity of events in the GM plant in case a sequencing strategy is used.
- 4.1.2 The outline and content of the document was further discussed. Further discussion is still needed.
- 4.1.3 Clarifications on the current and future use of sequencing methodologies for characterising the GM event were provided by EuropaBio representatives participating to the meeting.

### 5. Next meeting(s)

13 April 2018, TELE/WEB

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

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

# Scientific Panel on Genetically Modified Organisms (GMO) Minutes of the 4<sup>th</sup> meeting of the GMO Working group on a Technical Note on sequencing quality

**Held on 21 February 2018, Parma  
(Agreed on 1 March 2018)**

## **Participants**

- **Working Group Members:**

Josep Casacuberta, Huw Jones, Simon Moxon and Fabien Nogué

- **Hearing Experts<sup>1</sup>:**

none

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

EC: Hans Moons

- **EFSA:**

GMO Unit: Silvia Federici, Nikoletta Papadopoulou, Matthew Ramon

- **Others:**

EURL-GMFF observers: Cristian Savini (tele)

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

The Chair welcomed the participants. Apologies were received from Mauro Petrillo (EURL-GMFF).

## **2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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 Mandate to develop a technical note to the applicants on, and checking of, the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified (GM) event, and generational stability and integrity**

**[\(EFSA-Q-2017-00706\)](#)**

The Working Group further discussed the sequencing methodologies used in GMO applications in the frame of the updated outline of the Technical Note. In addition, the requirements for the sequencing quality when NGS is used to characterize the insert(s) and flanking regions were discussed. Further discussion is needed.

### **5. Next meeting(s)**

23 March 2018, Parma

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

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



# Scientific Panel on Genetically Modified Organisms (GMO) Minutes of the 3<sup>rd</sup> meeting of the GMO Working group on a Technical Note on sequencing quality

**Held on 23 January 2018, Parma  
(Agreed on 30 January 2018)**

## **Participants**

- **Working Group Members:**

Josep Casacuberta, Huw Jones, Simon Moxon and Fabien Nogué

- **Hearing Experts<sup>1</sup>:**

none

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

EC: Hans Moons

- **EFSA:**

GMO Unit: Silvia Federici, Nikoletta Papadopoulou, Matthew Ramon, Claudia Paoletti,

- **Others:**

EURL-GMFF observers: Cristian Savini

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

The Chair welcomed the participants. Apologies were received from Mauro Petrillo (EURL-GMFF).

## **2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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 Mandate to develop a technical note to the applicants on, and checking of, the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified (GM) event, and generational stability and integrity**

**[\(EFSA-Q-2017-00706\)](#)**

The Working Group discussed the first draft of the Technical note on the sequencing quality and proposed a new outline for the document. The outcome from the exercise at the JRC on the Sanger sequencing quality check was discussed considering the needs of EFSA when taking over this task. Further discussion is needed.

### **5. Next meeting(s)**

21 February 2018, Parma

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

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

# Scientific Panel on Genetically Modified Organisms (GMO) Minutes of the 2<sup>nd</sup> meeting of the GMO Working group on a Technical Note on sequencing quality

**Held on 11 December 2017, Parma  
(Agreed on 22 December 2017)**

## **Participants**

- **Working Group Members:**

Josep Casacuberta, Huw Jones (tele), Simon Moxon (tele) and Fabien Nogué

- **Hearing Experts<sup>1</sup>:**

none

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

EC: Hans Moons

- **EFSA:**

GMO Unit: Silvia Federici, Nikoletta Papadopoulou, Matthew Ramon

- **Others:**

EURL-GMFF observers: Cristian Savini and Mauro Petrillo

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

The Chair welcomed the participants.

## **2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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 Mandate to develop a technical note to the applicants on, and checking of, the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified (GM) event, and generational stability and integrity**

**[\(EFSA-Q-2017-00706\)](#)**

The Working Group discussed and edited the EFSA draft note on NGS. Further discussion is needed.

### **5. Next meeting(s)**

23 January 2018, Parma

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

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

# Scientific Panel on Genetically Modified Organisms Minutes of the 1<sup>st</sup> meeting of the GMO Working group on a Technical Note on sequencing quality

**Held on 1 December 2017, Parma  
(Agreed on 11 December 2017)**

## **Participants**

- **Working Group Members:**

Josep Casacuberta, Huw Jones, Simon Moxon and Fabien Nogué

- **Hearing Experts<sup>1</sup>:**

none

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

EC: Hans Moons

- **EFSA:**

GMO Unit: Silvia Federici, Nikoletta Papadopoulou, Matthew Ramon, Elisabeth Waigmann

- **Others:**

EURL-GMFF observers: Cristian Savini and Mauro Petrillo

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

The Chair welcomed the participants.

## **2. Adoption of agenda**

The agenda was adopted without changes.

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<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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 Mandate to develop a technical note to the applicants on, and checking of, the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified (GM) event, and generational stability and integrity**

**[\(EFSA-Q-2017-00706\)](#)**

The Working Group discussed the EFSA and EURL guidelines in the frame of this mandate. Further discussion is needed.

### **5. Next meeting(s)**

11 December 2017, Parma

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

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