



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 145th MEETING

Held on 8 July 2021, TELE/WEB

(Agreed on 30 July 2021)

Participants

■ Panel Members:

Jean-Louis Bresson, Tamas Dalmay, Ian Dewhurst, Michelle Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatkó, Francisco Javier Moreno, Ewen Mullins, Hanspeter Naegeli, Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano (item 4, 5.1 and 9.1 only), Giovanni Savoini, Eve Veromann and Fabio Veronesi

■ European Commission:

DG SANTE: Ilaria Ciabatti and Alexandre Huchelmann

■ EFSA:

GMO Unit: Ana Afonso, Michele Ardizzone, Giuseppe Condorelli, Giacomo De Sanctis, Silvia Federici, Antonio Fernández Dumont, Andrea Gennaro, Paschalina Grammatikou, Dafni Maria Kagkli, Anna Lanzoni, Paolo Lenzi, Aleksandra Lewandowska, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Franz Streissl and Riccardo Vríz

DATA Unit: José Ángel Gómez Ruiz

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 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>



3. Declarations of Interest of Panel 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. 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.

4. Report on written procedures since the 144th GMO Plenary meeting

Since the 144th Plenary meeting, two outputs have been adopted by written procedure:

4.1 Application for renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614, authorised under Regulation (EC) No 1829/2003 (Commission Decision 2011/354/EU) (EFSA-GMO-RX-018)⁴

The draft opinion was submitted for adoption at the 142nd Plenary meeting held on 27 January 2021⁵. It was agreed to adopt the opinion by written adoption after submission by the applicant of additional information (i.e. clarification on sequencing data). The text of the scientific opinion was adopted by written procedure on the 28 May 2021. The scientific opinion was published on the [EFSA website](#) and in the [EFSA Journal](#).

4.2 The minutes of the 144th Plenary meeting

The minutes of the 144th Plenary meeting were adopted by written procedure and published on 26 May 2021.⁶

5. Scientific topics for discussion

5.1. Application for authorisation of herbicide-tolerant genetically modified GHB811 cotton for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by BASF Agricultural Solutions (EFSA-GMO-ES-2018-154)⁷

Cotton GHB811 was developed to confer tolerance to glyphosate-containing herbicides and HPPD inhibitor herbicides such as isoxaflutole. The scope of the application EFSA-GMO-ES-2018-154 is for food and feed uses, import and processing and does not include cultivation in the European Union (EU).

Questions were raised and addressed throughout the different sections of the draft opinion. The GMO Panel revised the draft text, where appropriate, and subsequently adopted the opinion, which will be published on the EFSA website and in the [EFSA Journal](#).

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

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00420>

⁵ <https://www.efsa.europa.eu/sites/default/files/event/2021/142nd-plenary-meeting-gmo-panel.pdf>

⁶ <https://www.efsa.europa.eu/sites/default/files/2021-05/144th-plenary-meeting-gmo-panel-minutes.pdf>

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2018-0080>



5.2. Scientific opinion on *in -vivo* and *in -vitro* random mutagenesis techniques in plants⁸

The GMO Panel was informed that the public consultation on the draft opinion endorsed at the 144th Plenary meeting ended on the 30 June 2021.⁹ An overview of the received comments was presented. The Molecular Characterisation Working Group will address the comments and revise the text of the opinion accordingly. The scientific opinion will be submitted for possible adoption at 146th GMO Plenary meeting (29 - 30 September 2021).

6. New Mandates

6.1 Applications under Regulation (EC) No 1829/2003

None

6.2 Annual Post-market environmental monitoring reports of GM plants

No new mandate was received.

6.3 Other Requests and Mandates

EC mandated EFSA to deliver an updated scientific opinion on plants developed through cisgenesis and intragenesis techniques¹⁰. The mandate was accepted on 25 June 2021.

The chair of the Panel in consultation with the Head of Unit proposed to establish an *ad-hoc* working group (WG) to address the mandate. The GMO Panel agreed with the proposal for an *ad-hoc* WG to be chaired by Nils Rostoks. The appointment of the chair will be confirmed following ADoI clearance. The chair of the *ad-hoc* WG in consultation with the Head of Unit will identify the members of the *ad-hoc* WG.

7 Feedback from the Scientific Committee/the Scientific Panels, EFSA, the European Commission

7.1 Scientific Committee and other Scientific Panel(s) including their Working Groups

The Panel Chair reported on the discussions at the 104th Scientific Committee meeting held on the 30 June and 1 July 2021.¹¹

7.2 EFSA including its Working Groups/ Task Forces

On the 15 and 16 June 2021 EFSA organised a workshop on allergenicity assessment of proteins derived from biotechnology and novel food sources. The documents and presentations are available on the EFSA website.¹²

⁸ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00445>

⁹ <https://connect.efsa.europa.eu/RM/s/publicconsultation/a0c1v00000DOI9d/pc0011>

¹⁰ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00361>

¹¹ <https://www.efsa.europa.eu/sites/default/files/2021-05/104th-plenary-meeting-scientific-committee-open-observers-agenda.pdf>

¹² <https://www.efsa.europa.eu/en/events/gmo-workshop-allergenicity-assessment>



7.3 European Commission

The representatives of the European Commission (EC) informed the GMO Panel on their on-going activities, including approval procedures for applications for which the GMO Panel has delivered a positive scientific opinion.

8 Other scientific topics for information and/or discussion

8.1 Discussion on double transformation approaches for transgene integration

Some of the new applications currently under assessment by the WGs of the GMO Panel are characterised by a double transformation methodology aiming at removing marker genes or at integrating at a desired genomic region the expression cassette. The GMO Panel discussed the challenges double transformation poses to the risk assessment. The GMO panel highlighted the need to treat the products of double transformations with a specific approach. The topic will be proposed again in one of the next Plenary meetings for further discussion.

9 Any other business

9.1 Election of GMO Panel Chair, Vice Chairs and Ad-hoc experts

The election of the GMO Panel Chair and two Vice-chairs were carried out according to the Decision of the EFSA Management Board concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups.¹³ Ewen Mullins was elected as GMO Panel Chair. Tamas Dalmay and Nils Rostoks were elected as GMO Panel Vice-chairs. The mandate of the chair and vice chairs is of 3 years (until 2024). The Panel confirmed the need for all the currently existing Working Groups¹⁴ in order to assist the Panel in undertaking all necessary preparatory tasks in relation to draft scientific outputs falling under its remit, including the current composition and chairmanship.

9.2 Pre-information notice (PIN) for a call on *in silico*/*in vitro* tools to predict protein toxicity

The Panel was informed about the publications of a procurement to conclude to contracts 1) to develop *in-silico* methodologies to predict protein toxicity of novel proteins in the context of food and feed risk assessment and 2) on the identification of *in-vitro* toxicity testing approaches for novel proteins in the context of food and feed risk assessment. More information is available on the eTendering website.¹⁵

9.3 Publication of the annual post-market environmental monitoring reports of GM plants

EFSA informed that the statement on the assessment of the 2019 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in the EU has been published on the 7th July 2021 in the [EFSA website](#) and in the [EFSA Journal](#).

10 Adoption of the minutes and next meeting

The minutes of the current meeting were adopted by written procedure and will be published at: <https://www.efsa.europa.eu/en/events/event/145th-plenary-meeting-gmo-panel>

¹³ <https://www.efsa.europa.eu/sites/default/files/2021-02/expertselection.pdf>

¹⁴ The existing working groups are 1) Applications – CompERA; 2) Applications - food/feed; 3) Applications - molecular characterisation; 4) Allergenicity; 5) Gene drive and 6) SynBio GM Plants Food&Feed Risk Assessment further information is available at <https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo#working-groups>

¹⁵ <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8841>



The 146th GMO Plenary meeting will be held on 29 - 30 September 2021 online.