



# SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

## MINUTES OF THE 139<sup>th</sup> MEETING

**Held on 14-15 October 2020, TELE/WEB**

**(Agreed on 06 November 2020)**

### Participants

■ Panel Members:

Jean-Louis Bresson, Tamas Dalmay, Ian Dewhurst, Michelle Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Javier Moreno, Ewen Mullins, Hanspeter Naegeli, Fabien Nogu , Nils Rostoks, Jose Juan Sanchez Serrano, Giovanni Savoini, Eve Veromann and Fabio Veronesi

■ Hearing expert: - none

■ European Commission:

DG SANTE: Iliaria Ciabatti, Juliette-Marie Margueritte, Alexandre Huchelmann and Olga Orlova

■ Contractors:

Andreas Lang (BURO LANG), Virgile Baudrot (INRAE), Antoine Mess an (INRAE), Costanti Stefanescu (Museu de Ci ncies Naturals de Granollers) and Samuel Soubeyrand (INRAE)

■ EFSA:

GMO Unit: Ana Afonso, Fernando  lvarez, Michele Ardizzone, Giacomo De Sanctis, Yann Devos, Silvia Federici, Antonio Fern ndez Dumont, Andrea Gennaro, Jos  Angel Gomez Ruiz, Dafni Kagkli, Anna Lanzoni, Paolo Lenzi, Sylvie Mestdagh, Franco Maria Neri, Lorenz Oberkofler, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Franz Streissl, Riccardo Vrizz

### 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.



### 3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, 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 138<sup>th</sup> GMO Plenary meeting

The minutes of the 138<sup>th</sup> Plenary meeting were adopted by written procedure and published on 27 July 2020.

### 5. Scientific topic(s) for discussion

#### 5.1 Scientific opinion on genetically modified organisms engineered with Gene drives (gene drive modified organisms) and their implications for risk assessment methodologies ([EFSA-Q-2018-00619](#))

The scientific officer of the GMO Unit in charge reminded the GMO Panel about the background of the mandate from the European Commission (hereafter mentioned as 'EC'), the development of the draft scientific output by the *ad hoc* Working Group<sup>3</sup>, including the evaluation of the comments received during the public consultation.

The draft scientific opinion as well as the public comments were already discussed at the GMO Panel meeting on 01-02 July 2020. Over summer, the *ad hoc* Working Group revised the draft opinion in the light of the comments received.

During the meeting, the GMO Panel reviewed the draft text, where appropriate. The GMO Panel adopted the opinion, which will be published on the EFSA website and in the [EFSA Journal](#). A technical report on the public consultation will also be made available online.

#### 5.2 Scientific opinion on plants developed using type 1 and type 2 Site-Directed Nuclease and Oligonucleotide Directed Mutagenesis ([EFSA-Q-2019-00297](#))

The scientific officer of the GMO Unit in charge reminded the GMO Panel about the background of the mandate from the EC, the development of the draft scientific output by the Working Group of the GMO Panel on molecular characterization<sup>4</sup> (hereafter mentioned as 'MC WG'), including the evaluation of the comments received during the public consultation.

The draft scientific opinion as well as the public comments were already discussed at the GMO Panel meeting on 01-02 July 2020. Over summer the MC WG revised the text of the draft opinion in the light of the comments received.

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<sup>1</sup> [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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>3</sup> <https://www.efsa.europa.eu/en/gmo/working-groups>

<sup>4</sup> <https://www.efsa.europa.eu/en/gmo/working-groups>



During the meeting, the GMO Panel reviewed the draft text, where appropriate. The GMO Panel adopted the opinion, which will be published on the EFSA website and in the [EFSA Journal](#). A technical report on the public consultation will also be made available online.

### **5.3 Scientific opinion on synthetic biology developments in plants, environmental risk assessment aspects (ERA) ([EFSA-Q-2018-01000](#))**

The scientific officer of the GMO Unit in charge reminded the GMO Panel about the background of the mandate from the EC, the development of the draft scientific output by the *ad hoc* Working Group<sup>5</sup>, including the evaluation of the comments received during the public consultation.

The draft scientific opinion as well as the public comments were already extensively discussed<sup>6</sup> at the GMO Panel meeting on 01-02 July 2020. Over summer the *ad hoc* Working Group revised and restructured the draft opinion in the light of the comments received.

During the meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the opinion, which will be published on the EFSA website and in the [EFSA Journal](#). A technical report on the public consultation will also be made available online.

## **6. Mandates**

### **6.1 Application for authorization of genetically modified soybean DAS-81419-2 x DAS-44406-6 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences Europe on behalf of Dow AgroSciences LLC EFSA-GMO-NL-2016-132 ([EFSA-Q-2016-00195](#))**

The double-event stack soybean DAS-81419-2 x DAS-44406-6 was obtained by conventional crossing of two single transformation events DAS-81419-2 and DAS-44406-6. The two single events produce Cry1F, Cry1Ac, AAD-12, PAT and 2mEPSPS proteins that confer resistance against certain lepidopteran insect pests and tolerance to application of 2,4-dichlorophenoxyacetic acid, glufosinate-ammonium and glyphosate herbicides. Application EFSA-GMO-NL-2016-132 was submitted by Dow AgroSciences Europe for the placing of soybean DAS-81419-2 x DAS-44406-6 on the EU market for food/feed uses, import and processing under Regulation (EU) No 503/2013.

A scientific officer of the GMO Unit reminded that, in accordance with the regulatory requirements, the two single transformation events were previously assessed by the GMO Panel. He led the GMO Panel through the text of the draft opinion, pointed out the peculiarities of the risk assessment and drew Panel's attention to the latest modifications.

Questions were raised and addressed throughout the reading of the different sections of the draft opinion. The GMO Panel revised the draft text, where appropriate.

The GMO Panel adopted the opinion, which will be published on the EFSA website and in the [EFSA Journal](#).

<sup>5</sup> <https://www.efsa.europa.eu/en/gmo/working-groups>

<sup>6</sup> <https://www.efsa.europa.eu/sites/default/files/event/2020/138th-plenary-meeting-gmo-panel-open-observers-minutes.pdf>



## **6.2 Application for renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 × MON 810 EFSA-GMO-RX-017 ([EFSA-Q-2019-00524](#))**

Maize MON 88017 × MON 810 was developed to confer resistance to certain coleopteran and lepidopteran pests and tolerance to glyphosate-based herbicides. Following a thorough risk assessment by EFSA, maize event MON 88017 × MON 810 was authorized for food/feed uses, import and processing in the European Union in 2010 (see Commission Decision 2010/429/EU). In 2019 the applicant asked the European Commission to renew the authorisation for the placing on the market of maize MON 88017 × MON 810 and submitted application EFSA-GMO-RX-017 in support to their request. The GMO Panel assessed application EFSA-GMO-RX-017 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines.

Additional information (i.e. updated literature search) is still to be submitted by the applicant. The GMO Panel reviewed the current text.

It was agreed that, once the missing information will be provided, the GMO Panel will assess it and, where appropriate, amend the text of the draft opinion. A revised draft opinion will be presented to the GMO Panel for adoption by written procedure.

## **7. New Mandates**

### **7.1 Applications under Regulation (EC) No 1829/2003**

Since the last meeting of the GMO Panel, EFSA has received two applications:

- EFSA-GMO-NL-2020-167 on canola MS11 x RF3 x MON 88302 and all its sub-combinations ([EFSA-Q-2020-00537](#));
- EFSA-GMO-BE-2020-168 on soybean IND-00410-5 ([EFSA-Q-2020-00639](#)).

### **7.2 Annual Post-market environmental monitoring reports of GM plants**

No new mandate was received.

### **7.3 Other Requests and Mandates**

No new mandate was received.

## **8. Feedback from the Scientific Committee/the Scientific Panels, EFSA, the European Commission**

### **8.1 Scientific Committee and other Scientific Panel(s) including their Working Groups**

This agenda item was not discussed due to time constraint.

### **8.2 EFSA including its Working Groups/ Task Forces**

This agenda item was not discussed due to time constraint.



### 8.3 European Commission

The representative of the European Commission provided feedback on recent meetings held at the European Commission.

## 9. Any other business

### 9.1 Draft frame for protocol development

This agenda item was not discussed due to time constraint.

### 9.2 Development of a spatially- and temporally-explicit model to quantify risks to non-target Lepidoptera associated with the ingestion of genetically modified *Bt*-maize pollen deposited on their host plants ([EFSA-Q-2017-00702](#))

The contractor explained the background for this work, i.e. that the assessment of possible adverse effects that the cultivation of some genetically modified insect-resistant maize (e.g. MON810, Bt11 or 1507) might have on non-target Lepidoptera. Although these GM plants are produced to kill targeted lepidopteran pests, they may also affect non-target (NT) Lepidoptera likely to be exposed to GM maize pollen deposited on host-plants in and nearby maize MON810, Bt11 or 1507 fields.

The GMO Panel developed mathematical models designed to simulate and predict potential adverse effects resulting from the exposure of NT Lepidoptera to pollen from maize MON810, Bt11 or 1507 at field scales. To reduce exposure of NT Lepidoptera potentially occurring in European protected habitats to maize MON810, Bt11 or 1507 pollen, the EFSA GMO Panel recommended mitigation measures between GM maize fields and protected habitats to risk managers. However, the GMO Panel also acknowledged some limitations and uncertainties of the models that needed to be addressed. Therefore, EFSA decided to outsource the development of a landscape-based model to take into account ecological and environmental diversities and to provide risk managers with adequate information to support the decisions in the frame of on-going and future cultivation authorisations.

The contractor presented the results of its work, including a comprehensive expert elicitation exercise to collect additional evidence. According to the terms of reference of the contract, the contractor inquired on all parameters of the model as defined by the GMO Panel (e.g. toxicity levels for Bt-maize pollen, pollen deposition scenarios, susceptibilities of NT Lepidoptera to the lepidopteran-active Bt-proteins of interest, adoption rates of lepidopteran-active Bt-maize in specific regions at the landscape level). The GMO Panel was also informed that an overall uncertainty analysis workshop will be organised to further inquire on the uncertainties of the model. The contractor concluded by pointing out on the need to gather field data from monitoring activities.

### 9.3 Feedback from individual dialogues with Panel members

A scientific officer of the GMO Unit reported on the outcome of the individual dialogues with Panel members as follow up to 2020 Experts survey. Panel members shared suggestions for improving the current way of working. The GMO Unit welcomes all the suggestions striving to a streamlined risk assessment. The feasibility of implementation of the suggestions is being investigated.



#### **9.4 Update on activities related to allergenicity**

This agenda item was not discussed due to time constraint.

#### **9.5 Recommendations for WG and Panel meetings**

The GMO Panel was informed about recent recommendations on meetings chairing. Based on EFSA's decision whether the agenda topics are sensitive and/or complex meetings can be chaired by the WG appointed chair or by EFSA staff.

### **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/139th-plenary-meeting-gmo-panel>

The 140<sup>th</sup> GMO Plenary meeting will be held on 9 November 2020 online.