

# Scientific Panel on GMO

## Minutes of the 126<sup>th</sup> plenary meeting

**Held on 17 – 18 October 2018, Parma (Italy)**

**(Agreed on 18 October 2018)**

### Participants

■ Panel Members:

Jean-Louis Bresson, Tamas Dalmay, Michelle M. Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Ewen Mullins, Hanspeter Naegeli, Fabien Nogue, Nils Rostoks, Giovanni Savoini, Jose Juan Sanchez Serrano, Eve Veromann, Fabio Veronesi

■ Hearing Experts<sup>1</sup>:

None

■ European Commission representatives:

Hans Moons and Alexandre Huchelmann (DG SANTE)

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Giacomo De Sanctis, Yann Devos, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Marina Koukoulanaki, Anna Lanzoni, Sylvie Mestdagh, Franco Maria Neri, Claudia Paoletti, Konstantinos Paraskevopoulos, Tommaso Raffaello, Matthew Ramon and Elisabeth Waigmann

Other EFSA Units/Directorates: none

■ Observers (in application of the guidelines for observers<sup>2</sup>): None

■ Others: None

### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ian Dewhurst. Fabien Nogue attended the meeting remotely.

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<sup>1</sup> As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

<sup>2</sup> <http://www.efsa.europa.eu/en/stakeholders/observers.html>

In particular the Chair welcomed Michelle M. Epstein<sup>3</sup>, Ian Hejatko and Giovanni Savoini who did not attend the inaugural meeting of the 2018-2021 GMO Panel that took place on 4-5 July 2018.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of Interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, EFSA screened the Annual Declarations of Interest filled in by the experts invited to 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. Report on written adoption procedure since 125<sup>th</sup> Plenary meeting**

The minutes of the 125<sup>th</sup> plenary meeting held on 4-5 July 2018 were adopted on 18 July 2018 by written procedure and were published on 19 July 2018 on the [EFSA website](#).

## **5. Scientific outputs submitted for discussion and/or possible adoption**

### **5.1. Assessment of genetically modified maize MZHG0JG for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2016-133) ([EFSA-Q-2016-00583](#))**

Maize MZHG0JG was developed to confer tolerance to glyphosate-containing and glufosinate-ammonium-containing herbicides. Application EFSA-GMO-DE-2016-133 was submitted by Syngenta for the placing of maize MZHG0JG on the EU market, import and processing for food and feed uses under Regulation (EC) No 1829/2003.

Application EFSA-GMO-DE-2016-133 was submitted to EFSA after the entry into force of Regulation (EU) No 503/2013<sup>6</sup>. In this respect

<sup>3</sup> Michelle Epstein was nominated member of the GMO Panel by EFSA Management Board on 12 September 2018.

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

<sup>6</sup> Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European

application EFSA-GMO-DE-2016-133 was fully compliant with the legal requirements laid down in Regulation (EU) No 503/2013 (e.g. literature review/search, mandatory 90-day animal feeding study, estimated intake and dietary exposure assessment).

Even though the quality of the literature search is considered acceptable by the GMO Panel, the scientific opinion includes recommendations to applicants for further improvement of their future literature searches.

A member of the EFSA GMO Unit informed the GMO Panel that application EFSA-GMO-DE-2016-133 fell within the transition period of 2015 Guidance Document of the GMO Panel on agronomic, phenotypic, and compositional characterisation. Consequently some provisions of the aforementioned guidance applied and are reflected in the text of the scientific opinion. For the first time, the draft text of the scientific opinion contains a more comprehensive section on comparative analysis, including considerations on (1) the quality of the test material used for the field trials and (2) the representativeness (e.g. meteorological conditions, management practices) of experimental sites to the receiving environments where the GM maize is likely to be grown.

In this meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the draft opinion, which will be published on the EFSA website and on the EFSA Journal.

A member of the EFSA GMO Unit introduced the GMO Panel to the procedure regarding the consultation of Competent Authorities of EU Member States on each valid GMO application as required by Regulation (EC) No 1829/2003. During its evaluation, the GMO Panel takes into account comments falling within its remit and relevant for the risk assessment of the GM crop at stake. According to the aforementioned Regulation, opinions of the EU Member States are published in an Annex to the scientific opinion of the GMO Panel.

## **5.2. Assessment of genetically modified cotton LLCotton25 for its authorisation renewal for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-010) ([EFSA-Q-2017-00814](#))**

LLCotton25 was developed to confer tolerance to glufosinate-ammonium-containing herbicides. With the submission of application EFSA-GMO-RX-010 under Regulation (EC) No 1829/2003, the applicant Bayer requested the renewal of the initial authorisation for food and feed uses, import and processing of LLCotton25 within the European Union.

The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and

evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant.

In addition, the applicant provided sequence data on the LLCotton25 event using material from a commercial variety that, according to the applicant, may be imported into the EU at the time of this renewal application. Against this background a member of the EFSA GMO Unit made clear that the 2015 Guidance Document of the GMO Panel for renewal applications of GM food and feed does not explicitly ask for an up-to-date/revised sequence of the initial transformation event. As explained in the aforementioned Guidance Document, the risk assessment of GM food and/or feed up to renewal is usually conducted under the assumption that the events' sequence is identical to the sequence of the originally assessed event.

Even though the quality of the literature search is considered acceptable by the GMO Panel, the scientific opinion includes recommendations to applicants for further improvement of their future literature searches.

The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. The GMO Panel concluded that there is no evidence in the renewal application EFSA-GMO-RX-010 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on LLCotton25.

In this meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the draft opinion, which will be published on the EFSA website and on the EFSA Journal.

### **5.3. Assessment of genetically modified soybean MON 89788 for its authorisation renewal for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011) ([EFSA-Q-2017-00826](#))**

Soybean MON 89788 was developed to confer tolerance to glyphosate-containing herbicides. With the submission of application EFSA-GMO-RX-011 under Regulation (EC) No 1829/2003, the applicant Monsanto requested the renewal of the initial authorisation for food and feed uses, import and processing of soybean MON 89788 within the European Union.

The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original

application. Under the assumption that the DNA sequence of the event in soybean MON 89788 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concluded that there is no evidence in renewal application EFSA-GMO-RX-011 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 89788.

Even though the quality of the literature search is considered acceptable by the GMO Panel, the scientific opinion includes recommendations to applicants for further improvement of their future literature searches.

In this meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the draft opinion, which will be published on the EFSA website and on the EFSA Journal.

## **6. New Mandates**

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

The following applications were received:

- Application EFSA-GMO-NL-2018-152 from Bayer on maize MON 87427 x MON 89034 x MON 810 x MIR162 x MON 87411 x MON 87419,
- Application EFSA-GMO-NL-2018-153 from BASF on soybean GMB151,
- Application EFSA-GMO-NL-2018-154 from BASF on cotton GHB811,
- Application EFSA-RX-016 from Syngenta for the renewal of authorisation of maize Bt11.

### **6.2. Annual post-market environmental monitoring reports of GM plants**

EFSA expects to receive the annual post-market environmental monitoring (PMEM) report from Monsanto for the 2017 growing season of GM maize MON 810 in the EU.

### **6.3. Other Requests and Mandates**

EFSA recently received the following mandates from the European Commission:

- On Synthetic Biology
  - o The initial scope of the mandate was, for sake of prioritisation and timely delivery, restricted to microorganisms and plants for environmental release.
  - o The GMO Panel will take the leadership on plants whereas the EFSA Scientific Committee (SCER) will be in charge of microorganisms.

- Main objective of the mandate is to determine whether the existing guidelines are adequate or whether there is a need for updated guidance.
  - A first draft opinion is expected by March 2020 prior to a public consultation.
  - The GMO Panel addressed the 'definition' and 'scope' of synthetic biology (rather a cluster of 'developments' bringing new methodological considerations). The GMO Panel agreed that these new methodologies bring up major challenges.
  - A member of the GMO Panel explained that the Scientific Committees of EC/DG SANTE<sup>7</sup> already published three opinions on Synthetic Biology. Similarly to EFSA way of working, the EC Scientific Committee is assisted by dedicated Working Group(s).
- On GMOs engineered with Gene Drives and their implications for risk assessment methodologies
- The mandate is available on the EFSA Register of Questions, [here](#). According to the Terms of Reference, EFSA is requested
    - to identify potential risks in terms of impact on human and animal health and the environment,
    - to identify potential novel hazards,
    - to determine whether the existing guidelines are adequate or whether there is a need for updated guidance.
  - A first draft opinion is expected by March 2020 prior to a public consultation.
  - Proposed way of working:
    - EFSA will kick off the activities with organisms most likely to be released in a near future (i.e. insects).
    - An *ad hoc* Working Group will be established,
    - At the upcoming meeting of the GMO Network (see item 9.3), EU Member States will be consulted on related activities and relevant expertise.

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

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

A Vice-Chair of the GMO Panel reported on the inaugural meeting of the 2018-2021 Scientific Committee of EFSA. At that meeting the Scientific

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<sup>7</sup> The Scientific Committees on Consumer safety (SCCS), on Health and Environmental Risks (SCHER) and on Emerging and Newly Identified Health Risks (SCENIHR)

Committee took stock of the development and/or implementation of cross-cutting guidance documents.

The minutes of the 90<sup>th</sup> plenary meeting of the Scientific Committee can be found [here](#).

## **7.2. EFSA including its Working Groups /Task Forces**

None

## **7.3. European Commission**

The European Commission recently called for EFSA's views on

- the publication by Santos-Vigil et al. (2018),<sup>8</sup>
- additional sequencing data on GM soybean DAS-81419-2.

The representative of the European Commission informed the GMO Panel that next PAFF meeting will take place on 16 November 2018. EFSA staff was asked to present scientific opinions recently adopted by the GMO Panel.

## **8. Other scientific topics for information and/or discussion**

### **8.1. Compliance with Good Laboratory Practices in GMO applications**

A member of the EFSA GMO Unit introduced the requirement of Regulation (EU) No 503/2013 for applicants to submit studies compliant with ISO or GLP quality standards. Whereas non-toxicological studies can be conducted under an ISO or GLP regime, toxicological studies such as 90-day feeding studies with rodents must be GLP-compliant. Regulation (EU) No 503/2013 enables applicants to deviate from compliance to quality standards for studies that were initiated before its entry into force. Consequently studies submitted as part of GMO applications are checked for compliance with the quality standards required by law.

The GMO Panel was also informed of the EFSA initiative, in close collaboration with EU Member States, to audit studies received in applications and facilities conducting these studies.

### **8.2. Recent explanatory notes**

A member of the EFSA GMO Unit presented the technical note on the quality of DNA sequencing for the molecular characterisation of GM plants:

- Late 2017 the European Commission tasked EFSA to develop guidelines explaining the requirements and recommendations for the use of DNA sequencing, including Next-Generation Sequencing (NGS),

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<sup>8</sup> <https://doi.org/10.1016/j.intimp.2018.05.029>

information in the context of the risk assessment of GMOs with respect to (1) the sequencing of insert(s) and flanking regions, (2) the insertion site analysis and (3) the generational stability/integrity. To address this mandate, EFSA established an *ad hoc* Working Group on 'Sequencing Quality'.

- The aforementioned Working Group developed the technical note providing guidance to applicants on (1) what information pertaining to sequencing methodology and datasets should be provided, (2) the format of the data, as well as (3) the format for presenting the requested data. Annexes to the note will help the applicants in submitting the necessary information in the desired format.
- The note was adopted by the GMO Panel on 14 June 2018 and published on the EFSA website and on the EFSA Journal on 11 July 2018.
- The quality check of sequencing data currently conducted by the Joint Research Centre (JRC) was taken over by EFSA for new applications submitted as of 1<sup>st</sup> October 2018.
- The Head of the GMO Unit explained to the Panel members that applicants were the driver in using NGS for the molecular characterisation of GM plants. In this respect the technical note was not meant to introduce additional data requirements.

A member of the EFSA GMO Unit presented the explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin:

- Our experience with applications showed that applicants provide 'forage' data obtained from whole plants or from different parts of the plants. There was a need for a harmonized definition of 'forage' suitable of the risk assessment of GM feed.
- The note provides definition of forage for crops such as maize, soybean, sugar beet. Since rapeseed and cotton are not known to be used as forage, related data are not considered necessary for the risk assessment of GM rapeseed or cotton.
- The note was published on the EFSA website and on the EFSA Journal on 29 January 2018. The note is applicable to all applications submitted for authorisation of GM food and feed in the EU market, submitted 24 months after the publication of the note.

A member of the EFSA GMO Unit presented the explanatory note on the determination of newly expressed proteins (NEPs) levels in the context of GMO applications for market authorisation in the EU:

- The note is meant to further explain data requirements pertaining to NEPs levels laid down in 2011 EFSA Guidance Document on Food and Feed safety and in Regulation (EU) No 503/2013. The note addresses

the analytical methods for an optimized extraction of NEPs from plant tissues and their quantification. The scope of the note is limited to the determination of NEPs levels, and therefore it does not cover the measurement of endogenous proteins, or the prior steps such as field trials design and sampling strategy.

- When applicants consider the extraction method, they should take into account (1) its efficiency, (2) the possible tissue disruption/cell lysis, and (3) the use of an appropriate extraction buffer (protease inhibitors as preferred option). For the NEPs quantification, applicants should demonstrate that the method is sensitive, specific and repeatable. The note also provides additional information regarding e.g. samples stability, extraction and quantification from processed food/feed products. Finally the note gives recommendations to applicants on the presentation of the results.
- The note was published on the EFSA website and on the EFSA Journal on 20 August 2018. Since applicants may need to generate new plant material before determining NEPs levels, the recommendations described in the explanatory note will be applicable for GM plant applications submitted 24 months after its publication.

## **9. Any other business**

### **9.1. Calendar 2019 plenaries**

The 2019 calendar of plenary and Working Groups meetings was shared with the GMO Panel.

### **9.2. Ad hoc meeting with industry representatives**

In the context of the EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products, the GMO Unit is used to meet the European Association for Bioindustries (EuropaBio) once a year.

The *ad hoc* meeting provides an opportunity for open dialogue with industry representatives. The meeting agenda is the outcome of discussion between both parties and usually addresses technical, legal and administrative issues. The meeting marks an important step in enhanced dialogue among the parties.

Next meeting will take place on 24 (pm) and 25 (am) October 2018.

### **9.3. Annual meeting of the GMO Network of Member States**

The Head of the GMO Unit explained that EFSA is used to meet the EU Member States risk assessors on a yearly basis. Next meeting will take place on 8 (pm) and 9 (am) November 2018.

This year the agenda agreed by EFSA and Member States targets mainly Molecular Characterisation- and Food/Feed-related topics. In addition MS

will also update the network on ongoing activities linked to recent mandates that EFSA received from the European Commission (see item 6.3).

#### **9.4. Workshop organized by RAGES**

EFSA will attend the Workshop organized by the Risk Assessment of Genetically Engineered Organisms in the EU and Switzerland (RAGES) on 30 October 2018.

#### **10. Adoption of the minutes of the current meeting**

The minutes of the current meeting were adopted on 18 October 2018.