



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 130TH MEETING

Web-conference, 3 April 2019, Parma (Italy)

(Agreed on 11 April 2019)

Participants

■ GMO Panel Members:

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

■ European Commission and/or Member States representatives:

Hans Moons, Beatrice Marquez-Garrido, (DG SANTE)

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Anna Lanzoni, Karine Lheureux, Ana Martin Camargo, Sylvie Mestdagh, Franco Maria Neri, Irina Olaru, Konstantinos Paraskevopoulos, Nikoletta Papadopoulou and Tommaso Raffaello.

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 Working Groups 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 panel 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 129th GMO Plenary meeting

The minutes of the 129th GMO Plenary meeting were adopted by the GMO Panel by written procedure on 8 March 2019 and published on the [EFSA website](#) on 12 March 2019.

5. Scientific topics for discussion

5.1. Human dietary exposure assessment to newly expressed proteins in GM foods ([EFSA-Q-2019-00143](#))

Over the last years applicants submitted human dietary exposure assessments in support to their applications for the placing on the market of GMO in accordance with Regulation (EC) No 1829/2003 and Regulation (EC) No 503/2013. During the evaluation of these data, the GMO Panel and its working group (WG) on Food/Feed acknowledged some heterogeneity in the dietary exposure assessments conducted by different applicants.

Based on this, it was considered necessary to harmonise the way human dietary exposure in the area of GM food is estimated. An EFSA statement on "Human dietary exposure assessment to newly expressed proteins in GM foods" has been prepared providing guidelines to the applicants. In a nutshell, this statement aims at explaining to applicants (1) how to estimate human dietary exposure to newly expressed proteins (2) how to use the available consumption data (summary statistics) and the concentration data for the exposure estimations, and hence (3) what information and data should be submitted in the dossiers. A member of the GMO Unit presented the content of the draft document to the GMO Panel. Consequently, Panel members commented the document that will be published on the EFSA website and in the [EFSA Journal](#).

The member of the GMO Unit explained that the requirements laid down in the document will be subject to a transitional period of 2 months as of the document's publication date. This 'grace period' before the implementation of the document is driven by the fact that no new data need to be generated but the guidelines provided mainly refer to how the available data (concentration and consumption) should be used and presented. The GMO Panel was also informed that applicants already got insights of the content of the document at the *ad hoc* meeting between EFSA and industry representatives of 24-25 October 2018. The meeting was followed up by a letter to EuropaBio summarizing the key elements described in the EFSA statement.

5.2. Application for authorization of genetically modified *Brassica napus* MS11 for food and feed uses, import and processing submitted under

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



Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-BE-2016-138) (EFSA-Q-2016-00857)

Application EFSA-GMO-BE-2016-138 was submitted by Bayer CropScience for the placing on the EU market of *Brassica napus* Ms11 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. Application EFSA-GMO-BE-2016-138 was submitted to EFSA after the entry into force of Regulation (EU) No 503/2013. In this respect application EFSA-GMO-BE-2016-138 is 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).

A member of the EFSA GMO Unit introduced the peculiarities of this male sterile rapeseed event (e.g. event not intended to be marketed but commercially of interest in combination with the restorer line Rf3) and the technical limitations (e.g. suitable test material, herbicide treatment, comparator) encountered by the applicant to perform field trials in line with the applicable guidelines. The GMO Panel discussed and commented the draft text on the comparative analysis, and in particular the experimental set-up. Further discussion on the analysis of agronomic, phenotypic and compositional data in the light of the test material used for the analysis is needed.

6. New Mandates

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

Not applicable.

6.2. Annual Post-market environmental monitoring reports of GM plants

Not applicable.

6.3. Other Requests and Mandates

Not applicable.

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

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

In response to mandates from the European Commission, EFSA established two ad hoc WG; (1) on GMOs engineered with Gene Drives, and (2) on Synthetic Biology. In order to prepare the GMO Panel to adopt the final outcomes of these lengthy and complex queries, the Unit committed to update regularly the Panel about the progress made by the ad hoc WGs:

- (1) At last WG meeting, focus was on human disease vectors (mosquitoes) and crop pests (fruit fly). The workload was divided in sub-groups to make sure that appropriate expertise takes the lead. EFSA in close collaboration with the WG is getting prepared for the Workshop on the problem formulation for the environmental risk assessment of gene drive modified insects will take place on 15 May 2019.
- (2) The latest meeting of the SynthBio WG took place on 25 March 2019; the WG started addressing the case-studies. Next meeting is scheduled on 8 May 2019.



7.2. EFSA including its Working Groups/ Task Forces

Not applicable.

7.3. European Commission

The representative of the European Commission provided feedback on recent meetings held at the European Commission and informed the GMO Panel of next meetings.

8. Other scientific topics for information and/or discussion

8.1. Risk assessment of GM oilseed rape 73496

A scientific officer of the GMO Unit informed the Panel of latest developments on GM oilseed rape 73496. Relevant information is currently awaited from the applicant. As soon as received this information will be scheduled for discussion at the next meeting of the WG on Molecular Characterization.

9. Adoption of the minutes

The minutes of the current meeting will be adopted by written procedure and published at <https://www.efsa.europa.eu/en/events/event/190227>.

10. Next meeting(s)

The 131st GMO Plenary meeting will be held on 22 and 23 May 2019 in Parma.