

Scientific Panel on GMO

Minutes of the 125th plenary meeting

**Held on 4-5 July, 2018, Parma (Italy)
(Agreed on 18 July 2018)**

Participants

■ Panel Members

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

■ Hearing Experts:

Not applicable

■ European Commission and/or Member States representatives:

Beatrice Marquez-Garrido (DG SANTE)

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Chiara Belvederi, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Marina Koukoulanaki, Anna Lanzoni, Sylvie Mestdagh, Franco Maria Neri, Yustina Olshevska, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Tommaso Raffaello, Matthew Ramon, Kamila Sfugier and Elisabeth Waigmann

■ Observers:

Not applicable

■ Others:

Not applicable

1. Welcome and apologies for absence

The Head of the GMO Unit, Elisabeth Waigmann, welcomed the participants and thanked them for their commitment towards EFSA. Apologies were received from Jan Hejatkó and Giovanni Savoini. She also mentioned the unexpected recent withdrawal of one appointed panel member, Adinda De Schrijver. She wished to all members of the 2018-2021 GMO Panel success and a fruitful exchange for the panel term ahead.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², 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. Round table presentation of GMO Panel Members and GMO Unit

A round table presentation of the GMO Panel members, the GMO Unit members and representative of the European Commission took place.

5. GMO Panel & GMO Unit: roles and responsibilities

The Head of the GMO Unit introduced the overall frame for the risk assessment of GMOs by EFSA, its GMO Panel and supporting Working Groups. She presented the respective roles and responsibilities of experts and staff throughout the risk assessment process.

6. Overview on applications submitted under Regulation (EC) No 1829/2003

A scientific officer of the GMO Unit presented the European legal framework for GMOs, the EFSA procedure on GMO applications and the status of applications received under Regulation (EC) No 1829/2003.

7. GMO risk assessment: overall data requirements

Scientific officers of the GMO Unit presented the different pillars of the GMO risk assessment: i.e. molecular characterisation, comparative analysis, food/feed safety assessment, environmental risk assessment and post-market environmental monitoring. References were made to the legislation into force as well as to existing guidance documents and technical notes to applicants.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

8. Election of panel chair and vice-chairs

The election of the Chair and the two Vice-Chairs took place following the guidelines laid down in the Decision of the EFSA Management Board concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups³, 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 work⁴, and the Decision of the Executive Director of the European Food Safety Authority on Declarations of Interest⁵.

Hanspeter Naegeli was elected Chair of the GMO Panel; Nils Rostoks and Tamas Dalmay were elected Vice-Chairs of the GMO Panel.

9. Presentation and discussion on GMO applications

Scientific officers of the GMO Unit led the GMO Panel through the risk assessment of a soybean single transformation event (application EFSA-GMO-DE-2012-111) and a draft scientific opinion on a maize stack event (application EFSA-GMO-NL-2016-131). Both applications were used to illustrate how guidance documents are applied and to highlight peculiarities of the safety evaluation for these distinct types of GM transformation events.

9.1 Application EFSA-GMO-DE-2012-111 on soybean SYHT0H2 (EFSA-Q-2012-00753)

The scope of application EFSA-GMO-DE-2012-111 covers the import and processing for all food and feed uses of soybean SYHT0H2 in the European Union. Soybean SYHT0H2 is a single transformation event that confers tolerance to glufosinate-based and HPPD-inhibiting herbicides.

Scientific officers of the GMO Unit presented the outline of the risk assessment of soybean SYHT0H2 and explained the outstanding issues. Available datasets were presented and put into the context of the risk assessment as defined by EFSA guidance documents. The GMO Panel was also made aware of data gaps for specific areas of the risk assessment of soybean SYHT0H2. Additional information is currently awaited from the applicant. Further discussion is needed upon submission of the requested information.

³ <https://www.efsa.europa.eu/sites/default/files/paneloperation170601.pdf>

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

9.2 Application EFSA-GMO-NL-2016-131 on maize MIR162 x MON 87427 x MON 89034 x NK603 ([EFSA-Q-2016-00148](#))

Maize MON 87427 x MON 89034 x MIR162 x NK603 was obtained by conventional crossing of GM maize lines MON 87427, MON 89034, MIR162 and NK603. Maize MON 87427 and NK603 produce CP4EPSPS, which confers tolerance to glyphosate. Maize MON 89034 produces two newly expressed proteins, Cry1A.105 and Cry2Ab2, which confer resistance to specific lepidopteran pests. Maize MIR162 produces Vip3A and PMI proteins, which confer resistance to specific lepidopteran pests and function as a selection marker, respectively.

The scope of application EFSA-GMO-NL-2016-131 includes the four-event stack MON 87427 x MON 89034 x MIR162 x NK603 and all subcombinations, independently of their origin. According to the 'single first' principle, the risk assessment of stacks starts as soon as all parental lines/single transformation events are assessed and considered safe.

A scientific officer of the GMO Unit led the GMO Panel through the text of the draft opinion on application EFSA-GMO-NL-2016-131. Questions were raised and addressed throughout the reading of the sections on molecular characterisation, comparative assessment, food/feed safety assessment and environmental risk assessment.

It was highlighted that a major peculiarity of such application on a stack event of a segregating crop (e.g. maize, rapeseed) is linked to its scope and the legal obligation to assess the stack event as well as all its subcombinations, independently of their origin. Even though some subcombinations might not be supported by a specific dataset, they must be risk assessed. The risk assessment strategy of such subcombinations was discussed and endorsed by the GMO Panel at its [115th plenary meeting](#). This strategy was implemented in several GMO Panel scientific opinions, e.g. scientific opinions on application [EFSA-GMO-DE-2010-86](#) and [EFSA-GMO-BE-2013-118](#). The risk assessment of these subcombinations is conducted following a weight of evidence approach that takes as a starting point results of the assessments of the single events, the comprehensive dataset produced for the four-event stack maize, and all the data available for subcombinations previously assessed by the EFSA GMO Panel as stand-alone dossiers.

A scientific officer of the GMO Unit drew the attention of the GMO Panel to the legal requirement laid down in Regulation⁶ (EU) No 503/2013 pertaining to 90-day feeding studies with whole food and feed in rodents. Since application EFSA-GMO-NL-2016-131 was submitted after the entry into force of the aforementioned Regulation, for each single event stacked

⁶ 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 Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. Official Journal of the European Union 8.6.2016, L157/1-48

in the four-event maize MON 87427 x MON 89034 x MIR162 x NK603 a 90-day study should be provided by the applicant.

In compliance with the EU legislation, EFSA requested additional information pertaining to the 90-day rodent feeding studies with single events. Further discussion is needed upon submission of the requested information.

10. Re-establishment of standing Working Groups and nomination of WG chairs

The GMO Panel is organised into three standing Working Groups to deal with the risk assessment of GMO market authorisation applications. The former standing Working Groups will be discontinued and re-established *de novo*:

- Applications – Molecular Characterisation (MC WG),
- Applications – Food and Feed (FF WG),
- Applications – Comparative and Environmental Risk Assessment (CompERA WG).

The new Panel members were assigned to these standing Working Groups according to their expertise.

The Chairs of the standing Working Groups were nominated by the Panel Chair in consultation with the Head of the GMO Unit:

- Chair of the MC WG: Nils Rostoks
- Chair of the FF WG: Javier F. Moreno
- Chair of the CompERA WG: Ewen Mullins

11. Meeting dates: plenary and Working Group meetings in 2018-2019

A scientific officer presented to the Panel the dates of plenary and Working Groups meetings for 2018 and 2019.

12. Mandates other than applications

12.1 Annual Post-market environmental monitoring reports of GM plants

12.2 Sequencing mandates

A mandate on New sequencing information of genetically modified soybean event A2704-12 was received.

12.3 Other generic mandates

13. Feedback from EFSA and the European Commission

13.1 Grants and procurements

13.2 European Commission

The European Commission (EC) representative updated the Panel on recent generic mandates to EFSA, i.e. mandates on Gene Drive and Synthetic Biology.

14. Introduction to technicalities : live demonstration

14.1 Document Management Platform (DMS)

The panel was informed that the EFSA Document Management System and its functions will be presented at the Working Group meetings.

14.2 Phone/tele-meetings: how to use Skype for Business

A scientific officer explained to Panel members how to connect and what to do in case of technical difficulties.