GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 142nd MEETING

Held on 27 January 2021, TELE/WEB

(Agreed on 4 February 2021)

Participants

- Panel Members:

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

- European Commission:

Marta Cubria Radio, Alexandre Huchelmann and Juliette-Marie Margueritte (DG SANTE)

- EFSA:

GMO Unit: Ana Afonso, Michele Ardizzone, Federica Ceriani, Giacomo De Sanctis, Yann Devos, Silvia Federici, Antonio Fernández Dumont, Andrea Gennaro, Dafni Kagkli, Anna Lanzoni, Paolo Lenzi, Sylvie Mestdagh, Franco Maria Neri, Lorenz Oberkofler, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Franz Streissl and Riccardo Vriz

DATA Unit: José Ángel Gómez Ruiz

TS Unit: Ingrida Miliute and Claudia Paoletti

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 Independence[2] and the Decision of the Executive Director on Competing Interest Management[3] 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 140th GMO Plenary meeting

Since the 140th 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 maize MON 88017 x MON 810, authorised under Regulation (EC) No 1829/2003 (Commission Decision 2010/429/EU) (EFSA-GMO-RX-017)[4]

The draft opinion of this application was presented for adoption at the 140th Plenary meeting held on 14-15 October 2020[5]. It was agreed to adopt the opinion by written adoption after submission by the applicant of additional information (i.e. updated literature search). The text of the scientific opinion was adopted by written procedure on the 9 December 2020. The scientific opinion was published on the EFSA website and in the EFSA Journal.

4.2 The minutes of the 141st Plenary meeting

The minutes of the 141st Plenary meeting were adopted by written procedure and published on 4 December 2020.

5. Scientific topics for discussion

5.1 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)[6]

Cotton GHB614 was developed to confer tolerance to glyphosate-containing herbicides. Following a thorough risk assessment by EFSA, cotton GHB614 was authorized for food/feed uses, import and processing in the European Union in 2011 (Commission Decision 2011/354/EU and Commission Implementing Decision (EU) 2019/1195 amending Decision 2011/354/EU). In 2020 the applicant asked the European Commission to renew the authorisation for the placing on the market of cotton GHB614 and submitted application EFSA-GMO-RX-018 in support to their request. The GMO Panel assessed application EFSA-GMO-RX-018 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines. Clarification on bioinformatic analyses information is still to be submitted by the applicant.

[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] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00524
[5] https://www.efsa.europa.eu/sites/default/files/event/2020/139th-plenary-meeting-gmo-panel-minutes.pdf
[6] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00420

The GMO Panel reviewed the current text, where appropriate. 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 circulated via email to the GMO Panel and, if no further questions will be identified during the revision, the opinion will be proposed for adoption by written procedure.

5.2 Request for placing on the market of genetically modified GMB151 soybean in accordance with Regulation (EC) No. 1829/2003, submitted by BASF Agricultural Solutions Belgium (EFSA-GMO-NL-2018-153)[7]

Soybean GMB151 was developed to confer tolerance to HPPD inhibitor herbicides such as isoxaflutole and resistance to nematodes. The scope of the application EFSA-GMO-BE-2018-153 is for food and feed uses, import and processing and does not include cultivation in the European Union (EU).

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 according to EFSA procedures.

5.3 Application for authorisation of genetically modified oilseed rape 73496 submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2012-109)[8]

Oilseed rape 73496 was developed to confer tolerance to glyphosate. The tolerance is conferred due to the expression of a GAT (glyphosate acetyl transferase) protein. The compositional analyses of oilseed rape 73496 seeds revealed an increase in the concentration of N-acetyl amino acids (NAA) The risk assessment of NAA in oilseed rape 73496 and derived food and feed was presented. The Panel discussed and agreed on the next steps of the risk assessment of oilseed rape 73496.

5.4 Application for authorisation of LBFLFK canola import in the European Union submitted under Regulation (EC) No 1829/2003 by BASF Agriculture Solutions (EFSA-GMO-DE-2019-157)[9]

Canola LBFLFK expresses ten new proteins (desaturases and elongases) to synthesise Ω-3 long-chain polyunsaturated fatty acids (LC-PUFAs), including EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) and an acetohydroxy acid synthase to confer tolerance to imaxamox-based herbicides. The aspects of relevance for the risk assessment of canola LBFLFK with particular attention to the newly expressed proteins (NEPs) were introduced. Considerations on the toxicological assessment of the NEPs in canola LBFLFK were presented. The GMO Panel discussed how to progress with the assessment and agreed to plan targeted discussions across WGs to optimise and strengthen the risk assessment of this complex event.

5.5 Mandate to assess additional information related to the application for authorisation of food and feed containing, consisting of and produced from genetically modified soybean MON 87796 x MON 89788 (EFSA-GMO-NL-2010-85)[10]

In September 2015 the GMO Panel adopted a scientific opinion on genetically modified soybean MON 87769 x MON 89788 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2010-85). The scientific opinion was inconclusive because the lack of data on dietary exposure to refined bleached deodorised oil from soybean MON 87769 × MON 89788. The EFSA Panel therefore could not complete the human health and nutrition assessment of soybean MON 87769 x MON 89788.
In May 2019 EC mandated EFSA to consider additional information provided by the applicant.

[7] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00781
[8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00617
[9] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00394
[10] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00329

The Panel was updated on the progresses made with the mandate after the last Plenary discussion[11]. Deadline to submit additional information is end of January 2021. It was agreed that, once the missing information will be provided, the GMO Panel will assess it and update the text of the draft scientific opinion. The draft will be circulated to the Panel for possible adoption via written procedure.

6. New Mandates

6.1 Applications under Regulation (EC) No 1829/2003

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

EFSA-GMO-NL-2020-170 Request for placing on the market of genetically modified MON 95379 maize for import, processing and all uses as any other maize excluding cultivation, authorised under Regulation (EC) No 1829/2003 (Commission Decision 2011/891/EU)[12]

EFSA-GMO-NL-2020-171 Request for placing on the market of genetically modified DP4114xMON89034xMON87411xDAS-40278-9 maize for all food and feed uses, import and processing but excluding cultivation, authorised under Regulation (EC) No 1829/2003 (Commission Decision 2011/891/EU)[13]

EFSA-GMO-NL-2020-172 Request for placing on the market of genetically modified DP515635-4 maize for all food and feed uses, import and processing but excluding cultivation, authorised under Regulation (EC) No 1829/3003 (Commission Decision 2011/891/EU)[14]

EFSA-GMO-RX-019 Application for renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 x 3006-210-23, authorised under Regulation (EC) No 1829/2003 (Commission Decision 2011/891/EU)[15]

EFSA-GMO-RX-020 Application for renewing the authorisation for the placing on the market of food and feed products containing, consisting of, or produced from genetically modified soybean A5547-127 and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation (EC) No 1829/2003 (Commission Decision 2011/891/EU)[16]

6.2 Annual Post-market environmental monitoring reports of GM plants

On the 23 December 2020 EU mandated EFSA to assess the annual post-market environmental monitoring (PMEM) report from Bayer for the 2019 growing season of GM maize MON 810 in the EU.[17]

6.3 Other Requests and Mandates

- On 6 June 2018, EC mandated EFSA to deliver a scientific opinion on the adequacy of the existing Guidance for risk assessment of food and feed from genetically modified plants (GMP) on plants and microorganisms made by Synthetic Biology (SynBio).[18]
- Main objective of the mandate is to determine whether the existing guidelines on GM plants and microorganisms are adequate for the risk assessment.

[11] https://www.efsa.europa.eu/sites/default/files/event/2020/138th-plenary-meeting-gmo-panel-open-observers-minutes.pdf
[12] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00786
[13] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00833
[14] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00834
[15] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00792
[16] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2021-00003
[17] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2021-00029
[18] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2021-00052

- EFSA recently finalised the scientific opinions on the molecular characterization and environmental risk assessment aspects for plants[19] (GMO Panel) and microorganisms[20] (EFSA Scientific Committee). As agreed with the EC the GMO panel is requested to deliver the second part of the mandate on GMP focusing on food and feed risk assessment considerations.
- The chair of the Panel in consultation with the head of Unit proposed to establish an ad-hoc working group (WG) to cover the specific needs of the mandate. The GMO Panel agreed to set an ad-hoc WG to be chaired by Hanspeter Naegeli. The chair of the ad-hoc WG in consultation with the head of Unit will identify experts to become members of this new ad hoc WG.
- On 17 November 2020 EC mandated EFSA to consider the new sequencing information of genetically modified cotton DAS-24236-5 x DAS-21Ø23-5[21]
- On 5 January 2021 EC mandated EFSA to complement its original scientific opinion on oilseed rape MS11 (EFSA-GMO-BE-2016-138), taking into account additional information provided by the applicant. [22]

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 Chair of the GMO Panel reported on ongoing activities, new guidance documents in the remit of the Scientific Committee as well as on the Workshop on Artificial Intelligence in Risk Assessment held on the 11 December 2020.

7.2 EFSA including its Working Groups/ Task Forces

None

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 scientific opinion.

8 Other scientific topics for information and/or discussion

None

9 Any other business

9.1 Update Transparency Regulation

The Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004,

[19] https://www.efsa.europa.eu/en/efsajournal/pub/6301
[20] https://www.efsa.europa.eu/en/efsajournal/pub/6263
[21] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00796
[22] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2021-00044

(EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC was published on the 6th of September 2019. On 27 March 2021, the new requirements of the Transparency Regulation (TR) shall be in effect. Changes regarding Management Board, Scientific Committee and Scientific Panels will be applicable as of 1 July 2022.

EFSA's documents processes and tools in a view of the Transparency regulation:

Practical Arrangements (PAs) are binding means to interpret and implement the legal framework provided by the TR. In this they belong to the group of other implementing measures like implementing rules, e.g. on standard data formats, and sectoral guidance documents. By specifying the details for the implementation of required processes, the PAs commit to how the TR will be applied by EFSA. They were drafted following extensive consultation with stakeholders, the European Commission and EU Member States throughout 2020. The PAs cover areas such as proactive transparency, confidentiality, notification of studies, pre-submission advice and consultation of third parties and PAs on the processing of applications for access to documents held by EFSA. All PAs are published on the EFSA website.

EFSA is updating 27 guidance documents (12 administrative and 15 scientific). The scientific part of scientific guidance documents remains untouched whereas the administrative part was revised. Administrative guidance documents update in line with the PAs. All guidance documents will be published by 27th March 2021.

Technology. *Salesforce* will be used for Pre-Submission Advice, Notification of Studies, Public access to documents, Public Consultation. *FSCAP* – dossiers e-submission except pesticides. *IUCLID* – dossier e-submission for pesticides (PPP and MRLs.) *Appian* – workflow automation for EFSA's risk assessment and confidentiality assessment work. *Microsoft Azure* – Secure storage and controlled access, dissemination, proactive disclosure.

Upgraded EFSA website starts in February 2021. New dissemination portal OpenEFSA will begin in the middle of February. The portal will serve for accessing documents, such as dossiers and studies (non-confidential versions), meetings' agenda and minutes, etc.

External matters: engagement, training and communication. EFSA and SANTE jointly defined principles for interaction with stakeholders and the engagement channels: Sounding Board, Technical Groups, dedicated space in EFSA website. External training are being provided during January - March 2021 and published on the EFSA website.

9.2 Calendar Plenaries 2022

The calendar of the Plenary meetings 2022 was communicated to the GMO Panel.

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/142nd-plenary-meeting-gmo-panel

The 143rd GMO Plenary meeting will be held on 17-18 March 2021 online.